CorMedix Inc. Form 424B5 February 19, 2013

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Registration No. 333-185737

**Prospectus Supplement** 

(To prospectus dated January 10, 2013)

761,429 Shares of Series A Convertible Preferred Stock and

Warrant to Purchase 400,000 Shares of Common Stock

We are offering directly to an existing institutional investor 761,429 shares of our Series A Non-Voting Convertible Preferred Stock, par value \$0.001 per share, and a five-year warrant (exercisable immediately), referred to herein as the Warrant, to purchase up to an aggregate of 400,000 shares of our common stock at an exercise price of \$1.50 per share (and the common stock issuable from time to time upon conversion of the Series A Preferred Stock and upon exercise of the Warrant). The Series A Preferred Stock and the Warrant will be issued separately.

Our common stock trades on the NYSE MKT under the trading symbol "CRMD." The closing price of our common stock on February 15, 2013 was \$0.87. There is no established public trading market for the Series A Preferred Stock or the Warrant and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock or the Warrant on any national securities exchange or any other market.

Each share of Series A Preferred Stock is convertible into one (1) share of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting the Series A Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of our common stock then issued and outstanding. In the event of our liquidation, dissolution or winding up, the holders of our Series A Preferred Stock will receive a payment equal to \$0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of our common stock. Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock.

Investing in our securities involves a high degree of risk. These risks are described under the caption <u>"Risk Factors"</u> beginning on page S-8 of this prospectus supplement and in the accompanying prospectus and the documents incorporated by reference therein.

Per Share Total

Offering price \$0.70 \$533,000 Proceeds, before expenses, to us \$0.70 \$533,000

We expect that delivery of the securities being offered pursuant to this prospectus supplement will be made to the purchaser on or about February 19, 2013.

As of February 15, 2013, the aggregate market value of our outstanding common stock held by non-affiliates was \$10,308,704, based on 11,408,274 shares of our common stock outstanding on February 15, 2013, of which 10,308,704 shares were held by non-affiliates, and a price of \$1.00 per share, the closing price for our common stock on January 8, 2013. During the 12 calendar months prior to and including the date of this prospectus, we have offered securities with an aggregate market value of \$1,161,429 pursuant to General Instruction I.B.6 of Form S-3, all of which have been offered pursuant to this prospectus supplement.

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

**Prospectus Supplement dated February 19, 2013** 

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You should rely only on the information incorporated by reference or provided in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction where it is unlawful to make such offer or solicitation. You should not assume that the information contained in this prospectus supplement or the accompanying prospectus, or any document incorporated by reference in this prospectus supplement or the accompanying prospectus, is accurate as of any date other than the date on the front cover of the applicable document. Neither the delivery of this prospectus supplement nor any distribution of securities pursuant to this prospectus supplement shall, under any circumstances, create any implication that there has been no change in the information set forth or

incorporated by reference into this prospectus supplement or in our affairs since the date of this prospectus supplement. Our business, financial condition, results of operations and prospects may have changed since that date.

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#### ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement is part of a registration statement (No. 333-185737) that we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under the registration statement, we registered the offering by us of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, from time to time in one or more offerings. This prospectus supplement provides specific information about the offering by us of the Series A Preferred Stock and the Warrant under the shelf registration statement. This document is in two parts. The first part is the prospectus supplement, which adds to and updates information contained in the accompanying prospectus. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus, on the other hand, you should rely on the information in this prospectus supplement.

In making your investment decision, you should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with any other information. If you receive any information not authorized by us, you should not rely on it. We are not making an offer to sell the securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained or incorporated by reference in this prospectus supplement or the accompanying prospectus is accurate as of any date other than its respective date.

It is important for you to read and consider all of the information contained in this prospectus supplement and the accompanying prospectus in making your investment devcision. We include cross-references in this prospectus supplement and the accompanying prospectus to captions in these materials where you can find additional related discussions. The table of contents in this prospectus supplement provides the pages on which these captions are located.

We are offering to sell, and seeking an offer to buy, the Series A Preferred Stock and the Warrant only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the Series A Preferred Stock and the Warrant in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the Series A Preferred Stock and the Warrant and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Before purchasing any securities, you should carefully read both this prospectus supplement and the accompanying prospectus, together with the additional information described under the heading, "Where You Can Find More Information," in the accompanying prospectus.

Unless the context otherwise requires, "CorMedix," the "company," "we," "us," "our" and similar names refer to CorMedix In-

#### 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 supplement, the accompanying 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 words such as "may," "might," "should," "anticipate," "estimate," "expect," "projects," "intends," "believes" and words such as "may," "might," "should," "anticipate," "estimate," "expect," "projects," "intends," "believes" and words such as "may," "might," "should," "anticipate," "estimate," "expect," "projects," "intends," "believes" and words such as "may," "believes" and "ma 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: our ability to obtain FDA and foreign approval of our product candidates, especially Neutrolin®; our need to obtain additional funding and our ability to obtain future funding on acceptable terms, or at all; our ability to maintain the listing of our common stock on the NYSE MKT; 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 the accompanying prospectus and otherwise incorporated by reference herein, and in our most recent annual report on Form 10-K and 10-K/A, as revised or supplemented by our most recent quarterly report on Form 10-Q, 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 supplement, the accompanying 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 respective dates of this prospectus supplement, the accompanying prospectus or the date of the document incorporated by reference in this prospectus supplement or the accompanying prospectus. We expressly disclaim any obligation to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by federal securities laws.

#### PROSPECTUS SUPPLEMENT SUMMARY

The following summary is qualified in its entirety by, and should be read together with, the more detailed information and financial statements and related notes thereto appearing elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. Before you decide to invest in our securities, you should read the entire prospectus supplement and the accompanying prospectus carefully, including the risk factors and the financial statements and related notes incorporated by reference in this prospectus supplement and the accompanying prospectus.

#### 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. Specifically, our goal is to treat kidney disease by reducing the commonly associated cardiovascular and metabolic complications - in effect, "treating the kidney to treat the heart." As of the date of this prospectus, we have 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, that we believe address potentially large market opportunities in the instances in which a central venous catheter is used, such as hemodialysis, intensive care units, oncology and total parenteral nutrition patients.

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

During the third quarter of 2011, we received a notice from the U.S. Food and Drug Administration, or FDA, that Neutrolin had been assigned to the Center for Drug Evaluation and Research, or CDER, 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 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.

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 European Union, or 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 have successfully completed the stage 2 audit with TÜV SÜD. We anticipate receiving a CE Mark approval in the first 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 in the first half of 2013. However, we cannot be assured of CE Mark approval of Neutrolin or the planned commercialization timeline.

In anticipation of receiving CE Marking approval, on January 10, 2013, we entered into an agreement with MKM Co-Pharma GmbH, or MKM, regarding Neutrolin, pursuant to which, MKM hired a national sales manager, Joachim Petrak, to market Neutrolin in Germany, as described in more detail below. Assuming the receipt of a CE Mark and the launch of Neutrolin in Europe, we intend to meet with the FDA to determine the pathway for U.S. approval of Neutrolin, which we expect will entail a Phase 3 trial.

#### **Recent Developments**

On September 20, 2012, we completed an initial closing of our private placement of 850 units, each unit consisting of (i) a one-year \$1,000 principal amount 9% senior convertible note (the "Notes"), convertible into shares of our common stock at a conversion price of \$0.35 per Note, and (ii) a five-year redeemable warrant, to purchase 2,500 shares of our common stock at a purchase price of \$0.40 per share. We received gross proceeds of \$850,000 and net proceeds of approximately \$689,000 in the September 20, 2012 initial closing. The maturity date of the Notes issued in the initial closing is September 20, 2013.

On November 13, 2012, we held the second and final closing of the private placement, and issued an additional 474 units for a total gross amount of \$474,000. The maturity date of the Notes issued in the final closing is November 13, 2013. Together with the sale of 850 units at the initial closing, we issued and sold in the private placement an aggregate total of 1,324 units for aggregate gross proceeds of \$1,324,000. The total net proceeds (net of placement agent and legal fees) of the private placement to us were \$1,095,600, including \$689,000 net proceeds previously received by us at the initial closing and \$406,600 net proceeds received by us in the final closing. We issued to the investors warrants to purchase an aggregate of 3,310,000 shares of our common stock. We paid the placement agent for the private placement a total of \$109,900 in fees and issued it warrants to purchase an aggregate of 331,000 shares. The placement agent warrants have the same terms as those issued to the investors.

On December 24, 2012, we announced the following changes to our executive team.

Randy Milby was promoted to Chief Executive Officer, effective January 1, 2013. Mr. Milby previously served as our Chief Operating Officer.

Richard M. Cohen became our Chief Financial Officer, effective January 1, 2013, and continues as Executive Chairman and a director of CorMedix. Mr. Cohen previously served as our Interim Chief Financial Officer and Interim Chief Executive Officer.

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Antony E. Pfaffle, M.D., a director on our board, joined the executive team as Acting Chief Scientific Officer, effective January 1, 2013.

Mark Klausner, M.D., our current Chief Medical Officer, will depart CorMedix effective February 28, 2013 upon expiration of his employment agreement with CorMedix.

Mr. Milby will continue to work with the board and build the management team to drive our strategy forward with respect to the planned receipt of CE Mark approval for Neutrolin and subsequent commercial launch of Neutrolin in Europe and the planned expansion into countries beyond Europe. Dr. Pfaffle, in his capacity as Acting Chief Scientific Officer, will provide scientific support and will focus on the development of key opinion leader relationships throughout Europe.

On January 11, 2013, we filed an initial registration statement with the SEC to register the resale of the shares of common stock issuable upon the conversion of the Notes. We have agreed to use our commercially reasonable efforts to have the registration statement declared effective within 120 days after the date of the final closing, which is March 13, 2013.

On January 10, 2013, we entered into an Agreement for Work on Pharmaceutical Advertising with MKM Co-Pharma GmbH regarding Neutrolin, for which we anticipate receiving a CE Mark approval in Europe in the first quarter of 2013. Pursuant to the agreement, MKM hired a national sales manager, Joachim Petrak, to market Neutrolin in Germany according to a negotiated work plan. While the plan may be revised, it currently provides that the sales manager will market Neutrolin in three phases. In the first phase, from January to March 2013, the sales manager will visit hemodialysis centers and doctors to, among other things, provide them information and promotional materials. The sales manager will also produce a market review of our product, conduct test sales of Neutrolin in Germany, negotiate wholesaler relationships for initial orders of our product and determine sales projections for launching Neutrolin. In the second phase, from April to May 2013, assuming receipt of CE Mark approval, the sales manager will launch Neutrolin, generating sales on a best efforts basis, and supervise sales representatives. After that time, the sales manager will be responsible for growing Neutrolin sales and expanding the advertising plan

On February 1, 2013, we received notice from the NYSE MKT LLC, or NYSE MKT, that it granted us an extension until April 15, 2013 to regain compliance with the continued listing standards of the NYSE MKT. The NYSE MKT is continuing our listing pursuant to the extension. The NYSE MKT had previously notified us on April 20, 2012 the that we were not in compliance with Section 1003(a)(iv) of the NYSE MKT Company Guide in that we had sustained losses which are so substantial in relation to our overall operations or our existing financial resources, or our financial condition had become so impaired that it appeared questionable, in the opinion of the NYSE MKT, as to whether we will be able to continue operations and/or meet our obligations as they mature. We were afforded an opportunity to submit a plan of compliance to the NYSE MKT and, on May 17, 2012, we presented a plan to the NYSE MKT. On June 27, 2012, the NYSE MKT accepted our plan to regain compliance with its continued listing standards and granted us an extension until August 22, 2012. On September 21, 2012, the NYSE MKT granted us another extension until January 31, 2013 to regain compliance with the continued listing standards of the NYSE MKT. We will be subject to periodic review by the NYSE MKT during the extension to April 15, 2013. Failure to make progress consistent with the plan or to regain compliance with continued listing standards by the end of the extension period could result in us being delisted from the NYSE MKT.

#### **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, establishing manufacturing for our product candidates and maintaining and improving our patent portfolio.

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 supplement or accompanying prospectus.

#### THE OFFERING

Series A Preferred Stock we are offering pursuant to the

prospectus supplement

761,429 shares of Series A Preferred Stock. This prospectus supplement also relates to the offering of the shares of common stock issuable upon conversion of the Series A Preferred Stock.

## Conversion

Each share of Series A Preferred Stock is convertible into one (1) share of our common stock at any time at the option of the holder, except that the Series A Preferred Stock provides that a holder will be prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 3.99% of the total number of shares of our common stock then issued and outstanding.

## Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of the Series A Preferred Stock will receive a payment equal to \$0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock, the holders of Series A Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

## Voting Rights

Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock.

#### Dividends

Holders of Series A Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series A Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Warrant we are offering pursuant to this prospectus supplement

Warrant, exercisable immediately, to purchase up to 400,000 shares of common stock, for an exercise price of \$1.50 per share. The Warrant entitles the investor to purchase one share of our common stock for every share of Series A Preferred Stock purchased by such investor in the offering. The Warrant provides that a holder will be prohibited form exercising the Warrant if, as a result of such exercise, such holder, together with its affiliates, would beneficially own more than 3.99% of the total number of shares of our common stock then issued and outstanding.

This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise, if any, of the Warrant.

**Common stock** 

to be

outstanding

11,408,274 shares<sup>(1)</sup>

after this offering

# Use of proceeds

We estimate that the net proceeds from this offering, after deducting offering expenses, will be approximately \$463,000 . We intend to use the net proceeds for general corporate purposes, including the development and commercialization of Neutrolin, research and development of other product candidates, potential product acquisitions and/or potential acquisitions of complementary businesses, and working capital and capital expenditures. Pending the application of the net proceeds, we intend to invest the net proceeds generally in short-term, investment grade, interest bearing securities. See "Use of Proceeds" on page S-26 of this prospectus supplement.

## Risk Factors

See "Risks Related To This Offering" beginning on page S-8 of this prospectus supplement or otherwise incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities.

## **NYSE MKT common stock symbol** CRMD

The number of shares of our common stock that will be issued and outstanding immediately after this offering as (1)shown above is based on 11,408,274 shares of common stock issued and outstanding as of February 15, 2013 and excludes the following:

- 400,000 shares of common stock issuable upon exercise of the Warrant offered hereby;
- 761,429 shares of common stock issuable upon conversion of the Series A Preferred Stock offered hereby;
- 2,300,000 shares of our common stock reserved for issuance under our 2006 Stock Plan, of which 2,135,630 shares were issuable upon exercise of outstanding options with a weighted-average exercise price of \$1.26;
- warrants for 4,263,569 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 17,869 shares of common stock with an exercise price of \$10.66 per share and an expiration date of January 30, 2013 issued to consultants;
- 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;
- outstanding Senior Convertible Notes issued in our 2012 private placement with an aggregate face value of \$1,324,000, convertible into an aggregate of 3,782,858 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; and

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.

#### RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K and 10-K/A, as revised or supplemented by our most recent quarterly report on Form 10-Q, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. You should also consider the risks described below and all of the other information contained in this prospectus supplement and the accompanying prospectus, and incorporated by reference into this prospectus supplement and the accompanying prospectus, including our financial statements and related notes, before investing in our securities. If any of the possible events described in those sections actually occur, our business, business prospects, cash flow, results of operations or financial condition could be harmed. In this case, the trading price of our common stock could decline, and you might lose all or part of your investment in our securities.

## Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of operating losses, and expect to incur 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 a net loss of approximately \$2.2 million for the nine months ended September 30, 2012 and approximately \$6.7 million for the year ended December 31, 2011. As of September 30, 2012, we had an accumulated deficit of approximately \$45.2 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.

Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its audited financial statements for the year ended December 31, 2011 and may do so again in the future.

In their report accompanying our audited financial statements for the year ended December 31, 2011, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going a 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 first 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. Our ability to continue as a going concern will depend, in large part, 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 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 first 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. We have recently 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:

- · delays in product development, pre-clinical and clinical testing, or manufacturing;
- · unplanned expenditures in product development, pre-clinical and 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 current Good Manufacturing Practices requirements, referred to 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. 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 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 Acting Chief Scientific Officer. Dr. Mark Klausner, our current part-time Chief Medical Officer, will cease employment on February 28, 2013. We cannot be certain that the changes in management will not negatively affect our business in the future or that additional changes in management and in the composition of our board of directors will not occur. Additionally, we may be negatively impacted by a lack of accounting expertise, lack of internal control processes (which include lack of segregation of duties for cash disbursements and cash reconciliations), lack of accuracy and timeliness of financial reporting as a result of the 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 the date of this supplemental prospectus, 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's patent's claims. We believe we will receive the Appeals' Board final written decision sometime in the first quarter 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 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, such as with MKM Co-Pharma GmbH, will be successful, or that we will be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third-parties.

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

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

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. All of our manufacturing processes currently are, and we expect them to continue to be, outsourced to third parties. Specifically, we will rely on one or more manufacturers to supply us and/or our distribution partners with commercial qualities of Neutrolin. If, for any reason, we become unable to rely on our current sources for the manufacture of Neutrolin or any other product candidates, either for clinical trials or for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for pre-clinical, clinical, and commercial purposes. We may not be successful in identifying such additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. Such third-party manufacturers must receive FDA or applicable foreign approval before they can produce clinical material or commercial product, and any that are identified may not receive such approval or may fail to maintain such approval. In addition, we may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacturing if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected.

Before we could begin to commercially manufacture our product candidates on our own, we must obtain regulatory approval of the manufacturing facility and process. The manufacture of drugs for clinical and commercial purposes must comply with cGMP and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements would require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. We would also have to pass a pre-approval inspection prior to FDA or non-U.S. regulatory agency approval. Failure to pass a pre-approval inspection may significantly delay regulatory approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition, and results of operations could be materially adversely affected.

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

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

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

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

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

## Risks Related to Our Series A Preferred Stock and 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 February 15, 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;
- · developments or disputes concerning patents or other proprietary rights;

general economic, industry and market conditions;

• 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 15, 2013, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

- warrants for 4,263,569 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 17,869 shares of common stock with an exercise price of \$10.66 per share and an expiration date of January 30, 2013 issued to consultants;
- 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 3,782,858 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; and
- 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.

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 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. Even without registration, the shares issuable upon conversion of the Senior Convertible Notes generally will be freely tradable in late March and mid-May of 2013, depending on the date of issuance of the Senior Convertible Notes, except for shares held by our affiliates.

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

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

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

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be further diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders.

Pursuant to our 2006 Stock Plan, our Board of Directors is authorized to award up to a total of 2,300,000 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. As of February 15, 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. 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.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions in our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated Bylaws, as well as provisions of the General Corporation Law of the State of Delaware, or DGCL, may discourage, delay or prevent a merger, acquisition or other change in control of our company, even if such a change in control would be beneficial to our stockholders. These provisions include the following:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- · prohibiting our stockholders from fixing the number of our directors; and
- establishing advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by the board of directors. This provision could have the effect of discouraging, delaying or preventing someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. Any provision of our Amended and Restated Certificate of Incorporation, as amended, or Amended and Restated Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

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. We incurred a net loss of approximately \$2.2 million for the nine months ended September 30, 2012 and as of September 30, 2012 we had a deficit accumulated during the development stage of approximately \$45.2 million. On April 20, 2012, the NYSE MKT notified us that we were not in compliance with certain listing standards 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. 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. 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. We will be subject to periodic review by the NYSE MKT during the extended plan period to April 15, 2013. 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 <sup>®</sup> or in the Pink Sheets <sup>®</sup> (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.

## **Risks Related To This Offering**

The substantial number of shares of our common stock issuable upon conversion of the Series A Preferred Stock sold in this offering, together with the shares issuable upon exercise of the Warrant sold in this offering, could cause the price of our common stock to decline.

In this offering we are selling 761,429 shares of our Series A Preferred Stock, which are convertible into 761,429 shares of our common stock, or approximately 6.7% of our outstanding common stock as of February 15, 2013 (excluding the shares of common stock issuable upon exercise of the Warrant). In addition, accompanying the Series A Preferred Stock sold in this offering will be a Warrant to purchase up to 400,000 shares of our common stock. If the Warrant offered under this prospectus supplement is exercised, together with the common stock issuable upon conversion of the Series A Preferred Stock offered pursuant to this prospectus supplement, it would represent approximately 10.2% of our outstanding common stock as of February 15, 2013. This sale and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

If you purchase the Series A Preferred Stock sold in this offering and assuming its conversion into shares of our common stock, you will experience immediate dilution in your investment.

Because the price per share of our Series A Preferred Stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the Series A Preferred Stock you purchase in this offering, assuming conversion of the Series A Preferred Stock into shares of our common stock. Based on a public offering price of \$0.70 per share of Series A Preferred Stock, and a net tangible book value per share of our common stock of \$ (0.01) as of September 30, 2012, if you purchase shares of Series A Preferred Stock in this offering, assuming conversion of the Series A Preferred Stock into shares of our common stock, you will suffer immediate and substantial dilution of \$0.67 per share with respect to the net tangible book value of the common stock. The shares of common stock issuable upon exercise of the Warrant have not been included in this calculation. See "Dilution" for a more detailed discussion of the dilution you will incur if you purchase Series A Preferred Stock in this offering.

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

## There is no public market for the Series A Preferred Stock or the Warrant in this offering.

There is no established public trading market for the Series A Preferred Stock or the Warrant being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock or the Warrant on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the Series A Preferred Stock and the Warrant will be limited.

### **USE OF PROCEEDS**

We estimate that the net proceeds from this offering will be approximately \$463,000, excluding the proceeds, if any, from the exercise of the Warrant, and after deducting our estimated offering expenses. If the Warrant is purchased and fully exercised for cash, we would receive additional proceeds of \$600,000.

We intend to use the net proceeds from the sale of our securities by us under this prospectus supplement and the accompanying prospectus for general corporate purposes, including the development and commercialization of Neutrolin, research and development of other product candidates, potential product acquisitions and/or potential acquisitions of complementary businesses, and working capital and capital expenditures. Pending the application of the net proceeds, we intend to invest the net proceeds generally in short-term, investment grade, interest bearing securities.

#### **DILUTION**

Our net tangible book value on September 30, 2012 was \$ (116,822), or \$(0.01) per share. "Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares outstanding. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by the purchaser of the Series A Preferred Stock in this offering and net tangible book value per share of our common stock immediately after this offering. For purposes of this calculation, the shares of our common stock issuable upon exercise of the Warrant have not been included.

After giving effect to the sale of 761,429 shares of Series A Preferred Stock in this offering at an offering price of \$0.70 per share, assuming the conversion of all 761,429 shares of our Series A Preferred Stock into 761,429 shares of our common stock and after deducting all estimated offering expenses payable by us, our pro forma net tangible book value as of September 30, 2012 would have been approximately \$346,178, or \$0.03 per share of common stock. This represents an immediate increase in net tangible book value of \$0.04 per share to our existing stockholders and an immediate dilution in net tangible book value of \$0.67 per share to the investor participating in this offering. The following table illustrates this dilution per share to the investor participating in this offering:

Offering price per share of Series A Preferred Stock		\$0.70
Net tangible book value per share as of September 30, 2012	\$(0.01)	
Increase in net tangible book value per share attributable to new investor purchasing our securities in this offering	\$0.04	
Pro forma net tangible book value per share after giving effect to the offering Dilution per share to new investor purchasing our securities in this offering	\$0.03	\$0.67

The above illustration of dilution per share to the investor participating in this offering assumes no exercise of outstanding options or warrants to purchase shares of our common stock.

The above discussion and table are based on 11,408,274 shares of our common stock outstanding as of September 30, 2012. This number excludes:

- 400,000 shares of common stock issuable upon the exercise of the Warrant offered hereby;
- warrants for 4,263,569 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 17,869 shares of common stock with an exercise price of \$10.66 per share and an expiration date of January 30, 2013 issued to consultants;
- 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 3,782,858 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; and
- 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.

To the extent that options or warrants outstanding as of September 30, 2012 have been or may be exercised or other shares issued, the investor purchasing our Series A Preferred Stock (including shares of common stock issuable upon conversion of the Series A Preferred Stock and exercise of the Warrant) in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

### **CAPITALIZATION**

The following table sets forth our cash and cash equivalents and our capitalization as of September 30, 2012 on:

an actual basis; and

on a pro forma basis to reflect our receipt of the estimated net proceeds from our sale of 761,429 shares of Series A Preferred stock in the offering at an offering price of \$0.70 per share, after deducting estimated offering expenses payable by us.

	At September 30, 2012 (unaudited)		
	Actual	Pro Forma	
Cash and cash equivalents	\$992,341	\$1,455,341	
Stockholders' equity:			
Preferred stock, \$0.001 par value: 2,000,000 shares authorized, actual and pro forma;			
no shares issued and outstanding actual, and 761,429 shares issued and outstanding,		761	
pro forma			
Common stock, \$0.001 par value: 80,000,000 shares authorized, actual and pro forma;	11,408	11,408	
11,408,274 shares issued and outstanding, actual and pro forma	11,400		
Deferred stock issuances	(146)	(146)	
Additional paid-in capital	45,057,016	45,519,255	
Deficit accumulated during the development stage	(45,185,100)	(45,185,100)	
Total capitalization	\$116,822	\$346,178	

The pro forma number of shares to be outstanding immediately after this offering as shown above is based on 11,408,274 shares outstanding as of September 30, 2012 and excludes:

- 400,000 shares of common stock issuable upon exercise of the Warrant offered hereby;
- 761,429 shares of common stock issuable upon conversion of the Series A Preferred Stock offered hereby;
  - 2,300,000 shares of our common stock reserved for issuance under our 2006 Stock Plan, of which 2,135,630 shares were issuable upon exercise of outstanding options with a weighted-average exercise price of \$1.26;
- warrants for 4,263,569 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 17,869 shares of common stock with an exercise price of \$10.66 per share and an expiration date of January 30, 2013 issued to consultants;

- 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;
- outstanding Senior Convertible Notes issued in our 2012 private placement with an aggregate face value of \$1,324,000, convertible into an aggregate of 3,782,858 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; and
- 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.

#### DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering (i) 761,429 shares of our Series A Preferred Stock, and (ii) a warrant to purchase 400,000 shares of our common stock. This offering also includes an aggregate of 761,429 shares of our common stock issuable upon the conversion of the Series A Preferred Stock and an aggregate of 400,000 shares of our common stock issuable upon exercise of the Warrant. The Series A Preferred Stock and the Warrant are immediately separable and will be issued separately. The common stock offered by this prospectus supplement and the accompanying prospectus upon the conversion of the Series A Preferred Stock and the exercise of the Warrant is described in the accompanying prospectus under the heading "Description of Common Stock." The Series A Preferred Stock and the Warrant offered by this prospectus supplement and the accompanying prospectus are described in the immediately following section of this prospectus supplement. The following description is subject to, and qualified in its entirety by, (a) the certificate of designation for the Series A Preferred Stock, which was filed as an exhibit to our Current Report on Form 8-K filed with the SEC on February 19, 2013, and (b) the Warrant, the form of which was filed as an exhibit to our Current Report on Form 8-K filed with the SEC on February 19, 2013. You should review a copy of the certificate of designation and the form of warrant for a complete description of the powers, preferences, rights, qualifications, limitations and restrictions applicable to each of the Series A Preferred Stock and the Warrant.

#### Common Stock

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption "Description of Common Stock" starting on page 25 of the accompanying prospectus.

#### Series A Preferred Stock

General

Under the terms of our Amended and Restated Certificate of Incorporation, as amended, our board of directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Our board of directors has designated 761,429 of the 2,000,000 authorized shares of preferred stock as our Series A Non-Voting Convertible Preferred Stock, par value \$0.001 per share.

Rank
The Series A Preferred Stock will rank:
senior to our common stock;
senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A Preferred Stock; and
on parity with any class or series of our capital stock hereafter created specifically ranking by its terms on parity with the Series A Preferred Stock,
junior to any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock,
in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.
Conversion
Each share of Series A Preferred Stock is convertible into one (1) share of our common stock (subject to adjustment a provided in the certificate of designation for the Series A Preferred Stock) at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 3.99% of the total number of shares of our common stock then issued and outstanding.
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Liquidation	Preference
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In the event of our liquidation, dissolution or winding up, holders of Series A Preferred Stock will receive a payment equal to \$0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock and holders of Series A Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

Voting Rights

Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock or the certificate of designation for the Series A Preferred Stock.

Dividends

Holders of Series A Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series A Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption

We are not obligated to redeem or repurchase any shares of Series A Preferred Stock. Shares of Series A Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing

There is no established public trading market for the Series A Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock on any national securities exchange or trading system.

#### Fundamental Transactions

If, at any time that shares of Series A Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series A Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of one share of common stock.

#### Warrant

The following summary of certain terms and provisions of the Warrant offered in this offering is subject to, and qualified in its entirety by reference to, the terms and provisions set forth in the Warrant.

#### Warrant

Exercisability. The holder may exercise the Warrant at any time from the date of issuance and expiring on the five-year anniversary of such issuance date. The Warrant will be exercisable, at the option of the holder, in whole or in part by delivering to us a duly executed exercise notice, followed within three (3) trading days by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). At the direction of the investor, the number of warrant shares that may be acquired by the holder upon exercise of the Warrant may be limited to the extent necessary to insure that, following such exercise (or other issuance), the total number of shares of common stock then beneficially owned by the holder and its affiliates and any other persons whose beneficial ownership of common stock would be aggregated with the holder's for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, does not exceed 3.99% of the total number of issued and outstanding shares of common stock (including for such purpose the shares of common stock issuable upon such exercise).

*Exercise Price*. The exercise price of the Warrant is \$1.50 per share of Series A Preferred Stock being purchased. The exercise price is subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock.

Payment of Exercise Price. The holder of the Warrant must provide payment of the exercise price of the shares being acquired upon exercise of the Warrant in cash or by wire transfer, provided that if there is no effective registration statement registering the common stock issuable upon exercise of the Warrant, the Warrant may be exercised solely by means of net exercise.

*Transferability*. Subject to applicable laws and the restriction on transfer set forth in the Warrant, the Warrant may be transferred at the option of the holder upon surrender of the Warrant to us together with the appropriate instruments of transfer.

#### Fundamental Transactions

If we enter into, or are a party to, a fundamental transaction pursuant to which our stockholders are entitled or required to receive securities issued by another company or cash or other assets in exchange for our common stock, which we refer to as a corporate event, the holder of the Warrant will have the right to receive, upon exercise of the Warrant, consideration as if such holder had exercised the Warrant immediately prior to such fundamental transaction.

#### Cash Distributions

If at any time we declare a distribution to all holders of our common stock in cash, referred to as a Cash Distribution (excluding any distribution in connection with a fundamental transaction, as described above, or the liquidation, dissolution or winding up of our company, whether voluntary or involuntary), then the number of shares issuable upon exercise of the Warrant shall be increased by multiplying such number by a fraction, the numerator of which shall be the aggregate volume-weighted average price, or VWAP, on the trading day immediately preceding such record date of all common stock outstanding at the close of business on such record date, and the denominator of which shall be (i) the aggregate VWAP on the trading day immediately preceding such record date of all common stock outstanding at the close of business on such record date minus (ii) the amount of cash to be distributed. If the amount of cash to be distributed as described above is equal to or greater than the aggregate VWAP on the trading day immediately preceding such record date of all common stock on such record date, in lieu of the foregoing adjustment, an amount equal to (x) the total amount of the cash distribution multiplied by (y) (A) the maximum number of shares of common stock that could be issued if the Warrant were exercised in accordance with its terms, and divided by (B) the sum of (I) the maximum number of shares of common stock that could be issued if the Warrant were exercised plus (II) the number of shares of common stock outstanding at the close of business on such record date, shall not be distributed,

but instead shall be placed in a segregated account and paid to the holder upon exercise of the Warrant after such record date.

*Registration Rights.* In the event that the registration statement (of which this prospectus supplement is a part) pursuant to which the shares issuable upon exercise of the Warrant are registered is not effective, we must take action to resume the effectiveness of that registration statement or file another registration statement and have it declared effective.

*Rights as a Shareholder*. Except as otherwise provided in the Warrant or by virtue of the holder's ownership of our common stock, the holder of the Warrant does not have the rights or privileges of holders of our common stock, including any voting rights, until it exercises its Warrant.

Waivers and Amendments. Any term of the Warrant may be amended or waived with our written consent and the written consent of the holder of the Warrant.

#### PLAN OF DISTRIBUTION

We are offering the Series A Preferred Stock and the Warrant (including the shares of common stock issuable upon conversion of the Series A Preferred Stock and exercise of the Warrant) directly to the purchaser hereunder. We currently anticipate that the closing of the sale of such securities under this prospectus supplement will take place on or about February 19, 2013. On the closing date, we will issue the shares of Series A Preferred Stock and the Warrant to the investor and we will receive funds in the amount of the aggregate Series A Preferred Stock purchase price of \$533,000.

We have entered into a securities purchase agreement, dated as of February 18, 2013, with the purchaser relating to the sale of our Series A Preferred Stock and the Warrant under this prospectus supplement (including the shares of common stock issuable upon conversion of the Series A Preferred Stock and exercise of the Warrant). Our obligation to issue and sell securities to the purchaser is subject to the conditions set forth in the securities purchase agreement, which may be waived by us in our discretion. The purchaser's obligation to purchase securities is subject to conditions set forth in the securities purchase agreement as well, which also may be waived.

The Series A Preferred Stock and the Warrant were offered directly to the purchaser without a placement agent, underwriter, broker or dealer. The expenses of this offering payable by us are estimated to be approximately \$70,000.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is VStock Transfer, LLC. The transfer agent's address is 77 Spruce Street, Suite 201, Cedarhurst, New York 11516 and its telephone number is (212) 828-8436.

We will act as our own transfer agent and registrar for the Series A Preferred Stock and the Warrant.

#### **LEGAL MATTERS**

Certain legal matters with respect to the shares of Series A Preferred Stock and the Warrant (including the shares of common stock issuable upon conversion of the Series A Preferred Stock and exercise of the Warrant) offered hereby have been passed upon by Wyrick Robbins Yates & Ponton LLP, Raleigh, North Carolina.

#### **EXPERTS**

The balance sheets of CorMedix Inc. as of December 31, 2011 and 2010 and the related statements of operations, changes in stockholders' equity, and cash flows for the years then ended and for the period from July 28, 2006 (inception) to December 31, 2011 have been audited by CohnReznick LLP, independent registered public accounting firm, as stated in their report, which includes an explanatory paragraph relating to our ability to continue as a going concern, which is incorporated herein by reference. Such financial statements have been incorporated herein by reference in reliance on the report of CohnReznick LLP given upon their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND ADDITIONAL INFORMATION ABOUT US

We have filed a registration statement on Form S-3 with the SEC for the securities we are offering by this prospectus supplement. This prospectus supplement does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information. We will provide to each person, including any beneficial owner, to whom a prospectus supplement is delivered, a copy of any or all of the information that has been incorporated by reference in the prospectus supplement but not delivered with the prospectus supplement. We will provide this information upon oral or written request, free of charge. Any requests for this information should be made by calling or sending a letter to the Secretary of the Company, c/o CorMedix Inc., at our office located at 745 Route 202-206, Suite 303, Bridgewater, New Jersey 08807.

We are required to file annual and quarterly reports, current reports, proxy statements, and other information with the SEC. We make these documents publicly available, free of charge, on our website at www.cormedix.com as soon as reasonably practicable after filing such documents with the SEC. You can read our SEC filings, including the registration statement, on the SEC's website at http://www.sec.gov. You also may read and copy any document we file with the SEC at its public reference facility at:

Public Reference Room

100 F Street N.E.

Washington, DC 20549.

Please call the SEC at 1-800-732-0330 for further information on the operation of the public reference facilities.

### INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus supplement and the accompanying prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act of 1933, as amended, with the SEC with respect to the securities being offered pursuant to this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus omit certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities being offered pursuant to this prospectus supplement and the accompanying prospectus. Statements in this prospectus supplement and the accompanying prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in "Where You Can Find More Information." The documents we are incorporating by reference into this prospectus supplement are:

our Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended December 31, 2011, filed with the SEC pursuant to Section 13 of the Exchange Act on March 19 and April 26, 2012, respectively;

our Quarterly Report on Form 10-Q for the three-month period ended March 31, 2012, filed with the SEC pursuant to Section 13 of the Exchange Act on May 15, 2012;

our Quarterly Report on Form 10-Q and Form 10-Q/A for the six-month period ended June 30, 2012, filed with the SEC pursuant to Section 13 of the Exchange Act on August 13 and September 6, 2012, respectively;

our Quarterly Report on Form 10-Q for the nine-month period ended September 30, 2012, filed with the SEC pursuant to Section 13 of the Exchange Act on November 13, 2012;

our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on January 4, January 11, March 5, March 23, April 24, May 3, June 14, July 2, September 25, October 11, October 16, November 6, November 15, December 3, December 7 and December 26, 2012, and January 16, February 7 and February 19, 2013; and

our preliminary proxy statement and definitive proxy statement on Schedule 14A, filed with the SEC pursuant to Section 14 of the Exchange Act, for the 2012 annual meeting of stockholders on September 27 and October 17, 2012, respectively.

In addition, all documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, before the date our offering is terminated or completed are deemed to be incorporated by reference into, and to be a part of, this prospectus supplement.

Any statement contained in this prospectus supplement and the accompanying prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus will be deemed to be modified or superseded for purposes of this prospectus supplement and the accompanying prospectus to the extent that a statement contained in this prospectus supplement and the accompanying prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement and the accompanying prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to CorMedix, Inc., Attention: Secretary, 745 Route 202-206, Suite 303, Bridgewater, New Jersey 08807, (908) 517-9500.

You should rely only on information contained in, or incorporated by reference into, this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus supplement and the accompanying prospectus or incorporated by reference in this prospectus supplement and the accompanying prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

Prospectus
\$30,000,000 of
Common Stock,
Preferred Stock,
Warrants,
Debt Securities and/or
Units
From time to time, we may offer up to \$30,000,000 of any combination of the securities described in this prospectus, either individually or in units, in one or more offerings in amounts, at prices and on the terms that we will determine a the time of offering. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.
Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. We will specify in any accompanying prospectus supplement the terms of any offering. You should read this prospectus and the applicable prospectus supplement, as well as any documents incorporated by reference in this prospectus and any prospectus supplement, carefully before you invest in any securities. <b>This prospectus may not be used by us to consummate a sale of securities unless accompanied by the applicable prospectus supplement.</b>

We will sell these securities directly to our stockholders or to other purchasers or through agents on our behalf or through underwriters or dealers as designated from time to time. If any agents or underwriters are involved in the sale of any of these securities, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions or discounts.

Our common stock trades on the NYSE MKT under the trading symbol "CRMD." On January 7, 2013, the last reported sale price of our common stock was \$0.93 per share. We recommend that you obtain current market quotations for our

common stock prior to making an investment decision.

As of January 7, 2013, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was approximately \$9,587,095, which was calculated based on 10,308,704 shares of our outstanding common stock held by non-affiliates and on a price of \$0.93 per share, the last reported sale price for our common stock on January 7, 2013. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our common stock in a public primary offering with a value exceeding one-third of our public float in any 12-month period unless our public float subsequently rises to \$75.0 million or more. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

You should carefully read this prospectus, the prospectus supplement relating to any specific offering of securities and all information incorporated by reference herein and therein.

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 January 10, 2013.

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#### **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this shelf registration process, we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of \$30,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering.

This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. Prospectus supplements may also add, update or change information contained or incorporated by reference in this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus and the applicable prospectus supplement, includes all material information relating to this offering. You should carefully read this prospectus, the applicable prospectus supplement, the information and documents incorporated herein and therein by reference and the additional information under the heading "Where You Can Find More Information" before making an investment decision.

You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated herein by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

This prospectus may not be used to consummate sales of our securities, unless it is accompanied by a prospectus supplement.

Unless the context otherwise requires, "CorMedix" the "company," "we," "us," "our" and similar names refer to CorMedix Inc

## PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in 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, before making an investment decision.

#### 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. Specifically, our goal is to treat kidney disease by reducing the commonly associated cardiovascular and metabolic complications — in effect, "treating the kidney to treat the heart." As of the date of this prospectus, we have 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, that we believe address potentially large market opportunities in the instances in which a central venous catheter is used, such as hemodialysis, intensive care units, oncology and total parenteral nutrition patients.

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

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

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.

We have successfully completed the stage 2 audit with TÜV SÜD. We anticipate receiving a CE Mark approval by the end of the fourth quarter of 2012 or in the first 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 in the first half of 2013. However, we cannot be assured of CE Mark approval of Neutrolin or the planned commercialization timeline.

We are currently exploring the various means 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 will entail a Phase 3 trial.

## **Recent Developments**

On September 20, 2012, we completed an initial closing of our private placement of 850 Units, each Unit consisting of (i) a one-year \$1,000 principal amount 9% Senior Convertible Note, convertible into shares of our common stock at a conversion price of \$0.35 per Note, and (ii) a five-year redeemable Warrant, to purchase 2,500 shares of our common stock at a purchase price of \$0.40 per share. We received gross proceeds of \$850,000 and net proceeds of approximately \$689,000 in the September 20, 2012 initial closing. The maturity date of the Notes issued in the initial closing is September 20, 2013.

On November 13, 2012, we held the second and final closing of the private placement, and issued an additional 474 Units for a total gross amount of \$474,000. The maturity date of the Notes issued in the final closing is November 13, 2013. Together with the sale of 850 Units at the initial closing, we issued and sold in the private placement an aggregate total of 1,324 Units for aggregate gross proceeds of \$1,324,000. The total net proceeds (net of placement agent and legal fees) of the private placement to us were \$1,095,600, including \$689,000 net proceeds previously received by us at the initial closing and \$406,600 net proceeds received by us in the final closing. We issued to the investors Warrants to purchase an aggregate of 3,310,000 shares of our common stock. We paid the placement agent for the private placement a total of \$109,900 in fees and issued it warrants to purchase an aggregate of 331,000 shares. The placement agent warrants have the same terms as those issued to the investors.

We have agreed to file an initial registration statement with the SEC to register the resale of the shares of common stock issuable upon the conversion of the Notes and the exercise of the Warrants within 60 days after the final closing, which is January 11, 2013. Also, we have agreed to use our commercially reasonable efforts to have the registration statement declared effective within 120 days after the date of the final closing, which is March 13, 2013.

On December 24, 2012, we announced the following changes to our executive team.

Randy Milby has been promoted to Chief Executive Officer, effective January 1, 2013. Mr. Milby previously served as our Chief Operating Officer.

Richard M. Cohen will serve as Chief Financial Officer, effective January 1, 2013, and will continue as Executive ·Chairman and director of CorMedix. Mr. Cohen previously served as our Interim Chief Financial Officer and Interim Chief Executive Officer.

Antony E. Pfaffle, M.D., a director on our board, joins the executive team as Acting Chief Scientific Officer, effective January 1, 2013.

Mark Klausner, M.D., our current Chief Medical Officer, will depart CorMedix effective February 28, 2013 upon expiration of his employment agreement with CorMedix.

Mr. Milby will continue to work with the board and build the management team to drive our strategy forward with respect to the planned receipt of CE Mark approval for Neutrolin and subsequent commercial launch of Neutrolin in Europe and the planned expansion into countries beyond Europe. Dr. Pfaffle in this capacity will provide scientific support and will focus on the development of key opinion leader relationships throughout Europe.

#### **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, establishing manufacturing for our product candidates and maintaining and improving our patent portfolio.

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.

#### **Offerings Under This Prospectus**

We may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, with a total value of up to \$30,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of any offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

The prospectus supplement also may add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

This prospectus may not be used to consummate a sale of any securities unless it is accompanied by a prospectus supplement.

We may sell the securities directly to investors or to or through agents, underwriters or dealers. We, and our agents or underwriters, reserve the right to accept or reject all or part of any proposed purchase of securities. If we offer securities through agents or underwriters, we will include in the applicable prospectus supplement:

- ·the names of those agents or underwriters;
- ·applicable fees, discounts and commissions to be paid to them;
- ·details regarding over-allotment options, if any; and
- ·the net proceeds to us.

#### Common Stock

We may issue shares of our common stock from time to time. The holders of common stock are entitled to one vote per share on all matters to be voted upon by stockholders. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably any dividends that may be declared from time to time by our board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of any preferred stock then outstanding.

#### Preferred Stock

We may issue shares of our preferred stock from time to time, in one or more series. Our board of directors will determine the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by stockholders. Convertible preferred stock will be convertible into our common stock or exchangeable for our other securities. Conversion may be mandatory or at your option or both and would be at prescribed conversion rates.

If we sell any series of preferred stock under this prospectus and applicable prospectus supplements, we will fix the rights, preferences, privileges and restrictions of the preferred stock of such series in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the applicable prospectus supplement related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

#### **Warrants**

We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from these securities. We will evidence each series of warrants either by agreements with each investor or warrant certificates that we will issue under a separate agreement. If we issue warrant certificates, we expect to enter into warrant agreements with a bank or trust company that we select to be our warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the applicable prospectus supplement related to the particular series of warrants being offered, as well as the warrant agreements and warrant certificates that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant agreement or warrant certificate containing the terms of the warrants we are offering before the issuance of the warrants.

#### **Debt Securities**

We may offer debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. The senior debt securities will rank equally with any other unsecured and unsubordinated debt. The subordinated debt securities will be subordinate and junior in right of payment, to the extent and in the manner described in the instrument governing the debt, to all of our senior indebtedness. Convertible debt securities will be convertible into or exchangeable for our common stock or our other securities. Conversion may be mandatory or at your option or both and would be at prescribed conversion rates.

With respect to any debt securities that we issue, we will issue such debt securities under an indenture, which we would enter into with the trustee named in the indenture. Any indenture would be qualified under the Trust Indenture Act of 1939.

#### **Units**

We may issue units consisting of common stock, preferred stock, debt securities and/or warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. In this prospectus, we have summarized

certain general features of the units. We urge you, however, to read the applicable prospectus supplement related to the series of units being offered, as well as the unit agreements that contain the terms of the units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference reports that we file with the SEC, the form of unit agreement and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

#### RISK FACTORS

Investing in our securities involves risk. The prospectus supplement applicable to each offering of our securities will contain a discussion of the risks applicable to an investment in our company. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed below and under the heading "Risk Factors" in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K and 10-K/A, as revised or supplemented by our most recent quarterly report on Form 10-Q, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future.

## Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of operating losses, and expect to incur 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 a net loss of approximately \$2.2 million for the nine months ended September 30, 2012 and approximately \$6.7 million for the year ended December 31, 2011. As of September 30, 2012, we had an accumulated deficit of approximately \$45.2 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.

Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its audited financial statements for the year ended December 31, 2011 and may do so again in the

future.

In their report accompanying our audited financial statements for the year ended December 31, 2011, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going a 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 first 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. Our ability to continue as a going concern will depend, in large part, on our ability to obtain additional financing. Thereafter, our ability to generate positive cash flow from operation 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 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 first 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. We have recently 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:

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