CorMedix Inc.
Form 424B3
April 21, 2015

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-203300

Prospectus

$40,000,000 of Shares

Common Stock

We have entered into an At-the-Market Issuance Sales Agreement, which we refer to as the sales agreement, with MLV & Co. LLC, or MLV, relating to the sale of shares of our common stock offered by this prospectus. In accordance with the terms of the sales agreement, under this prospectus we may offer and sell shares of our common stock, $0.001 par value per share, having an aggregate offering price of up to $40,000,000 from time to time through MLV, acting as agent.

Our common stock is traded on the NYSE MKT under the symbol “CRMD.” The last reported sale price of our common stock on April 17, 2015 was $8.47 per share.

Sales of our common stock, if any, under this prospectus will be made by any method permitted that is deemed an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through the Exchange, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. MLV is not required to sell any specific amount, but will act as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

MLV will be entitled to compensation at a commission rate of up to 3% of the gross sales price per share sold. In connection with the sale of the common stock on our behalf, MLV may be deemed to be an “underwriter” within the meaning of the Securities Act and the compensation of MLV may be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to MLV with respect to certain liabilities, including liabilities under the Securities Act.

Investing in our common stock involves a high degree of risk. Please read the information contained in and incorporated by reference under the heading “Risk Factors” beginning on page 6 of this prospectus, the section captioned “Item 1A—Risk Factors” in our most recently filed annual report on Form 10-K, which is incorporated by reference into this prospectus, and under similar headings in the other documents that are filed after the date hereof and 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 April 17, 2015.

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus relates to the offering of our common stock. Before buying any of the common stock that we are offering, we urge you to carefully read this prospectus, together with the information incorporated by reference as described under the headings "Where You Can Find More Information" and "Incorporation of Certain Information by Reference" in this prospectus. These documents contain important information that you should consider when making your investment decision.

This prospectus describes the specific terms of the common stock we are offering and also adds to, and updates information in any document incorporated by reference into this prospectus. To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained any document incorporated by reference into this prospectus that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference into this prospectus— the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in, or incorporated by reference into, this prospectus and in any free writing prospectus that we may authorize for use in connection with this offering. We have not, and MLV has not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and MLV is not, making an offer to sell or soliciting an offer to buy our securities in any jurisdiction in which an offer or solicitation is not authorized or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information appearing into this prospectus, the documents incorporated by reference into this prospectus, and in any free writing prospectus that we may authorize for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus, the documents incorporated by reference into this prospectus, and any free writing prospectus that we may authorize for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus entitled "Where You Can Find More Information" and "Incorporation of Certain Information by Reference."

We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus outside the United States. This prospectus does 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 by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Our primary executive offices are located at 1430 U.S. Highway 206, Suite 200, Bedminster, NJ 07921, and our telephone number is (908) 517-9500. Our website address is www.cormedix.com. The information contained on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus.

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

Neutrolin® is our registered trademark and the CorMedix logo is our trademark. All other trade names, trademarks and service marks appearing in this prospectus are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this

prospectus, appear with the trade name, trademark or service mark notice and then throughout the remainder of this prospectus without trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus, including the information incorporated by reference into this prospectus, and the information referred to under the heading "Risk Factors" in this prospectus beginning on page 6, and in the documents incorporated by reference into this prospectus.

Our Company

Overview

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

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

Our primary product is Neutrolin, a catheter lock solution, is for the prevention of catheter-related infections and thrombosis in the central venous catheter markets such as dialysis, critical care, and oncology. We believe this is a multi-billion dollar global market opportunity. There are seven million central venous catheters and 160 million peripheral catheters placed per year in patients in the United States. There are 1.7 million infections per year of which 25% are due to catheter related bloodstream infections (CRBSI), which are also referred to as central line associated bloodstream infections (CLABSI). The mortality rate ranges from 20 to 25%. Neutrolin is a novel formulation of taurolidine, citrate and heparin 1000 u/ml that provides a combination preventative solution to decrease the development of biofilm, which reduces infection and thrombosis thereby keeping catheters operating optimally in the clinical settings in hemodialysis, critical care/intensive care and oncology. Hemodialysis using a tunneled central vein catheter was our initial target market with Germany being the first market in which we launched Neutrolin as a medical device in December 2013. Hemodialysis patients represent over 30 million catheter/dialysis treatment days per year in the U.S. and Europe. The market in the critical care/intensive care units is 15 million catheter days per year in the United States alone. There were over 13 million patients living with cancer in the United States in 2010 with an estimated 4 million having a long-term central venous catheter. However, when stages of disease, chemotherapy regimens and catheter types are factored, the oncology market is of a similar order. Infection and thrombosis represent key complications among critical care/intensive care and cancer patients with central venous catheters. These complications can lead to treatment delays and increased costs to the healthcare system when they occur due to hospitalizations, need for IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the central venous catheter, related treatment costs and increased mortality when they occur. We estimate that catheter related bloodstream infections and thrombosis cost the U.S. healthcare system approximately $5 billion dollars each year.

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

notified body managing our CE Mark application. In the fourth quarter of 2011, we successfully completed our stage 1 audit with TÜV SÜD and we successfully completed the stage 2 audit in the third quarter of 2012.

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

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, in 2013, we began the commercial launch of Neutrolin in Germany for the prevention of catheter-related bloodstream infections, or CRBI, and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia and The Netherlands for such treatment.

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

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

In late 2013, we met with the FDA to determine the pathway for U.S. approval of Neutrolin. Based on our discussions with the FDA, we expect to conduct at least one Phase 3 clinical trial in hemodialysis catheters and one Phase 3 clinical trial in oncology/total parenteral nutrition. We have worked with the FDA to design the protocol for a planned Phase 3 trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an investigational new drug application, or IND, in September 2014. In October 2014, the FDA informed us that it had determined that the IND is not subject to a clinical hold, and that the Phase 3 clinical trial in hemodialysis patients can be initiated in the U.S. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

Neutrolin has Class III CE mark approval for use in the European Union and was recently approved to enter a Phase 3 clinical trial program in the United States where it will be reviewed as a new drug. The U.S. Food and Drug Administration (FDA) designated Neutrolin as a Qualified Infectious Disease Product (QIDP) for oncology, hemodialysis, and critical care/intensive care patients, where catheter-related blood stream infections and clotting can be life-threatening. The QIDP designation will make Neutrolin eligible to benefit from certain incentives such as FDA priority review, fast-track status and it also provides an additional five years of market exclusivity in addition to the five years granted for a New Chemical Entity under Hatch-Waxman patent exclusivity.

In January 2015, the FDA granted Fast Track designation to Neutrolin® Catheter Lock Solution, pursuant to the Food and Drug Administration Safety and Innovation Act (FDASIA). Fast Track designation is granted to drug products designed to treat a serious condition, for which clinical data has been generated and shown to potentially address an unmet medical need. The Fast Track designation of Neutrolin provides CorMedix with the opportunity to meet with the FDA on a more frequent basis during the review process, and also ensures an expedited review of any marketing application.

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

Recent Developments

From January 1, 2015 to April 17, 2015, warrants to purchase 2,597,591 shares of our common stock were exercised on a cashless basis resulting in the issuance of 2,158,033 shares of common stock.

From January 1, 2015 to April 17, 2015, 42,500 shares of our Series C-3 preferred stock were converted into 425,000 shares of our common stock.

In March 2015, all 454,546 shares of our Series B preferred stock were converted into 454,546 shares of our common stock.

In March 2015, 2,817 shares of our Series E preferred stock were converted into 61,598 shares of our common stock.

From January 1, 2015 to April 17, 2015, stock options to purchase 280,000 shares of our common stock were exercised resulting in gross proceeds to us of $323,900.

From January 1, 2015 to April 17, 2015, the following warrants were exercised, resulting in aggregate gross proceeds to us of approximately $10.2 million:

150,000 shares of our common stock with an exercise price of $0.90 per share;
125,000 shares of our common stock with an exercise price of $0.40 per share;
353,500 shares of our common stock with an exercise price of $2.50 per share; and
2,651,287 shares of our common stock with an exercise price of $3.4375 per share.

On March 2, 2015, our Board of Directors approved an extension to April 30, 2015 of the expiration date for our publicly traded warrants.

On March 2, 2015, the NYSE MKT notified us that we had regained compliance with the NYSE MKT listing requirements because, as of February 26, 2015, we qualified for the market capitalization exception in Section 1003(a) of the NYSE MKT Company Guide.

In March 2015, we issued two warrants for an aggregate of 283,400 common shares with an exercise price of $7.00 per share and a term of five years as a result of entering into the Backstop Agreement with Manchester Securities Corp.

Corporate History and Information

We were organized as a Delaware corporation on July 28, 2006 under the name "Picton Holding Company, Inc." and we changed our corporate name to "CorMedix Inc." on January 18, 2007. Our operations to date have been primarily limited to organizing and staffing, licensing product candidates, developing clinical trials for our product candidates, seeking regulatory approvals for Neutrolin, establishing manufacturing for our product candidates and maintaining and improving our patent portfolio and launching Neutrolin in the E.U and other foreign countries.

Our executive offices are located at 1430 US Highway 206, Suite 200, Bedminster, NJ 07921. Our telephone number is (908) 517-9500. Our website address is www.cormedix.com. Information contained in, or accessible through, our website does not constitute part of this prospectus.

The Offering	
Common stock offered by us	Shares having an aggregate offering price of up to $40.0 million.
Common stock to be outstanding after this offering (1)	Up to 4,405,286 shares, assuming sales at a price of $9.08 per share, which was the closing price on the NYSE MKT on April 2, 2015. Actual number of shares issued will vary depending on the sales price under this offering.
Manner of offering	"At the market offering" that may be made from time to time through our sales agent, MLV & Co. LLC. See "Plan of Distribution" on page 30.
Use of proceeds	We intend to use the net proceeds from this offering, if any, for general corporate purposes, including clinical trials, research and development expenses and general and administrative expenses. See "Use of Proceeds" on page 27.
NYSE MKT symbol	"CRMD"
Risk factors	Investing in our common stock involves a high degree of risk. Please read the information contained in and incorporated by reference under the heading "Risk Factors" beginning on page 6, the section captioned "Item 1A—Risk Factors" in our most recently filed annual report on Form 10-K, which is incorporated by reference into this prospectus, and under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus.

(1) The number of shares of our common stock that will be outstanding immediately after this offering as shown above is based on 27,864,841 shares outstanding as of March 31, 2015. The number of shares outstanding as of March 31, 2015, as used throughout this prospectus, unless otherwise indicated, excludes:

- warrants for 227,273 shares of common stock issued in July 2013 with an exercise price of $1.50 that expire on July 30, 2018;
- warrants for 500,000 shares of common stock issued in May 2013 with an exercise price of $0.65 per share that expire on May 30, 2019;
- warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment agreement with an exercise price of $1.50 per share that expire on April 11, 2018;
- warrants for 2,443,139 shares of our common stock issued in connection with our IPO with an exercise price of $3.4375 per share that expire on April 30, 2015;
- warrants for 390,720 shares of our common stock held by Manchester Securities Corp. issued in connection with our IPO with an exercise price of $3.4375 per share that expire on March 24, 2016;
- options to purchase an aggregate of 1,015,000 shares of our common stock issued to our officers, directors, employees and non-employee consultants under our Amended and Restated 2006 Stock Incentive Plan, or the 2006 Stock Plan, with a weighted average exercise price of $0.68 per share;
- options to purchase an aggregate of 2,999,500 shares of our common stock issued to our officers, directors and non-employee consultants under our 2013 Stock Plan, with a weighted average exercise price of $1.98 per share;
- warrants issued to investors in our 2012 private placement to purchase an aggregate of 337,500 shares of our common stock with an exercise price of $0.40 per share, of which 312,500 expire on September 20, 2017 and 25,000 expire on November 13, 2017;

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

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

warrants for 750,000 shares of common stock with an exercise price of $0.90 that expire on October 22, 2019;

warrants for 750,000 shares of common stock with an exercise price of $0.90 that expire on January 8, 2020;

Series C-2 Preferred Stock convertible into 1,500,000 shares of common;

Series C-3 Preferred Stock convertible into 1,365,000 shares of common stock;

Series D Preferred Stock convertible 1,479,240 shares of common stock;

Series E Preferred Stock convertible 1,959,759 shares of common stock;

warrants for 682,500 shares of common stock issued in March 2014 with an exercise price of $2.50 per shares that expire on September 9, 2019;

a warrant for 200,000 shares of common stock with an exercise price of $7.00 that expires on March 3, 2020 issued on March 3, 2015, to Manchester Securities Corp. in connection with the Backstop Financing; and

a warrant for 83,400 shares of common stock with an exercise price of $7.00 that expires on March 3, 2020 issued on March 25, 2015, to Kingsbrook Opportunities Master Fund LP in connection with the Backstop Financing.

RISK FACTORS

Investing in our securities involves risk. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed below 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 which is on file with the SEC and is 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 additional operating losses in 2015.

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 $20.5 million for the year ended December 31, 2014. As of December 31, 2014, we had an accumulated deficit of approximately $76.2 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. Neutrolin was launched in December 2013 and is currently distributed in Germany and Saudi Arabia. We have not generated any significant commercial revenue and do not expect to generate substantial revenues from Neutrolin until late 2015 at the earliest, and might never generate significant revenues from the sale of Neutrolin or any other products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: successfully marketing Neutrolin in Germany and other countries in which it is approved for sale; obtaining necessary regulatory approvals for Neutrolin from the other applicable European and Middle East agencies, other foreign agencies and the FDA and international regulatory agencies for any other products; successful completion of the development of our other product candidates; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We are not currently profitable and may never become profitable.

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

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

negatively impact the value of our securities.

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

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

We believe that our cash resources as of December 31, 2014, after giving effect to the receipt of approximately $6.8 million from the exercises of warrants and stock options in January through March 31, 2015, will be sufficient to enable us to fund our projected operating requirements into the fourth quarter of 2015. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our research and development efforts more rapidly than we presently anticipate. We can provide no assurances that any financing or strategic relationships will be available to us on acceptable terms, or at all. We expect to incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other markets, increase our business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

On March 3, 2015, we entered into a backstop agreement with an existing institutional investor, Manchester Securities Corp., an affiliate of Elliott Associates, L.P., pursuant to which Manchester has agreed to lend us, at our request, up to $4,500,000 less the dollar amount of gross proceeds received by us upon the exercise of warrants to purchase common stock issued in connection with our initial public offering on or before April 30, 2015, provided that the loan may not exceed $3,000,000. We were able to access this financing until April 30, 2015. However, because we have received approximately $5.7 million from the exercise of warrants issued in connection with our initial public offering, we cannot and will not access the loan.

We may seek to sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in fixed obligations and could also result in covenants that would restrict our operations. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders.

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

Based on our cash resources at December 31, 2014, we believe that existing cash will be sufficient to enable us to fund our projected operating requirements into the third quarter of 2015, after giving effect to the receipt of approximately $2 million from the exercises of warrants and stock options through March 9, 2015 and the $2.5 million of availability under the Backstop Agreement, dated March 3, 2015, with Manchester Securities Corp. As a result, our independent registered public accounting firm in their report to accompany our audited financial statements for the year ended December 31, 2014, expressed substantial doubt as to our ability to continue as a going concern. A “going concern” opinion could impair our ability to finance our operations through the sale of debt or equity securities or through bank financing. Our ability to continue as a going concern will depend, on our ability to obtain additional financing. Thereafter, our ability to generate positive cash flow from operations will depend on our ability to successfully commercialize Neutrolin, which is uncertain. Additional capital may not be available on reasonable

terms, or at all. If adequate financing is not available, we would be required to terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain aspects of our technologies, or potential markets that we would not otherwise relinquish. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operation. These and other factors raise substantial doubt about our ability to continue as a going concern.

During the first quarter of 2015, we received proceeds of $6.8 million from the exercise of warrants and stock options which we believe will be sufficient to fund operations into the fourth quarter of 2015. As a result of the proceeds received, we will not be able to access the loan under the Backstop Agreement. The proceeds received through March 31, 2015 have not alleviated the substantial doubt about our ability to continue as a going concern issued by our independent registered public accounting firm, which will be reassessed each reporting period. To alleviate such concern, we will need to have sufficient liquidity to fund our operations for 12 months from each reporting period.

Our continued operations will depend on whether we are able to generate substantial revenue from the sale of Neutrolin and on our ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products, until it achieves profitability, if ever. However, we can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. We expect to incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other foreign markets, increase our business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

The financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should we be unable to continue as a going concern.

Our efforts to explore strategic alternatives aimed at accelerating Neutrolin’s development and commercialization and maximizing shareholder value may not result in any definitive transaction or deliver the expected benefits, and may create a distraction for our management and uncertainty that may adversely affect our operating results and business.

As announced on March 4, 2015, the Board has commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. No timetable has been set for completion of this evaluation process, and there can be no assurance that any transaction will result. The Board has engaged investment bank Evercore Group L.L.C. to provide financial advice and assist the Board with its evaluation process. Strategic alternatives we may pursue could include, but are not limited to, joint ventures or partnering or other collaboration agreements, licensing arrangements, or another transaction intended to maximize shareholder value, such as a merger, a sale of the Company or some or all of its assets, or another strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

There are various uncertainties and risks relating to our evaluation and negotiation of possible strategic alternatives and our ability to consummate a definitive transaction, including:

expected benefits may not be successfully achieved;

evaluation and negotiation of a proposed transaction may distract management from focusing our time and resources on execution of our operating plan, which could have a material adverse effect on our operating results and business;

the process of evaluating proposed transactions may be time consuming and expensive and may result in the loss of business opportunities;

perceived uncertainties as to our future direction may result in increased difficulties in retaining key employees and recruiting new employees, particularly senior management;

even if our Board of Directors negotiates a definitive agreement, successful integration or execution of the strategic alternative will be subject to additional risks;

the current market price of our common stock may reflect a market assumption that a transaction will occur, and during the period in which we are considering a transaction, the market price of our common stock could be highly volatile; and

a failure to complete a transaction could result in a negative perception by investors in the Company generally and could cause a decline in the market price of our common stock, as well as lead to greater volatility in the market price of our common stock, all of which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives.

Risks Related to the Development and Commercialization of Our Product Candidates

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

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

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

CRMD003 (Neutrolin) – IND filed with the FDA for a planned Phase 3 trial was accepted in October 2014 and we are seeking one or more strategic partners or other sources of capital to undertake the planned Phase 3 trial and to complete the development of Neutrolin in the U.S.; and

CRMD004 - currently in the pre-clinical phase.

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

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

Successful development and commercialization of our products is uncertain.

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

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

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

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

failure to receive regulatory approvals;

emergence of superior or equivalent products;

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

failure to achieve market acceptance.

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

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

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

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

slower than expected rates of patient recruitment;

failure to recruit a sufficient number of patients;

modification of clinical trial protocols;

changes in regulatory requirements for clinical trials;

lack of effectiveness during clinical trials;

emergence of unforeseen safety issues;