CorMedix Inc.
Form POS AM
March 13, 2015
As filed with the Securities and Exchange Commission on March 13, 2015
Registration Statement No. 333-163380

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Post-Effective Amendment No. 2
to FORM S-1 on
FORM S-3

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

CORMEDIX INC.
(Exact name of registrant as specified in its charter)

Delaware	2834	20-5894890
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

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Bedminster, New Jersey 07921
Telephone: (908) 517-9500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

RANDY MILBY
Chief Executive Officer
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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer (Do not check if smaller reporting company)	o	Smaller reporting company	x

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Post-Effective Amendment No. 2 to our registration statement on Form S-1 (File No. 333-163380) (the "Registration Statement") is being filed to update the Registration Statement to include information from our annual report on Form 10-K for the year ended December 31, 2014, filed on March 12, 2015, and to coincidentally convert the Registration Statement on Form S-1 into a Form S-3. This amended Registration Statement relates to the continued registration of 1,705,000 shares of common stock issuable upon exercise of the outstanding investor warrants. As of March 12, 2015, the following securities issued to the underwriter of our initial public offering and registered under the Post-Effective Amendment No. 1. had been sold: (i) the 2,406 Units underlying the underwriter's Unit purchase warrant with an exercise price of $7.80 per Unit, (ii) 1,548 shares of common stock underlying the underwriter's Units upon cashless exercise, (iii) the 774 warrants underlying the underwriter's Units with an exercise price of $3.4375 per share upon cashless exercise, and (iv) the 774 shares of common stock underlying the warrants in the underwriter's Units. All shares of common stock offered hereby are being offered on a delayed or continuous basis. We are not registering any additional securities under this Post-Effective Amendment. All filing fees payable in connection with the registration of these securities were previously paid by us in connection with the filing of the Form S-1.

The information in this prospectus is not complete and may be changed. We may not sell these securities or accept an offer to buy these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated March 13, 2015

Prospectus

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

This prospectus relates to the issuance of up to 1,705,000 shares of our common stock, $0.001 par value per share, issuable upon the exercise of outstanding warrants, at an exercise price of $3.4375 per share, that were issued by us on March 30, 2010, pursuant to a master warrant agreement, dated as of March 30, 2010, or the Warrant Agreement, between us and Onyx Stock Transfer, LLC (now VStock Transfer, LLC). The warrants expire on April 30, 2015.

No underwriter or other person has been engaged to facilitate the sale of the securities in this offering.

Our common stock trades on the NYSE MKT under the trading symbol “CRMD.” On March 12, 2015, the closing-price of our common stock was $8.05 per share.

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

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

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

The date of this prospectus is _____, 2015.

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ABOUT THIS PROSPECTUS

This prospectus is part of a post-effective amendment to a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, using a continuous offering process. This prospectus relates to the offer and sale of up to 1,705,000 shares of our common stock issuable upon the exercise of outstanding warrants, at an exercise price of $3.4375 per share.

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the cover of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security. Our

business, financial condition, results of operations and prospects may have changed since those dates.

We urge you to carefully read this prospectus and any applicable prospectus supplement, together with the information incorporated herein by reference as described under the heading “Where You Can Find More Information” and “Incorporation of Documents by Reference.”

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

PROSPECTUS SUMMARY

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

Overview

We seek to in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious diseases in cardiac, renal and oncology patients. As of the date of this 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. 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. There are approximately 780,000 hemodialysis patients in the United States and the European Union, or EU. 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. We project that 91,000 patients in the European Union and 104,000 patients in the United States have these catheters in place. These hemodialysis patients represent over 30 million catheter/dialysis treatment days per year in the U.S. and Europe, which we believe represents a conservative market potential of $300 to $400 million. 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.

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

In January 2015, warrants to purchase 1,217,779 shares of our common stock were exercised on a cashless basis resulting in the issuance of 857,324 shares of common stock.

In January and February 2015, 31,500 shares of our Series C-3 preferred stock were converted into 315,000 shares of our common stock.

In February 2015, stock options to purchase 30,000 shares of our common stock were exercised resulting in gross proceeds to us of $63,000.

In January through March 9, 2015, the following warrants were exercised, resulting in aggregate gross proceeds to us of approximately $2 million:

125,000 shares of our common stock with an exercise price of $0.90 per share;

305,000 shares of our common stock with an exercise price of $2.50 per share; and

321,844 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.

On March 3, 2015, we retained Evercore Group, L.L.C., as our financial advisor to explore strategic alternatives, in order to accelerate the global development of our product Neutrolin® catheter lock solution and maximize shareholder value.

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 may access this financing until April 30, 2015. To access the loan, we must meet customary conditions.

In consideration for the backstop financing, we issued to Manchester a warrant, exercisable for five years, to purchase 200,000 shares of our common stock at a per share exercise price of $7.00, and we extended by one year to March 24, 2016, the expiration date of a warrant that Manchester holds to purchase 390,720 shares of common stock at a per share exercise price of $3.4375. We also agreed to correct erroneous wording contained in the amended and restated warrant that we issued to Manchester in September 2014 to purchase 500,000 shares of our common stock, which amendment was immaterial and did not affect the terms of the warrant. Manchester will be prohibited from exercising any of the warrants and the note, if issued, if, as a result of such exercise, it, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding. Manchester may waive the ownership limitation, provided that any such waiver will be effective 61 days after notice is delivered to us.

The note, if issued, will be our unsecured senior obligation. The note will bear interest at the rate of 6.0% per annum. The note will have a term of five years. We may prepay the note beginning one year after its issuance. The note and any accrued interest thereon will be convertible at the election of Manchester into shares of our common stock. The conversion price will be the lower of (i) 80% of the closing price on the day preceding the issuance date of the note, and (ii) 80% of the average of the seven dollar volume-weighted average price immediately prior to the issuance date of the note. The conversion price will be subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock. Manchester will be prohibited from converting the note if, as a result of such conversion, it, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding. Manchester may waive the ownership limitation, provided that any such waiver will be effective 61 days after notice is delivered to us.

We also entered into a registration rights agreement with Manchester whereby Manchester can demand that we register the shares issuable upon exercise of the new and amended warrants, and shares issuable upon conversion of the note, if issued.

We also granted Manchester the right for as long as it or its affiliates hold any of our common stock or securities convertible into our common stock the right to appoint up to two members to our Board of Directors and/or to have up to two observers attend Board meetings in a non-voting capacity.

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 U.S. 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

Securities offered by us	Up to 1,705,000 shares of our commons stock issuable from time to time upon exercise of the investor warrants. The exercise price of the warrants is $3.4375 per share. The warrants expire on April 30, 2015.
Common stock to be outstanding immediately after this offering	24,166,668 shares of our common stock if the warrants are exercised in full.(1)
Use of proceeds	We may receive up to a total of approximately $5,860,937 in gross proceeds, and up to a total of approximately $5,780,937 after deducting estimated expenses of $80,000. However, as we are unable to predict the timing or amount of potential exercises of the warrants, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds are allocated to working capital. It is possible that the warrants may expire and may never be exercised.
Risk Factors	Investing in our securities involves a high degree of risk. See “Risks Factors” beginning on page 6 of this prospectus otherwise incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities.
NYSE MKT listing	Our common stock is listed on the NYSE MKT under the symbol “CRMD.”

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

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;

Series B Preferred Stock convertible into 454,546 shares of common stock;

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

warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment agreement with an exercise price of $1.50 per share that expire on April 11, 2018;

warrants for 1,947,849 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;

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 with an exercise price of $3.90 that expire on March 24, 2015;

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

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

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

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

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

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

warrants for 1,000,000 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 stock;

Series C-3 Preferred Stock convertible into 1,790,000 shares of common stock;

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

Series E Preferred Stock convertible into 2,021,358 shares of common stock; and

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of operating losses, and expect to 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, without giving effect to the receipt of approximately $2 million from the exercises of warrants and stock options in January through March 9, 2015, will be sufficient to enable us to fund our projected operating requirements into the second quarter of 2015. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our 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 may access this financing until April 30, 2015. To access the loan, we must meet customary conditions.

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.

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;

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

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

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

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

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

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

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

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

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

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

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

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

In the United States, we have no current application for, and have not received the regulatory approvals required for, the commercial sale of any of our products. None of our product candidates has been determined to be safe and effective in the United States, and we have not submitted an NDA or PMA to the FDA for any product. Although we have received approval from the FDA to proceed with a planned Phase 3 trial for Neutrolin, we do not have immediate plans to initiate that trial and are seeking one or more strategic partners or other sources of capital to start that trial. However, we might not obtain any commercial partner or financing and may never start the Phase 3 trial.

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

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. The failure to obtain or maintain reimbursement coverage for any of our products could materially harm our operations.

Physicians and patients may not accept and use our products.

Even with the CE Mark approval of Neutrolin, and even if we receive FDA or other foreign regulatory approval for Neutrolin or other product candidates, physicians and patients may not accept and use our products. 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 Neutrolin to generate substantially all of our product revenues for the foreseeable future, the failure of Neutrolin 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 Neutrolin or any other product candidate 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 with the industry 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 includes the sale of commercial products. We have expanded our insurance coverage to include the sale of commercial products due to the receipt of the CE Mark approval, but we may be unable to maintain such coverage or obtain commercially reasonable product liability insurance for any other 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, as well as foreign, 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, as well as foreign, 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, Randy Milby, a director and our Chief Executive Officer, Harry O'Grady, our Chief Financial Officer, and Dr. Antony Pfaffle, a director and Chief Scientific Officer. We have an employment agreement with Mr. Milby but this agreement cannot ensure our retention of him. 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.

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.

Our success will depend upon the expansion of our operations to commercialize Neutrolin and the effective management of any 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, including the failure to make any required milestone or other payments. 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, which was January 20, 2008, 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, the gel formation of Neutrolin. 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 which we currently believe are most material to our business are as follows:

U.S. Patent No. 8,541,393 (expiring in November 2024) (the "Prosl Patent") - use of Neutrolin for preventing infection and maintenance of catheter patency in hemodialysis catheters (for CRMD003);

U.S. Patent No. 6,166,007 (expiring May 2019) (the "Sodemann Patent") - a method of inhibiting or preventing infection and blood coagulation at a medical prosthetic device (for CRMD003);

European Patent EP 1 442 753 (expiring February 2023) (the "Polaschegg Patent") - use of a thixotropic gel as a catheter locking composition, and method of locking a catheter (for CRMD004); and

European Patent EP 1 814 562 B1 (expiring October 12, 2025) (the "Prosl European Patent") - a low heparin catheter lock solution for maintaining and preventing infection in a hemodialysis catheter.

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 above mentioned patents and patent applications are exclusively licensed to us. To support our patent strategy, we have engaged in a review of patentability and certain freedom to operate issues, including performing certain searches. However, patentability and certain 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.

Ongoing and future 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 we may become subject to proceedings initiated by our competitors or other third parties or the PTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. In addition, 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. We recently initiated court proceedings in Germany for patent infringement and unfair use of our proprietary information related to Neutrolin (as described below). We also recently had opposition proceedings brought against the European Patent and the German utility model patent which are the basis of our infringement proceedings (as described below). The defense and prosecution of these ongoing and any future 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. An adverse determination in litigation or PTO or foreign proceedings to which we may become a party could subject us to significant liabilities, including damages, 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 European 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 counterpart of 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 of the prior art. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, 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 counterpart of the Sodemann Patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the counterpart of the Sodemann Patent claims. We received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, we were notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed our response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. Geistlich did not file a further statement within the required timeline. On November 5, 2014, the Opposition Division at the EPO issued the interlocutory decision to maintain the patent on the basis of the claims as amended during the appeal proceedings. This decision becomes final if no further appeal is lodged by Geistlich by January 15, 2015. As of the date of this report, we have not received a communication from the European Patent Office that

Geistlich has filed such an appeal.

On September 9, 2014, we filed in the Mannheim, Germany District Court a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of our European Patent EP 1 814 562 B1, which was granted by the European Patent Office on January 8, 2014 (the “Prosl European Patent”). The Prosl European Patent covers a low heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, we claim that the Defendants infringe on the Prosl European Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl European Patent. We believe that our patent is sound, and we are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. An oral hearing in this action was scheduled for and held on January 30, 2015. The date for rendering judgment is scheduled for March 27, 2015. This judgment is subject to appeal. Separately, TauroPharm has filed an opposition with the European Patent Office against the Prosl European Patent alleging that it lacks novelty and inventive step. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters.

In the same complaint against the same Defendants, we also alleged an infringement (requesting the same remedies) of ND Partners' utility model DE 20 2005 022 124 U1 which is basically identical to the Prosl European Patent in its main aspects and claims. The Mannheim court separated the two proceedings so that the patent and the utility model proceeding are now tried separately and independently from each other due to the slightly differing requirements for both IP rights. An oral hearing with regard to the utility model has been scheduled for March 27, 2015. TauroPharm has filed a cancellation action against the utility model before the German Patent and Trademark Office based on the same arguments as the opposition against the Prosl European Patent. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of this matter.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of our proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using our proprietary information relating to the composition and manufacture of our product Neutrolin®, which is approved for sale in Germany, in its manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100TM and TauroLock-HEP500TM. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine as well as citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. A hearing in this matter has been scheduled in the District Court of Cologne for June 18, 2015.

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 and maintain 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 medical devices and pharmaceutical products; for other products we may also rely on such marketing collaborations or out-licensing or our product candidates. Specifically, for Neutrolin, we have entered into an agreement with human4farma to market and sell Neutrolin in Germany and a distributor agreement with a Saudi Arabian and a South Korean company for sales and marketing in those two countries (upon receipt of approval to

market in South Korea). In addition, we have independent sales representatives marketing and selling in Austria and The Netherlands. Assuming we receive applicable regulatory approval for other markets, we plan to enter into distribution agreements with one or more third parties for the sale of Neutrolin in various European, Middle East and other markets. However, there can be no assurance that we will be able to successfully maintain those relationships or establish and maintain additional marketing, sales, or distribution relationships. Nor can there be assurance that such relationships 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 and maintain 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.

We currently have no internal marketing and sales organization and have no experience as a company in marketing medical devices or drug products. If we are unable to establish our own marketing and sales capabilities, or enter into agreements with third parties, to market and sell our products after they are approved, we may not be able to generate product revenues.

We do not have an internal sales organization for the marketing, sales and distribution of any drug products. In order to commercialize any products, we must develop these capabilities on our own or make arrangements with third parties for the marketing, sales and distribution of our products. The establishment and development of our own sales force would be expensive and time consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capability. As a result, we may seek one or more third party organizations to handle some or all of the sales and marketing of Neutrolin, which we have done with independent companies in Germany and in Saudi Arabia and South Korea (upon receipt of approval to market in South Korea) and with independent sales representatives in Austria and The Netherlands. However, we may not be able to enter into or maintain arrangements with third parties to sell Neutrolin on favorable terms or at all. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize Neutrolin or any other product candidates that we develop, which would negatively impact our ability to generate product revenues. Further, whether we commercialize products on our own or rely on a third party to do so, our ability to generate revenue will be dependent on the effectiveness of the sales force. In addition, to the extent we rely on third parties to commercialize our approved products, we will likely receive less revenues than if we commercialized these products ourselves.

We have entered into an agreement with independent companies to market Neutrolin in Germany and in Saudi Arabia and, upon regulatory approval, South Korea. We also have independent sales representatives in Austria and The Netherlands. Consequently, we will be dependent on these firms and individuals for the success of sales in these countries and any continued success of the marketing and sales of Neutrolin in these countries. If these firms or individuals do not perform for whatever reason, our business, prospects and results of operations will be materially adversely affected. Finding a replacement organization for these or any other organizations or individuals with which we might contract could be difficult, which would further harm our business, prospects and results of operations.

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 Neutrolin and any other product candidate require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. All of our manufacturing processes currently are, and we expect them to continue to be, outsourced to third parties. Specifically, we will rely on one or more manufacturers to supply us and/or our distribution partners with commercial quantities of Neutrolin. If,

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

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

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

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

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

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

Risks Related to our Common Stock

We have identified a material weakness in our internal control over financial reporting, and our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur.

We have identified material weaknesses in our internal control over financial reporting related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting associated with our financing activities as well as the European commercialization and start up related activities. We have taken initial measures to remediate these weaknesses by increasing internal review processes, in addition to the previously established accounting oversight committee, which is comprised of members of our senior management and our third party GAAP advisor. The hiring of our full-time Chief Financial Officer in July 2014 and our increased use of external advisors were key steps in bolstering our financial infrastructure. We continue to build

on our infrastructure to address these weaknesses. However, we cannot be assured that these weaknesses will be fully remediated or that other material weaknesses will not be discovered.

A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be satisfied. Internal control over financial reporting and disclosure controls and procedures are designed to give a reasonable assurance that they are effective to achieve their objectives. We cannot provide absolute assurance that all of our possible future control issues will be detected. These inherent limitations include the possibility that judgments in our decision making can be faulty, and that isolated breakdowns can occur because of simple human error or mistake. The design of our system of controls is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed absolutely in achieving our stated goals under all potential future or unforeseeable conditions. Because of the inherent limitations in a cost effective control system, misstatements due to error could occur and not be detected. This and any future failures could cause investors to lose confidence in our reported financial information, which could have a negative impact on our financial condition and stock price.

Our common stock price has fluctuated considerably and is likely to remain volatile, in part due to the limited market for our common stock and you could lose all or a part of your investment.

During the period from the completion of our initial public offering, or IPO, on March 30, 2010 through March 11, 2015, the high and low sales prices for our common stock were $9.48 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:

market acceptance of Neutrolin in those markets in which it is approved for sale;

our need for additional capital;

the receipt of or failure to obtain additional regulatory approvals for Neutrolin, including FDA approval in the U.S.;

results of clinical trials of our product candidates, including our planned Phase 3 trial for Neutrolin in the U.S., or those of our competitors;

our entry into or the loss of a significant collaboration;

regulatory or legal developments in the United States and other countries, including changes in the healthcare payment systems;

changes in financial estimates or investment recommendations by securities analysts relating to our common stock;

announcements by our competitors of significant developments, strategic partnerships, joint ventures or capital commitments;

changes in key personnel;

variations in our financial results or those of companies that are perceived to be similar to us;

market conditions in the pharmaceutical and medical device sectors and issuance of new or changed securities analysts' reports or recommendations;

general economic, industry and market conditions;

developments or disputes concerning patents or other proprietary rights;

future sales or anticipated sales of our securities by us or our stockholders; and

any other factors described in this "Risk Factors" section.

In addition, the stock markets in general, and the stock of pharmaceutical and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price

of our common stock, regardless of our actual operating performance.

For these reasons and others, an investment in our securities is risky and invest only if you can withstand a significant loss and wide fluctuations in the value of your investment.

A significant number of additional shares of our common stock may be issued at a later date, and their sale could depress the market price of our common stock.

As of February 28, 2015, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

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;

Series B Preferred Stock convertible into 454,546 shares of common stock;

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 (decreased to 500,000 shares as of January 31, 2015);

warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment agreement with an exercise price of $1.50 per share that expire on April 11, 2018;

warrants for 3,646,380 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 that expire on March 24, 2016.

a warrant to purchase 774 shares of our common stock issued to the underwriters of our IPO with an exercise price of $3.4375 per share that expire on April 30, 2015;

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

options to purchase an aggregate of 1,035,000 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 $0.73 per share;

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

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

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 (decreased to 750,000 shares as of January 31, 2015);

warrants for 875,000 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 1,475,000 shares of common stock;

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

Series E Preferred Stock convertible 2,021,358 shares of common stock; and

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

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.

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

Pursuant to our 2006 Stock Plan, our Board of Directors is authorized to award up to a total of 2,300,000 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. As of February 28, 2015, options to purchase 1,035,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $0.73 per share, and options to purchase 2,599,500 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of $1.44 per share were outstanding. In addition, at February 28, 2015, there were outstanding warrants to purchase an aggregate of 10,167,446 shares of our common stock at prices ranging from $0.40 to $3.4375, and shares of our outstanding Series B, C-2, C-3, D and E preferred stock convertible into an aggregate of 6,930,144 shares of our common stock. Stockholders will experience dilution in the event that additional shares of common stock are issued under our 2006 Stock Plan or 2013 Stock Plan, or options issued under our 2006 Stock Plan or 2013 Stock Plan are exercised, or any warrants are exercised for, or preferred stock shares are converted to, common stock.

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

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

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- 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.

If we fail to comply with the continued listing standards of the NYSE MKT, it 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 and maintaining a minimum level of stockholders' equity. In 2012 and 2014, we received notices from the NYSE MKT that we did not meet continued listing standards of the NYSE MKT as set forth in Part 10 of the Company Guide. Specifically, we were not in compliance with Section 1003(a)(i) and Section 1003(a)(ii) of the Company Guide because we reported stockholders' equity of less than the required amounts. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide and were subject to possible delisting. In March 2015, we regained compliance with the NYSE MKT listing requirements due to our market capitalization, pursuant to Section 1003(a) of the Company Guide. However, there can be no assurance that we will continue to meet the continued listing standards of the NYSE MKT.

If our common stock were no longer listed on the NYSE MKT, investors might only be able to trade on the OTC Bulletin Board ® or in the Pink Sheets ® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our common stock not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

Because the average daily trading volume of our common stock has been low historically, 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 has been low historically, 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 regulations 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. A security listed on a national securities exchange is exempt from the definition of a penny stock. Our common stock is listed on the NYSE MKT and so is not considered a penny stock. However, if we fail to maintain our common stock's listing on the NYSE MKT, our common stock would be considered a penny stock. In that event, our common stock would be 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.

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 our Series D and E Non-Voting Convertible Preferred Stock, we may not declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of those preferred shares remain 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.

USE OF PROCEEDS

We may receive up to a total of approximately $5,780,937 in net proceeds after deducting estimated expenses of $80,000. However, as we are unable to predict the timing or amount of potential exercises of the warrants, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds are allocated to working capital. It is possible that the warrants may expire and may never be exercised.

DILUTION

Our net tangible book value on December 31, 2014 was $(3,634,472), or $(0.1618) 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 warrant exercise price paid by you in this offering and net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 1,705,000 shares of common stock upon the exercise of the warrants at an exercise price of $3.4375 per share, assuming all warrants are exercised, and after deducting $80,000 in estimated offering expenses, our pro forma net tangible book value as of December 31, 2014 would have been approximately $(9,415,410), or $(0.3896) per share of common stock. This represents an immediate increase in net tangible book value of $0.2278 per share to our existing stockholders and an immediate dilution in net tangible book value of $3.0479 per share to the holders of warrants exercising the warrants in this offering. The following table illustrates this dilution per share to the warrant holders who exercise in this offering, assuming all warrants are exercised:

Exercise price per warrant		$3.4375
Net tangible book value per share as of December 31, 2014	$(0.1618)	
Increase in net tangible book value per share attributable to investors exercising the warrants in this offering	$0.2278	
Pro forma net tangible book value per share after giving effect to the offering		(0.3896)
Dilution per share to warrant holders exercising in this offering		$3.0479

The above discussion and table are based on 22,461,668 shares of our common stock outstanding as of December 31, 2014 and excludes the following securities outstanding on December 31, 2014:

- 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;

Series B Preferred Stock convertible into 454,546 shares of common stock;

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

- warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment agreement with an exercise price of $1.50 per share that expire on April 11, 2018;

- warrants for 1,947,849 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;

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 with an exercise price of $3.90 that expire on March 24, 2015;

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

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

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

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

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

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

warrants for 1,000,000 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 stock;

Series C-3 Preferred Stock convertible into 1,790,000 shares of common stock;

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

Series E Preferred Stock convertible into 2,021,358 shares of common stock; and

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

The above illustration of dilution per share to the warrant holders exercising in this offering assumes no exercise of outstanding preferred shares or options or other warrants to purchase shares of our common stock. To the extent that options, warrants or preferred shares outstanding as of December 31, 2014 or issued thereafter have been or may be exercised or converted or other shares issued, the warrant holders exercising 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.

PLAN OF DISTRIBUTION

All of the securities offered by this prospectus are being offered and sold directly by us, without an underwriter. The holders of the warrants may purchase the shares of our common stock directly from us by exercising their outstanding warrants.

DIVIDEND POLICY

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 our Series D and E Non-Voting Convertible Preferred Stock, we may not declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of those preferred shares remain 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.

DESCRIPTION OF OUR CAPITAL STOCK

Common Stock

Pursuant to our Amended and Restated Certificate of Incorporation, as amended, we are authorized to issue 80,000,000 shares of common stock, $0.001 par value per share. As of January 31, 2015, we had 23,461,008 shares of common stock outstanding.

The following summary of certain provisions of our common stock does not purport to be complete. You should refer to our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated Bylaws. We filed our Amended and Restated Certificate of Incorporation, as amended, as an exhibit to our definitive proxy statement on Schedule 14A with the SEC on October 17, 2012 and filed our Amended and Restated Bylaws as an exhibit to the registration statement on Form S-1 filed with the SEC on March 1, 2010. We filed a Certificate of Designation for each of our Series B, C-2, C-3, D and E non-voting preferred stock as exhibits to our current reports on Form 8-K on July 26, 2013, October 23, 2013 and January 9, 2014, and amendments to the Certificate of Designation for each of our Series C-2, C-3, D and E non-voting preferred stock on September 16, 2014. The summary below is also qualified by provisions of applicable law.

The holders of our common stock are entitled to one vote per share on all matters to be voted on by the stockholders, and there are no cumulative voting rights. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of common stock present in person or represented by proxy, subject to any voting rights granted to holders of any preferred stock.

The holders of common stock are entitled to receive ratable dividends, if any, payable in cash, in stock or otherwise if, as and when declared from time to time by our board of directors out of funds legally available for the payment of dividends, subject to any preferential rights that may be applicable to any outstanding preferred stock. In the event of a liquidation, dissolution, or winding up of our company, after payment in full of all outstanding debts and other liabilities, the holders of common stock are entitled to share ratably in all remaining assets, subject to prior distribution rights of preferred stock, if any, then outstanding. No shares of common stock have preemptive rights or other subscription rights to purchase additional shares of common stock. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable, and the shares of common stock included in this registration statement will be fully paid and nonassessable. The rights, preferences and privileges of holders of our common stock will be subject to, and might be adversely affected by, the rights of holders of any preferred stock that we may issue in the future. All shares of common stock that are acquired by us shall be available for reissuance by us at any time.

Preferred Stock

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. Of the 2,000,000 shares of preferred stock authorized, our board of directors has designated (all with par value of $0.001 per share): 454,546 shares as Series B Non-Voting Convertible Preferred Stock; 150,000 shares as Series C-2 Non-Voting Convertible Preferred Stock; 200,000 shares as Series C-3 Non-Voting Convertible Preferred Stock; 73,962 shares as Series D Non-Voting Convertible Preferred Stock; and 92,440 shares as Series E Non-Voting Convertible Preferred Stock. At January 31, 2015, we had outstanding: 454,546 shares as Series B Non-Voting Convertible Preferred Stock, 150,000 shares as Series C-2 Non-Voting Convertible Preferred Stock; 177,500 shares as Series C-3 Non-Voting Convertible Preferred Stock; 73,962 shares as Series D Non-Voting Convertible Preferred

Stock; and 92,440 shares as Series E Non-Voting Convertible Preferred Stock. The Series A Non-Voting Convertible Preferred Stock and Series C-1 Non-Voting Convertible Preferred Stock that was previously designated has all been converted to shares of common stock.

Series B Non-Voting Convertible Preferred Stock

Rank

The Series B Preferred Stock ranks:

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 B Preferred Stock;

on parity with the Series C-2 Preferred Stock and the Series C-3 Preferred Stock and any class or series of our capital stock hereafter created specifically ranking by its terms on parity with the Series B Preferred Stock; and

junior to any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series B 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 B Preferred Stock is convertible into one share of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock) at a per share price of $1.10 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series B 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 Series B Preferred Stock will receive a payment equal to $0.001 per share of Series B 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 B Preferred Stock and holders of Series B 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 B 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 B Preferred Stock will be required to amend the terms of the Series B Preferred Stock or the certificate of designation for the Series B Preferred Stock.

Dividends

Holders of Series B Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series B 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 B Preferred Stock. Shares of Series B 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 B Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series B Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions

If, at any time that shares of Series B 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 B 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 a share of common stock.

Series C-2 and C-3 Non-Voting Convertible Preferred Stock

The Series C-2 and C-3 Preferred Stock, referred to collectively as the Series C Preferred Stock, have identical rights, privileges and terms, as described below.

Rank

The Series C Preferred Stock will rank:

senior to our common stock;

senior to any class or series of capital stock created after the issuance of the Series C Preferred Stock;

on parity with the Series B Non-Voting Convertible Preferred Stock; and

junior to the Series D Non-Voting Convertible Preferred Stock and Series E Non-Voting Convertible 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 C Preferred Stock is convertible into 10 shares of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock) at a per share price of $1.00 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series C 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 9.99% 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 Series C Preferred Stock will receive a payment equal to $10.00 per share of Series C 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 C Preferred Stock and holders of Series C 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 C Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of two thirds of the outstanding Series C-2 and Series C-3 Preferred Stock, respectively, will be required to amend the terms of the Series C-2 and C-3 Preferred Stock or the certificate of designation for the Series C-2 and C-3 Preferred Stock, respectively.

Dividends

Holders of Series C Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series C 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 C Preferred Stock. Shares of Series C 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 C Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series C Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions

If, at any time that shares of Series C 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 C 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 a share of common stock.

Debt Restriction

As long as any the Series C-2 Preferred Stock is outstanding, we cannot incur any indebtedness other than indebtedness existing prior to September 15, 2014, trade payables incurred in the ordinary course of business consistent with past practice, and letters of credit incurred in an aggregate amount of $3.0 million at any point in time.

Series D Non-Voting Convertible Preferred Stock

Rank

The Series D Preferred Stock will rank:

senior to our common stock;

senior to any class or series of capital stock created after the issuance of the Series D Preferred Stock;

senior to the Series B Non-Voting Convertible Preferred Stock, the Series C-2 Non-Voting Convertible Preferred Stock and the Series C-3 Non-Voting Convertible Preferred Stock; and

on parity with the Series E Non-Voting Convertible 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 D Preferred Stock is convertible into 20 shares of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock) at a per share price of $0.35 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series D 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 9.99% 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 Series D Preferred Stock will receive a payment equal to $21.00 per share of Series D Preferred Stock on parity with the payment of the liquidation preference due the Series E Preferred Stock, but before any proceeds are distributed to the holders of common stock, Series B Non-Voting Convertible Preferred Stock, the Series C-2 Non-Voting Convertible Preferred Stock and the Series C-3 Non-Voting Convertible Preferred Stock. After the payment of this preferential amount, holders of Series D 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 that participates with the common stock in such distributions.

Voting Rights

Shares of Series D 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 D Preferred Stock will be required to amend the terms of the Series D Preferred Stock or the certificate of designation for the Series D Preferred Stock.

Dividends

Holders of Series D Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series D 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 D Preferred Stock. Shares of Series D 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 D Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series D Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions

If, at any time that shares of Series D 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 D 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 a share of common stock.

Debt Restriction

As long as any the Series D Preferred Stock is outstanding, we cannot incur any indebtedness other than indebtedness existing prior to September 15, 2014, trade payables incurred in the ordinary course of business consistent with past practice, and letters of credit incurred in an aggregate amount of $3.0 million at any point in time.

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Series E Non-Voting Convertible Preferred Stock

Rank

The Series E Preferred Stock will rank:

senior to our common stock;

senior to any class or series of capital stock created after the issuance of the Series E Preferred Stock;

senior to the Series B Non-Voting Convertible Preferred Stock, the Series C-2 Non-Voting Convertible Preferred Stock and the Series C-3 Non-Voting Convertible Preferred Stock; and

on parity with the Series D Non-Voting Convertible 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 E Preferred Stock is convertible into 21.8667 shares of our common stock (subject to adjustment as provided in the certificates of designation for the Series E Preferred Stock) at a per share price of $0.75 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series E 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 9.99% 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 Series E Preferred Stock will receive a payment equal to $49.20 per share of Series E Preferred Stock on parity with the payment of the liquidation preference due the Series D Preferred Stock, but before any proceeds are distributed to the holders of common stock, Series B Non-Voting Convertible Preferred Stock, the Series C-2 Non-Voting Convertible Preferred Stock and the Series C-3 Non-Voting Convertible Preferred Stock. After the payment of this preferential amount, holders of Series E 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 that participates with the common stock in such distributions.

Voting Rights

Shares of Series E 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 E Preferred Stock will be required to amend the terms of the Series E Preferred Stock or the certificate of designation for the Series E Preferred Stock.

Dividends

Holders of Series E Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series E 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 E Preferred Stock. Shares of Series E 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 E Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series E Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions

If, at any time that shares of Series E 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 E 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 a share of common stock.

Debt Restriction

As long as any the Series E Preferred Stock is outstanding, we cannot incur any indebtedness other than indebtedness existing prior to September 15, 2014, trade payables incurred in the ordinary course of business consistent with past practice, and letters of credit incurred in an aggregate amount of $3.0 million at any point in time.

Other Covenants

In addition to the debt restrictions above, as long as any the Series E Preferred Stock is outstanding , we cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of our assets or property; redeem, repurchase or pay any cash dividend or distribution on any of our capital stock (other than as permitted, which includes the dividends on the Series D Preferred Stock and the Series E Preferred Stock); redeem, repurchase or prepay any indebtedness; or engage in any material line of business substantially different from our current lines of business.

Purchase Rights

In the event we issue any options, convertible securities or rights to purchase stock or other securities pro rata to the holders of common stock, then the a holder of Series E Preferred Stock will be entitled to acquire, upon the same terms a pro rata amount of such stock or securities as if the Series E Preferred Stock had been converted to common stock.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC. The transfer agent’s address is 18 Lafayette Place, Woodmere, New York 11598 and its telephone number is (212) 828-8436.

We act as our own transfer agent and registrar for the Series B, C-2, C-3, D and E Preferred Stock.

CERTAIN PROVISIONS OF DELAWARE LAW AND OF OUR AMENDED AND RESTATED CERTIFICATE OF INCORPORATION AND AMENDED AND RESTATED BYLAWS

Certain provisions of DGCL and our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated Bylaws discussed below may have the effect of making more difficult or discouraging a tender offer, proxy contest or other takeover attempt. These provisions are expected to encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of increasing our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-takeover Law

We are subject to Section 203 of the DGCL, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date the person became an interested stockholder, unless:

- the board of directors approves the transaction in which the stockholder became an interested stockholder prior to the date the interested stockholder attained that status;
- when the stockholder became an interested stockholder, he or she owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers and certain shares owned by employee benefits plans; or
- on or subsequent to the date the business combination is approved by the board of directors, the business combination is authorized by the affirmative vote of at least 66 2/3% of the voting stock of the corporation at an annual or special meeting of stockholders.

Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or is an affiliate or associate of the corporation and within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock.

The existence of Section 203 of the DGCL would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of our common stock.

Charter Documents

Our Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company. First, our Amended and Restated Bylaws limit who may call special meetings of the stockholders, such meetings may only be called by the chairman of the board, the chief executive officer, the board of directors or holders of an aggregate of at least 15% of our outstanding entitled to vote. Second, our Amended and Restated Certificate of Incorporation does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. Third, our Amended and Restated Bylaws provide that the number of directors on our board, which may range from five to nine directors, shall be exclusively fixed by our board, which has set the

number of directors at seven. Fourth, newly created directorships resulting from any increase in our authorized number of directors and any vacancies in our board resulting from death, resignation, retirement, disqualification or other cause (including removal from office by a vote of the shareholders) will be filled by a majority of our board then in office. Finally, our Amended and Restated Bylaws establish procedures, including 90-day advance notice requirement, with regard to the nomination of candidates for election as directors and stockholder proposals. These and other provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and Delaware law could discourage potential acquisition proposals and could delay or prevent a change in control or management of our company.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed upon by Wyrick Robbins Yates & Ponton LLP, Raleigh, North Carolina.

EXPERTS

The consolidated balance sheet of CorMedix Inc. as of December 31, 2014 and the related consolidated statements of operations, changes in stockholders' equity (deficiency), and cash flows for the year then ended have been audited by Friedman LLP, independent registered public accounting firm, as stated in their report (which includes an explanatory paragraph relating to the company's ability to continue as a going concern as discussed in Note 2 of the financial statements), which is incorporated by reference. The consolidated balance sheet of CorMedix Inc. as of December 31, 2013, and the related consolidated statements of operations, changes in stockholders' equity (deficiency), and cash flows for the year then ended have been audited by CohnReznick LLP, independent registered public accounting firm, as stated in their report, 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 respective authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Exchange Act and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC's web site at http://www.sec.gov. Our common stock is listed on the NYSE MKT, and you can read and inspect our filings at the offices of the NYSE MKT at 20 Broad Street, New York, NY 10005.

This prospectus is only part of a registration statement on Form S-1 that we have filed with the SEC under the Securities Act and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

INCORPORATION OF DOCUMENTS BY REFERENCE

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings, including the registration statement and exhibits, are available to the public at the SEC's website at http://www.sec.gov. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at (800) SEC-0330 for information on the operating rules and procedures for the public reference room.

The SEC allows us to "incorporate by reference" into this prospectus certain information that we have filed with SEC. 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. We filed a registration statement on Form S-3 under the Securities Act with the SEC with respect to the securities being offered pursuant to this prospectus. This prospectus omits 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. Statements in this 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 are:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC pursuant to Section 13 of the Exchange Act on March 12, 2015; and

our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on January 9, January 10, January 13, February 25, February 28, March 5, April 8, May 15, May 16, May 23, May 28 (Form 8-K/A), June 17, June 26, July 24, August 14, September 12, September 16, September 22, September 25, October 27, December 4 and December 23, 2014, and January 15, January 20, January 29, February 6, February 9 (Form 8-K/A), and March 9, 2015.

In addition, all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed in such forms that are related to such items unless such Form 8-K expressly provides to the contrary) 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 or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this 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.

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, 1430 U.S. Highway 206, Suite 200, Bedminster, NJ 07921, (908) 517-9500.

We maintain an Internet site at http://www.cormedix.com. Our SEC filings are available on our website. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

We estimate that expenses payable by us in connection with the offering described in this registration statement will be as follows:

SEC registration fee	$ 1,556.00
Legal fees and expenses	$ 25,000**
Accounting fees and expenses	$ 30,000**
Printing expenses	$ 5,000**
Miscellaneous	$ 18,443.40**
Total	$ 80,000**

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* Registration fees of $1,556.60 were paid in connection with the original filing of the registration statement.
** Estimated as permitted under Item 511 of Regulation S-K.

Item 15. Indemnification of Directors and Officers.

Section 145 of the DGCL permits a corporation, under specified circumstances, to indemnify its directors, officers, employees or agents against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by them in connection with any action, suit or proceeding brought by third parties by reason of the fact that they were or are directors, officers, employees or agents of the corporation, if such directors, officers, employees or agents acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reason to believe their conduct was unlawful. In a derivative action, that is one by or in the right of the corporation, indemnification may be made only for expenses actually and reasonably incurred by directors, officers, employees or agents in connection with the defense or settlement of an action or suit, and only with respect to a matter as to which they will have acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made if such person will have been adjudged liable to the corporation, unless and only to the extent that the court in which the action or suit was brought will determine upon application that the defendant directors, officers, employees or agents are fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to the DGCL, our Amended and Restated Certificate of Incorporation, as amended provides that no director will be personally liable to our company or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to our company or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived any improper personal benefit. Our Amended and Restated Bylaws provide that we will generally indemnify our directors, officers, employees or agents to the fullest extent permitted by the law against all losses, claims, damages or similar events. We have obtained liability insurance for each director and officer for certain losses arising from claims or charges made against them while acting in their capacities as directors or officers of our Company.

Item 16. Exhibits.

(a) The following exhibits are filed as part of this Registration Statement:

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.1	Form of Amended and Restated Certificate of Incorporation.	S-1/A	3/01/2010	3.3	
3.2	Form of Amended and Restated Bylaws.	S-1/A	3/02/2010	3.4	
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated December 3, 2012.	10-K	3/27/2013	3.3	
3.4	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on February 18, 2013, as corrected on February 19, 2013.	8-K	2/19/2013	3.3	
3.5	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on July 26, 2013.	8-K	7/26/2013	3.4	
3.6	Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.5	
3.7	Certificate of Amendment to Certificate of Designation of Series C-1 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.10	
3.8	Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.6	
3.9	Certificate of Amendment to Certificate of Designation of Series C-2 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.11	
3.10	Certificate of Designation of Series C-3 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.9	
3.11	Certificate of Designation of Series D Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 4, 2013.	8-K	10/23/2013	3.7	
3.12	Certificate of Amendment to Certificate of Designation of Series D Non-Voting	8-K	1/09/2014	3.12	

	Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 21, 2014.			
3.13	Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on October 21, 2013.	8-K	10/23/2013	3.8

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.14	Certificate of Amendment to Certificate of Designation of Series E Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 8, 2014.	8-K	1/09/2014	3.13	
4.1	Specimen of Common Stock Certificate.	S-1/A	3/19/2010	4.1	
4.2	Specimen Unit certificate.	S-1/A	3/19/2010	4.2	
4.3	Specimen warrant certificate.	S-1/A	3/19/2010	4.3	
4.4	Form of warrant agreement.	S-1/A	3/19/2010	4.4	
4.5	Common Stock Exchange and Stockholder Agreement dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC.	S-1	11/25/2009	4.6	
4.6	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7	
4.7	Form of Third Bridge Warrant.	S-1/A	1/20/2010	4.18	
4.8	Form of 9% Senior Convertible Note due 2013.	10-Q	11/13/2012	4.1	
4.9	Form of Purchaser Warrant.	10-Q	11/13/2012	4.2	
4.10	Form of Placement Agent Warrant.	10-Q	11/13/2012	4.3	
4.11	Form of Subscription Agreement.	10-Q	11/13/2012	4.4	
4.12	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5	
4.13	Form of Senior Secured Convertible Note.	8-K	5/24/2013	4.19	
4.14	Form of Warrant issued on February 19, 2013.	8-K	2/19/2013	4.13	
4.15	Form of Warrant issued on May 30, 2013.	8-K	5/24/2013	4.20	
4.16	Form of Warrant issued on July 30, 2013.	8-K	7/26/2013	4.21	
4.17	Form of Warrant issued on October 22, 2013.	8-K	1/09/2014	4.23	
4.18	Form of Warrant issued on January 8, 2014.				
4.19	Form of Warrant issued on March 10, 2014	8-K	03/05/2014	4.24	
4.20	Warrant issued March 3, 2015.	8-K	03/04/2015	4.1	
4.21	Amended and Restated Warrant originally issued May 30, 2013.	8-K	03/04/2015	4.2	
4.22	Amended and Restated Warrant originally issued March 24, 2010.	8-K	03/04/2015	4.3	
4.23	Form of Convertible Note.	8-K	03/04/2015	4.4	
4.24	Registration Rights Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	03/04/2015	4.5	
4.25	Amended and Restated Warrant originally issued May 30, 2013.	8-K	3/04/2015	4.2	
4.26		8-K	3/04/2015	4.3	

	Amended and Restated Warrant originally issued March 24, 2010.				
4.27	Form of Convertible Note.	8-K	3/04/2015	4.4	
4.28	Registration Rights Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	3/04/2015	4.5	
5.1	Opinion of Wyrick Robbins Yates & Ponton LLP.	S-1	2/05/2015	5.1	
21.1	List of Subsidiaries.	10-K	3/27/2013	21.1	
23.1	Consent of Friedman LLP, Independent Registered Public Accounting Firm.				x
23.2	Consent of CohnReznick LLP, Independent Registered Public Accounting Firm.				
23.3	Consent of Wyrick Robbins Yates & Ponton LLP (included as part of Exhibit 5.1).	S-1	2/05/2015	23.2	
24.1	Power of Attorney.	S-1	2/05/2015	24.1	

(b) None.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933 (the "Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment hereof) which, individually or in the aggregate, represent a fundamental change in the information in this registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement;

(2) That, for the purpose of determining any liability under the Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) That, for purposes of determining any liability under the Act to any purchaser:

(1) Each prospectus filed by the registrant pursuant to Rule 424(b)(3)shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(2) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(c) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(d) Insofar as indemnification for liabilities arising under the Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission, or SEC, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all the requirements for filing a Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bedminster, State of New Jersey, on March 13, 2015.

CORMEDIX INC.

By: /s/ Randy Milby
Randy Milby
Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Capacity	Date
/s/ Randy Milby Randy Milby	Director and Chief Executive Officer (Principal Executive Officer)	March 13, 2015
/s/ Harry O'Grady Harry O'Grady	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2015
/s/ Matthew P. Duffy* Matthew P. Duffy	Director	March 13, 2015
/s/ Michael W. George* Michael W. George	Director	March 13, 2015
/s/ Steven W. Lefkowitz* Steven W. Lefkowitz	Director	March 13, 2015
/s/Taunia Markvicka Taunia Markvicka	Director	March 13, 2015
/s/ Antony E. Pfaffle, M.D.* Antony E. Pfaffle, M.D.	Director and Chief Scientific Officer	March 13, 2015
*By: /s/ Randy Milby Randy Milby, Attorney-in-Fact		March 13, 2015