CorMedix Inc.
Form S-3
March 13, 2015
As filed with the Securities and Exchange Commission on March 13, 2015
Registration Statement No. 333-_____

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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.)

1430 U.S. Highway 206, Suite 200
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
CorMedix Inc.
1430 U.S. Highway 206, Suite 200
Bedminster, New Jersey 07921
Telephone: (908) 517-9500
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

ALEXANDER M. DONALDSON
Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, North Carolina 27607
Telephone: (919) 781-4000
Fax: (919) 781-4865

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum aggregate offering price per share (2)	Proposed maximum aggregate offering price	Amount of registration fee
Common stock, $0.001 par value per share	2,450,883	7.81	$19,141,396.23	$2,224.23

(1) Represents 2,450,883 shares of the registrant's common stock underlying warrants exercisable at an exercise price of $3.4375 per share. In addition, pursuant to Rule 416 under the Securities Act of 1933, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for purposes of calculating the registration fee under Rule 457(c) under the Securities Act, based on the average of the high and low prices reported on the NYSE MKT on March 12, 2015.

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.

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

2,450,883

SHARES OF COMMON STOCK

This prospectus relates to the sale of an aggregate of 2,450,883 shares of our common stock, $0.001 par value per share, issuable upon the exercise of warrants held by the selling stockholders identified in this prospectus, including their transferees, pledgees, donees or successors. The selling stockholders may sell the common stock from time to time in public transactions or in privately negotiated transactions, without limitation, through any means described in the section hereof entitled “Plan of Distribution,” at market prices prevailing at the time of sale or at negotiated prices. The timing and amount of any sale are within the sole discretion of the selling stockholders. We will not receive any proceeds from the sale of shares registered under this prospectus.

No underwriter or other person has been engaged to facilitate the sale of shares of our common stock in this offering. We are paying the cost of registering the shares of our common stock covered by this prospectus as well as various other related expenses. The selling stockholders are responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of their shares of our common stock.

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 registration statement on Form S-3 that we filed with the Securities and Exchange Commission. Under this registration statement, the selling stockholders may offer and resell, from time to time, up to 2,450,883 shares of our common stock that may be issued upon the exercise of warrants. We will not receive any of the proceeds from these sales, except that upon any exercise of the warrants, we will receive the exercise price of the warrants. We are paying certain expenses related to the registration of the shares of common stock pursuant to the registration statement of which this prospectus forms a part.

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, and the selling stockholders 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

The selling stockholders identified beginning on page 25 of this prospectus are offering on a resale basis a total of 2,450,883 shares of our common stock issuable upon the exercise of the following warrants issued in connection with our 2010 initial public offering, or IPO:

warrants for 503,034 shares of our common stock issued to pre-IPO investors with an exercise price of $3.4375 per share that expire on March 31, 2015; and

warrants for 1,947,849 shares of our common stock issued to pre-IPO investors with an exercise price of $3.4375 per share that expire on April 30, 2015.

Common stock offered by the selling stockholders	2,450,883 shares
Common stock outstanding before the offering (1)	23,461,008 shares
Common stock to be outstanding after the offering (2)	25,911,891 shares
Common stock NYSE MKT Symbol	CRMD

(1) Based on the number of shares outstanding as of January 31, 2015.

(2) Does not include as of January 31, 2015: (i) 1,065,000 shares reserved for issuance upon the exercise of outstanding options issued under our Amended and Restated 2006 Stock Incentive Plan, with a weighted average exercise price of $0.77; (ii) 5,000,000 shares reserved for issuance under our 2013 Incentive Stock Plan, of which 2,599,500 shares are issuable upon exercise of outstanding options with a weight average exercise price of $1.44; (iii) 454,546 shares reserved for issuance upon the conversion of our outstanding Series B preferred stock; (iv) 1,500,000 shares reserved for issuance upon the conversion of our outstanding Series C-2 preferred stock; (v) 1,775,000 shares reserved for issuance upon the conversion of our outstanding Series C-3 preferred stock; (vi) 1,479,240 shares reserved for issuance upon the conversion of our outstanding Series D preferred stock; (vii) 2,021,358 shares reserved for issuance upon the conversion of our outstanding Series E preferred stock; (viii) 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 that expire on March 24, 2015; (ix) a warrant issued to a pre-IPO investor to purchase up to 390,720 shares of common stock with an exercise price of $3.4375 per share that expires on March 24, 2016; (x) warrants issued to investors in our IPO to purchase up to 1,705,000 shares of common stock at an exercise price of $3.4375 per share that expire on March 24, 2015; (xi) 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; (xii) warrants issued to the placement agent for our 2012 private placement to purchase an aggregate of 795 shares of our common stock with an exercise price of $0.40 per share, which expire on September 20, 2017; (xiii) a warrant for 400,000 shares of our common stock issued on February 19, 2013 with an exercise price of $1.50 that expires on February 19, 2018; (xiv) a warrant for 125,000 shares of our common stock 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; (xv) 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; (xvi) a warrant for 227,273 shares of common stock issued in July 2013 with an exercise price of $1.50 that expire July 30, 2018; (xvii) warrants for 750,000 shares of common stock issued in October 2013 with an exercise price of $0.90 that expire on October 22, 2019; (xviii) warrants for 875,000 shares of common stock issued in January 2014 with an exercise price of $0.90 that expire on January 8, 2020; and (xix) 1,036,000 shares reserved for issuance upon the exercise of warrants issued in March 2014 with an exercise price of $2.50 per

share.

The selling stockholders acquired the warrants on March 30, 2010, upon the conversion of convertible notes purchased by them in one or more of the following financing transactions: (i) a 12% convertible note financing that we effected in June through September of 2007 and August of 2008 (the "12% Note Financing"), (ii) an 8% convertible note sold to Galenica, Ltd. in April, 2009 (the "Galenica Note Financing"); (iii) an 8% convertible note financing that we effected in October and November of 2009 (the "8% Note Financing"); and (iv) 8% convertible notes sold to each of Paramount Biosciences, LLC and the Lindsay A. Rosenwald Trusts in September 2009 (the "Paramount/Rosenwald Note Financing"). The conversion of the convertible notes in all three financings occurred automatically, pursuant to the terms of the respective notes, upon the closing of our initial public offering on March 30, 2010 (the "IPO"). For more details on the 12% Note Financing, the Galenica Financing, the 8% Note Financing, the Paramount/Rosenwald Note Financing and the selling stockholders, see "Selling Stockholders" beginning on page 25.

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.