CorMedix Inc.
Form S-3
May 27, 2016

As filed with the Securities and Exchange Commission on May 27, 2016
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	20-5894890
(State or other jurisdiction of incorporation or organization)	(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, Esq.
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Raleigh, North Carolina 27607
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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 the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(c) under the Securities Act, check the following box. o

If this Form is a post-effective amendment filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. 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 x
Non-accelerated filer o (Do not check if smaller reporting company)	Smaller reporting company o

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum aggregate offering price per unit (2)	Proposed maximum aggregate offering price	Amount of registration fee
Common stock, $0.001 par value per share	4,006,468	$ 2.86	$ 11,458,498.48	$ 1,153.87

(1) Represents 4,006,468 shares of the registrant's common stock underlying warrants exercisable at a weighted average exercise price of $1.64 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 May 25, 2016.

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 May 27, 2016

Prospectus

4,006,468

SHARES OF COMMON STOCK

This prospectus relates to the sale of an aggregate of 4,006,468 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 May 25, 2016, the closing price of our common stock was $2.93 per share.

Investing in our securities involves a high degree of risk. These risks are described under the caption “Risk Factors” beginning on page 8 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 _____, 2016

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

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 4,006,468 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 for cash, 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 supplement and any applicable 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 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 and any applicable prospectus supplement 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 or any applicable prospectus supplement 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.

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, any applicable prospectus supplement and the documents we have filed with the SEC that are incorporated herein and therein 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 CorMedix's ongoing and planned Phase 3 trials for Neutrolin® in the U.S.; obtaining regulatory approvals to conduct clinical trials and to commercialize CorMedix's approved products and product candidates, including approval of Neutrolin in the U.S. by the U.S. Food and Drug Administration and marketing of Neutrolin in countries other than Europe; the risks associated with the launch of Neutrolin in new markets; CorMedix's ability to enter into, execute upon and maintain collaborations with third parties for its development and marketing programs; the risks and uncertainties associated with CorMedix's ability to manage its limited cash resources; the outcome of clinical trials of CorMedix's product candidates and whether they demonstrate these candidates' safety and effectiveness; obtaining additional financing to support CorMedix's research and development and clinical activities and operations; CorMedix's dependence on its collaborations and its license relationships; CorMedix's ability to identify and enter into strategic transactions; CorMedix's ability to maintain its listing on the NYSE MKT; achieving milestones under CorMedix's collaborations: CorMedix's dependence on preclinical and clinical investigators, preclinical and clinical research organizations, manufacturers, sales and marketing organizations, and consultants; and protecting the intellectual property developed by or licensed to CorMedix. Please also see the discussion of risks and uncertainties under "Risk Factors" below and otherwise incorporated by reference herein, and in our most recent annual report on Form 10-K, as revised or supplemented by any of our subsequently filed quarterly reports on Form 10-Q, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus, any applicable prospectus supplement or in any document incorporated herein or therein by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the respective dates of this prospectus or any applicable prospectus supplement or the date of the document incorporated by reference in this prospectus or any applicable prospectus supplement. We expressly disclaim any obligation to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by federal securities laws.

PROSPECTUS SUMMARY

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

Overview

We in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious and inflammatory diseases. We have in-licensed the worldwide rights to develop and commercialize our product candidate, CRMD003 (Neutrolin®), which we believe addresses potentially large market opportunities in the instances in which a central venous catheter is used, such as hemodialysis, intensive care units, oncology and patients receiving total parenteral nutrition, IV hydration, and/or IV medications.

Neutrolin is an anti-infective solution 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 250,000 catheter related bloodstream infections (CRBSIs) in the United States per year. 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 468,000 hemodialysis patients in the United States. 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. These hemodialysis patients represent over 127 million catheter/dialysis treatment days per year in the U.S., which we believe represents a conservative market potential of $300 to $400 million. The market in the critical care/intensive care units is 28.5 million catheter days per year in the United States alone. There were over 14.5 million patients living with cancer in the United States as of 2014 with an estimated 7.7 million having a long-term central venous catheter. However, when stages of disease, chemotherapy regimens and catheter types are factored, the oncology market represents 90 million catheter days. 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.

International

In late 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 then limited resources, we decided 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 late 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.

In July 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 for such treatment in Austria, Germany, Italy, Malta, Saudi Arabia, Bahrain, Qatar, Kuwait, United Arab Emirates and The Netherlands.

We have entered into agreements with a German contract sales company and with 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 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.

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.

United States

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 plan to conduct at least one Phase 3 clinical trial in hemodialysis catheters and one Phase 3 clinical trial in oncology/total parenteral nutrition. We worked with the FDA to design the protocol for a 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 could be initiated in the U.S.

In December 2015, our Phase 3 clinical trial in hemodialysis catheters or Catheter Lock Solution Investigational Trial (“LOCK-IT-100”) began with the enrollment and dosing of the first patient. The LOCK-IT-100 trial is a prospective, multicenter, randomized, double-blind, placebo-controlled, active control trial which aims to demonstrate the efficacy and safety of Neutrolin in preventing CRBSIs in subjects receiving hemodialysis therapy as treatment for end stage renal disease. The primary endpoint for the trial is freedom from CRBSIs. The trial will evaluate whether Neutrolin is superior to the active control heparin by documenting the incidence of CRBSI and the time until the occurrence of CRBSI. Key secondary endpoints are catheter patency which is defined as required use of tissue plasminogen activating factor (tPA) or removal of catheter due to dysfunction and catheter removal for any reason. An exploratory endpoint of biofilm analysis will be evaluated in the first 200 catheters removed.

The FDA has designated Neutrolin as a Qualified Infectious Disease Product, or 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 provides an additional five years of market exclusivity in addition to the five years granted for a New Chemical Entity. In addition, 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 or FDASIA highlighting the large unmet need to prevent infections in the U.S healthcare system. 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.

In June 2015, we received guidance from the FDA on the acceptable design of the second planned pivotal Phase 3 trial in oncology/total parenteral nutrition patients and are working with the FDA to finalize the details. We plan to initiate the Phase 3 trial in oncology/total parenteral nutrition in the first quarter of 2017, depending on our ability to raise additional capital and our ability to complete the hemodialysis catheters trial within our expected budget, although we also plan to continue to seek one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

We are evaluating opportunities for the possible expansion of indications for taurolidine. Provisional patents have been submitted in four areas, antimicrobial sutures, nanofiber webs, wound management, and osteoarthritis and visco-supplementation. There exists a need to control and protect against surgical site infections upon closure with sutures. We believe taurolidine could offer benefits not currently available in marketed antimicrobial sutures. We also believe that the nanofiber webs used for absorbable meshes could benefit from taurolidine's minimal inflammatory response and infection control. Taurolidine incorporated into webs or hydrogels could also be used for wound management especially wounds in less sterile environments and burn patients. Lastly, incorporating taurolidine into formulations for osteoarthritis and visco-supplementation may benefit from taurolidine's anti-inflammatory and anti-infection properties.

In March 2015, we commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. We engaged investment bank Evercore Group L.L.C. to provide financial advice and assist us with our evaluation process. After the process with Evercore, we announced in July 2015 that we expect to continue to pursue product development and commercialization opportunities as we move forward with the planned Phase 3 clinical trials, rather than pursuing a possible sale of our company as this time. We continue to retain Evercore and will work with them as potential opportunities are presented to us.

Corporate History and Information

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

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

THE OFFERING

This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to 4,006,468 shares of our common stock issuable upon the exercise of the following warrants:

- warrants for 227,273 shares of common stock issued in July 2013 with an exercise price of $1.50 that expire on July 30, 2018;
- warrants for 500,000 shares of common stock issued in May 2013 with an exercise price of $0.65 per share that expire on May 30, 2019;
- warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment agreement with an exercise price of $1.50 per share that expire on April 11, 2018;
- warrants issued to investors in our 2012 private placement to purchase an aggregate of 312,500 shares of our common stock with an exercise price of $0.40 per share that expire on September 20, 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 that 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 expires on February 19, 2018;
- warrants for 750,000 shares of common stock with an exercise price of $0.90 that expire on October 22, 2019;
- warrants for 725,000 shares of common stock with an exercise price of $0.90 that expire on January 8, 2020;
- warrants for 682,500 shares of common stock issued in March 2014 with an exercise price of $2.50 per shares that expire on September 10, 2019;
- a warrant for 200,000 shares of common stock with an exercise price of $7.00 that expires on March 3, 2020; and;
- a warrant for 83,400 shares of common stock with an exercise price of $7.00 that expires on March 25, 2020.

	4,006,468 shares
Common stock offered by the selling stockholders	36,138,323 shares
Common stock outstanding before the offering (1)	40,144,791 shares
Common stock to be outstanding after the offering (2)	CRMD
Common stock NYSE MKT Symbol	

(1) Based on the number of shares outstanding as of March 31, 2016.

(2) Assumes the exercise of all of the warrants for which the underlying shares are being offered by this prospectus.

Use of Proceeds

The 4,006,468 shares issuable upon the exercise of warrants and that are being offered for resale by the selling stockholders will be sold for the accounts of the selling stockholders named in this prospectus. As a result, all proceeds from the sales of the 4,006,468 shares of common stock currently outstanding and offered for resale hereby will go to the selling stockholders and we will not receive any proceeds from the resale of those shares of common stock by the selling stockholders.

We may receive up to a total of $6,596,277.50 in gross proceeds if all of the warrants are exercised hereunder for cash. 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.

After the exercise of any of the warrants, we would not receive any proceeds from the resale of those shares by the selling stockholders because those shares will be sold for the accounts of the selling stockholders named in this prospectus.

We will incur all costs associated with this registration statement and prospectus.

Dividend Policy

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. Further, pursuant to the terms of our Series D and Series 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. See “Dividend Policy.”

RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of operating losses, and expect to incur additional operating losses in 2016.

We were established in July 2006 and have only a limited operating history. 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 $18.2 million for the year ended December 31, 2015 and $4.2 million for the three months ended March 31, 2016. As of March 31, 2016, we had an accumulated deficit of approximately $98.6 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 as we develop and commercialize Neutrolin. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Neutrolin was launched in December 2013 and is currently available for distribution in Germany, Austria, The Netherlands, Malta, Italy, The Kingdom of Saudi Arabia, Bahrain, Qatar, Kuwait and United Arab Emirates. We have not generated any significant commercial revenue and do not expect to generate substantial revenues from Neutrolin until it is approved by the FDA and launched in the U.S. market, 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; 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 and generate substantial earnings from it, 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 including the ongoing and planned clinical trials, seek regulatory approvals for Neutrolin, 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, Malta, the Kingdom of Saudi Arabia, Bahrain, Qatar, Kuwait and the United Arab Emirates 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., we cannot sell Neutrolin 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 March 31, 2016, will be sufficient to enable us to fund our projected operating requirements for at least the next twelve months following the balance sheet date. However, we need to raise additional funds during 2016 to fund the completion of our ongoing hemodialysis clinical trial and to commence and complete our planned Phase 3 oncology/total parenteral nutrition clinical trial in the U.S. If we are unable to raise additional funds when needed, we may not be able to complete our ongoing Phase 3 clinical trial or commence and complete our planned Phase 3 clinical trials or commercialize Neutrolin and we could be required to delay, scale back or eliminate some or all of our research and development programs. 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, prepare for and undertake our ongoing and planned Phase 3 clinical trials, pursue business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

To raise needed capital, we may 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 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.

In March 2015, the Board commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. The Board engaged the investment bank Evercore Group L.L.C. to provide financial advice and assist the Board with its evaluation process. No transaction has materialized to date and there can be no assurance that any transaction will result. 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. After the process with Evercore, we announced in July 2015 that we expect to continue to pursue product development and commercialization opportunities as we move forward with the planned Phase 3 clinical trials, rather than pursuing a possible sale of our company as this time. We continue to retain Evercore and will work with them as potential opportunities are presented to us. 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 only product is only recently 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 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 candidate is 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; and

- CRMD003 (Neutrolin) - Phase 3 trial in hemodialysis catheters initiated in December 2015; planned Phase 3 trial in oncology/total parenteral nutrition expected to initiate in first quarter of 2017, 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.

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 a German company to market and sell Neutrolin in Germany, which launched in Germany in the fourth quarter of 2013. We also have entered into agreements with a Saudi Arabian company to market and sell Neutrolin in Saudi Arabia, and with 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 the United Arab Emirates 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 2 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. We have received approval from the FDA to proceed with our ongoing Phase 3 clinical trial for Neutrolin in hemodialysis catheters and our planned Phase 3 trial in oncology/total parenteral nutrition. In December 2015, we initiated the Phase 3 trial in hemodialysis catheters however, we will not initiate the oncology/total parenteral nutrition trial until we receive sufficient funding. We are seeking one or more strategic partners or other sources of capital to complete

the Phase 3 trial in hemodialysis and to start the Phase 3 trial for oncology/total parenteral nutrition. However, we might not obtain any commercial partner or financing and may never start the Phase 3 clinical trial for oncology/total parenteral nutrition.

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 Neutrolin will depend on obtaining coverage and reimbursement for use of Neutrolin 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. Further, significant uncertainty exists as to the reimbursement status of newly approved health care products. We initially expect to sell Neutrolin directly to hospitals and key dialysis center operators, but also plan to expand its usage into intensive care, oncology and total parenteral nutrition patients needing catheters, including Medicare patients. All of these potential customers are healthcare providers who depend upon reimbursement by government and commercial insurance payors for dialysis and other treatments. Reimbursement is strictly governed by these insurance payors. We believe that Neutrolin would be eligible for coverage under various reimbursement programs, including hospital inpatient diagnosis-related groups (DRGs), outpatient ambulatory payment classification (APCs) and the End-Stage Renal Disease Prospective Payment System (ESRD PPS) or under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule, depending on the treatment setting. However, coverage by any of these reimbursement programs is not assured, and even if coverage is granted it could later be revoked or modified under future regulations. Further, the U.S. Centers for Medicare & Medicaid Services (CMS), which administers Medicare and works with states to administer Medicaid, has adopted and will continue to adopt and/or amend rules governing reimbursement for specific treatments, including those we intend to address such as dialysis and ESRD PPS. We anticipate that CMS and private insurers will increasingly demand that manufacturers demonstrate the cost effectiveness of their products as part of the reimbursement review and approval process. Rising healthcare costs have also lead many European and other foreign countries to adopt healthcare reform proposals and medical cost containment measures. Any measures affecting the reimbursement programs of these governmental and private insurance payors, including any uncertainty in the medical community regarding their nature and effect on reimbursement programs, could have an adverse effect on purchasing decisions regarding Neutrolin, as well as limit the prices we may charge for Neutrolin. The failure to obtain or maintain reimbursement coverage for Neutrolin or any other 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

We are subject to a putative securities class action, which may require significant management time and attention and significant legal expenses and may result in an unfavorable outcome, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

On July 7, 2015, a putative class action lawsuit was commenced against us and certain of our current and former officers in the United States District Court for the District of New Jersey, captioned Li v. Cormedix Inc., et al., Case 3:15-cv-05264. On September 4, 2015, two individuals, Shahm Martini and Paul Chretien (the "Martini Group"), filed a Motion to Appoint Lead Plaintiff. On that same date, another individual, Elaine Wood, filed a competing Motion to Appoint Lead Plaintiff. On September 18, 2015, the Martini Group withdrew its motion. Thereafter, on September 22, 2015, the Court appointed Elaine Wood as Lead Plaintiff and, on October 2, 2015, appointed the Rosen Law Firm as Lead Counsel.

On December 1, 2015, Lead Plaintiff filed an Amended Complaint asserting claims that we and Steven Lefkowitz, Randy Milby and Harry O'Grady (the "Cormedix Defendants") violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. The Amended Complaint also names as defendants several unrelated entities that allegedly were paid stock promoters. Lead Plaintiff alleges generally that the Cormedix Defendants made materially false or misleading statements and omissions concerning, among other things, the competitive landscape for our Neutrolin product and the alleged use of stock promoters. The Amended Complaint seeks unspecified damages, interest, attorneys' fees, and other costs.

On February 1, 2016, the Cormedix Defendants filed a motion to dismiss all claims asserted against them in the Amended Complaint on the grounds, among others, that the Amended Complaint fails to adequately allege: (1) material misstatements or omissions; (2) scienter by any of the Cormedix Defendants; or (3) loss causation. The parties are in the process of briefing that motion and oral argument currently is scheduled for July 18, 2016.

While we believe that we have substantial legal and factual defenses to the claims in the class action and intend to continue vigorously defending the case there can be no assurance as to the outcome of this class action litigation.

In addition, there is the potential for additional shareholder litigation, and we could be similarly materially and adversely affected by such matters.

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 prevention or 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, and Dr. Antony Pfaffle, a director and Chief Scientific Officer. Mr. Milby is expected to transition out of his role as Chief Executive Officer and we have begun a search for his replacement. Our future success will depend in part on our ability to identify, hire, and retain additional personnel including a new Chief Executive Officer. 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. 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); 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 initiate or 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 initiated court proceedings in Germany for patent infringement and unfair use of our proprietary information related to Neutrolin (as described below). We also have 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 (“Geistlich”) brought an action against the European Sodemann Patent covering our Neutrolin product candidate, which is owned by ND Partners, LLC (“NDP”) and licensed to us pursuant to the License and Assignment Agreement between us and NDP. This action was brought at the Board of the European Patent Office (“EPO”) opposition division (the “Opposition Board”) based upon alleged 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 Opposition Board 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 requesting a dismissal of the appeal and maintenance of the patent as granted. On November 28, 2012, the Board of Appeals of the EPO (the “Appeals Board”) 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 claims of the counterpart of the Sodemann Patent. We received the Appeals Board’s 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 EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills 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 its 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 Opposition

Board 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 became final as no further appeal was lodged by Geistlich.

On September 9, 2014, we filed in the District Court of Mannheim, Germany 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 EPO on January 8, 2014 (the "Prosl European Patent"). The Prosl European Patent covers a low dose 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 are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm has filed an opposition with the EPO 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 NDP's utility model DE 20 2005 022 124 U1 (the "Utility Model"), which we believe is fundamentally identical to the Prosl European Patent in its main aspects and claims. The Court separated the two proceedings and the Prosl European Patent and the Utility Model claims are now being tried separately. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office based on the similar arguments as those in the opposition against the Prosl European Patent.

On March 27, 2015, the District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100TM and TauroLock-HEP500TM products. A hearing before the same court was held on January 30, 2015 on the separate, but related, question of infringement of the Prosl European Patent by TauroPharm.

The Court issued its decisions on May 8, 2015 staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of us that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the EPO, in the case of the Prosl European Patent, or the German Patent and Trademark Office (the "German PTO"), in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by us for injunctive and other relief until such time as the EPO or the German PTO has ruled on the underlying validity of the Prosl European Patent and the Utility Model.

Both the opposition proceedings against the Prosl European Patent before the EPO and the cancellation action against the Utility Model before the German PTO are ongoing. In its preliminary consideration of the matter, the EPO (and the German Patent and Trademark Office) regarded the patent as not inventive or novel due to publication of prior art. Oral proceedings before the Opposition Division at the EPO were held on November 25, 2015, at which the three judge patent examiner panel considered arguments related to the validity of the Prosl European Patent. The hearing was adjourned due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in another hearing. A date for such further hearing has not been scheduled yet. As with the unfair competition matter, we expect that this matter will be under review and consideration by the Office for some time, with a determination not likely to be made before mid-2016. While we continue to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent and the Utility Model validly claim inventions that will be found to be such by the EPO and the German PTO, there can be no assurance that we will prevail in this matter. The German PTO has scheduled a hearing in the cancellation proceeding for May 11, 2016 which has, however, been rescheduled to June 29, 2016 due to conflicting

court appointments of some members of the legal team. We therefore do not expect a decision from the German PTO in the Utility Model matter before mid- 2016, with any such decision also being subject to appeal.

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 its proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and 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. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider our claims. The judge made no decision on the merits of our complaint. On January 14, 2016, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. We have prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ within the same deadline and both parties have filed further writs at the end of April setting out their respective argumentation in more detail. A date for a further oral hearing has not been scheduled yet.

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 of our product candidates. Specifically, for Neutrolin, we have entered into an agreement with a German company to market and sell Neutrolin in Germany and a distributor agreement with each of 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 the Middle East 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 currently rely and intend to continue to rely on third parties to market and sell Neutrolin. If we are unable to enter into or maintain agreements with third parties to market and sell Neutrolin or any other product after approval or are unable to establish our own marketing and sales capabilities, we may not be able to generate significant or any product revenues.

We do not have an internal sales organization. To date we have relied, and intend to continue to rely, on third parties for the marketing, sales and distribution of Neutrolin and any other product we might develop. However, we may not be able to maintain current and future arrangements or enter into new arrangements with third parties to sell Neutrolin or any other product on favorable terms or at all. In that event, we would have to develop our own marketing and sales force. 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. In addition, the use of third parties to commercialize our approved products reduces the revenues that we would receive if we commercialized these products ourselves.

We have entered into agreements 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 the Middle East and The Netherlands. We intend to seek a sales partner in the U.S. if Neutrolin receives FDA approval. Consequently, we will be dependent on these firms and individuals for the success of sales in these and any other countries in which approval is granted. 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 new or replacement organization for sales and marketing 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

Prior to fiscal 2015, we had identified a material weakness in our internal control over financial reporting, and our current internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur.

In the several years prior to fiscal 2015, we had identified a material weakness in our internal control over financial reporting that was related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting treatments associated with our financing activities and European expansion. While we remediated this material weakness in 2015, we cannot be assured that material weaknesses will not arise again.

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 May 25, 2016, the high and low sales prices for our common stock were $10.40 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 March 31, 2016, 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;
- warrants for 500,000 shares of common stock issued in May 2013 with an exercise price of $0.65 per share that expire on May 30, 2019;
- warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment agreement with an exercise price of $1.50 per share that expire on April 11, 2018;
- options to purchase an aggregate of 775,000 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 $0.78 per share;
- options to purchase an aggregate of 3,708,545 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 $2.11 per share;
- warrants issued to investors in our 2012 private placement to purchase an aggregate of 337,500 shares of our common stock with an exercise price of $0.40 per share, of which 312,500 expire on September 20, 2017 and 25,000 expire on November 13, 2017 (the warrant for 25,000 shares with an expiration date of November 13, 2017 was exercised in May 2016);
- a warrant for 795 shares of our common stock issued to the placement agent for our 2012 private placement with an exercise price of $0.40 per share, which expires on September 20, 2017;
- a warrant to purchase 400,000 shares of our common stock issued on February 19, 2013 with an exercise price of $1.50 that expire on February 19, 2018;
- warrants for 750,000 shares of common stock with an exercise price of $0.90 that expire on October 22, 2019;
- warrants for 725,000 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 1,365,000 shares of common stock;
- Series D Preferred Stock convertible 1,479,240 shares of common stock;
- Series E Preferred Stock convertible 1,959,759 shares of common stock;
- warrants for 682,500 shares of common stock issued in March 2014 with an exercise price of $2.50 per shares that expire on September 10, 2019;
- warrants for 200,000 shares of common stock with an exercise price of $7.00 that expire on March 3, 2020; and;

- warrants for 83,400 shares of common stock with an exercise price of $7.00 that expire on March 25, 2020.

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 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 8,000,000 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants, proposed to be increased to 11,000,000 shares at our 2016 annual meeting of stockholders to be held on June 13, 2016. As of March 31, 2016, options to purchase 775,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $0.78 per share, and options to purchase 3,708,545 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of $2.11 per share were outstanding. In addition, at March 31, 2016, there were outstanding warrants to purchase an aggregate of 4,031,468 shares of our common stock at prices ranging from $0.40 to $7.00 (a warrant covering 25,000 shares was exercised in May 2016), and shares of our outstanding Series C-2, C-3, D and E preferred stock convertible into an aggregate of 6,303,999 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

The 4,006,468 shares issuable upon the exercise of currently outstanding warrants that are being offered for resale by the selling stockholders will be sold for the accounts of the selling stockholders named in this prospectus. As a result, all proceeds from the sales of the 4,006,468 shares of common stock issuable upon the exercise of currently outstanding warrants and offered for resale hereby will go to the selling stockholders and we will not receive any proceeds from the resale of those shares of common stock by the selling stockholders.

We may receive up to a total of $6,596,277.50 in gross proceeds if all of the warrants are exercised hereunder for cash. 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.

After the exercise of any of the warrants, we would not receive any proceeds from the resale of those shares by the selling stockholders because those shares will be sold for the accounts of the selling stockholders named in this prospectus.

We will incur all costs associated with this registration statement and prospectus.

DETERMINATION OF OFFERING PRICE

The prices at which the shares of common stock offered by this prospectus may actually be sold will be determined by the prevailing public market price for shares of our common stock, by negotiation between the selling stockholders and buyers of our common stock in private transactions or as otherwise described in “Plan of Distribution.”

DILUTION

The common stock to be sold by the selling stockholders upon conversion of their warrants is common stock that is issuable upon such exercise. To the extent the common stock underlying the warrants is issued, there will be dilution to the ownership interests of our existing stockholders.

SELLING STOCKHOLDERS

The following table set forth certain information regarding the selling stockholders and the shares of common stock beneficially owned by them, which information is available to us as of March 31, 2016. The selling stockholders may offer the shares under this prospectus from time to time and may elect to sell some, all or none of the shares set forth under this prospectus. However, for the purposes of the table below, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders. In addition, a selling stockholder may have sold, transferred or otherwise disposed of all or a portion of that holder's shares of common stock since the date on which the selling stockholder provided information for this table. We have not made independent inquiries about such transfers or dispositions. See the section entitled "Plan of Distribution" beginning on page 35.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, or the Exchange Act. The percentage of shares beneficially owned prior to the offering is based on 36,138,323 shares of our common stock outstanding as of March 31, 2016.

Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Before Any Sale		% of Class		Number of Shares of Common Stock Offered	Shares of Common Stock Beneficially Owned After Sale of All Shares of Common Stock Pursuant to this Prospectus (1)		
						Number of Shares	% of Class	
Warrants issued in Fall 2012								
MW Bridges LLC	1,453,269	(2)	3.9	%	62,500	1,390,769	3.7	%
Bruce D. Walck	250,000	(3)	*		250,000	-0-	-0-	
George Carris	795	(4)	*		795	-0-	-0-	
Warrants issued in February 2013								
ICS Opportunities Ltd.	767,273	(5)	2.1	%	400,000	367,273	1.0	%
Warrants issued in April 2013								
ND Partners	1,386,077	(6)	3.7	%	125,000	1,261,077	3.4	%
Warrants issued in May 2013								
Manchester Securities Corporation	3,720,730	(7)	9.8	%	500,000	3,220,730	8.6	%
Warrants issued in July 2013								
ICS Opportunities Ltd.	767,273	(5)	2.1	%	227,273	540,000	1.5	%

Warrants issued in October 2013									
Elliott Associates LP	3,720,730	(7)	9.8	%	262,500	3,458,230	9.1	%	
Elliot International LP	3,720,730	(7)	9.8	%	487,500	3,233,230	8.6	%	
Warrants issued in January 2014									
Gary Gelbfish	750,000	(8)	2.0	%	250,000	500,000	1.4	%	
Randy Milby	1,453,269	(2)	3.9	%	118,500	1,334,769	3.6	%	
MW Bridges LLC	1,453,269	(2)	3.9	%	6,500	1,446,769	3.9	%	
Stephen Lefkowitz	994,640	(9)	2.7	%	22,500	972,140	2.6	%	
Wade Capital Corp Money Purchase Plan	994,640	(9)	2.7	%	15,000	979,640	2.7	%	
ND Partners	1,386,077	(6)	3.7	%	250,000	1,136,077	3.1	%	
William Vanjonack	7,500	(10)	*		7,500	-0-	-0-		
Chaim Gulkowitz	25,000	(10)	*		25,000	-0-	-0-		
The Joan Haratani Revocable Trust	30,000	(11)	*		10,000	20,000	*		
Robin M. Silva	10,000	(10)	*		10,000	-0-	-0-		
Polly S. and Cielito B. Cortez	30,000	(11)	*		10,000	20,000	*		
Warrants issued in March 2014									
Kingsbrook Opportunities Master Fund LP	275,900	(12	*		192,500	83,400	*		
Empery Asset Master, LTD	350,000	(13)	1.0	%	283,500	66,500	*		
Empery Tax Efficient LP	350,000	(13)	1.0	%	66,500	283,500	*		
Integrated Core Strategies (US) LLC	767,273	(5)	2.1	%	140,000	627,273	1.7	%	
Warrants issued in March 2015									
Manchester Securities Corporation	3,720,730	(7)	9.8	%	200,000	3,520,730	9.3	%	
Kingsbrook Opportunities Master Fund LP	275,900	(12)	*		83,400	192,500	*		
TOTAL	10,051,184	(14)	26.9	%	(15) 4,006,468	6,044,716	(14)(15)	15.3	% (14)

* Represents beneficial ownership of less than one percent of the outstanding shares of our common stock.

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(1) Assumes that each selling stockholder will sell all of its shares of common stock issuable upon the exercise of their warrants subject to sale pursuant to this prospectus, although in the individual line items we give effect to only the individual sale of that designated number of shares.

(2) Consists of (i) 57,026 shares of common stock held by Randy Milby, (ii) 196,243 shares of our common stock held by MW Bridges LLC, of which Mr. Milby is Managing Partner, (iii) 762,500 shares of our common stock issuable upon exercise of stock options, (iii) 62,500 shares of our common stock issuable upon exercise of warrants to purchase shares of our common stock with an exercise price of $0.40 per share issued in our 2012 private placement which expire on September 20, 2017 held by MW Bridges LLC, (iv) 237,000 shares of our common stock issuable upon conversion of 23,700 shares of our Series C-3 non-voting convertible preferred stock, (v) 13,000 shares of our common stock issuable upon conversion of 1,300 shares of our Series C-3 non-voting convertible preferred stock held by MW Bridges LLC, (vi) 118,500 shares of our common stock issuable upon exercise of 2014 warrants with an exercise price of $0.90 that expire on January 8, 2020, and (vii) 6,500 shares of our common stock issuable upon exercise of 2014 warrants with an exercise price of $0.90 that expire on January 8, 2020 held by MW Bridges LLC.

(3) Consists of shares issuable upon the exercise of warrants issued to investors in our 2012 private placement to purchase shares of our common stock with an exercise price of $0.40 per share which expire on September 20, 2017.

(4) Consists of shares issuable upon the exercise of warrants 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.

(5) Consists of shares issuable upon the exercise of (i) 400,000 warrants issued on February 19, 2013 with an exercise price of $1.50 that expires on February 19, 2018, (ii) 227,273 warrants issued in July 2013 with an exercise price of $1.50 that expire on July 30, 2018 and (iii) 140,000 shares issuable upon the exercise of warrants issued in March 2014 with an exercise price of $2.50 per shares that expire on September 9, 2019. ICS Opportunities Ltd. and Integrated Core Strategies (US) LLC are affiliated entities.

(6) Consists of (i) 511,077 shares of common stock, (ii) 500,000 shares of our common stock issuable upon conversion of 50,000 shares of our Series C-3 non-voting convertible preferred stock, (iii) 125,000 shares issuable upon the exercise of warrants issued 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, and (iv) 250,000 shares issuable upon the exercise of warrants with an exercise price of $0.90 that expire on January 8, 2020.

(7) Due to the Ownership Limitation (as defined below), Elliott Associates, L.P. (“Elliott Associates”) may be deemed the beneficial owner of 3,720,730 shares of our common stock through securities held by it and by Manchester Securities Corp., a wholly-owned subsidiary of Elliott Associates (“Manchester”), and Elliott International, L.P., a wholly-owned subsidiary of Elliott Associates (“Elliott International”). Notwithstanding the above, Elliott Associates beneficially holds: (i) 1,730,200 shares of our common stock held by Manchester, (ii) May 2013 warrants exercisable for 500,000 shares of our common stock, with an exercise price of $0.65 per share that expire on May 30, 2019,

(iii) 52,500 shares of our Series C-2 non-voting convertible preferred stock convertible into 525,000 shares of our common stock, (iv) October 2013 warrants exercisable for 262,500 shares of our common stock with an exercise price of $0.90 that expire on October 22, 2019, (v) 97,500 shares of our Series C-2 non-voting convertible preferred stock held by Elliott International convertible into 975,000 shares of our common stock, (vi) October 2013 warrants held by Elliott International exercisable for 487,500 shares of our common stock with an exercise price of $0.90 that expire on October 22, 2019, (vii) 73,962 shares of our Series D non-voting convertible preferred stock held by Manchester convertible into 1,479,240 shares of our common stock, (viii) 89,623 shares of our Series E non-voting convertible preferred stock held by Manchester convertible into 1,959,759 shares of our common stock and (ix) March 2015 warrants held by Manchester Securities Corp. exercisable for 200,000 shares of our common stock with an exercise price of $7.00 that expire on March 3, 2020 (the May 2013 warrants, the October 2013 warrants and the March 2105 warrants shall collectively be referred to herein as the “Convertible Securities”). However, in accordance with Rule 13d-4 under the Exchange Act, the number of shares of our common stock into which the Convertible Securities are convertible or exercisable, as applicable, are limited pursuant to the terms of the Convertible Securities to that number of shares of our common stock which would result in Elliott Associates having aggregate beneficial ownership of, with respect to the May 2013 warrants, the October 2013 warrants, the March 2015 warrants, the Series C-2 preferred stock, the Series D preferred stock and the Series E preferred stock, 9.99% of the total issued and outstanding shares of our common stock (the "Ownership Limitation"). In determining the number of shares and percentage of ownership after the sale of the shares offered hereby by Manchester, Elliott Associates and Elliott International, additional derivative securities beneficially owned by Manchester, Elliott Associates or Elliott International have not be included. Elliott Associates disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Convertible Securities if such conversion or exercise would cause Elliott Associates’ aggregate beneficial ownership to exceed or remain above the applicable Ownership Limitation (as is currently the case). Therefore, Elliott Associates disclaims beneficial ownership of any shares of our common stock issuable upon any conversion or exercise of the May 2013 warrants, the October 2013 warrants, the Series C-2 preferred stock, the Series D preferred stock and the Series E preferred stock, which conversion of exercise would be prohibited by the ownership limitation. The business address of Elliott Associates is 40 West 57th Street, 30th Floor, New York, New York 10019. Based solely on information contained in a Schedule 13D filed with the SEC on August 11, 2015 by Elliott Associates and other information known to us.

(8) Consists of (i) 500,000 shares of our common stock issuable upon conversion of 50,000 shares of our Series C-3 non-voting convertible preferred stock, and (ii) 250,000 shares issuable upon the exercise of warrants with an exercise price of $0.90 that expire on January 8, 2020.
(9) Consists of (i) 117,399 shares of our common stock held by Mr. Lefkowitz individually, (ii) 10,000 shares of our common stock held by Mr. Lefkowitz's spouse, (iii) 174,741 shares of our common stock held by Wade Capital Money Purchase Plan, an entity for which Mr. Lefkowitz has voting and investment control, (iv) 580,000 shares of our common stock issuable upon exercise of stock options, (v) 45,000 shares of our common stock issuable upon conversion of 4,500 shares of our Series C-3 convertible preferred stock held by Mr. Lefkowitz individually, (vi) 30,000 shares of our common stock issuable upon conversion of 3,000 shares of our Series C-3 convertible preferred stock held by Wade Capital Money Purchase Plan, (vii) 22,500 shares of our common stock issuable upon exercise of 2014 warrants with an exercise price of $0.90 that expire on January 8, 2020 held by Mr. Lefkowitz individually, and (viii) 15,000 shares of our common stock issuable upon exercise of 2014 warrants with an exercise price of $0.90 that expire on January 8, 2020 held by Wade Capital Money Purchase Plan.
(10) Consists of shares issuable upon the exercise of warrants with an exercise price of $0.90 that expire on January 8, 2020.
(11) Consists of (i) 20,000 shares of our common stock issuable upon conversion of 2,000 shares of our Series C-3 non-voting convertible preferred stock, and (ii) 10,000 shares issuable upon the exercise of warrants with an exercise price of $0.90 that expire on January 8, 2020.
(12) Consists of (i) 192,500 shares issuable upon the exercise of warrants issued in March 2014 with an exercise price of $2.50 per shares that expire on September 9, 2019 and (ii) 83,400 shares issuable upon the exercise of warrants with an exercise price of $7.00 that expire on March 25, 2020.
(13) Consists of (i) 283,500 shares issuable upon the exercise of warrants to Empery Asset Master, LTD, and (ii) 66,500 shares issuable upon the exercise of warrants to Empery Tax Efficient LP, which warrants were issued in March 2014 with an exercise price of $2.50 per shares that expire on September 9, 2019. Empery Asset Master, LTD and Empery Tax Efficient LP are affiliated entities.
(14) Duplicate stockholders removed from calculation.
(15) The total assumes the sale of all shares offered by the selling stockholders under this prospectus.

Information about any other selling stockholders will be included in prospectus supplements or post-effective amendments, if required. Information about the selling stockholders may change from time to time. Any changed information with respect to which we are given notice will be included in prospectus supplements.

Certain Relationships and Transactions with the Selling Stockholders

In the last three fiscal years, we had the following transactions with the following selling stockholders.

Manchester Securities Corp.

As of October 8, 2012, Manchester Securities Corp. ("Manchester"), a wholly-owned subsidiary of Elliott Associates, L.P. and an existing institutional investor, beneficially owned approximately 23.8% of our voting capital stock. In addition, on September 20, 2012, Elliott Associates, L.P. purchased, indirectly through Manchester Securities Corp., in a private placement, $400,000 of (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

On September 15, 2014, we entered into consent and exchange agreements with Kingsbrook Opportunities Master Fund LP ("Kingsbrook") and Elliot International, L.P. and Manchester (collectively, "Elliott"). Each of Elliot and Kingsbrook beneficially owns in excess of 5% of the outstanding shares of our common stock. Elliot beneficially owns all of our outstanding Series C-2 preferred stock (and related warrants) and Series D preferred stock. At the time, Elliott and Kingsbrook beneficially owned all of our outstanding Series E preferred stock and related warrants. Pursuant to the exchange agreements, we amended and restated the Series C-2 preferred stock, Series D preferred stock and Series E preferred stock and the related warrants to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. We also removed the preferred dividend payable on the Series D preferred stock and Series E preferred stock. In exchange for the removal of the anti-dilution, price reset, change of control and dividend provisions from the Series C-2 preferred stock, Series D preferred stock and Series E preferred stock and the related warrants, we decreased the exercise price of the warrants issued in May 2013 from $1.00 to $0.65 and the exercise price of the warrants issued in October 2013 from $1.25 to $0.90. We also increased the conversion ratio of the Series E preferred stock from 20 shares to 21.8667 shares of common stock for every share of Series E preferred stock. In addition, we issued 16,562 shares of our Series D preferred stock to Elliott in satisfaction of the 9.0% payment-in-kind dividend on the Series D preferred stock, and issued 36,086 shares of Series E preferred stock to Elliott and 1,140 shares of Series E preferred stock to Kingsbrook in satisfaction of the 8.0% payment-in-kind dividend on the Series E preferred stock.

On March 3, 2015, we entered into a backstop agreement with, Manchester pursuant to which Manchester agreed to lend us, at our request, up to $4,500,000 less the dollar amount of gross proceeds received by us upon the exercise of warrants to purchase common stock issued in connection with our initial public offering on or before April 30, 2015, provided that the loan may not exceed $3,000,000. We were able to access this financing until April 30, 2015. However, the amount we received from the exercise of those warrants prior to April 30, 2015, exceeded the amount that would have allowed us to access the loan and, as a result, we could not and did not access the loan. 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, which warrant expired unexercised. 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. 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, pursuant to which Manchester appointed a director in August 2015 and another director in April 2016. Finally, we 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.

Kingsbrook Opportunities Master Fund LP

On September 15, 2014, we entered into consent and exchange agreements with Kingsbrook Opportunities Master Fund LP ("Kingsbrook") and Elliot International, L.P. and Manchester (collectively, "Elliott"). Each of Elliot and Kingsbrook beneficially owns in excess of 5% of the outstanding shares of our common stock. Elliot beneficially owns all of our outstanding Series C-2 preferred stock (and related warrants) and Series D preferred stock. At the time, Elliott and Kingsbrook beneficially owned all of our outstanding Series E preferred stock and related warrants. Pursuant to the exchange agreements, we amended and restated the Series C-2 preferred stock, Series D preferred stock and Series E preferred stock and the related warrants to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. We also removed the preferred dividend payable on the Series D preferred stock and Series E preferred stock. In exchange for the removal of the anti-dilution, price reset, change of control and dividend provisions from the Series C-2 preferred stock, Series D preferred stock and Series E preferred stock and the related warrants, we decreased the exercise price of the warrants issued in May 2013 from $1.00 to $0.65 and the exercise price of the warrants issued in October 2013 from $1.25 to $0.90. We also increased the conversion ratio of the Series E preferred stock from 20 shares to 21.8667 shares of common stock for every share of Series E preferred stock. In addition, we issued 16,562 shares of our Series D preferred stock to Elliott in satisfaction of the 9.0% payment-in-kind dividend on the Series D preferred stock, and issued 36,086 shares of Series E preferred stock to Elliott and 1,140 shares of Series E preferred stock to Kingsbrook in satisfaction of the 8.0% payment-in-kind dividend on the Series E preferred stock.

In March 2015, in connection with entering into the backstop agreement with Manchester, we issued to Kingsbrook a warrant, exercisable for five years, to purchase 83,400 shares of our common stock at a per share exercise price of $7.00.

Integrated Core Strategies (US) LLC

On March 4, 2014, we sold to Integrated Core Strategies (US) LLC 400,000 units in a registered direct offering. Each unit consisted of one share of our common stock and 0.35 of a warrant, each to purchase one share of our common stock, which resulted in an aggregate of 400,000 shares of common stock and a warrant to purchase 140,000 shares of common stock. The purchase price was $2.50 per unit. The warrants have an exercise price of $3.10 per share, are exercisable commencing six months from the date of issuance, and have a term of five years from the date of exercisability. At the time, Integrated Core Strategies (US) LLC, along with affiliated entities, beneficially owned in excess of 5% of the outstanding shares of our common stock. September 15, 2014, we entered into consent and exchange agreement with Integrated Core Strategies (US) LLC to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. In exchange, we agreed to decrease the exercise price of the warrants from $3.10 to $2.50. The sale and the subsequent exchange were on the same terms as those provided to all other investors in the March 2014 financing.

Gary A. Gelbfish, M.D.

On September 20, 2012, Dr. Gary A. Gelbfish, a former director, purchased, in a private placement, $100,000 of (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement. On January 8, 2014, Dr. Gelbfish purchased, in a private placement, 50,000 shares of our Series C-3 convertible preferred stock and a warrant to purchase 250,000 shares of our common stock at an exercise price of $1.25 per share (which warrant is exercisable for five years after January 8, 2015), all on the same terms as other investors in the private placement.

Steven W. Lefkowitz

On September 20, 2012 and November 13, 2013, Steven W. Lefkowitz, a director and former interim Chief Financial Officer, purchased, indirectly through Wade Capital Corporation Money Purchase Plan (an entity for which he has voting and investment control) and individually, in a private placement, $35,000 and $15,000, respectively (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

On January 8, 2014, Mr. Lefkowitz purchased, indirectly through Wade Capital Corporation Money Purchase Plan (an entity for which he has voting and investment control) and individually, in a private placement, 4,500 and 3,000 shares, respectively, of our Series C-3 convertible preferred stock and warrants to purchase 22,500 and 15,000 shares, respectively, of our common stock at an exercise price of $1.25 per share (which warrants are exercisable for five years after January 8, 2015), all on the same terms as other investors in the private placement. On September 15, 2014, we entered into a consent and exchange agreement with the holders of our Series C-3 preferred stock and related warrants, including Mr. Lefkowitz, pursuant to which, we amended and restated the Series C-3 preferred stock and the related warrants to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. The exchange was on the same terms as those provided to all other investors in the January 2014 Series C-3 financing.

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Randy Milby

On September 20, 2012, Randy Milby, our Chief Executive Officer and a director, purchased, indirectly through MW Bridges LLC (an entity for which he is Managing Partner, and has voting and investment control), in a private placement, $50,000 of (i) 9% senior convertible notes, convertible into shares of our common stock, at a conversion price of $0.35 per share; and (ii) a five-year redeemable warrant to purchase common stock at an exercise price of $0.40 per share, all on the same terms as other investors in the private placement.

On January 8, 2014, Mr. Milby purchased, indirectly through MW Bridges LLC (an entity for which he is Managing Partner, and has voting and investment control) and individually, in a private placement, 23,700 and 1,300 shares, respectively, of our Series C-3 convertible preferred stock and warrants to purchase 118,500 and 6,500 shares, respectively, of our common stock at an exercise price of $1.25 per share (which warrants are exercisable for five years after January 8, 2015), all on the same terms as other investors in the private placement. On September 15, 2014, we entered into a consent and exchange agreement with the holders of our Series C-3 preferred stock and related warrants, including Mr. Milby, pursuant to which, we amended and restated the Series C-3 preferred stock and the related warrants to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. The exchange was on the same terms as those provided to all other investors in the January 2014 Series C-3 financing.

Cora M. Tellez

On January 8, 2014, Cora M. Tellez, a director and the Chair of our Board, purchased, in a private placement, 5,000 shares of our Series C-3 convertible preferred stock and a warrant to purchase 25,000 shares of our common stock at an exercise price of $1.25 per share (which warrant is exercisable for five years after January 8, 2015), all on the same terms as other investors in the private placement. On September 15, 2014, we entered into a consent and exchange agreement with the holders of our Series C-3 preferred stock and related warrants, including Ms. Tellez, pursuant to which, we amended and restated the Series C-3 preferred stock and the related warrants to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. The exchange was on the same terms as those provided to all other investors in the January 2014 Series C-3 financing.

PLAN OF DISTRIBUTION

We anticipate that the selling stockholders and their pledgees, donees, transferees and other successors-in-interest may sell all or a portion of the shares offered by this prospectus from time to time on securities exchanges or in private transactions, at fixed prices, at market prices prevailing at the time of sale, at prices reasonably related to the market price or at negotiated prices. Sale of the shares offered by this prospectus may be effected by one or more of the following methods:

- ordinary brokerage transactions and transactions in which the broker solicits purchases
- sales to one or more brokers or dealers as principal, and resale by those brokers or dealers for their account, including resales to other brokers and dealers
- block trades in which a broker or dealer attempts to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction
- privately negotiated transactions with purchasers
- an exchange distribution in accordance with the rules of the applicable exchange
- settlement of short sales entered into after the date of this prospectus
- a combination of any such methods of sale or
- any other method permitted pursuant to applicable law.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. No such broker-dealer will receive compensation in excess of that permitted applicable Financial Industry Regulatory Authority, or FINRA, rules. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act of 1933, as amended (referred to as the Securities Act). Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the selling stockholders. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that agent, dealer or broker-dealer under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing

or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

We are not aware as of the date of this prospectus of any agreements between any selling stockholder and any broker-dealers regarding the sale of the shares offered by this prospectus, although we have made no inquiry in that regard. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

Any selling stockholder may be deemed to be an "underwriter" within the meaning of the Securities Act. Any broker, dealer or other agent executing a sell order on behalf of a selling stockholder may be considered to be an underwriter within the meaning of the Securities Act, in which case commissions received by any of these brokers, dealers or agents and profit on any resale of the shares may be considered to be underwriting commissions under the Securities Act.

The selling stockholders may also sell shares under Rule 144 of the Securities Act, if available, rather than under this prospectus.

All costs, fees and expenses of registration incurred in connection with the offering will be borne by us. All selling and other expenses incurred will be borne by the selling stockholders. We have agreed to indemnify certain of the investors against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

DIVIDEND POLICY

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Further, pursuant to the terms of our Series D and Series 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. Subject to the foregoing, 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.

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 March 31, 2016, we had 36,138,323 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 March 31, 2016, we had outstanding: 150,000 shares as Series C-2 Non-Voting Convertible Preferred Stock; 136,500 shares as Series C-3 Non-Voting Convertible Preferred Stock; 73,962 shares as Series D Non-Voting Convertible Preferred Stock; and 89,623 shares as Series E Non-Voting Convertible Preferred

Stock. The Series A Non-Voting Convertible Preferred Stock, Series B 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 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.

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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.

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 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.

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 balance sheets of CorMedix Inc. as of December 31, 2015 and 2014 and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2015, and management's assessment of the effectiveness of intern control over financial reporting as of December 31, 2015 (which is included in management's report on internal control over financial reporting in the Annual Report on Form 10-K for the year ended December 31, 2015), have been incorporated herein by reference in reliance on the report of Friedman LLP, independent registered public accounting firm, given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL 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-3 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

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

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed with the SEC pursuant to Section 13 of the Exchange Act on March 15, 2016;

- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC pursuant to Section 13 of the Exchange Act on May 10, 2016;

- our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on January 19, 2016, March 15, 2016, April 13, 2016, April 21, 2016, April 25, 2016 and May 2, 2016; and

- our definitive proxy statement on Schedule 14A for the 2016 annual meeting of stockholders, filed with the SEC pursuant to Section 14 of the Exchange Act on May 4, 2016.

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

Any statement contained in this prospectus and any applicable prospectus supplement or in a document incorporated or deemed to be incorporated by reference into this prospectus and any applicable prospectus supplement will be deemed to be modified or superseded for purposes of this prospectus and any prospectus supplement to the extent that a statement contained in this prospectus and any applicable prospectus supplement or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus and any applicable prospectus supplement 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 and any applicable prospectus supplement.

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 US Highway 206, Suite 200, Bedminster, New Jersey 07921, (908) 517-9500.

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

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	$1,154	
Legal fees and expenses	$20,000	*
Accounting fees and expenses	$15,000	*
Printing expenses	$5,000	*
Miscellaneous	$3,846	*
Total	$45,000	*

*Estimated as permitted under Rule 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 as amended April 19, 2016.	10-Q	5/10/2016	3.1	
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

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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 Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on January 21, 2014.	8-K	1/09/2014	3.12	
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	
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	Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC.	S-1	11/25/2009	4.7	
4.3	Form of Registration Rights Agreement.	10-Q	11/13/2012	4.5	
4.4	Form of Warrant issued on February 19, 2013.	8-K	2/19/2013	4.13	
4.5	Form of Warrant issued on May 23, 2013.	8-K	5/24/2013	4.20	
4.6	Form of Warrant issued on July 25, 2013.	8-K	7/26/2013	4.21	
4.7	Form of Warrant issued on October 22, 2013.	8-K	10/18/2013	4.22	
4.8	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23	
4.9	Form of Warrant issued on March 10, 2014	8-K	03/05/2014	4.24	
4.10	Warrant issued March 3, 2015.	8-K	03/04/2015	4.1	

4.11	Amended and Restated Warrant originally issued May 30, 2013.	8-K	03/04/2015	4.2
4.12	Amended and Restated Warrant originally issued March 24, 2010.	8-K	03/04/2015	4.3
4.13	Form of Convertible Note.	8-K	03/04/2015	4.4
4.14	Registration Rights Agreement, dated March 3, 2015, by and between CorMedix Inc. and Manchester Securities Corp.	8-K	03/04/2015	4.5

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
5.1	Opinion of Wyrick Robbins Yates & Ponton LLP.				x
21.1	List of Subsidiaries.	10-K	3/27/2013	21.1	
23.1	Consent of Friedman LLP, Independent Registered Accounting Firm				x
23.3	Consent of Wyrick Robbins Yates & Ponton LLP (included as part of Exhibit 5.1).				x
24.1	Power of Attorney (included in the signature page hereto).				x

(b) Financial statement schedule.

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;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

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

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by Registrant pursuant to Section 13 and Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

(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.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) 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

(ii) 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.

(5) That, for the purpose of determining liability of the Registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this Registration Statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned Registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned Registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.

(b) 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.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 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.

(d) The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

(e) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act (“Act”) in accordance with the rules and regulations prescribed by the Commission under section 305(b)(2) of the Act.

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 of the requirements for filing on Form S-3 and has duly caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bedminster, State of New Jersey, on May 27, 2016.

CORMEDIX INC.

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

POWER OF ATTORNEY

We, the undersigned officers and directors of CorMedix Inc., do hereby constitute and appoint Randy Milby and Antony Pfaffle, or either of them, our true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Registration Statement, and to file the same, with exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite are necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorney-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement on Form S-3 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 and Principal Financial Officer)	May 27, 2016
/s/ Janet Dillione Janet Dillione	Director	May 27, 2016
/s/ Matthew P. Duffy Matthew P. Duffy	Director	May 27, 2016
/s/ Michael W. George Michael W. George	Director	May 27, 2016
/s/ Myron Kaplan Myron Kaplan	Director	May 27, 2016
/s/ Steven W. Lefkowitz Steven W. Lefkowitz	Director	May 27, 2016

/s/ Taunia Markvicka Taunia Markvicka	Director	May 27, 2016
/s/ Antony E. Pfaffle, M.D. Antony E. Pfaffle, M.D.	Director and Chief Scientific Officer	May 27, 2016
/s/ Cora M. Tellez Cora M. Tellez	Director	May 27, 2016