

CorMedix Inc.
Form 424B5
December 08, 2017

Prospectus Supplement Filed pursuant to Rule 424(b)(5)
(to Prospectus dated April 17, 2015) Registration No. 333-203300

\$20,000,000 of Shares

Common Stock

We have entered into an At-the-Market Issuance Sales Agreement, dated April 8, 2015, referred to as the original agreement, with MLV & Co. LLC, or MLV. On December 8, 2017, we entered into an amendment to the original agreement, which together with the original agreement is referred to as the sales agreement, to increase the amount of common stock that we may offer and sell pursuant to the sales agreement and to replace MLV with B. Riley FBR, Inc., or B. Riley FBR, as sales agent. B. Riley FBR is an affiliate of MLV. The sales agreement relates to the sale of shares of our common stock offered by this prospectus supplement. In accordance with the terms of the sales agreement, under this prospectus supplement we may offer and sell shares of our common stock, \$0.001 par value per share, having an aggregate offering price of up to \$20,000,000 from time to time through B. Riley FBR, acting as agent.

Our common stock is traded on the NYSE American under the symbol “CRMD.” The last reported sale price of our common stock on December 7, 2017 was \$0.55 per share.

Sales of our common stock, if any, under this prospectus supplement will be made by any method permitted that is deemed an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act. B. Riley FBR is not required to sell any specific amount, but will act as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

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

Investing in our common stock involves a high degree of risk. Please read the information contained in and incorporated by reference under the heading “Risk Factors” beginning on page S-9 of this prospectus supplement, the section captioned “Item 1A—Risk Factors” in our most recently filed annual report on Form 10-K, which is incorporated by reference into this prospectus supplement, and under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus supplement.

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

B. Riley FBR

The date of this prospectus supplement is December 8, 2017.

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ABOUT THIS PROSPECTUS SUPPLEMENT

On April 9, 2015, we filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-3 (File No. 333-203300) utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement was declared effective on April 17, 2015. Under this shelf registration process, we may, from time to time, sell up to \$100.0 million in the aggregate of common stock, preferred stock, warrants, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, of which up to an aggregate of \$20.0 million may be sold in this offering in the form of shares of common stock.

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

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

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

We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities

offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Our primary executive offices are located at 400 Connell Drive, Suite 5000, Berkeley Heights, NJ 07922, and our telephone number is (908) 517-9500. Our website address is www.cormedix.com. The information contained on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus supplement.

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

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

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

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement, including the information incorporated by reference into this prospectus supplement, and the information referred to under the heading “Risk Factors” in this prospectus supplement beginning on page S-8, and in the documents incorporated by reference into this prospectus supplement.

Our Company

Overview

We are a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases.

Our primary focus is to develop our lead product candidate, Neutrolin® (also known as CRMD003), for potential commercialization in the U.S. and other key markets. We have in-licensed the worldwide rights to develop and commercialize Neutrolin, which is a novel anti-infective solution (a formulation of taurolidine, citrate and heparin 1000 u/ml) under development in the U.S. for the reduction and prevention of catheter-related infections and thrombosis in patients requiring central venous catheters in clinical settings such as dialysis, critical/intensive care, and oncology. 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. We believe Neutrolin has the potential to address a significant unmet medical need and represents a potential large market opportunity.

We initiated one Phase 3 clinical trial in hemodialysis patients with a central venous catheter (“LOCK-IT-100”) in December 2015. The FDA has indicated that two pivotal trials to demonstrate safety and effectiveness of Neutrolin will be required by the U.S. Food and Drug Administration (“FDA”) to secure marketing approval in the United States.

In April 2017, a safety review by an independent Data and Safety Monitoring Board, or DSMB was completed. The DSMB unanimously concluded that it is safe to continue the LOCK-IT-100 clinical trial as designed based on its evaluation of data from the first 279 patients randomized on trial.

On August 2, 2017, we announced that the FDA had agreed to key changes to the LOCK-IT-100 clinical trial. We believe that the changes endorsed by the FDA facilitate our ability to complete the ongoing Phase 3 clinical trial in hemodialysis patients with central venous catheters, as previously announced, by year-end 2018. We sought guidance from the FDA to address, in part, the apparent overall lower rate of catheter-related blood stream infection (CRBSI) events as announced in April 2017. Changes made to the protocol were 1) the utilization of a Clinical Adjudication Committee (CAC) to assess suspected CRBSIs; 2) the use of the CAC to critically and independently assess suspected CRBSIs in a blinded fashion based on a single positive blood culture and supporting documentation, rather than two positive blood cultures as previously required; 3) the ability to capture cases occurring outside of dialysis centers to facilitate more complete capture of CRBSI events in the study, particularly when patients present with CRBSI events outside of the dialysis center setting (emergency rooms or urgent care centers); and 4) a revision of the design of the study to detect a treatment effect of 55% or greater when comparing

the Neutrolin and heparin control arms. The FDA agreed that cases adjudicated by the CAC to be CRBSI events and the per protocol definition of CRBSI events will be included in the primary analysis of the primary efficacy endpoint of the LOCK-IT-100 study. The amended study assumptions including a reduction in statistical power have resulted in a reduction in the total number of CRBSI events required from 161 events to 56 events to complete the study.

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We believe that these changes will allow the identification of more infections, enabling a single interim analysis, which is anticipated to occur early in the first quarter of 2018 based on 28 CRBSI events. Should the interim analysis show sufficient efficacy it may be possible to conclude the study earlier than projected. Further, based on our experience in the LOCK-IT-100 trial, we are reassessing the structure of our planned second Phase 3 clinical trial to seek efficiencies and improvements in its design and execution.

In July 2013, we received CE Mark approval for Neutrolin. As a result, in December 2013, we commercially launched Neutrolin in Germany for the prevention of catheter-related bloodstream infections and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in certain European Union and Middle Eastern countries for such treatment. In April 2017, we entered into a commercial collaboration with Hemotech SAS covering France and French overseas territories.

We are evaluating opportunities for the possible expansion of taurolidine as a platform compound for use in certain medical devices. Patent applications have been filed in wound closure, surgical meshes, wound management, and osteoarthritis, including visco-supplementation. Based on initial feasibility work, we are advancing preclinical studies for three product candidates: surgical meshes, suture materials, and hydrogels. There exists a need to control and protect against surgical site infections upon wound closure and we believe taurolidine may provide benefits not currently available in marketed antimicrobial medical devices. It may also provide a significant advantage in devices for burn victims and use in less sterile environments. We expect to develop and pursue FDA clearance for these potential products by the 510(k) pathway and will seek to establish development/commercial partnerships as these programs advance. We are also involved in a pre-clinical research collaboration for the use of taurolidine as a possible combination treatment for rare orphan pediatric tumors.

Recent Developments

On November 29, 2017, our Board of Directors approved hiring Dr. Gary Gelbfish, one of our directors, as a consultant to assist in our planned interim analysis for the ongoing LOCK IT 100 clinical trial for Neutrolin. For his services, we will pay Dr. Gelbfish \$800.00 per hour and will pay him for services rendered since November 10, 2017. As a result of this arrangement, Dr. Gelbfish has resigned from the Audit Committee and the Board has appointed Myron Kaplan to replace him on the Audit Committee.

On November 22, 2017, the Opposition Division at the European Patent Office (EPO) in Munich, Germany held an oral hearing to consider an opposition brought by TauroPharm GmbH against CorMedix's European Patent EP 1,814,562 B1, also known as the Prosl European Patent, alleging that it lacks novelty and inventive step. The Prosl European Patent covers the formulation of taurolidine and citrate with low dose heparin in a catheter lock solution for maintaining patency and preventing infection in hemodialysis catheters.

At the hearing, the panel held that the Prosl European Patent would be invalidated because it did not meet the requirements of novelty based on a technical aspect of the European intellectual property law. CorMedix disagrees with this decision and plans to appeal. Our appeal will be based, in part, on the written opinion to be issued by the Opposition Division, which is expected by the first quarter 2018. CorMedix continues to believe that the Prosl European Patent is indeed novel and that its validity should be maintained. In addition, the ongoing Unfair Competition litigation brought by CorMedix against TauroPharm is not affected and will continue.

Based on the advice of our U.S. patent counsel, we expect that, due to differences between the novelty requirements in intellectual property law in Europe and the U.S., the validity of our U.S. patent covering Neutrolin will be unaffected by a decision from the EPO. Importantly, the Company believes that the U.S. Food and Drug

Administration's (FDA) designation of Neutrolin as a Qualified Infectious Disease Product (QIDP) provides the most significant protection for its intellectual property. Having this designation means that, upon FDA approval for the prevention of catheter-related blood stream infections in patients with end-stage renal disease receiving hemodialysis through a central venous catheter, Neutrolin would have five years of market exclusivity in the U.S. Beyond this, Neutrolin will have an additional five years of protection due to its status as a new chemical entity, and a further six months if granted pediatric exclusivity. Together, these designations are expected to serve as a significant barrier to entry in the U.S. marketplace for a period of ten and a half years following commercial launch and, in any case, would be effective after any potential patent protection expired.

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Based on an extensive analysis of the global market potential for Neutrolin, we believe the U.S. represents a substantially more valuable commercial market for this product than the European market. Therefore, we have been focusing most of our resources on seeking regulatory approval of Neutrolin in the U.S. for multiple, high-value indications, beginning with the prevention of catheter-related blood stream infections in hemodialysis patients, which is currently in Phase 3 development.

On November 20, 2017, we announced an agreement to sell an aggregate of 624,246 shares of our common stock to all of our directors and executive officers and to certain of our employees at a per share purchase price of \$0.48. This common stock financing will reduce the number of shares issuable under the warrants that we may be required to issue to two institutional investors pursuant to a Backstop Agreement, dated November 9, 2017, among those institutional investors and our company, which is discussed below, from an aggregate of up to an additional 473,664 shares to 445,245 shares.

On November 9, 2017, we entered into a securities purchase agreement with Elliott Associates, L.P. and Elliott International, L.P., (the “Buyers”), long-term institutional investors in CorMedix, pursuant to which, on November 16, 2017, we sold \$2 million of our newly designated Series F Convertible preferred stock (“Series F Stock”) at \$1,000 per share.

On November 9, 2017, we also entered a backstop agreement with the Buyers pursuant to which the Buyers have agreed to purchase from us, at our request, up to an additional \$3 million of shares of the Series F Stock at \$1,000 per share. We may request purchases under the backstop agreement from January 15, 2018 until March 31, 2018.

As consideration for the backstop financing, we will issue the Buyers warrants, exercisable for three years, to purchase, in the aggregate, up to 947,329 shares (subject to adjustment) of our common stock at a per share exercise price of \$0.001. The number of shares issuable under the warrant was determined by the closing price of our common stock on November 8, 2017, which was \$0.5278. The number of shares issuable under the warrants will be reduced to the extent that we raise equity capital from investors other than the Buyers that offsets the \$3 million backstop amount.

Gross proceeds of the securities purchase agreement and the backstop agreement, if the backstop agreement is used in full, total an aggregate of \$5,000,000 (assuming cashless exercise of the warrants).

Each share of Series F Stock is convertible into shares of our common stock, at the option of the Buyers, at an effective price of \$0.6334 per share, which represents a 20% premium to the closing price of our common stock on November 8, 2017. The conversion price of the Series F Stock is subject to anti-dilution adjustment for customary recapitalization events such as stock splits, as well as full ratchet anti-dilution protection in the event that we do not obtain the subordination of the Series C-3 preferred stock to that of the Series F Stock (as described below) or obtain stockholder approval of the issuance of common stock that exceeds NYSE American rules (as described below). The Series F Stock will be mandatorily convertible on April 2, 2018, subject to certain equity conditions, at the lower of \$0.6334 and a 10% discount to the notional price at which an equity or equity linked transaction in an amount of \$5 million or more is completed by March 31, 2018, or if no such transaction is completed, a 10% discount to the closing price of the stock on March 31, 2018.

The Series F Stock is non-voting and has no dividend right outside of receiving dividends in the same form as we pay to holders of shares of our common stock.

The Series F Stock contains a prohibition on its conversion if, as a result of such conversion, we would have issued shares of our common stock in an aggregate amount equal to 13,336,939 shares, which is 20% of our shares of

common stock outstanding on November 9, 2017, unless we have received the approval of our stockholders for such overage.

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The Buyers will be prohibited from converting Series F Stock into shares of our common stock to the extent that, as a result of such conversion, the Buyers, together with their affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding. In the event of our liquidation, dissolution, or winding up, holders of the Series F Stock will receive a payment equal to \$1,000 per share of Series F Stock, subject to adjustment, before any proceeds are distributed to the holders of common stock. Shares of the Series F Stock will rank:

senior to all common stock and the Series C-2, Series C-3 Convertible Preferred Stock (subject to the us obtaining any consent, waiver or other authorization from the holders of the Series C-3 Convertible Preferred Stock necessary for the subordination of the Series C-3 Convertible Preferred Stock to the Series F Preferred Stock), Series D Non-Voting Convertible Preferred Stock, Series E Non-Voting Convertible Stock; and

senior to any class or series of capital stock hereafter created.

in each case, as to distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

As a part of the financing, we also entered into a registration rights agreement with the Buyers whereby the Buyers can demand that we register the shares issuable upon exercise of the warrants, and shares issuable upon conversion of the Series F Stock, if issued.

No placement agent or underwriter was involved in the offerings.

We intend to use the net proceeds of the offerings for general corporate purposes, working capital and capital expenditures.

Corporate History and Information

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

Our executive offices are located at 400 Connell Drive, Suite 5000, Berkeley Heights, NJ 07922. Our telephone number is (908) 517-9500. Our website address is www.cormedix.com. Information contained in, or accessible through, our website does not constitute part of this prospectus supplement.

The Offering

Common stock offered by us Shares having an aggregate offering price of up to \$20.0 million.

Common stock to be outstanding after this offering (1) Up to 36,363,636 shares, assuming sales at a price of \$0.55 per share, which was the closing price on the NYSE American on December 7, 2017. Actual number of shares issued will vary depending on the sales price under this offering.

Manner of offering “At the market offering” that may be made from time to time through our sales agent, B. Riley FBR. See “Plan of Distribution” on page S-31.

Use of proceeds We intend to use the net proceeds from this offering, if any, for general corporate purposes, including clinical trials, research and development expenses and general and administrative expenses. See “Use of Proceeds” on page S-28.

NYSE American symbol “CRMD”

Risk factors Investing in our common stock involves a high degree of risk. Please read the information contained in and incorporated by reference under the heading “Risk Factors” beginning on page S-9, the section captioned “Item 1A—Risk Factors” in our most recently filed annual report on Form 10-K, which is incorporated by reference into this prospectus supplement, and under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus supplement.

(1) The number of shares of our common stock that will be outstanding immediately after this offering as shown above is based on 67,025,419 shares outstanding as of December 7, 2017. The number of shares outstanding as of December 7, 2017, as used throughout this prospectus supplement, unless otherwise indicated, excludes:

warrants for 473,664 shares of common stock issued on November 16, 2017 with an exercise price of \$0.001 and warrants for up to an additional 473,664 shares potentially issuable to the same backstop investors with an exercise price of \$0.001;

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 120,000 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 \$1.44 per share;

options to purchase an aggregate of 4,845,795 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 \$2.05 per share;

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;

Series C-3 Preferred Stock convertible into 1,040,000 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;

Series F Preferred Stock convertible into 3,157,562 shares of common stock, subject to adjustment;

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;

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

Series A warrants for 4,391,977 shares of common stock with an exercise price of \$0.75 that expire on September 10, 2018;

Series B warrants for 13,964,476 shares of common stock with an exercise price of \$1.05 that expire on August 10, 2022;

underwriter warrants for 1,117,158 shares of common stock with an exercise price of \$0.9375 that expire on August 10, 2022;

restricted stock units for 61,414 shares of common stock with an average grant date fair value of \$2.22 per share;
and

624,246 shares of common stock that we are contracted to sell to all of our directors and executive officers and to certain of our employees at a per share purchase price of \$0.48.

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RISK FACTORS

Investing in our securities involves risk. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed below together with all of the other information contained or incorporated by reference in the accompanying prospectus or appearing or incorporated by reference in this prospectus supplement. You should also consider the risks, uncertainties and assumptions discussed under the heading “Risk Factors” included in our most recent annual report on Form 10-K which is on file with the SEC and is incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future.

Risks Related to Our Financial Position and Need for Additional Capital

We have a history of operating losses, expect to incur additional operating losses in the future and may never be profitable.

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 net losses of approximately \$24.6 million, \$18.2 million and \$20.5 million for the years ended December 31, 2016, 2015 and 2014, respectively, and \$7.6 million, \$12.7 million and \$22.7 million for the three months ended March 31, 2017, the six months ended June 30, 2017, and the nine months ended September 30, 2017, respectively. As of September 30, 2017, we had an accumulated deficit of approximately \$141.9 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. As a result, we expect to experience negative cash flow as we fund our operating losses and capital expenditures. 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 certain European Union and Middle East countries. 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 have received a going concern opinion from our independent registered public accounting firm.

Our operations are subject to a number of factors that can affect our operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of our product candidates; the ability to obtain regulatory approval to market our products; ability to manufacture successfully; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, our products; our ability to negotiate favorable licensing or other manufacturing and marketing agreements for our products; and our ability to raise capital to support our operations.

To date, our commercial operations have not generated sufficient revenues to enable profitability. As of September 30, 2017, we had an accumulated deficit of approximately \$141.9 million, and incurred net losses from operations of \$22.7 million for the nine months then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the ongoing hemodialysis Phase 3 clinical trial in the U.S.) and our other operating requirements, management believes that our existing cash and short-term investments at September 30, 2017 will fund

our operations through the first quarter of 2018 after taking into consideration the net proceeds received in October 2017 from sales of common stock under our at the market common stock sales program and the received and available proceeds from the November 2017 financing with Elliott. These factors raise substantial doubt regarding our ability to continue as a going concern. We will need additional funding to complete the LOCK-IT 100 hemodialysis clinical trial in the U.S. which commenced in December 2015 as well as to initiate the planned second Phase 3 clinical trial that will be required in order to file an NDA with the FDA.

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As a result of the above matters, our independent registered public accounting firm indicated in its report on our December 31, 2016 financial statements that there is substantial doubt about our ability to continue as a going concern. A “going concern” opinion indicates that the financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. Therefore, you should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of our creditors, and potentially be available for distribution to our stockholders, in the event of liquidation.

Our continued operations will ultimately depend on our ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of our products in order to complete our ongoing and planned Phase 3 clinical trials and until we achieve profitability, if ever. We can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. Without this funding, we could be required to delay, scale back or eliminate some or all of our research and development programs which would likely have a material adverse effect on our business.

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 certain European Union and Middle East countries, 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 September 30, 2017, even after taking into consideration the net proceeds received in October 2017 from sales of common stock under our at the market common stock sales program and the received and available proceeds from the November 2017 financing with Elliott, will not be sufficient to enable us to fund our projected operating requirements for at least the next 12 months following the balance sheet date. We will need additional funding thereafter to complete our ongoing Phase 3 hemodialysis clinical trial in the U.S., as well initiate as our planned second Phase 3 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, commence and complete our planned Phase 3 clinical trial 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, conduct our ongoing Phase 3 clinical trial and prepare for our planned second Phase 3 clinical trial, seek FDA approval of Neutrolin in the U.S., commercialize Neutrolin in Europe and other markets, pursue business development activities, and incur additional legal costs to defend our intellectual property.

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.

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. In March 2015, the Board of Directors commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. The Board of Directors previously engaged the investment bank Evercore Group L.L.C. to provide financial advice and assist the Board of Directors with its 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 at that time. No transaction materialized pursuant to the Evercore engagement. We terminated the arrangement with Evercore in July 2016. Although we will remain open to and consider strategic partnerships, there can be no assurance that any transaction will present itself.

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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

If we are unable to successfully complete our Phase 3 LOCK-IT-100 clinical trial, or if such clinical trial takes longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete the Phase 3 LOCK-IT-100 clinical trial is dependent in part upon the rate of enrollment of patients, the rate we collect, clean, lock and analyze the clinical trial database, and the frequency with which CRBSI events occur. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new products are approved for the indication we are studying. In addition, the LOCK-IT-100 clinical trial is designed to continue until a pre-determined number of events have occurred in the patients enrolled. Event-driven trials such as LOCK-IT-100 are subject to delays and other risks stemming from patient withdrawal and from lower than expected event rates. The lower event rate will require that we enroll more patients than initially anticipated, which would require us to incur additional costs and extend the anticipated time for completion of the trial in order to achieve the desired number of events. If we experience delays in patient enrollment

in our clinical trial, or if we experience other issues related to the number of events or other trial results, we may incur additional costs and delays in the trial, and may not be able to complete the clinical trial in a cost-effective or timely manner, which would have an adverse effect on our development program for Neutrolin as a treatment for catheter related bloodstream infections.

Neutrolin is only approved in Europe and is still in development in the U. S.

Neutrolin currently and for at least the near future is our only current product as well as our only late-stage product candidate. Neutrolin has received CE Mark approval in Europe, and we launched it in Germany in December 2013. We also are pursuing development of Neutrolin in the U.S. Our product commercialization and 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.

In April 2017, we entered into a commercial collaboration with Hemotech SAS covering France and certain overseas territories. We 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 a commercial presence in Germany and the United Arab Emirates. 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 be 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. 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, Kuwait and Bahrain.

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. We have not submitted an NDA, PMA or 510(K) 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 as the first of our required two Phase 3 studies. We are assessing the structure of our planned second Phase 3 clinical trial to seek efficiencies and improvements in its design and execution. Financing will be required to complete our current Phase 3 trial and to begin and execute our planned second Phase 3 trial. However, we might not obtain any financing and may never start the planned second Phase 3 trial.

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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 led 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.

In anticipation that CMS and private payers will demand that we demonstrate the cost effectiveness of Neutrolin as part of the reimbursement review and approval process, we have incorporated health economic evaluations into our ongoing clinical studies to support this review in the context of the prospective use of Neutrolin in dialysis, the ICU and oncology settings. However, our studies might not be sufficient to support coverage or reimbursement at levels that allow providers to use Neutrolin.

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.

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Because we expect sales of Neutrolin to generate substantially all of our product revenues for the foreseeable future, the failure of Neutrolin to find market acceptance would harm our business and would require us to seek additional financing.

Risks Related to Our Business and Industry

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and medical device companies that are pursuing other forms of 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.

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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.

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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, Khoso Baluch, a director and our Chief Executive Officer, Robert Cook, our Chief Financial Officer and John Armstrong, our Executive Vice President for Technical Operations. Our future success will depend in part on our ability to identify, hire, and retain current and additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, our work force is located in the New York 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:

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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:

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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. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administration panel to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such loss of patent protection could have a material adverse impact on our business.

In addition to patents, we also rely on trade secrets and proprietary know-how. We take measures to protect this information by entering into confidentiality and inventions agreements with our employees and some, but not all, of our scientific advisors, consultants, and collaborators. However, 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 or dispute ownership 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.

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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. 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 our response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. 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 (the “German PTO”) 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 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 made a final decision on the underlying validity of the Prosl European Patent and the Utility Model.

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The opposition proceeding against the Prosl European Patent before the EPO is ongoing. In its preliminary consideration of the matter, the EPO (and the German PTO) 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 a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of prior art. In October 2016, TauroPharm submitted a further writ to the EPO requesting a date for the hearing and bringing forward further arguments, in particular in view of the recent decision of the German PTO on the invalidity of the utility model. The EPO held a further oral hearing on November 22-23, 2017. At the hearing, the panel held that the Prosl European Patent would be invalidated because it did not meet the requirements of novelty based on a technical aspect of the European intellectual property law. We disagree with this decision and plan to appeal. Our appeal will be based, in part, on the written opinion to be issued by the Opposition Division, which is expected by the first quarter 2018. We continue to believe that the Prosl European Patent is indeed novel and that its validity should be maintained. There can be no assurance that we will prevail in this matter.

The German PTO held a hearing in the validity proceedings relating to the Utility Model on June 29, 2016, at which the panel affirmed its preliminary finding that the Utility Model was invalid based upon prior publication of a reference to the benefits that may be associated with adding heparin to a taurolidine based solution. The decision is subject to appeal and has only a declaratory effect, as the Utility Model had expired in November 2015. Furthermore, it has no bearing on the ongoing consideration of the validity and possible infringement of the Prosl Patent by the EPO. We filed an appeal against the ruling on September 7, 2016.

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 TauroLock™, 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 further oral hearing in this matter was held on November 15, 2016. In this hearing, the court heard arguments from us and TauroPharm concerning the allegations of unfair competition. The court made no rulings from the bench, and indicated that it is prepared to further examine the underlying facts of our allegations. On March 7, 2017, the court issued another interim decision in the form of a court order outlining again several issues relating to the argumentation of both sides in the proceedings. In particular the court requested us to further specify our requests and to further substantiate in even more detail which know-how was provided by Biolink to TauroPharm by whom and when. The court also raised the question whether the know-how provided at the time to TauroPharm could still be considered to be secret know-how or may have become public in the meantime. The court granted both sides the opportunity to reply to this court order and provide additional facts and evidence until May 15, 2017. Both parties have submitted further writs in this matter and the court has now scheduled a further hearing for May 8, 2018. We intend to continue to pursue this matter, and to provide additional supplemental documentary and other evidence as may be necessary to support our

claims. This litigation is not affected by the EPO decision on the Prosl European Patent and will continue.

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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 in Europe and the Middle East 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 a distributor agreement with each of a Saudi Arabian, an Emirati and a South Korean company for sales and marketing (upon receipt of approval to market in South Korea). In April 2017, we announced a commercial collaboration with Hemotech SAS covering France and certain overseas territories. 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.

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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 Saudi Arabia, the United Arab Emirates and France, and, upon regulatory approval, South Korea. We may 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 may 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.

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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 certain 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 December 7, 2017, 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 or continue. 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.

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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 ongoing and planned Phase 3 trials 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 you should 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 December 7, 2017, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

warrants for 473,664 shares of common stock issued on November 16, 2017 with an exercise price of \$0.001 and warrants for up to an additional 473,664 shares potentially issuable to the same backstop investors with an exercise price of \$0.001;

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;

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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 120,000 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 \$1.44 per share;

options to purchase an aggregate of 4,845,795 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 \$2.05 per share;

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;

150,000 shares of Series C-2 Preferred Stock, which are convertible into 1,500,000 shares of common stock;

104,000 shares of Series C-3 Preferred Stock, which are convertible into 1,040,000 shares of common stock;

73,962 shares of Series D Preferred Stock, which are convertible into 1,479,240 shares of common stock;

89,623 shares of Series E Preferred Stock, which are convertible into 1,959,759 shares of common stock;

2,000 shares of Series F Preferred Stock, which are convertible into 3,157,562 shares of common stock, subject to adjustment;

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;

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

Series A warrants for 4,391,977 shares of common stock with an exercise price of \$0.75 that expire on September 10, 2018;

Series B warrants for 13,964,476 shares of common stock with an exercise price of \$1.05 that expire on August 10, 2022;

underwriter warrants for 1,117,158 shares of common stock with an exercise price of \$0.9375 that expire on August 10, 2022; and

restricted stock units for 61,414 shares of common stock with an average grant date fair value of \$2.22 per share.

The possibility of the issuance of these shares, as well as the actual sale of such shares, could substantially reduce the market price for our common stock and impede our ability to obtain future financing.

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

To date, our commercial operations have not generated sufficient revenues to enable profitability. As of September 30, 2017, we had an accumulated deficit of approximately \$141.9 million, and incurred net losses from operations of \$22.7 million for the nine months then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the ongoing hemodialysis Phase 3 clinical trial in the U.S.) and our other operating requirements, management believes that our existing cash and short-term investments at September 30, 2017 will fund our operations through the first quarter of 2018 after taking into consideration the net proceeds received in October 2017 from sales of common stock under our at the market common stock sales program and the received and available proceeds from the November 2017 financing with Elliott. We will need additional funding to complete the LOCK-IT-100 hemodialysis clinical trial in the U.S. which commenced in December 2015 as well as to initiate the planned second Phase 3 clinical trial that will be required in order to file an NDA with the FDA. Further, 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 2013 Stock Plan, our Board of Directors is authorized to award up to a total of 11,000,000 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. As of December 7, 2017, options to purchase 120,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of \$2.44 per share, and options to purchase 4,845,795 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of \$2.05 per share were outstanding. In addition, at December 7, 2017, there were outstanding warrants to purchase an aggregate of 23,640,448 shares of our common stock at prices ranging from \$0.001 to \$7.00, and shares of our outstanding Series C-2, C-3, D, E and F preferred stock convertible into an aggregate of 9,136,561 (subject to adjustment for the Series F preferred stock) 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.

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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 American, it may result in a delisting of our common stock from the exchange.

Our common stock is currently listed for trading on the NYSE American, and the continued listing of our common stock on the NYSE American 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 American that we did not meet continued listing standards of the NYSE American 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 American 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 American.

If our common stock were no longer listed on the NYSE American, 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 American 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 American and so is not considered a penny stock. However, if we fail to maintain our common stock's listing on the NYSE American, 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.

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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.

Additional Risks Related to This Offering

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

Because we have not designated the amount of net proceeds from this offering to be used for any particular purpose, our management will have broad discretion as to the application of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of the offering. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development and commercialization of our product candidates.

You may experience immediate and substantial dilution.

The offering price per share in this offering may exceed the net tangible book value per share of our common stock outstanding prior to this offering. Assuming that an aggregate of 36,363,636 shares of our common stock are sold

during the term of the sales agreement with B. Riley FBR at a price of \$0.55 per share, the last reported sale price of our common stock on the NYSE American on December 7, 2017, for aggregate gross proceeds of \$20.0 million, after deducting commissions and estimated aggregate offering expenses payable by us, you will experience immediate dilution of \$0.2521 per share, representing the difference between our as-adjusted net tangible book value per share as of September 30, 2017, after giving effect to this offering and the assumed offering price. The exercise of outstanding stock options and warrants may result in further dilution of your investment. See the section entitled “Dilution” below for a more detailed illustration of the dilution you would incur if you participate in this offering.

You may experience future dilution as a result of future equity offerings.

We will need significant additional funds to complete the U.S development of Neutrolin. In order to raise additional capital, we plan to offer in the future additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

Words such as "may," "might," "should," "anticipate," "estimate," "expect," "projects," "intends," "plans," "believes" and words of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management's current judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to: the cost, timing and results of the planned and ongoing Phase 3 trials for Neutrolin® in the U.S., including variances in the expected rate of catheter-related bloodstream infection events and the resources needed to commence and complete those trials; the risks and uncertainties associated with CorMedix's ability to manage its limited cash resources; CorMedix's ability to continue as a going concern; CorMedix's ability to obtain financing to support its research and development and clinical activities and operations; CorMedix's ability to gain alignment with the FDA on proposed protocol changes its LOCK-IT 100 trial; later developments with the FDA that may be inconsistent with the FDA's acceptance of interim analyses of the LOCK-IT 100 trial; obtaining regulatory approvals to conduct clinical trials and to commercialize CorMedix's product candidates, including the planned second Phase 3 trial of Neutrolin and the marketing of Neutrolin in countries other than Europe; the outcome of clinical trials of CorMedix's product candidates and whether they demonstrate these candidates' safety and effectiveness; 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; CorMedix's dependence on its collaborations and its license relationships; CorMedix's ability to maintain its listing on the NYSE American; 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" above, and contained in the accompanying prospectus and otherwise incorporated by reference herein, and in our most recent annual report on Form 10-K as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference.

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

USE OF PROCEEDS

We currently intend to use the net proceeds from this offering, if any, for general corporate purposes, including clinical trials, research and development expenses, and general and administrative expenses.

The amounts and timing of our use of the net proceeds from this offering will depend on a number of factors, such as the timing and progress of our research and development efforts, the timing and progress of any collaborative or strategic partnering efforts, and the competitive environment for our planned products. As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. Accordingly, our management will have broad discretion in the timing and application of these proceeds. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short-term, interest-bearing instruments.

DILUTION

Our net tangible book value as of September 30, 2017 was approximately \$9,676,292, or \$0.1561 per share of common stock. Net tangible book value per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding. After giving effect to the sale by us of the full \$20.0 million of common stock that may be offered in this offering at an assumed offering price of \$0.55 per share, which was the closing price of our common stock on the NYSE American on December 7, 2017, and after deducting estimated offering commissions and expenses payable by us, our as-adjusted net tangible book value as of September 30, 2017 would have been approximately \$28,976,292, or \$0.2979 per share of common stock. This represents an immediate increase in the net tangible book value of \$0.1418 per share to our existing stockholders and an immediate and substantial dilution in net tangible book value of \$0.2521 per share to new investors. The following table illustrates this hypothetical per share dilution:

Assumed public offering price per share	\$0.55
Net tangible book value per share as of September 30, 2017	\$0.1561
Increase in net tangible book value per share attributable to this offering	\$0.1418
As adjusted net tangible book value per share as of September 30, 2017, after giving effect to this offering	\$0.2979
Dilution per share to new investors purchasing shares in this offering	\$0.2521

The table above assumes for illustrative purposes that an aggregate of 36,363,636 shares of our common stock are sold at a price of \$0.55 per share, the last reported sale price of our common stock on the NYSE American on December 7, 2017, for aggregate gross proceeds of \$20.0 million. The shares sold in this offering, if any, will be sold from time to time at various prices. An increase of \$0.14 per share in the price at which the shares are sold from the assumed offering price of \$0.55 per share shown in the table above, assuming all of our common stock in the aggregate amount of \$20.0 million is sold at that price, would increase our adjusted net tangible book value per share after the offering to \$0.3216 per share and would increase the dilution in net tangible book value per share to new investors in this offering to \$0.3684 per share, after deducting commissions and estimated aggregate offering expenses payable by us. A decrease of \$0.14 per share in the price at which the shares are sold from the assumed offering price of \$0.55 per share shown in the table above, assuming all of our common stock in the aggregate amount of \$20.0 million is sold at that price, would decrease our adjusted net tangible book value per share after the offering to

\$0.2651 per share and would decrease the dilution in net tangible book value per share to new investors in this offering to \$0.1449 per share, after deducting commissions and estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

To the extent that any outstanding options or warrants are exercised, new options are issued under our 2006 Stock Incentive Plan or our 2013 Stock Incentive Plan or we otherwise issue additional shares of common stock in the future, there will be further dilution to new investors.

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The above discussion and table are based on 61,978,609 shares of our common stock outstanding as of September 30, 2017 and excludes the following securities outstanding on September 30, 2017:

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 120,000 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 \$1.44 per share;

options to purchase an aggregate of 4,826,429 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 \$2.07 per share;

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;

Series C-3 Preferred Stock convertible into 1,040,000 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;

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

Series A warrants for 13,964,476 shares of common stock with an exercise price of \$0.75 that expire on September 10, 2018 (decreased to 4,414,476 shares at September 30, 2017);

Series B warrants for 13,964,476 shares of common stock with an exercise price of \$1.05 that expire on August 10, 2022;

underwriter warrants for 1,117,158 shares of common stock with an exercise price of \$0.9375 that expire on August 10, 2022; and

restricted stock units for 61,414 shares of common stock with an average grant date fair value of \$2.22 per share.

Also excluded from the discussion and table above are the following securities issued after September 30, 2017:

5,625 shares of common stock issued upon the exchange of 22,500 warrants;

5,041,185 shares of common stock issued in sales under the at the market common stock sales program;

warrants for 473,664 shares of common stock issued on November 16, 2017 with an exercise price of \$0.001 and warrants for up to an additional 473,664 shares potentially issuable to the same backstop investors with an exercise price of \$0.001;

Series F Preferred Stock convertible into 3,157,562 shares of common stock, subject to adjustment; and

624,246 shares of common stock that we are contracted to sell to all of our directors and executive officers and to certain of our employees at a per share purchase price of \$0.48.

MARKET FOR COMMON STOCK

Our common stock trades on the NYSE American under the symbol “CRMD.” The following table sets forth the high and low sales prices for our common stock for the periods indicated as reported by NYSE American:

Fiscal Year 2017	High	Low
First Quarter	\$2.48	\$1.44
Second Quarter	\$1.64	\$0.36
Third Quarter	\$0.45	\$0.32
Fourth Quarter (through December 7, 2017)	\$0.78	\$0.48

Fiscal Year 2016 High Low

First Quarter	\$2.88	\$1.15
Second Quarter	\$4.54	\$1.72
Third Quarter	\$3.12	\$1.35
Fourth Quarter	\$3.26	\$1.46

Fiscal Year 2015 High Low

First Quarter	\$9.90	\$1.63
Second Quarter	\$10.40	\$3.20
Third Quarter	\$4.31	\$1.72
Fourth Quarter	\$2.96	\$1.72

Based upon information furnished by our transfer agent, at December 7, 2017, we had approximately 61 holders of record of our common stock.

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.

PLAN OF DISTRIBUTION

We have entered into an At-the-Market Issuance Sales Agreement, referred to as the original agreement, with MLV. On December 8, 2017, we entered into an amendment to the original agreement, which together with the original agreement is referred to as the sales agreement, to increase the amount of common stock that we may offer and sell pursuant to the sales agreement and to replace MLV with B. Riley FBR. B. Riley FBR is an affiliate of MLV. Pursuant to the sales agreement, we may issue and sell up to \$20,000,000 of our common stock from time to time through B. Riley FBR acting as agent, subject to certain limitations, including the number or dollar amount of shares registered under the registration statement to which the offering relates. The form of the sales agreement was filed as an exhibit to the registration statement of which this prospectus supplement is a part, and the amendment, dated December 8, 2017, was filed as an exhibit to a Current Report on Form 8-K filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are incorporated by reference in this prospectus supplement. The sales, if any, of shares made under the sales agreement will be made by any method that is deemed an “at the market offering” as defined in Rule 415 promulgated under the Securities Act. We may instruct B. Riley FBR not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or B. Riley FBR may suspend the offering of common stock upon notice and subject to other conditions.

Prior to the amendment, through December 7, 2017, we had sold an aggregate of 13,909,889 shares under the sales agreement for aggregate gross proceeds of approximately \$39.5 million. The \$20,000,000 offered under this prospectus supplement includes the unsold portion of approximately \$500,000 of common stock that remained available under the prior prospectus prior to the execution of the amendment of the original agreement.

Each time we wish to issue and sell common stock under the sales agreement, we will notify B. Riley FBR of the number or dollar value of shares to be issued, the dates on which such sales are anticipated to be made, any minimum price below which sales may not be made and other sales parameters as we deem appropriate. Once we have so instructed B. Riley FBR, unless B. Riley FBR declines to accept the terms of the notice, B. Riley FBR has agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such shares up to the amount specified on such terms. The obligations of B. Riley FBR under the sales agreement to sell our common stock is subject to a number of conditions that we must meet.

We will pay B. Riley FBR commissions for its services in acting as agent in the sale of common stock. B. Riley FBR will be entitled to a commission equal to 3% of the gross proceeds from the sale of common stock offered hereby. In addition, we have agreed to reimburse certain expenses of B. Riley FBR in an amount not to exceed \$25,000. We estimate that the total expenses for the offering, excluding compensation payable to B. Riley FBR under the terms of the sales agreement, will be approximately \$100,000.

Settlement for sales of common stock will generally occur on the second business day following the date on which any sales are made, or on some other date that is agreed upon by us and B. Riley FBR in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sale of the common stock on our behalf, B. Riley FBR will be deemed to be an “underwriter” within the meaning of the Securities Act and the compensation of B. Riley FBR will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to B. Riley FBR against certain civil liabilities, including liabilities under the Securities Act. We have also agreed to reimburse B. Riley FBR for certain other specified expenses.

The offering of our common stock pursuant to the sales agreement will terminate upon the earlier of (i) the sale of all of our common stock provided for in this prospectus supplement or (ii) termination of the sales agreement as provided

therein.

B. Riley FBR and its affiliates may in the future provide various investment banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, B. Riley FBR will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus supplement.

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DESCRIPTION OF OUR COMMON STOCK

Pursuant to our Amended and Restated Certificate of Incorporation, as amended, we are authorized to issue 160,000,000 shares of common stock, \$0.001 par value per share. As of December 7, 2017, we had 67,025,419 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 the amendment to the Amended and Restated Certificate that increased our authorized capital and common stock in a Current Report on Form 8-K with the SEC on August 10, 2017. We 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, E and F non-voting preferred stock as exhibits to our current reports on Form 8-K on July 26, 2013, October 23, 2013, January 9, 2014, and November 13, 2017, respectively, 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.

LEGAL MATTERS

Wyrick Robbins Yates & Ponton LLP, Raleigh, North Carolina, will pass upon the validity of the common stock offered by this prospectus supplement. B. Riley FBR is being represented in connection with this offering by Duane Morris LLP, Newark, New Jersey.

EXPERTS

Friedman LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal years ended December 31, 2016 and 2015, as set forth in their report (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph referring to the Company's ability to continue as a going concern), and the effectiveness of our internal control over financial reporting as of December 31, 2016, as set forth in their report, both of which are included in our

Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference. Our consolidated financial statements are incorporated by reference in reliance on Friedman LLP's report given on their authority as experts in accounting and auditing.

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WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement and the accompanying prospectus are part of the registration statement on Form S-3 we filed with the SEC under the Securities Act and do not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus supplement or the accompanying prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference into this prospectus supplement or the accompanying prospectus for a copy of such contract, agreement or other document. Because we are subject to the information and reporting requirements of the Exchange Act, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus. Information in this prospectus supplement supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus supplement, while information that we file later with the SEC will automatically update and supersede the information in this prospectus supplement. The documents we are incorporating by reference are:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 16, 2017;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the SEC on May 10, 2017;

our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed with the SEC on August 9, 2017;

our Quarterly Report on Form 10-Q for the quarter ended September 20, 2017, filed with the SEC on November 9, 2017;

our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on April 20, April 28, May 3, June 13, June 27, July 12, August 1, August 2, August 7, August 9 (Form 8-K/A), August 10, August 28, August 30, September 1, September 5, November 13, November 20, December 4, December 5 and December 8, 2017; and

all of the filings pursuant to the Securities Exchange Act of 1934, as amended, after the date of the filing of the registration statement and prior to the effectiveness of the registration statement.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to

the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus supplement is a part and prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates the termination of the offering of the common stock made by this prospectus supplement and will become a part of this prospectus supplement from the date that such documents are filed with the SEC. Information in such future filings updates the information provided in this prospectus supplement.

Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

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The information relating to us contained in this prospectus supplement should be read together with the documents incorporated herein by reference.

Upon oral or written request and at no cost to the requester, we will provide to any person, including a beneficial owner, to whom a prospectus supplement is delivered, a copy of any or all of the information that has been incorporated by reference in this prospectus supplement but not delivered with this prospectus supplement. All requests should be made to: CorMedix Inc., Attention: Secretary, 400 Connell Drive, Suite 5000, Berkeley Heights, NJ 07922, (908) 517-9500.

You should rely only on the information incorporated by reference or provided in this prospectus supplement. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus supplement or the documents incorporated herein by reference is accurate as of any date other than the date on the front of this prospectus supplement or those documents.

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Prospectus

\$100,000,000 of
Common Stock,
Preferred Stock,
Warrants,
Debt Securities and/or
Units

From time to time, we may offer up to \$100,000,000 of any combination of the securities described in this prospectus, either individually or in units, in one or more offerings in amounts, at prices and on the terms that we will determine at the time of offering. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. We will specify in any accompanying prospectus supplement the terms of any offering. You should read this prospectus and the applicable prospectus supplement, as well as any documents incorporated by reference in this prospectus and any prospectus supplement, carefully before you invest in any securities. This prospectus may not be used by us to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

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

Our common stock trades on the NYSE MKT under the trading symbol "CRMD." On April 7, 2015, the last reported sale price of our common stock was \$9.24 per share. We recommend that you obtain current market quotations for our common stock prior to making an investment decision.

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

Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under "Risk Factors" beginning on page 7 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 April 17, 2015.

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ABOUT THIS PROSPECTUS

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

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

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

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

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

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

Neutrolin® is our registered trademark and the CorMedix logo is our trademark. All other trade names, trademarks and service marks appearing in this prospectus are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this prospectus, appear with the trade name, trademark or service mark notice and then throughout the remainder of this prospectus without trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it might not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including “Risk Factors” beginning on page 7 and our financial statements and related notes thereto incorporated by reference herein, before making an investment decision.

Our Company

Overview

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

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

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

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

completed our stage 1 audit with TÜV SÜD and we successfully completed the stage 2 audit in the third quarter of 2012.

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

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

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

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

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

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

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

Our other product candidate is CRMD004, which is the gel formulation of Neutrolin that we may develop for a variety of indications that include but are not limited to the treatment of wounds, skin infections, soft tissue infections, the prevention of catheter exit site infections and, based on the gel's thixotropic properties which cause it

to liquefy under pressure/kinetic energy, as a follow-on to our Neutrolin catheter lock solution. CRMD004 is currently in the pre-clinical stage of development.

Recent Developments

From January 1, 2015 to March 31, 2015, warrants to purchase 2,597,591 shares of our common stock were exercised on a cashless basis resulting in the issuance of 2,158,033 shares of common stock.

From January 1, 2015 to March 31, 2015, 42,500 shares of our Series C-3 preferred stock were converted into 425,000 shares of our common stock.

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

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

From January 1, 2015 to March 31, stock options to purchase 50,000 shares of our common stock were exercised resulting in gross proceeds to us of \$125,500.

From January 1, 2015 to March 31, 2015, the following warrants were exercised, resulting in aggregate gross proceeds to us of approximately \$6.7 million:

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

125,000 shares of our common stock with an exercise price of \$0.40 per share;

353,500 shares of our common stock with an exercise price of \$2.50 per share; and

1,645,358 shares of our common stock with an exercise price of \$3.4375 per share.

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

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

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

Corporate History and Information

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

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

Offerings Under This Prospectus

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

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

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

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

the names of those agents or underwriters;

applicable fees, discounts and commissions to be paid to them;

details regarding over-allotment options, if any; and

the net proceeds to us.

Common Stock

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

Preferred Stock

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

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

Warrants

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

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

Debt Securities

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

With respect to any debt securities that we issue, we will issue such debt securities under an indenture, which we would enter into with the trustee named in the indenture. The form of indenture was filed as an exhibit to the registration statement of which this prospectus is a part and is incorporated herein by reference. Any indenture would be qualified under the Trust Indenture Act of 1939.

Units

We may issue units consisting of common stock, preferred stock, debt securities and/or warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. In this prospectus, we have summarized certain general features of the units. We urge you, however, to read the applicable prospectus supplement related to the series of units being offered, as well as the unit agreements that contain the terms of the units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference reports that we file with the SEC, the form of unit agreement and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of operating losses, and expect to incur additional operating losses in 2015.

We were established in July 2006 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in the early stages of operation. We incurred a net loss of approximately \$20.5 million for the year ended December 31, 2014. As of December 31, 2014, we had an accumulated deficit of approximately \$76.2 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Neutrolin was launched in December 2013 and is currently distributed in Germany and Saudi Arabia. We have not generated any significant commercial revenue and do not expect to generate substantial revenues from Neutrolin until late 2015 at the earliest, and might never generate significant revenues from the sale of Neutrolin or any other products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: successfully marketing Neutrolin in Germany and other countries in which it is approved for sale; obtaining necessary regulatory approvals for Neutrolin from the other applicable European and Middle East agencies, other foreign agencies and the FDA and international regulatory agencies for any other products; successful completion of the development of our other product candidates; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We are not currently profitable and may never become profitable.

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

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

negatively impact the value of our securities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

expected benefits may not be successfully achieved;

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

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

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

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

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

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

Risks Related to the Development and Commercialization of Our Product Candidates

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

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

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

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

CRMD004 - currently in the pre-clinical phase.

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

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

Successful development and commercialization of our products is uncertain.

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

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

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

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

failure to receive regulatory approvals;

emergence of superior or equivalent products;

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

failure to achieve market acceptance.

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

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

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

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

slower than expected rates of patient recruitment;

failure to recruit a sufficient number of patients;

modification of clinical trial protocols;

changes in regulatory requirements for clinical trials;

lack of effectiveness during clinical trials;

emergence of unforeseen safety issues;

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

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

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

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

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

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

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

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

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

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

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

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

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

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

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply in the United States and abroad. Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA, foreign and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA or a foreign regulatory body to modify or withdraw product approval.

The successful commercialization of our products will depend on obtaining coverage and reimbursement for use of these products from third-party payors.

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and/or private health insurers, both in the U.S. and abroad. Without the financial support of these government or private third-party payors, the market for our products will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. Recent proposals to change the health care system in the United States have included measures that would limit or eliminate payments for medical products and services or subject the pricing of medical treatment products to government control. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors may not reimburse sales of our products or enable our collaborators to sell them at profitable prices. The failure to obtain or maintain reimbursement coverage for any of our products could materially harm our operations.

Physicians and patients may not accept and use our products.

Even with the CE Mark approval of Neutrolin, and even if we receive FDA or other foreign regulatory approval for Neutrolin or other product candidates, physicians and patients may not accept and use our products. Acceptance and use of our products will depend upon a number of factors including the following:

perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product;

cost-effectiveness of our product relative to competing products;

availability of reimbursement for our product from government or other healthcare payors; and

effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of Neutrolin to generate substantially all of our product revenues for the foreseeable future, the failure of Neutrolin to find market acceptance would harm our business and would require us to seek additional financing.

Risks Related to Our Business and Industry

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and medical device companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than we do, obtaining FDA or any other regulatory agency approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in processes, treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent,

make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that Neutrolin or any other product candidate will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA or any other regulatory agency. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept any of our products as a treatment of choice.

Furthermore, the pharmaceutical and medical device industry is diverse, complex, and rapidly changing. By its nature, the business risks associated with the industry are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA or other regulatory agency regulations preclude us from forecasting revenues or income with certainty or even confidence.

We face the risk of product liability claims and the amount of insurance coverage we hold now or in the future may not be adequate to cover all liabilities we might incur.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs. If the use of one or more of our or our collaborators' drugs or devices harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products.

We currently carry product liability insurance that covers our clinical trials. We cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold may not be adequate to cover all liabilities we might incur. Our insurance covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. This coverage includes the sale of commercial products. We have expanded our insurance coverage to include the sale of commercial products due to the receipt of the CE Mark approval, but we may be unable to maintain such coverage or obtain commercially reasonable product liability insurance for any other products approved for marketing.

If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we may be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products and do not have sufficient insurance coverage, our liability could exceed our total assets and our ability to pay the liability. A successful product liability claim or series of claims brought against us would decrease our cash and could cause the value of our capital stock to decrease.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local, as well as foreign, laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local, as well as foreign, laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

Healthcare policy changes, including reimbursement policies for drugs and medical devices, may have an adverse effect on our business, financial condition and results of operations.

Market acceptance and sales of Neutrolin or any other product candidates that we develop will depend on reimbursement policies and may be affected by health care reform measures in the United States and abroad. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for Neutrolin or any other product candidates that we develop. Also, we cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize Neutrolin or any other product candidates that we develop.

In the United States, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. The Patient Protection and Affordable Care

Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Healthcare Reform Act, substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. We anticipate that if we obtain approval for our products, some of our revenue may be derived from U.S. government healthcare programs, including Medicare. Furthermore, beginning in 2011, the Healthcare Reform Act imposed a non-deductible excise tax on pharmaceutical manufacturers or importers who sell “branded prescription drugs,” which includes innovator drugs and biologics (excluding orphan drugs or generics) to U.S. government programs. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have an adverse effect on our industry generally and our products specifically.

In addition to the Healthcare Reform Act, we expect that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able to charge for any products that are approved or the amounts of reimbursement available for these products from governmental agencies or other third-party payors or may increase the tax requirements for life sciences companies such as ours. While it is too early to predict what effect the Healthcare Reform Act or any future legislation or regulation will have on us, such laws could have an adverse effect on our business, financial condition and results of operations.

Health administration authorities in countries other than the United States may not provide reimbursement for Neutrolin or any of our other product candidates at rates sufficient for us to achieve profitability, or at all. Like the United States, these countries could adopt health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates.

Any reduction in reimbursement rates under Medicare or private insurers or foreign health care programs could negatively affect the pricing of our products. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in compensation costs, our business may materially suffer.

We are highly dependent on the principal members of our management and scientific staff, specifically, Randy Milby, a director and our Chief Executive Officer, Harry O'Grady, our Chief Financial Officer, and Dr. Antony Pfaffle, a director and Chief Scientific Officer. We have an employment agreement with Mr. Milby but this agreement cannot ensure our retention of him. Furthermore, our future success will also depend in part on our ability to identify, hire, and retain additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, our work force is located in the New Jersey metropolitan area, where competition for personnel with the scientific and technical skills that we seek is extremely high and is likely to remain high. Because of this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent former employees from competing with us.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

Over time, we expect to hire additional qualified personnel with expertise in clinical testing, clinical research and testing, government regulation, formulation and manufacturing, and sales and marketing. We compete for qualified individuals with numerous pharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining such qualified personnel will be critical to our success.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations to commercialize Neutrolin and the effective management of any growth, which could place a significant strain on our management and our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business may be materially harmed.

Risks Related to Our Intellectual Property

If we materially breach or default under any of our license agreements, the licensor party to such agreement will have the right to terminate the license agreement, which termination may materially harm our business.

Our commercial success will depend in part on the maintenance of our license agreements. Each of our license agreements provides the licensor with a right to terminate the license agreement for our material breach or default under the agreement, including the failure to make any required milestone or other payments. Additionally, our license agreement with Dr. Hans-Dietrich Polaschegg (referred to herein as the Polaschegg License Agreement) provides for a right of termination for, among other things, our failure to make a product with respect to either of the licensed technologies available to the market within eight years after (i) the effective date of the Polaschegg License Agreement, which was January 20, 2008, or (ii) the priority date of any new patent, whichever is later. Our intellectual property licensed under the Polaschegg License Agreement serves as a basis for CRMD004, the gel formation of Neutrolin. Should the licensor under any of our license agreements exercise such a termination right, we would lose our right to the intellectual property under the respective license agreement, which loss may materially harm our business.

If we and our licensors do not obtain protection for and successfully defend our respective intellectual property rights, our competitors may be able to take advantage of our research and development efforts to develop competing products.

Our commercial success will depend in part on obtaining further patent protection for our products and other technologies and successfully defending any patents that we currently have or will obtain against third-party challenges. The patents which we currently believe are most material to our business are as follows:

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

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

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

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

We are currently seeking further patent protection for our compounds and methods of treating diseases. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage;

our competitors, many of which have substantially greater resources than we have and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;

there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns; and

countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the United States Patent and Trademark Office, or PTO, and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

The above mentioned patents and patent applications are exclusively licensed to us. To support our patent strategy, we have engaged in a review of patentability and certain freedom to operate issues, including performing certain searches. However, patentability and certain freedom to operate issues are inherently complex, and we cannot provide assurances that a relevant patent office and/or relevant court will agree with our conclusions regarding patentability issues or with our conclusions regarding freedom to operate issues, which can involve subtle issues of claim interpretation and/or claim liability. Furthermore, we may not be aware of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product candidates, preventing the patentability of our product candidates to us or our licensors, or covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our product candidates.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we take measures to protect this information by entering into confidentiality and inventions agreements with our employees, scientific advisors, consultants, and collaborators, we cannot provide any assurances that these agreements will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are breached, or that our trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of our intellectual property may be greatly reduced.

Ongoing and future intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights.

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or we may become subject to proceedings initiated by our competitors or other third parties or the PTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. In addition, litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. We recently initiated court proceedings in Germany for patent infringement and unfair use of our proprietary information related to Neutrolin (as described below). We also recently had opposition proceedings brought against the European Patent and the German utility model patent which are the basis of our infringement proceedings (as described below). The defense and prosecution of these ongoing and any future intellectual property suits, PTO or foreign proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. An adverse determination in litigation or PTO or foreign proceedings to which we may become a party could subject us to significant liabilities, including damages, require us to obtain licenses from third parties, restrict or prevent us from selling our products in certain markets, or invalidate or render unenforceable our licensed or owned patents. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, brought an action against the European Sodemann Patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to us pursuant to the License and Assignment Agreement between us and ND Partners LLC. The action that was brought against the counterpart of the Sodemann Patent in Germany at the Board of the European Patent Office opposition division was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, we became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the counterpart of the Sodemann Patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the counterpart of the Sodemann Patent claims. We received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, we were notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed our response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. Geistlich did not file a further statement within the required timeline. On November 5, 2014, the Opposition Division at the EPO issued the interlocutory decision to maintain the patent on the basis of the claims as amended during the appeal proceedings. This decision becomes final if no further appeal is lodged by Geistlich by January 15, 2015. As of the date of this report, we have not received a communication from the European Patent Office that Geistlich has filed such an appeal.

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

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

On March 27, 2015, the Mannheim 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-HEP100 and HEP500 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 based upon the same circumstances. While the Court had indicated that it might render a decision in the patent infringement matter, it has now informed us that decisions in each of these related matters likely will be issued on May 8, 2015, although we cannot assure that any decision will be rendered on that date. The Court's decisions will be subject to appeal.

Parallel to the Court proceedings, both the opposition proceedings against the Prosl European Patent before the European Patent Office, or EPO, and the cancellation action against the Utility Model before the German Patent and Trademark Office, or German PTO, are ongoing. We do not expect a decision from the EPO before the middle of 2016 (in the case of the Prosl European Patent) or late 2015 from the German PTO (in the case of the Utility Model), with each such decision 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 our proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using our proprietary information relating to the composition and manufacture of our product Neutrolin®, which is approved for sale in Germany, in its manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100™ and TauroLock-HEP500™. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine as well as citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. A hearing in this matter has been scheduled in the District Court of Cologne for July 2, 2015.

If we infringe the rights of third parties we could be prevented from selling products and forced to pay damages and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to do one or more of the following:

obtain licenses, which may not be available on commercially reasonable terms, if at all;

abandon an infringing product candidate;

redesign our products or processes to avoid infringement;

stop using the subject matter claimed in the patents held by others;

pay damages; or

defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to Dependence on Third Parties

If we are not able to develop and maintain collaborative marketing relationships with licensees or partners, or create an effective sales, marketing, and distribution capability, we may be unable to market our products or market them successfully.

Our business strategy for Neutrolin relies on collaborating with larger firms with experience in marketing and selling medical devices and pharmaceutical products; for other products we may also rely on such marketing collaborations or out-licensing of our product candidates. Specifically, for Neutrolin, we have entered into an agreement with human4farma to market and sell Neutrolin in Germany and a distributor agreement with a Saudi Arabian and a South Korean company for sales and marketing in those two countries (upon receipt of approval to market in South Korea). In addition, we have independent sales representatives marketing and selling in Austria and The Netherlands. Assuming we receive applicable regulatory approval for other markets, we plan to enter into distribution agreements with one or more third parties for the sale of Neutrolin in various European, Middle East and

other markets. However, there can be no assurance that we will be able to successfully maintain those relationships or establish and maintain additional marketing, sales, or distribution relationships. Nor can there be assurance that such relationships will be successful, or that we will be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third-parties.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Common Stock

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

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

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

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

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

During the period from the completion of our initial public offering, or IPO, on March 30, 2010 through April 7, 2015, 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, 2015, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

warrants for 227,273 shares of common stock issued in July 2013 with an exercise price of \$1.50 that expire on July 30, 2018;

warrants for 500,000 shares of common stock issued in May 2013 with an exercise price of \$0.65 per share that expire on May 30, 2019;

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

warrants for 2,443,139 shares of our common stock issued in connection with our IPO with an exercise price of \$3.4375 per share that expire on April 30, 2015;

warrants for 390,720 shares of our common stock held by Manchester Securities Corp. issued in connection with our IPO with an exercise price of \$3.4375 per share that expire on March 24, 2016;

options to purchase an aggregate of 1,015,000 shares of our common stock issued to our officers, directors, employees and non-employee consultants under our Amended and Restated 2006 Stock Incentive Plan, or the 2006 Stock Plan, with a weighted average exercise price of \$0.68 per share;

options to purchase an aggregate of 2,999,500 shares of our common stock issued to our officers, directors and non-employee consultants under our 2013 Stock Plan, with a weighted average exercise price of \$1.98 per share;

warrants issued to investors in our 2012 private placement to purchase an aggregate of 337,500 shares of our common stock with an exercise price of \$0.40 per share, of which 312,500 expire on September 20, 2017 and 25,000 expire on November 13, 2017;

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

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

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

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

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

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

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

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

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

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

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

The possibility of the issuance of these shares, as well as the actual sale of such shares, could substantially reduce the market price for our common stock and impede our ability to obtain future financing.

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

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

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

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

Pursuant to our 2006 Stock Plan, our Board of Directors is authorized to award up to a total of 2,300,000 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. As of March 31, 2015, options to purchase 1,015,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of \$0.68 per share, and options to purchase 2,999,500 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of \$1.98 per share were outstanding. In addition, at March 31, 2015, there were outstanding warrants to purchase an aggregate of 6,890,327 shares of our common stock at prices ranging from \$0.40 to \$7.00, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

Words such as “may,” “might,” “should,” “anticipate,” “estimate,” “expect,” “projects,” “intends,” “plans,” “believes” and words of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management’s current judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to: the cost, timing and results of the planned Phase III trial for Neutrolin® in the U.S.; obtaining regulatory approvals to conduct clinical trials and to commercialize our product candidates, including marketing of Neutrolin in countries other than Europe; the risks associated with the launch of Neutrolin in new markets; our ability to enter into, execute upon and maintain collaborations with third parties for its development and marketing programs; our ability to achieve expected cost savings in our pharmaceutical manufacturing margins; the unpredictability of the size of the markets for, and market

acceptance of, Neutrolin; our ability to identify and enter into strategic transactions; our ability to maintain our listing on the NYSE MKT; the risks and uncertainties associated with our ability to manage our limited cash resources; the outcome of clinical trials of our product candidates and whether they demonstrate these candidates' safety and effectiveness; our dependence on our collaborations and our license relationships; achieving milestones under our collaborations; obtaining additional financing to support our research and development and clinical activities and operations; our dependence on preclinical and clinical investigators, preclinical and clinical research organizations, manufacturers, sales and marketing organizations, and consultants; protecting the intellectual property developed by or licensed to us; the unpredictability of the market acceptance of any of our products, including Neutrolin; our ability to sell any approved products and the prices we are able to realize; our ability to retain and hire necessary employees and to staff our operations appropriately; our ability to compete in our industry and innovation by our competitors; and our ability to stay abreast of and comply with new or modified laws and regulations that currently apply or become applicable to our business. Please also see the discussion of risks and uncertainties under "Risk Factors" below and contained in any supplements to this prospectus, and in our most recent annual report on Form 10-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference.

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

USE OF PROCEEDS

We cannot assure you that we will receive any proceeds in connection with securities offered by us pursuant to this prospectus. Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of our securities by us under this prospectus for general corporate purposes, including clinical trials, research and development expenses, and general and administrative expenses. We will set forth in the applicable prospectus supplement our intended use for the net proceeds received from the sale of any securities by us. Pending the application of the net proceeds, we intend to invest the net proceeds generally in short-term, investment grade, interest-bearing securities.

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through underwriters or dealers, through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

at a fixed price or prices, which may be changed;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices; or

at negotiated prices.

A prospectus supplement or supplements (and any related free writing prospectus that we may authorize to be provided to you) will describe the terms of the offering of the securities, including, to the extent applicable:

the name or names of the underwriters, if any;

the purchase price of the securities or other consideration therefor, and the proceeds, if any, we will receive from the sale;

any over-allotment options under which underwriters may purchase additional securities from us;

any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;

any public offering price;

any discounts or concessions allowed or reallocated or paid to dealers; and

any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

All securities we may offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate-covering or other short-covering transactions involve purchases of the securities, either through exercise of the over-allotment option or in the open market after the distribution is completed, to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Any underwriters that are qualified market makers on the NYSE MKT may engage in passive market making transactions in the common stock on the NYSE MKT in accordance with Regulation M under the Exchange Act, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

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, 2015, we had 27,864,841 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.

Issued and Outstanding 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, 2015, 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 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.

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.

Description of Preferred Stock That May Be Offered

Our board of directors has the authority, without further action by the stockholders, to issue up to 2,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by our stockholders. As of the date of this prospectus, no shares of preferred stock were outstanding. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation and could have the effect of delaying, deferring or preventing a change in control of our company.

We will fix the rights, preferences, privileges and restrictions of the preferred stock of each series in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. This description will include any or all of the following, as required:

the title and stated value;

the number of shares we are offering;

the liquidation preference per share;

the purchase price;

the dividend rate, period and payment date and method of calculation for dividends;

whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;

the procedures for any auction and remarketing, if any;

the provisions for a sinking fund, if any;

the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;

any listing of the preferred stock on any securities exchange or market;

whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;

whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;

voting rights, if any, of the preferred stock;

preemptive rights, if any;

restrictions on transfer, sale or other assignment, if any;

whether interests in the preferred stock will be represented by depositary shares;

a discussion of any material or special United States federal income tax considerations applicable to the preferred stock;

the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;

any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and

any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

If we issue shares of preferred stock under this prospectus, the shares will be fully paid and non-assessable.

The General Corporation Law of the State of Delaware, the state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provisions of any debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may

offer, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we may offer under a prospectus supplement may differ from the terms described below. For any debt securities that we may offer, an indenture (and any relevant supplemental indenture) will contain additional important terms and provisions, the form of which we filed as an exhibit to the registration statement of which this prospectus is a part and is incorporated therein by reference. We will file any definitive indenture as an exhibit to reports that we file with the SEC and incorporate by reference in this prospectus and the applicable prospectus supplement. Any indenture would be qualified under the Trust Indenture Act of 1939.

With respect to any debt securities that we issue, we will describe in each prospectus supplement the following terms relating to a series of debt securities:

the title;

the principal amount being offered, and if a series, the total amount authorized and the total amount outstanding;

any limit on the amount that may be issued;

whether or not we will issue the series of debt securities in global form, and if so, the terms and who the depository will be;

the maturity date;

the principal amount due at maturity;

whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a United States person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;

the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;

whether or not the debt securities will be convertible into shares of our common stock or our preferred stock and, if so, the terms of such conversion;

whether or not the debt securities will be secured or unsecured by some or all of our assets, and the terms of any secured debt;

the terms of the subordination of any series of subordinated debt;

the place where payments will be payable;

restrictions on transfer, sale or other assignment, if any;

our right, if any, to defer payment or interest and the maximum length of any such deferral period;

the date, if any, after which and the conditions upon which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemptions provisions;

the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;

whether the indenture will restrict our ability to pay dividends, or will require us to maintain any asset ratios or reserves;

whether we will be restricted from incurring any additional indebtedness, issuing additional securities, or entering into a merger, consolidation or sale of our business;

a discussion of any material or special United States federal income tax considerations applicable to the debt securities;

information describing any book-entry features;

any provisions for payment of additional amounts for taxes;

whether the debt securities are to be offered at a price such that they will be deemed to be offered at an “original issue discount” as defined in paragraph (a) of Section 1273 of the Internal Revenue Code of 1986, as amended;

the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;

events of default;

whether we and/or the indenture trustee may change an indenture without the consent of any holders;

the form of debt security and how it may be exchanged and transferred;

description of the indenture trustee and paying agent, and the method of payments; and

any other specified terms, preferences, rights or limitations of, or restrictions on, the debt securities and any terms that may be required by us or advisable under applicable laws or regulations.

We summarize below the material terms of the form of indenture or indicate which material terms will be described in the applicable prospectus supplement. The indenture:

does not limit the amount of debt securities that we may issue;

allows us to issue debt securities in one or more series;

does not require us to issue all of the debt securities of a series at the same time;

allows us to reopen a series to issue additional debt securities without the consent of the holders of the debt securities of such series; and

provides that the debt securities will be unsecured, except as may be set forth in the applicable prospectus supplement.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of any warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement may differ from the terms described below. With respect to any warrants that we offer, specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement that includes this prospectus or as an exhibit to reports that we file with the SEC and incorporated by reference in this prospectus:

the specific designation and aggregate number of, and the price at which we will issue, the warrants;

the currency or currency units in which the offering price, if any, and the exercise price are payable;

if applicable, the exercise price for shares of our common stock or preferred stock and the number of shares of common stock or preferred stock to be received upon exercise of the warrants;

in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at, and currency in which, this principal amount of debt securities may be purchased upon such exercise;

the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;

whether the warrants will be issued in fully registered form or bearer form, in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;

any applicable material U.S. federal income tax consequences;

the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;

the proposed listing, if any, of the warrants or the common stock issuable upon exercise of the warrants on any securities exchange;

if applicable, the date from and after which the warrants and the common stock will be separately transferable;

if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;

information with respect to book-entry procedures, if any;

the anti-dilution provisions of the warrants, if any;

any redemption or call provisions;

whether the warrants are to be sold separately or with other securities as parts of units; and

any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on, the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture; or

in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Transfer Agent and Registrar

The transfer agent and registrar for any warrants will be set forth in the applicable prospectus supplement.

DESCRIPTION OF UNITS

We might issue units composed of one or more debt securities, shares of common stock, shares of preferred stock and warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of unit agreement, warrant and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

We may choose to evidence each series of units by unit certificates that we would issue under a separate agreement. If we choose to evidence the units by unit certificates, we will enter into the unit agreements with a unit agent and will indicate the name and address of the unit agent in the applicable prospectus supplement relating to the particular series of units.

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

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

Delaware Anti-takeover Law

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

the board of directors approves the transaction in which the stockholder became an interested stockholder prior to the date the interested stockholder attained that status;

when the stockholder became an interested stockholder, he or she owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers and certain shares owned by employee benefits plans; or

on or subsequent to the date the business combination is approved by the board of directors, the business combination is authorized by the affirmative vote of at least 66 2/3% of the voting stock of the corporation at an annual or special meeting of stockholders.

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

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

Charter Documents

Our Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company. First, our Amended and Restated Bylaws limit who may call special meetings of the stockholders, such meetings may only be called by the chairman of the board, the chief executive officer, the board of directors or holders of an aggregate of at least 15% of our outstanding entitled to vote. Second, our Amended and Restated Certificate of Incorporation does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. Third, our Amended and Restated Bylaws provide that the number of directors on our board, which may range from five to nine directors, shall be exclusively fixed by our board, which has set the number of directors at seven. Fourth, newly created directorships resulting from any increase in our authorized number of directors and any vacancies in our board resulting from death, resignation, retirement, disqualification or other cause (including removal from office by a vote of the shareholders) will be filled by a majority of our board then in office. Finally, our Amended and Restated Bylaws establish procedures, including 90-day advance notice requirement, with regard to the nomination of candidates for election as directors and stockholder proposals. These and other provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and Delaware law could discourage potential acquisition proposals and could delay or prevent a change in control or management of our company.

LEGAL MATTERS

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

EXPERTS

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

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, 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>.

This prospectus is only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act of 1933, as amended, 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 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. This prospectus omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities being offered pursuant to this prospectus. Statements in this prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in “Where You Can Find More Information.” The documents we are incorporating by reference are:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 12, 2015;

our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on January 9, January 10, January 13, February 25, February 28, March 5, April 8, May 15, May 16, May 23, May 28 (Form 8-K/A), June 17, June 26, July 24, August 14, September 12, September 16, September 22, September 25, October 27, December 4 and December 23, 2014, and January 15, January 20, January 29, February 6, February 9 (Form 8-K/A), March 4, March 9, March 30, and April 9, 2015; and

all of the filings pursuant to the Securities Exchange Act of 1934, as amended, after the date of the filing of the registration statement and prior to the effectiveness of the registration statement.

In addition, all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed in such forms that are related to such items unless such Form 8-K expressly provides to the contrary) subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, before the date our offering is terminated or completed are deemed to be incorporated by reference into, and to be a part of, this prospectus.

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

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to CorMedix Inc., Attention: Secretary, 1430 U.S. Highway 206, Suite 200, Bedminster, NJ 07921, (908) 517-9500.

You should rely only on information contained in, or incorporated by reference into, this prospectus and any prospectus supplement. We have not authorized anyone to provide you with information different from that contained

in this prospectus or incorporated by reference in this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

\$20,000,000

Common Stock

PROSPECTUS SUPPLEMENT

B. Riley FBR

December 8, 2017