CorMedix Inc.
Form 424B3
April 17, 2018

Prospectus Filed pursuant to Rule 424(b)(3)
Registration No. 333-223562

$14,700,000

Common Stock

We have entered into an At Market Issuance Sales Agreement, dated March 9, 2018, with B. Riley FBR, Inc., or B. Riley FBR, as sales agent. 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 $14,700,000 from time to time through B. Riley FBR, acting as agent, which is an amount equal to one-third of our public float as of April 6, 2018.

Our common stock is traded on the NYSE American under the symbol “CRMD.” The last reported sale price of our common stock on April 13, 2018 was $0.24 per share.

Sales of our common stock, if any, under this prospectus will be made by any method permitted that is deemed an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act. 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.

As of April 6, 2018, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was approximately $44,400,000, which was calculated based on 81,903,027 shares of our outstanding common stock held by non-affiliates and on a price of $0.57 per share, the last reported sale price for our common stock on February 16, 2018. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our common stock in a public primary offering with a value exceeding one-third of our public float in any 12-month period unless our public float subsequently rises to $75.0 million or more. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

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

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

B. Riley FBR

The date of this prospectus is April 16, 2018.

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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, on Form S-3 utilizing a shelf registration process relating to the securities described in this prospectus. Under this shelf registration process, we may, from time to time, sell up to $70.0 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 $14.7 million may be sold in this offering in the form of shares of common stock, which is an amount equal to one-third of our public float as of April 6, 2018, as limited by General Instruction I.B.6 of Form S-3.

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

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

You should rely only on the information contained in, or incorporated by reference into, this prospectus and in any free writing prospectus that we may authorize for use in connection with this offering. We have not, and 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 into this prospectus, the documents incorporated by reference into this prospectus, and in any free writing prospectus that we may authorize for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus, the documents incorporated by reference into this prospectus,and any free writing prospectus that we may authorize for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus entitled “Where You Can Find More Information” and “Incorporation of Certain Information by Reference.”

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

Our primary executive offices are located at 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.

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

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

PROSPECTUS SUMMARY

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

OUR COMPANY

Overview

We 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.

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 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 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. We believe that these changes have allowed the identification of more infections, enabling a single interim analysis.

On February 20, 2018, we announced that the CAC had reviewed potential cases of CRBSI in the LOCK-IT-100 study that occurred through early December 2017, and identified 28 such cases. As previously agreed with FDA, an interim analysis will be performed when the first 28 CRBSIs case have been identified. The primary endpoint for the study is the reduction of CRBSI by Neutrolin in comparison to a heparin catheter lock solution. We are currently directing standard procedures to ensure the accuracy and completeness of the data required for conducting the interim analysis. This review includes data for all subjects in the study needed to assess the two secondary endpoints related to a reduction in catheter removal and catheter blockage, as well as the primary endpoint and safety information. Before the full dataset can be locked and the interim analysis can proceed, a number of weeks will be required to complete the quality assurance procedures appropriate for the amount of data generated inthe trial. The interim analysis will be provided to the Data Safety Monitoring Board for its review and recommendation upon completion. We project to complete patient enrollment in mid-year 2018, and anticipate that we will accumulate the requisite number of CRBSI events around the end of 2018.

We are evaluating opportunities for the possible expansion of taurolidine as a platform compound. Patent applications have been filed in wound closure, surgical meshes, wound management, and osteoarthritis, including visco-supplementation. We have had dialogue with the FDA on the regulatory pathway for these indications. The FDA has recently informed us that it regards taurolidine as a new chemical entity and therefore an unapproved drug. Consequently, there is no appropriate predicate device currently marketed in the U.S. on which a 510k approval process could be based. As a result, we will be required to submit a premarket approval application for marketing authorization for these indications. In the event that the New Drug Application for Neutrolin is approved by the FDA, the regulatory pathway can be revisited with the FDA. Although there will presumably still be no appropriate predicate, de novo Class II designation can be proposed, based on a risk assessment and a reasonable assurance of safety and effectiveness. We believe taurolidine can also provide benefits not currently available in marketed antimicrobial medical devices, including devices for burn victims and use in less sterile environments.

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. In February 2018, the FDA granted orphan drug designation to taurolidine for the treatment of neuroblastoma.

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 $14.7 million.
Common stock to be outstanding after this offering (1)	Up to 140,586,902 shares, assuming sales at a price of $0.25 per share, which was the closing price on the NYSE American on April 5, 2018. 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 32.
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 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 6, the section captioned "Item 1A—Risk Factors" in our most recently filed annual report on Form 10-K, which is incorporated by reference into this prospectus, and under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus.

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(1) The number of shares of our common stock that will be outstanding immediately after this offering as shown above is based on 81,786,902 shares outstanding as of March 31, 2018. The number of shares outstanding as of December 31, 2017, as used throughout this prospectus, unless otherwise indicated, excludes:

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

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

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

- 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 4,842,495 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;

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

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warrants for 725,000 shares of common stock with an exercise price of $0.90 that expire on January 8, 2020;

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

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

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

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

Series F Preferred Stock convertible into 12,345,679 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 4,078,226 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;

warrants for 564,858 shares of common stock with an exercise price of $0.001 that expire on November 16, 2020; and

restricted stock units for 97,529 shares of common stock with an average grant date fair value of $0.57 per share.

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RISK FACTORS

Investing in our common stock involves risk. Prior to making a decision about investing in our common stock, you should carefully consider the specific factors discussed below together with all of the other information contained or incorporated by reference in this prospectus. 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 have subsequently filed or may 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 $33 million and $24.6 million for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, we had an accumulated deficit of approximately $152.2 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 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 December 31, 2017, we had an accumulated deficit of $152.2 million, and incurred net losses from operations of $33.0 million for the year 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 the existing cash at December 31, 2017 plus funding raised through March 9, 2018 and a proposed new $3 million backstop facility, for which a binding term sheet was recently signed by us and Elliott

Management Corporation, will be sufficient to fund operations into the third quarter of 2018. If a definitive agreement can be negotiated and executed, we anticipate that the proposed backstop facility would be available for drawing between April 16, 2018 and July 31, 2018. These factors raise substantial doubt regarding our ability to continue as a going concern. We will need additional funding to complete the ongoing hemodialysis clinical trial in the U.S. which commenced in December 2015 and to continue the Neutrolin development program through to NDA filing and marketing approval.

As a result of the above matters, our independent auditors have indicated in their report on our December 31, 2017 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 December 31, 2017, plus funding raised through March 9, 2018 and a proposed new $3 million backstop facility, for which a binding term sheet was recently signed by us and Elliott Management Corporation, will be sufficient to fund operations into the third quarter of 2018. If a definitive agreement can be negotiated and executed, we anticipate that the proposed backstop facility would be available for drawing between April 16, 2018 and July 31, 2018. We will need additional funding thereafter to complete our ongoing and anticipated Phase 3 clinical trials in the U.S., and to continue the Neutrolin development program through to NDA filing and approval. If we are unable to raise additional funds when needed, we may not be able to complete our ongoing Phase 3 clinical trial, to complete the Neutrolin development program through to NDA filing and marketing approval 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 conduct our ongoing Phase 3 clinical trial and prepare for additional Phase 3 clinical trials, seek FDA approval of Neutrolin in the U.S., commercialize Neutrolin in Europe and other markets, pursue development of our medical devices and other 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.

At the time that we may need additional financing, we may not have sufficient authorized shares of common stock available, depending on the amount of the financing, the price of our common stock and our obligations to reserve shares for our outstanding convertible preferred stock, warrants and options. We currently have 160,000,000 shares of common stock authorized and at March 31, 2018, we had 81,786,902 shares outstanding and 37,753,594 shares reserved for issuance upon the exercise and conversion of our outstanding convertible preferred stock, warrants and options. To increase our authorized common stock, we would need stockholder approval to amend our certificate of incorporation, which approval may not be obtained.

Until the date that none of the shares of common stock or warrants that we issued to Elliott Associates, L.P. and Elliott International, L.P in November 2017 as part of the backstop financing are outstanding, we are prohibited from issuing or selling any securities convertible into common stock on terms more favorable than the backstop financing terms and with a conversion, exchange or exercise price that is based upon and/or varies with the trading prices of or quotations for the shares of our common stock or that is subject to being reset at some future date or upon the occurrence of specified or contingent events directly or indirectly related to our business (other than pursuant to a customary “weighted average” anti-dilution provision) or the market for our common stock or enter into any agreement to sell securities at a future determined price (other than standard and customary “preemptive” or “participation” rights and other than pursuant to an at-the-market offering through a registered broker-dealer). This restriction could make raising capital through the sale of equity securities very difficult and could have a material adverse impact on our business, financial condition and prospects.

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. A 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.

Our only product 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 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 mayhave 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. The design of our required second Phase 3 clinical trial has not been determined. Financing will be required to complete our current Phase 3 trial and to begin and execute our anticipated second Phase 3 trial. However, we might not obtain any financing and may never start the second Phase 3 trial.

The FDA recently informed us that it regards taurolidine as a new chemical entity and therefore an unapproved drug. Consequently, there is no appropriate predicate device currently marketed in the U.S. on which a 510k approval process could be based. As a result, we will be required to submit a premarket approval application for marketing authorization for these indications. In the event that the New Drug Application for Neutrolin is approved by the FDA,

the regulatory pathway can be revisited with the FDA. Although there will presumably still be no appropriate predicate, de novo Class II designation can be proposed, based on a risk assessment and a reasonable assurance of safety and effectiveness.

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

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

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

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

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

In anticipation that the 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.

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.

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.

Some of the provisions of the Healthcare Reform Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Healthcare Reform Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay, circumvent or loosen the implementation of certain provisions requirements mandated by the Healthcare Reform Act or otherwise circumvent some of the requirements for health insurance mandated by the Healthcare Reform Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Healthcare Reform Act. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Healthcare Reform Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 23, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Healthcare Reform Act-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans. Congress may consider other legislation to repeal or replace elements of the Healthcare Reform Act.

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, 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:

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;

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; 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. 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. Although 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, 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.

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 maybecome 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.

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 has ruled on the underlying validity of the Prosl European Patent and the Utility Model.

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.

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.

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 June 2016 decision of the German PTO on the invalidity of the utility model, which we have appealed. On November 22, 2017, the EPO in Munich, Germany held a further oral hearing in this matter. 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 during the second quarter of 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 with either the German PTO or the EPO. In addition, the ongoing Unfair Competition litigation against TauroPharm is not affected and will continue.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider our claims. The judge made no decision on the merits of our complaint. On January 14, 2016, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. We have prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ within the same deadline and both parties have filed further writs at the end of April setting out their respective argumentation in more detail. A 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 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 had scheduled a further hearing for May 8, 2018. After having been rescheduled several times, the hearing is now scheduled to take place on November 20, 2018. We intend to continue to pursue this matter, and to provide additional supplemental documentary and other evidence as may be necessary to support its claims.

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 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.

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.

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.

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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 9, 2018, 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.

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 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, 2018, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

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

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

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

options to purchase an aggregate of 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 5,381,613 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 $1.88 per share;

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

warrants for 725,000 shares of common stock with an exercise price of $0.90 that expire on January 8, 2020;

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

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

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

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

Series F Preferred Stock convertible into 12,345,679 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 4,078,226 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;

warrants for 564,858 shares of common stock with an exercise price of $0.001 that expire on November 16, 2020; and

restricted stock units for 97,529 shares of common stock with an average grant date fair value of $0.57 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.

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 December 31, 2017, we had an accumulated deficit of $152.2 million, and incurred net losses from operations of $33.0 million for the year 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 the existing cash at December 31, 2017 plus funding raised through March 9, 2018 and a proposed new $3 million backstop facility, for which a binding term sheet was recently signed by us and Elliott Management Corporation, will be sufficient to fund operations into the third quarter of 2018. If a definitive agreement can be negotiated and executed, we anticipate that the proposed backstop facility would be available for drawing between April 16, 2018 and July 31, 2018. Further, we will need additional funding to complete the hemodialysis clinical trial in the U.S. which commenced in December 2015 and to continue the Neutrolin development program through the NDA filing and marketing approval. 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 31, 2017, options to purchase 120,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of $1.44 per share, and options to purchase 4,842,495 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 31, 2017, there were outstanding warrants to purchase an aggregate of 23,417,891 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 9,136,560 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 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 one of the over-the-counter markets, including 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.

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, E and F 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 58,800,000 shares of our common stock are sold during the term of the sales agreement with B. Riley FBR at a price of $0.25 per share, the last reported sale price of our common stock on the NYSE American on April 5, 2018, for aggregate gross proceeds of $14.7 million, after deducting commissions and estimated aggregate offering expenses payable by us, you will experience immediate dilution of $0.09 per share, representing the difference between our as-adjusted net tangible book value per share as of December 31, 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, any applicable prospectus supplement and the documents we have filed with the SEC that are incorporated herein and therein by reference contain such “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995.

Words such as “may,” “might,” “should,” “anticipate,” “estimate,” “expect,” “projects,” “intends,” “plans,” “believes” and wor of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management’s current judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to: CorMedix’s ability to obtain financing to support its research and development and clinical activities and operations, including its LOCK-IT-100 clinical trial for Neutrolin; 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; later developments with the FDA that may be inconsistent with the FDA’s acceptance of any interim analyses of the LOCK-IT-100 trial; obtaining regulatory approvals to conduct clinical trials and to commercialize CorMedix’s product candidates, including the anticipated 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 otherwise incorporated by reference herein, and in our most recent annual report on Form 10-K, as revised or supplemented by any of our subsequently filed quarterly reports on Form 10-Q, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus, any applicable prospectus supplement or in any document incorporated herein or therein by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the respective dates of this prospectus or any applicable prospectus supplement or the date of the document incorporated by reference in this prospectus or any applicable prospectus supplement. We 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, 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 December 31, 2017 was approximately $7,193,351, or $0.10 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 $14.7 million of common stock that may be offered in this offering at an assumed offering price of $0.25 per share, which was the closing price of our common stock on the NYSE American on April 5, 2018, and after deducting estimated offering commissions and expenses payable by us, our as-adjusted net tangible book value as of December 31, 2017 would have been approximately $21,340,351, or $0.16 per share of common stock. This represents an immediate increase in the net tangible book value of $0.06 per share to our existing stockholders and an immediate and substantial dilution in net tangible book value of $0.09 per share to new investors. The following table illustrates this hypothetical per share dilution:

Assumed public offering price per share		$ 0.25
Net tangible book value per share as of December 31, 2017	$0.10	
Increase in net tangible book value per share attributable to this offering	0.06	
As adjusted net tangible book value per share as of December 31, 2017, after giving effect to this offering		0.16
Dilution per share to new investors purchasing shares in this offering		$ 0.09

The table above assumes for illustrative purposes that an aggregate of 58,800,000 shares of our common stock are sold at a price of $0.25 per share, the last reported sale price of our common stock on the NYSE American on April 5, 2018, for aggregate gross proceeds of $14.7 million. The shares sold in this offering, if any, will be sold from time to time at various prices. An increase of $0.06 per share in the price at which the shares are sold from the assumed offering price of $0.25 per share shown in the table above, assuming all of our common stock in the aggregate amount of $14.7 million is sold at that price, would increase our adjusted net tangible book value per share after the offering to $0.18 per share and would increase the dilution in net tangible book value per share to new investors in this offering to $0.13 per share, after deducting commissions and estimated aggregate offering expenses payable by us. A decrease of $0.06 per share in the price at which the shares are sold from the assumed offering price of $0.25 per share shown in the table above, assuming all of our common stock in the aggregate amount of $14.7 million is sold at that price, would decrease our adjusted net tangible book value per share after the offering to $0.15 per share and would decrease the dilution in net tangible book value per share to new investors in this offering to $0.04 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.

The above discussion and table are based on 71,413,790 shares of our common stock outstanding as of December 31, 2017 and excludes the following securities outstanding on December 31, 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 4,842,495 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 stock;

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

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

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

Series F Preferred Stock convertible into 12,345,679 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 4,078,226 shares of common stock with an exercise price of $0.75 that expire on September10, 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;

warrants for 564,858 shares of common stock issued on November 16, 2017 with an exercise price of $0.001 that expire on November 16, 2020; and

restricted stock units for 66,414 shares of common stock with an average grant date fair value of $2.08 per share.

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 ending 2018	High	Low
First Quarter	$ 0.59	$ 0.17
Second Quarter (through April 13, 2018)	$0.30	$0.18

Fiscal Year 2017	High	Low
First Quarter	$2.48	$1.44
Second Quarter	$1.64	$0.36
Third Quarter	$0.54	$0.32
Fourth Quarter	$0.77	$0.45

Fiscal Year 2016	High	Low
First Quarter	$2.88	$1.15
Second Quarter	$4.54	$1.83
Third Quarter	$3.12	$1.35
Fourth Quarter	$3.26	$1.46

Based upon information furnished by our transfer agent, at April 5, 2018, we had 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, Series E and Series F Non-Voting Convertible Preferred Stock, we may not declare or pay any dividends or make any distributions on any of our shares of common stock 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-Market Issuance Sales Agreement, referred to as the sales agreement, with B. Riley FBR, Inc., or. B. Riley FBR. Pursuant to the sales agreement, we may issue and sell up to $14,700,000 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 is a part and is incorporated by reference in this prospectus. 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.

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 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.

The $14,700,000 equals one-third of our public float as of April 6, 2018 (which was approximately $44,400,000), as limited by General Instruction I.B.6 of Form S-3.

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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 March 31, 2018, we had 81,786,902 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 an exhibit to our registration statement on Form S-1/A filed with the SEC on March 1, 2010, and filed amendments to the Amended and Restated Certificate of Incorporation as exhibits to our registration statement on Form S-1/A filed with the SEC on March 19, 2010, our annual report on Form 10-K filed with the SEC on March 27, 2013, and our current report on Form 8-K filed with the SEC on August 10, 2017. We filed an Amended and Restated Certificate of Designation for each of our Series C-2, C-3, D and E non-voting preferred stock as exhibits to our current report on Form 8-K on September 16, 2014, and the Amended and Restated Certificate of Designation for our Series F non-voting preferred stock on December 11, 2017. We filed our Amended and Restated Bylaws as an exhibit to our quarterly report on Form 10-Q filed with the SEC on May 10, 2016. 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.

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.

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

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

EXPERTS

The financial statements of CorMedix Inc. as of December 31, 2017 and 2016 and for the years then ended have been incorporated herein by reference in reliance on the report (which report expresses an unqualified opinion on the financial statements and includes an emphasis of matter paragraph referring to the substantial doubt regarding the Company's ability to continue as a going concern) of Friedman LLP, independent registered public accounting firm, given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of the registration statement on Form S-3 we filed with the SEC under the Securities Act and does not contain all the information set forth in the registration statement. Whenever a reference is made in this 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 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 DOCUMENTS 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. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. The documents we are incorporating by reference are:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC pursuant to Section 13 of the Exchange Act on March 19, 2018;

our Amendment to the Annual Report on Form 10-K/A for the fiscal year ended December 31, 2017, filed with the SEC pursuant to Section 13 of the Exchange Act on April 11, 2018;

our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on February 10, March 3, 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, December 8 and December 11, 2017, and February 20, February 26, February 27, and March 22, 2018;

the description of our common stock contained on Form 8-A (File No. 333-163380) filed with the SEC on March 19, 2010, including any amendment or report filed for the purpose of updating such description; and

all of the filings pursuant to the Exchange Act 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 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 and will become a part of this prospectus from the date that such documents are filed with the SEC. Information in such future filings updates and the information provided in this prospectus.

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.

The information relating to us contained in this prospectus 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 is delivered, a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with this prospectus. 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. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus or the documents incorporated herein by reference is accurate as of any date other than the date on the front of this prospectus or those documents.

$14,700,000

Common Stock

PROSPECTUS

B. Riley FBR

April 16, 2018