

CorMedix Inc.

Form POS AM

February 05, 2015

As filed with the Securities and Exchange Commission on February 5, 2015

Registration Statement No. 333-163380

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

POST EFFECTIVE AMENDMENT NO. 1  
TO AMENDMENT NO. 4 TO FORM S-1

REGISTRATION STATEMENT UNDER  
THE SECURITIES ACT OF 1933

CORMEDIX INC.

(Exact name of registrant as specified in its charter)

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

745 Route 202-206, Suite 303  
Bridgewater, New Jersey 08807  
Telephone: (908) 517-9500

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

RANDY MILBY  
Chief Executive Officer  
CorMedix Inc.

745 Route 202-206, Suite 303  
Bridgewater, New Jersey 08807  
Telephone: (908) 517-9500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

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

reinvestment plans, check the following box.

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

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

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

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

Large accelerated filer

Non-accelerated filer

(Do not check if smaller reporting company)

Accelerated filer

Smaller reporting company

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

#### EXPLANATORY NOTE

On November 11, 2009, we filed with the Securities and Exchange Commission, or the Commission, a registration statement on Form S-1 (File No. 333-163380), which was amended by pre-effective amendments filed on December 31, 2009, January 20, 2010, March 11, 2010 and March 19, 2010, or the Registration Statement or the Form S-1, to register the offer and sale of (i) 1,983,750 units (the "Units"), each consisting of two shares of common stock, \$0.001 par value per share, and a warrant to purchase one share of common stock, (ii) the 3,967,500 shares of common stock underlying the Units, (iii) the 1,983,750 warrants included in the Units, (iv) the 1,983,750 shares of common stock underlying the warrants, (v) the underwriter's Unit purchase warrant, (vi) the 36,570 Units underlying the underwriter's Unit purchase warrant, (vii) the 73,140 shares of common stock underlying the underwriter's Units, (viii) the 36,570 warrants in the underwriter's Units, and (ix) the 36,570 shares of common stock underlying the warrants in the underwriter's Units. The Registration Statement was declared effective by the Commission on March 24, 2010. On March 30, 2010, we issued (i) an aggregate of 1,925,000 Units to investors, and (ii) the underwriters Unit Purchase Warrant for 2,400 Units. On May 13, 2010, the investor Units separated and the shares of common stock and the warrants underlying the Units began trading separately. On February 19, 2013, we purchased 220,000 of the investor warrants from an investor. As of February 5, 2015, no investor warrants have been exercised and all investor warrants to purchase up to 1,705,000 shares of common stock were outstanding. As of February 5, 2015, the underwriter had not exercised its Unit purchase warrant.

This Post-Effective Amendment No. 1 to the Form S-1, or this Post-Effective Amendment, is being filed to maintain the registration of (i) the 1,705,000 shares of common stock issuable upon exercise of the outstanding investor warrants, (ii) the 2,406 Units underlying the underwriter's Unit purchase warrant, (iii) the 4,812 shares of common stock underlying the underwriter's Units, (iv) the 2,406 warrants underlying the underwriter's Units, and (v) the 2,406 shares of common stock underlying the warrants in the underwriter's Units. All securities offered hereby are being offered on a delayed or continuous basis. We are not registering any additional securities under this Post-Effective Amendment. All filing fees payable in connection with the registration of these securities were previously paid by us in connection with the filing of the Form S-1.

Registration of Common Stock Upon Exercise of Warrants, and Registration of Units Issuable Upon Exercise of the Underwriter's Unit Purchase Warrant, Common Stock and Warrants Issuable Upon Exercise of the Underwriter's Unit Purchase Warrant, and Common Stock Issuable Upon Exercise of Warrants Underlying the Underwriter's Unit Purchase Warrant

This Post-Effective Amendment also contains an updated prospectus relating to (i) an aggregate of up to 1,705,000 shares of common stock issuable upon the exercise of the warrants previously issued to investors on March 30, 2010, pursuant to a warrant agreement, dated as of March 30, 2010, between us and Onyx Stock Transfer, LLC (now VStock Transfer, LLC), (ii) the 2,406 Units underlying the underwriter's Unit purchase warrant, (iii) the 4,812 shares of common stock underlying the underwriter's Units, (iv) the 2,406 warrants underlying the underwriter's Units, and (v) the 2,406 shares of common stock underlying the warrants in the underwriter's Units. This Post-Effective Amendment is being filed in compliance with Section 10(a)(3) of the Securities Act.



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

Subject to completion, dated February 5, 2015

Prospectus

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

2,406 Units Underlying the Underwriter's Unit Purchase Warrant, 4,812 Shares of Common Stock Underlying the Underwriter's Units, 2,406 Warrants Underlying the Underwriter's Units, and 2,406 Shares of Common Stock Underlying the Warrants in the Underwriter's Units

This prospectus relates to the issuance of up to 1,705,000 shares of our common stock, \$0.001 par value per share, issuable upon the exercise of outstanding warrants, at an exercise price of \$3.4375 per share, that were issued by us on March 30, 2010, pursuant to a master warrant agreement, dated as of March 30, 2010, or the Warrant Agreement, between us and Onyx Stock Transfer, LLC (now VStock Transfer, LLC). This prospectus also relates to the issuance of the following securities to the underwriter of our initial public offering: (i) the 2,406 Units underlying the underwriter's Unit purchase warrant, (ii) the 4,812 shares of common stock underlying the underwriter's Units, (iii) the 2,406 warrants underlying the underwriter's Units, and (iv) the 2,406 shares of common stock underlying the warrants in the underwriter's Units. The Unit purchase warrant has an exercise price of \$7.80 per Unit and the underlying warrants have an exercise price of \$3.4375 per share, and all expire on March 24, 2015.

We are not offering any shares of our common stock for sale under this prospectus, and we will not receive any of the proceeds from the sale or other disposition of the shares of our common stock covered by this prospectus. However, we will receive the exercise price of any of the warrants exercised for cash.

Our common stock trades on the NYSE MKT under the trading symbol "CRMD." On February 4, 2015, the last reported sale price of our common stock was \$3.17 per share.

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

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

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

The date of this prospectus is \_\_\_\_\_, 2015.

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## ABOUT THIS PROSPECTUS

This prospectus is part of a post-effective amendment to a registration statement on Form S-1 that we filed with the Securities and Exchange Commission, or the SEC, using a “shelf” registration or continuous offering process. This prospectus relates to the offer and sale of up to 1,929,206 shares of our common stock to be offered from time to time upon exercise of the warrants.

You should read this prospectus and the information and documents incorporated by reference carefully because these documents contain important information you should consider when making your investment decision. See “Where You Can Find More Information” and “Incorporation of Documents by Reference.”

You should rely only on the information provided in this prospectus and the information and documents incorporated by reference into this prospectus. We have not authorized anyone to provide you with different information. This prospectus is not an offer to sell these securities. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front cover of this prospectus, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

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

## PROSPECTUS SUMMARY

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

### Overview

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

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

Our primary product is Neutrolin for the prevention of catheter-related infections in dialysis and non-dialysis markets. Neutrolin is a liquid formulation designed to prevent central venous catheter infection as well as catheter obstruction, also referred to as maintenance of catheter patency, in central venous catheters, which we initially launched in Germany in December 2013 for use in hemodialysis catheters. There are approximately 780,000 hemodialysis patients in the United States and the European Union, or EU. We believe the patients undergoing hemodialysis using a tunneled central vein catheter will be our initial target market. We project that 91,000 patients in the European Union and 104,000 patients in the United States have these catheters in place. These patients represent nearly 30 million hemodialysis sessions per year, which we believe represents a market potential of approximately \$300 - \$400 million.

During the third quarter of 2011, we received a notice from the U.S. Food and Drug Administration, or FDA, that Neutrolin had been assigned to the Center for Drug Evaluation and Research, or CDER, for review as a drug rather than a device. As a result of this, and given our limited resources, we decided to change our business strategy and focus the majority of our resources on the research and development of Neutrolin, rather than CRMD004 and to seek regulatory and commercialization approval for Neutrolin in Europe through a CE Mark application rather than pursue FDA approval at that time. During the first half of 2011, we submitted our design dossier to TÜV SÜD, the European notified body managing our CE Mark application. In the fourth quarter of 2011, we successfully completed our stage 1 audit with TÜV SÜD and we successfully completed the stage 2 audit in the third quarter of 2012.

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

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, in 2013, we began the commercial launch of Neutrolin in Germany for the prevention of catheter-related bloodstream infections, or CRBI, and maintenance of



catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia and The Netherlands for such treatment.

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

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

In January 2015, the FDA granted our request for Fast Track designation for Neutrolin and also designated Neutrolin as a Qualified Infectious Disease Product for oncology, hemodialysis and intensive care unit patients, where catheter-related blood stream infections and clotting can be life threatening.

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

Our other product candidate is CRMD004, which is the gel formulation of Neutrolin that we may develop for a variety of indications that include but are not limited to the treatment of wounds, skin infections, the prevention of catheter exit site infections and, based on the gel's thixotropic properties which cause it to liquefy under pressure/kinetic energy, as a follow-on to our Neutrolin catheter lock solution. CRMD004 is currently in the pre-clinical stage of development.

#### Recent Developments

In January 2015, we issued an aggregate of 857,324 shares of our common stock upon the cashless exercise of 467,779 warrants issued in May 2013 and 750,000 warrants issued in October 2013.

In January 2015, we issued an aggregate of 125,000 shares of our common stock upon the exercise of 125,000 warrants issued in January 2014 resulting in gross proceeds of \$112,500.

In January 2015, we issued an aggregate of 15,000 shares of our common stock upon the conversion of 1,500 Series C3 preferred stock we issued in January 2014.

#### 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,

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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 745 Route 202-206, Suite 303, Bridgewater, NJ 08807. Our telephone number is (908) 517-9500. Our website address is [www.cormedix.com](http://www.cormedix.com). Information contained in, or accessible through, our website does not constitute part of this prospectus.

## The Offering

Securities offered by us	<p>Up to 1,705,000 shares of our common stock issuable from time to time upon exercise of the investor warrants. The exercise price of the warrants is \$3.4375 per share. The warrants are currently exercisable and expire on March 24, 2015.</p> <p>Up to 2,406 Units upon exercise of the underwriter's Unit purchase warrant; up to 4,812 shares of common stock underlying the underwriter's Units; up to 2,406 warrants underlying the underwriter's Units; and up to 2,406 shares of common stock underlying the warrants in the underwriter's Units. The Unit purchase warrant has an exercise price of \$7.80 per Unit and the underlying warrants have an exercise price of \$3.4375 per share, and all are currently exercisable and expire on March 24, 2015.</p>
Common stock to be outstanding immediately after this offering	24,173,886 shares of our common stock if the warrants are exercised in full.(1)
Use of proceeds	We may receive up to a total of approximately \$5,887,957 in gross proceeds, and up to a total of approximately \$5,807,975 after deducting estimated expenses of \$80,000. However, as we are unable to predict the timing or amount of potential exercises of the warrants, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds are allocated to working capital. It is possible that the warrants may expire and may never be exercised.
Risk Factors	Investing in our securities involves a high degree of risk. See "Risks Factors" beginning on page 6 of this prospectus otherwise incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities.
<u>NYSE MKT listing</u>	Our common stock is listed on the NYSE MKT under the symbol "CRMD."

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

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

454,546 shares of common stock issuable upon conversion of the Series B Preferred Stock;

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

warrants for 125,000 shares issued to ND Partners in April 2013 in connection with the amendment to the license and assignment

agreement with an exercise price of \$1.50 per share that expire on April 11, 2018;

warrants for 2,118,569 shares of our common stock issued upon the conversion of convertible notes in connection with and as a result of our IPO with an exercise price of \$3.4375 per share that expire on March 24, 2015;

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

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

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

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

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

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

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

1,000,000 shares of common stock issuable upon exercise of warrants with an exercise price of \$0.90 that expire on January 8, 2020;

1,500,000 shares of common stock issuable upon conversion of the Series C-2 Preferred Stock;

1,790,000 shares of common stock issuable upon conversion of the Series C-3 Preferred Stock;

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1,479,240 shares of common stock issuable upon conversion of the Series D Preferred Stock;

2,021,358 shares of common stock issuable upon conversion of the Series E Preferred Stock; and

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

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

## RISK FACTORS

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

### Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of operating losses, and expect to have an operating loss for the year ended December 31, 2014.

We were established in July 2006 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in the early stages of operation. We incurred a net loss of approximately \$9.1 million for the year ended December 31, 2013, and a net loss of approximately \$18.2 million for the nine months ended September 30, 2014. As of September 30, 2014, we had an accumulated deficit of approximately \$74.0 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Having only launched Neutrolin in December 2013, we have no products that have generated any significant commercial revenue, do not expect to generate substantial revenues from Neutrolin until 2015 at the earliest, and might never generate significant revenues from the sale of Neutrolin or any other products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: successfully marketing Neutrolin in Germany and other countries in which it is approved for sale; obtaining necessary regulatory approvals for Neutrolin from the other applicable European and Middle East agencies, other foreign agencies and the FDA and international regulatory agencies for any other products; successful completion of the development of our other product candidates; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur losses and negative operating cash flow in the fiscal year ended December 31, 2014, and we may never achieve or maintain profitability. Until we successfully commercialize Neutrolin or other product candidates and generate substantial earnings from those products, we expect to incur losses and may never become profitable. We also expect to continue to incur significant operating and capital expenditures as we pursue the U.S. development of Neutrolin and anticipate that our expenses will increase substantially in the foreseeable future as we continue to undertake development and commercialization of Neutrolin and our other product candidates, undertake clinical trials of our product candidates, seek regulatory approvals for product candidates, implement additional internal systems and infrastructure, and hire additional personnel.

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

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



our stockholders and may require us to relinquish valuable rights.

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

Based on our expected cash resources at September 30, 2014, we previously believed that existing cash would be sufficient to enable us to fund our projected operating requirements into the third quarter of 2015. Due to higher than anticipated costs in sales and marketing to support oncology label expansion, increased business development activities, increased legal costs to defend our intellectual property and additional research and development activities to support product registration and future commercialization initiatives, we believe that our expected cash resources as of December 31, 2014 will be sufficient to enable us to fund our projected operating requirements into the second quarter of 2015. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable.

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

We anticipate that our independent registered public accounting firm will express substantial doubt as to our ability to continue as a going concern and may do so again in the future.

Based on our expected cash resources at December 31, 2014, we believe that existing cash will be sufficient to enable us to fund our projected operating requirements into the second quarter of 2015. As a result, we anticipate that in their report to accompany our audited financial statements for the year ended December 31, 2014, our independent registered public accounting firm will express substantial doubt as to our ability to continue as a going concern. A “going concern” opinion could impair our ability to finance our operations through the sale of debt or equity securities or through bank financing. Our ability to continue as a going concern will depend, on our ability to obtain additional financing. Thereafter, our ability to generate positive cash flow from operations will depend on our ability to successfully commercialize Neutrolin, which is uncertain. Additional capital may not be available on reasonable terms, or at all. If adequate financing is not available, we would be required to terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain aspects of our technologies, or potential markets that we would not otherwise relinquish. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

#### Risks Related to the Development and Commercialization of Our Product Candidates

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

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

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

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

complete the development of Neutrolin in the U.S.; and

CRMD004 - currently in the pre-clinical phase.

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

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

Successful development and commercialization of our products is uncertain.

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

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

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

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

failure to receive regulatory approvals;

emergence of superior or equivalent products;

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

failure to achieve market acceptance.

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

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

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

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

slower than expected rates of patient recruitment;

failure to recruit a sufficient number of patients;

modification of clinical trial protocols;

changes in regulatory requirements for clinical trials;

lack of effectiveness during clinical trials;

emergence of unforeseen safety issues;

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

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

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

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

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

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

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

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

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

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

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

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

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

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

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

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

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

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

Physicians and patients may not accept and use our products.

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

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

- cost-effectiveness of our product relative to competing products;

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are highly dependent on the principal members of our management and scientific staff, specifically, Randy Milby, a director and our Chief Executive Officer, Harry O’Grady, our Chief Financial Officer, and Dr. Antony Pfaffle, a director and Chief Scientific Officer. We have an employment agreement with Mr. Milby, but no other officers. Mr. Milby’s agreement cannot ensure our retention of him. Furthermore, our future success will also depend in part on our ability to identify, hire, and retain additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, our work force is located in the New Jersey metropolitan area, where competition for personnel with the scientific and technical skills that we seek is extremely high and is likely to remain high. Because of this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent former employees from competing with us.

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

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

We may not successfully manage our growth.

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

#### Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a

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



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

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

In the same complaint against the same Defendants, we also alleged an infringement (requesting the same remedies) of ND Partners' utility model DE 20 2005 022 124 U1 which is basically identical to the Prosl European Patent in its main aspects and claims. The Mannheim court separated the two proceedings so that the patent and the utility model proceeding are now tried separately and independently from each other due to the slightly differing requirements for both IP rights. An oral hearing with regard to the utility model has been scheduled for March 6, 2015. TauroPharm has filed a cancellation action against the utility model before the German Patent and Trademark Office based on the same arguments as the opposition against the Prosl European Patent. We cannot predict what other defenses the

Defendants may raise, or the ultimate outcome of this matter.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of our proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using our proprietary information relating to the composition and manufacture of our product Neutrolin®, which is approved for sale in Germany, in its manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100™ and TauroLock-HEP500™. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine as well as citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. A hearing in this matter has been scheduled in the District Court of Cologne for June 11, 2015.

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

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

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

abandon an infringing product candidate;

redesign our products or processes to avoid infringement;

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

pay damages; or

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

### Risks Related to Dependence on Third Parties

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

Our business strategy for Neutrolin relies on collaborating with larger firms with experience in marketing and selling medical devices and pharmaceutical products; for other products we may also rely on such marketing collaborations or out-licensing or our product candidates. Specifically, for Neutrolin, we have entered into an agreement with human4farma to market and sell Neutrolin in Germany and a distributor agreement with a Saudi Arabian and a South Korean company for sales and marketing in those two countries (upon receipt of approval to market in South Korea). In addition, we have independent sales representatives marketing and selling in Austria and The Netherlands. Assuming we receive applicable regulatory approval for other markets, we plan to enter into distribution agreements with one or more third parties for the sale of Neutrolin in various European, Middle East and other markets. However, there can be no assurance that we will be able to successfully maintain those relationships or establish and maintain additional marketing, sales, or distribution relationships. Nor can there be assurance that such relationships will be successful, or that we will be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third-parties.

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

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

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

negatively impact our ability to generate product revenues. Further, whether we commercialize products on our own or rely on a third party to do so, our ability to generate revenue will be dependent on the effectiveness of the sales force. In addition, to the extent we rely on third parties to commercialize our approved products, we will likely receive less revenues than if we commercialized these products ourselves.

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

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

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

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

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

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

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

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

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

#### Risks Related to our Common Stock

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

We have identified a material weakness in our internal control over financial reporting related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting treatments associated with our financing activities and European expansion. We have taken initial measures to remediate this weakness by increasing internal review processes, in addition to the previously established accounting oversight committee, which is comprised of members of our senior management and our third party GAAP advisor. The hiring of our full-time Chief Financial Officer in July 2014 was a key step in bolstering our financial infrastructure. We continue to build on our infrastructure to address this weakness. However, we cannot be assured

that this weakness will be remediated or that other material weaknesses will not be discovered.

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

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

During the period from the completion of our initial public offering, or IPO, on March 30, 2010 through February 4, 2015, the high and low sales prices for our common stock were \$4.00 and \$0.15, respectively. There is a limited public market for our common stock and we cannot provide assurances that an active trading market will develop. As a result of low trading volume in our common stock, the purchase or sale of a relatively small number of shares could result in significant share price fluctuations.

Additionally, the market price of our common stock may continue to fluctuate significantly in response to a number of factors, some of which are beyond our control, including the following:

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

our need for additional capital;

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

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

our entry into or the loss of a significant collaboration;

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

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

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

changes in key personnel;

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

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

general economic, industry and market conditions;

developments or disputes concerning patents or other proprietary rights;

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

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

In addition, the stock markets in general, and the stock of pharmaceutical and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the

operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

For these reasons and others, you should consider an investment in our common stock as 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 December 31, 2014, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

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

454,546 shares of common stock issuable upon conversion of the Series B Preferred Stock;



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

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

warrants for 4,043,569 shares of our common stock issued in connection with our IPO with an exercise price of \$3.4375 per share that expire on March 24, 2015;

a warrant to purchase 2,406 units with an exercise price of \$7.80 per unit issued to the underwriters of our IPO that, if exercised, would result in the issuance of an additional 4,812 shares of common stock and warrants to purchase an additional 2,406 shares of common stock with an exercise price of \$3.90 that expire on March 24, 2015;

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

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

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

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

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

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

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

1,000,000 shares of common stock issuable upon exercise of warrants with an exercise price of \$0.90 that expire on January 8, 2020;

1,500,000 shares of common stock issuable upon conversion of the Series C-2 Preferred Stock;

1,790,000 shares of common stock issuable upon conversion of the Series C-3 Preferred Stock;

1,479,240 shares of common stock issuable upon conversion of the Series D Preferred Stock;

2,021,358 shares of common stock issuable upon conversion of the Series E Preferred Stock; and

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

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

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

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

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

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

Pursuant to our 2006 Stock Plan, our Board of Directors is authorized to award up to a total of 2,300,000 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. As of December 31, 2014, options to purchase 1,065,000 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of \$0.77 per share, and options to purchase 2,599,500 shares of common stock issued under our 2013 Stock Plan at a weighted average exercise price of \$1.44 per share were outstanding. In addition, at December 31, 2014, there were outstanding warrants to purchase an aggregate of 11,520,762 shares of our common stock at prices ranging from \$0.40 to \$3.90, and shares of our outstanding Series B, C-2, C-3, D and E preferred stock convertible into an aggregate of 7,245,144 shares of our common stock. Stockholders will experience dilution in the event that additional shares of common stock are issued under our 2006 Stock Plan or 2013 Stock Plan, or options issued under our 2006 Stock Plan or 2013 Stock Plan are exercised, or any warrants are exercised for, or preferred stock shares are converted to, common stock.

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

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

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

- prohibiting our stockholders from fixing the number of our directors; and

- establishing advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by the board of directors. This provision could have the effect of discouraging, delaying or preventing someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. Any provision of our Amended and Restated Certificate of Incorporation, as amended, or Amended and Restated Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of

our common stock and could also affect the price that some investors are willing to pay for our common stock.

If we fail to comply with the continued listing standards of the NYSE MKT, it may result in a delisting of our common stock from the exchange.

Our common stock is currently listed for trading on the NYSE MKT, and the continued listing of our common stock on the NYSE MKT is subject to our compliance with a number of listing standards. These listing standards include the requirement for avoiding sustained losses and maintaining a minimum level of stockholders' equity. On May 19, 2014, we received a notice from the NYSE MKT that, based on our Form 10-Q for the quarter ended March 31, 2014, filed on May 15, 2014 with the Securities and Exchange Commission, we do not meet continued listing standards of the NYSE MKT as set forth in Part 10 of the Company Guide. Specifically, we are 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 \$2 million and \$4 million, respectively, as of March 31, 2014 and had net losses in our four most recent fiscal years ended December 31, 2013. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide. We submitted a plan of compliance to the NYSE MKT on June 18, 2014 to address how we intend to regain compliance with Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide. On July 18, 2014, we received notice from the NYSE MKT that the NYSE MKT had accepted our plan to regain compliance with the continued listing standards of the NYSE MKT. As a result, the NYSE MKT is continuing our listing and has granted us an extension until May 31, 2015 (the "Plan Period") to regain compliance with the continued listing standards of the NYSE MKT. We will be subject to periodic review by the NYSE MKT during the Plan Period. There can be no assurance that we will meet the continued listing standards of the NYSE MKT by the end of the Plan Period or, if we do meet the standards by the end of the Plan Period, that we will continue to meet such standards thereafter.

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

Because the average daily trading volume of our common stock has been low historically, the ability to sell our shares in the secondary trading market may be limited.

Because the average daily trading volume of our common stock on the NYSE MKT has been low historically, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. The average daily trading volume of our common stock may be low relative to the stocks of other exchange-listed companies, which could limit investors' ability to sell shares in the secondary trading market.

Penny stock regulations may impose certain restrictions on marketability of our securities.

The SEC has adopted regulations which generally define a "penny stock" to be any equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. A security listed on a national securities exchange is exempt from the definition of a penny stock. Our common stock is listed on the NYSE MKT and so is not considered a penny stock. However, if we fail to maintain our common stock's listing on the NYSE MKT, our common stock would be considered a penny stock. In that event, our common stock would be subject to rules that impose additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1,000,000 or annual income exceeding \$200,000, or \$300,000 together with their spouse). For transactions covered by such rules, the broker-dealer must make a special suitability determination for the purchase of such securities and have received the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the SEC relating to the penny stock market. The broker-dealer must also disclose the commission payable to both the broker-dealer and the registered representative, current quotations for the securities and, if the broker-dealer is the sole market maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the "penny stock" rules restrict the ability of broker-dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

Stockholders should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

- control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;

- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;

- "boiler room" practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;

excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

We do not intend to pay dividends on our common stock so any returns on our common stock will be limited to the value of our common stock.

We have never declared dividends on our common stock, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. Pursuant to the terms of our Series D and E Non-Voting Convertible Preferred Stock, we may not declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of those preferred shares remain outstanding. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors. Any return to holders of our common stock will be limited to the value of their common stock.

USE OF PROCEEDS

We may receive up to a total of approximately \$5,807,974 in net proceeds after deducting estimated expenses. However, as we are unable to predict the timing or amount of potential exercises of the warrants, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds are allocated to working capital. It is possible that the warrants may expire and may never be exercised.

PLAN OF DISTRIBUTION

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



## FINANCIAL STATEMENTS

Please see Part II, Item 8 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC on March 31, 2014, which is incorporated herein by reference, for our audited consolidated balance sheets as of December 31, 2013 and 2012 and the related consolidated statements of operations, changes in stockholders' equity (deficiency), and cash flows for the years then ended and for the period from July 28, 2006 (inception) to December 31, 2013.

Please see Part I, Item 1 in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014, filed with the SEC on May 15, 2014, August 14, 2014, and November 13, 2014, respectively, all of which are incorporated herein by reference, for our consolidated financial statements for the respective periods.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Please see Part I, Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC on March 31, 2014, and Part I, Item 2 in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014, filed with the SEC on May 15, 2014, August 14, 2014, and November 13, 2014, respectively, all of which are incorporated herein by reference, for our management's discussion and analysis of financial condition and results of operations for the respective periods.

## CHANGE IN INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Please see Item 4.01 in our Current Report on Form 8-K filed with the SEC on May 16, 2014, which is incorporated herein by reference, for information on the change in our independent registered public accounting firm for the year ended December 31, 2014 from CohnReznick LLP to Friedman LLP.

## BUSINESS

Please see Item 1 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC on March 31, 2014, which is incorporated herein by reference, for a discussion of our business.

### Legal Proceedings

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, brought an action against the European Sodemann Patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to us pursuant to the License and Assignment Agreement between us and ND Partners LLC. The action that was brought against the counterpart of the Sodemann Patent in Germany at the Board of the European Patent Office opposition division was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, we became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the counterpart of the Sodemann Patent covering Neutrolin®, but remanded the proceeding to the lower court to consider

restricting certain of the counterpart of the Sodemann Patent claims. We received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, we were notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014. We filed our response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. Geistlich did not file a further statement within the required timeline. On November 5, 2014, the Opposition Division at the EPO issued the interlocutory decision to maintain the patent on the basis of the claims as amended during the appeal proceedings. This decision becomes final if no further appeal is lodged by Geistlich by January 15, 2015. As of the date of this prospectus, we have not received a communication from the European Patent Office that Geistlich has filed such an appeal.

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

In the same complaint against the same Defendants, we also alleged an infringement (requesting the same remedies) of ND Partners' utility model DE 20 2005 022 124 U1 which is basically identical to the Prosl European Patent in its main aspects and claims. The Mannheim court separated the two proceedings so that the patent and the utility model proceeding are now tried separately and independently from each other due to the slightly differing requirements for both IP rights. An oral hearing with regard to the utility model has been scheduled for March 6, 2015. TauroPharm has filed a cancellation action against the utility model before the German Patent and Trademark Office based on the same arguments as the opposition against the Prosl Patent. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of this matter.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of our proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using our proprietary information relating to the composition and manufacture of our product Neutrolin®, which is approved for sale in Germany, in its manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100™ and TauroLock-HEP500™. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine as well as citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. A hearing in this matter has been scheduled in the District Court of Cologne for June 11, 2015.

#### Employees

As of December 31, 2014, we had five employees, including our customer service representative in Germany, and had one independent contractor working in the finance area in the U.S. We also engage various consultants and contractors for project management and research and development, manufacturing and regulatory development, marketing, financing, sales and marketing and administrative activities. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

#### Facilities

Our principal executive offices are located in approximately 3,500 square feet of office space in Bridgewater, New Jersey. We lease this office space pursuant to a lease agreement dated March 18, 2010 with UA Bridgewater Holdings, LLC. The lease agreement has an initial term of 60 months, commencing on April 1, 2010 and expiring on March 31, 2015, and lease payments began on July 1, 2010. We have been granted the option to extend the lease term for one additional period of three years, commencing the day following the then-current expiration date of the term, March 31, 2015, provided we deliver notice to the landlord no later than nine months prior to March 31, 2015. The

total 60 month lease obligation is approximately \$389,000. Our total remaining lease obligation was approximately \$21,000 as of December 31, 2013.

We have entered into sublease for 4,700 square feet of office space in Bedminster, New Jersey, which sublease runs from April 1, 2015 until March 31, 2018. Rent is \$5,000 per month plus occupancy costs such as utilities, maintenance and taxes. We can and expect to occupy the space beginning on March 1, 2015 for which month we are not obligated to pay rent, but must pay occupancy costs.

Our subsidiary leases its offices in Fulda, Germany pursuant to a lease agreement with ITZ GmbH. The lease has a term of 36 months which commenced on September 1, 2013 for a base monthly payment of €442. The total 36 month lease obligation is approximately €15,900 and the remaining lease obligation was approximately €14,100 as of December 31, 2013.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

## MANAGEMENT

Please see the sections captioned “Proposal No. 1 – Election of Directors” and “Corporate Governance” in our proxy statement on Schedule 14A for our 2014 annual meeting of stockholders, filed with the SEC on May 16, 2014, which is incorporated herein by reference, for a discussion of our management and corporate governance.

On July 21, 2014, we appointed Mr. Harry O’Grady as our Chief Financial Officer and Dr. Antony Pfaffle as our Chief Scientific Officer.

Mr. O’Grady has been the Vice President, Finance, CFO, for Dey/Mylan Specialty, L.P. since 2010. Prior to that, Mr. O’Grady was a Vice President, Finance – Sterile Business Unit, at Catalent Pharma Solutions, Inc. from 2008 through 2010. From 2006 through 2008, he was the Vice President, Business Planning and Administration, at Bayer Healthcare Pharmaceuticals, Inc. He was also the Vice President, Finance and Controlling at Bayer from 2004 through 2006, and the Controller at Bayer from 2001 to 2003. From 1995 through 2003, Mr. O’Grady held several other positions with Bayer. Mr. O’Grady, a certified public accountant, received his Bachelor of Business Administration in Accounting from Pace University, and his Masters of Business Administration from Lehigh University.

Dr. Pfaffle has been a director of CorMedix since February 2007 and, effective January 1, 2013, became our Acting Chief Scientific Officer. Dr. Pfaffle has been Director of Healthcare Research at Bearing Circle Capital, L.P., an investment fund, since May 2007. Dr. Pfaffle was an Advisory Medical Director for ParagonRx, an Inventive Company specializing in drug and device risk evaluation and mitigation. He was a Managing Director at Paramount BioCapital, Inc. and Senior Vice-President of Business Development at Paramount BioSciences, LLC from December 2005 to May 2007. Dr. Pfaffle was a Principal and Founder of Black Diamond Research, an investment research company, from July 2001 to December 2005. Dr. Pfaffle is an internist who practiced nephrology at New York Hospital-Weill Cornell Medical Center, Lenox Hill Hospital and Memorial Sloan-Kettering Cancer Center. Dr. Pfaffle received his M.D. from New York Medical College in 1989.

## TRANSACTIONS WITH RELATED PERSONS

Please see the section captioned “Certain Relationships and Related Transactions” in our proxy statement on Schedule 14A for our 2014 annual meeting of stockholders, filed with the SEC on May 16, 2014, which is incorporated herein by reference, for a discussion of our process for handling any transactions with related persons, of which there were none in 2013 and none in 2014, except as follows:

On January 8, 2014, the following individuals purchased shares of our Series C-3 convertible preferred stock and warrants to purchase shares of our common stock in a private placement, all on the same terms as other investors in the private placement, as follows:

Cora Tellez, director, 5,000 shares and a warrant to purchase 25,000 shares of our common stock;

Steven Lefkowitz, director, purchased (indirectly through Wade Capital Corporation Money Purchase Plan, an entity for which Mr. Lefkowitz has voting and investment control) and individually 4,500 and 3,000 shares, respectively, and warrants to purchase 22,500 and 15,000 shares, respectively; and

Randy Milby, our Chief Executive Officer and a director, indirectly through MW Bridges LLC (an entity for which he is Managing Partner, and has voting and investment control) and individually 23,700 and 1,300 shares, respectively, and warrants to purchase 118,500 and 6,500 shares, respectively.

On September 15, 2014, we entered into a consent and exchange agreement with the holders of our Series C-3 preferred stock and related warrants, including Ms. Tellez, Mr. Lefkowitz and Mr. Milby, pursuant to which, we amended and restated the Series C-3 preferred stock and the related warrants to remove anti-dilution, price reset and certain change of control provisions that caused those securities to be classified as derivative liabilities under U.S. generally accepted accounting principles. The exchange was on the same terms as those provided to all other investors in the January 2014 Series C-3 financing.

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

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

#### MARKET FOR OUR COMMON STOCK

Our common stock trades on the NYSE MKT 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 MKT.

Fiscal Year 2015		High	Low
First Quarter (through February 4)	\$	3.45	\$ 1.63
Fiscal Year 2014		High	Low
First Quarter	\$	3.20	\$ 1.24
Second Quarter	\$	2.56	\$ 1.25
Third Quarter	\$	2.12	\$ 1.69
Fourth Quarter	\$	1.97	\$ 1.29
Fiscal Year 2013		High	Low
First Quarter	\$	1.10	\$ 0.71
Second Quarter	\$	1.00	\$ 0.48
Third Quarter	\$	1.29	\$ 0.75
Fourth Quarter	\$	1.27	\$ 0.66

Based upon information furnished by our transfer agent, at January 30, 2015, we had approximately 90 holders of record of our common stock.

#### DIVIDEND POLICY

We have never declared dividends on our common stock, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. Pursuant to the terms of our Series D and E Non-Voting Convertible Preferred Stock, we may not declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of those preferred shares remain outstanding. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors. Any return to holders of our common stock will be limited to the value of their common stock.



## DESCRIPTION OF OUR CAPITAL STOCK

### Common Stock

Pursuant to our Amended and Restated Certificate of Incorporation, as amended, we are authorized to issue 80,000,000 shares of common stock, \$0.001 par value per share. As of December 31, 2014, we had 22,461,668 shares of common stock outstanding.

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

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

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

### Preferred Stock

Under the terms of our Amended and Restated Certificate of Incorporation, as amended, our board of directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Of the 2,000,000 shares of preferred stock authorized, our board of directors has designated (all with par value of \$0.001 per share): 454,546 shares as Series B Non-Voting Convertible Preferred Stock; 150,000 shares as Series C-2 Non-Voting Convertible Preferred Stock; 200,000 shares as Series C-3 Non-Voting Convertible Preferred Stock; 73,962 shares as Series D Non-Voting Convertible Preferred Stock; and 92,440 shares as Series E Non-Voting Convertible Preferred Stock. The Series A Non-Voting Convertible Preferred Stock and Series C-1 Non-Voting Convertible Preferred Stock that was previously designated has all been converted to shares of common stock.

Series B Non-Voting Convertible Preferred Stock

Rank

The Series B Preferred Stock ranks:

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

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

#### Conversion

Each share of Series B Preferred Stock is convertible into one share of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock) at a per share price of \$1.10 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 3.99% of the total number of shares of our common stock then issued and outstanding.

#### Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series B Preferred Stock will receive a payment equal to \$0.001 per share of Series B Preferred Stock before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series B Preferred Stock and holders of Series B Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

#### Voting Rights

Shares of Series B Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Preferred Stock will be required to amend the terms of the Series B Preferred Stock or the certificate of designation for the Series B Preferred Stock.

#### Dividends

Holders of Series B Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series B Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

#### Redemption

We are not obligated to redeem or repurchase any shares of Series B Preferred Stock. Shares of Series B Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

#### Listing

There is no established public trading market for the Series B Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series B Preferred Stock on any national securities exchange or trading system.

## Fundamental Transactions

If, at any time that shares of Series B Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series B Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

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

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

### Rank

The Series C Preferred Stock will rank:

senior to our common stock;  
senior to any class or series of capital stock created after the issuance of the Series C Preferred Stock;  
on parity with the Series B Non-Voting Convertible Preferred Stock; and  
junior to the Series D Non-Voting Convertible Preferred Stock and Series E Non-Voting Convertible Preferred Stock.

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

### Conversion

Each share of Series C Preferred Stock is convertible into 10 shares of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock) at a per share price of \$1.00 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series C Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding.

### Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series C Preferred Stock will receive a payment equal to \$10.00 per share of Series C Preferred Stock before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series C Preferred Stock and holders of Series C Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

### Voting Rights

Shares of Series C Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of two thirds of the outstanding Series C-2 and Series C-3 Preferred Stock, respectively, will be

required to amend the terms of the Series C-2 and C-3 Preferred Stock or the certificate of designation for the Series C-2 and C-3 Preferred Stock, respectively.

#### Dividends

Holders of Series C Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series C Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

## Redemption

We are not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

## Listing

There is no established public trading market for the Series C Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series C Preferred Stock on any national securities exchange or trading system.

## Fundamental Transactions

If, at any time that shares of Series C Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series C Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

## Debt Restriction

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

## Series D Non-Voting Convertible Preferred Stock

### Rank

The Series D Preferred Stock will rank:

senior to our common stock;  
senior to any class or series of capital stock created after the issuance of the Series D Preferred Stock;  
senior to the Series B Non-Voting Convertible Preferred Stock, the Series C-2 Non-Voting Convertible Preferred Stock and the Series C-3 Non-Voting Convertible Preferred Stock; and  
on parity with the Series E Non-Voting Convertible Preferred Stock.

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

### Conversion

Each share of Series D Preferred Stock is convertible into 20 shares of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock ) at a per share price of \$0.35 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series D Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding.



### Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series D Preferred Stock will receive a payment equal to \$21.00 per share of Series D Preferred Stock on parity with the payment of the liquidation preference due the Series E Preferred Stock, but before any proceeds are distributed to the holders of common stock, Series B Non-Voting Convertible Preferred Stock, the Series C-2 Non-Voting Convertible Preferred Stock and the Series C-3 Non-Voting Convertible Preferred Stock. After the payment of this preferential amount, holders of Series D Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock that participates with the common stock in such distributions.

### Voting Rights

Shares of Series D Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series D Preferred Stock will be required to amend the terms of the Series D Preferred Stock or the certificate of designation for the Series D Preferred Stock.

### Dividends

Holders of Series D Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series D Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

### Redemption

We are not obligated to redeem or repurchase any shares of Series D Preferred Stock. Shares of Series D Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

### Listing

There is no established public trading market for the Series D Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series D Preferred Stock on any national securities exchange or trading system.

### Fundamental Transactions

If, at any time that shares of Series D Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series D Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

### Debt Restriction

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



Series E Non-Voting Convertible Preferred Stock

Rank

The Series E Preferred Stock will rank:

senior to our common stock;  
senior to any class or series of capital stock created after the issuance of the Series E Preferred Stock;  
senior to the Series B Non-Voting Convertible Preferred Stock, the Series C-2 Non-Voting Convertible Preferred Stock and the Series C-3 Non-Voting Convertible Preferred Stock; and  
on parity with the Series D Non-Voting Convertible Preferred Stock.

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

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## Conversion

Each share of Series E Preferred Stock is convertible into 21.8667 shares of our common stock (subject to adjustment as provided in the certificates of designation for the Series E Preferred Stock) at a per share price of \$0.82 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series E Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding.

## Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series E Preferred Stock will receive a payment equal to \$49.20 per share of Series E Preferred Stock on parity with the payment of the liquidation preference due the Series D Preferred Stock, but before any proceeds are distributed to the holders of common stock, Series B Non-Voting Convertible Preferred Stock, the Series C-2 Non-Voting Convertible Preferred Stock and the Series C-3 Non-Voting Convertible Preferred Stock. After the payment of this preferential amount, holders of Series E Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock that participates with the common stock in such distributions.

## Voting Rights

Shares of Series E Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series E Preferred Stock will be required to amend the terms of the Series E Preferred Stock or the certificate of designation for the Series E Preferred Stock.

## Dividends

Holders of Series E Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series E Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

## Redemption

We are not obligated to redeem or repurchase any shares of Series E Preferred Stock. Shares of Series E Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

## Listing

There is no established public trading market for the Series E Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series E Preferred Stock on any national securities exchange or trading system.

## Fundamental Transactions

If, at any time that shares of Series E Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series E Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder

had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

### Debt Restriction

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

### Other Covenants

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

### Purchase Rights

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

### The Investor Warrants

An aggregate of 1,925,000 of the investor warrants were issued on March 30, 2010 pursuant to the terms of the Warrant Agreement between us and Onyx Stock Transfer, LLC (now VStock Transfer, LLC). The warrants are represented by warrant certificates, which detached from the units on May 13, 2010, and trade separately from the common stock. As of the date of this prospectus, an aggregate of 1,705,000 of the warrants are subject to the terms of the Warrant Agreement and may only be exercised or transferred in accordance with the terms thereof. A copy of the Warrant Agreement is filed as an exhibit to the registration statement of which this prospectus is a part. The warrants are exercisable at any time until March 24, 2015, at an exercise price of \$3.4375 per share. The exercise price and number of shares of common stock issuable on exercise of the warrants may be adjusted in certain circumstances, including but not limited to in the event of a stock split, stock dividend, recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for the issuances of common stock or securities convertible or exercisable into common stock at a price below their respective exercise prices.

### The Underwriter's Units

On March 30, 2010, we issued to the underwriter a warrant to purchase 2,406 Units. The Unit warrant has an exercise price of \$7.80 per Unit and may be exercised on a cashless basis. The warrants underlying the Unit warrant have an exercise price of \$3.4375 per share and may be exercised on a cashless basis. The Unit warrant, and the warrants underlying it, are currently exercisable and expire on March 24, 2015. The exercise price and number of shares of securities issuable on exercise of the Unit warrant and the warrants may be adjusted in certain circumstances, including but not limited to in the event of a stock split, stock dividend, recapitalization, reorganization, merger or consolidation. However, neither will be adjusted for the issuances of common stock or securities convertible or exercisable into common stock at a price below their respective exercise prices. The Unit warrant is not redeemable by us. The Unit warrant and the 2,406 Units (including the shares of common stock and warrants underlying the Units) were deemed compensation by the Financial Industry Regulatory Authority ("FINRA") and were therefore subject to a 180-day lock-up from the date of issuance pursuant to Rule 5110(g)(1) of FINRA.

Transfer Agent and Registrar

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

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

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

## Principal Stockholders

The following table shows the number of shares of our common stock beneficially owned as of December 31, 2014 by:

each person known by us to own beneficially more than 5% of the outstanding shares of our common stock;

each director and nominee for director;

each of our executive officers named in the Summary Compensation Table below (the “Named Executive Officers”); and

all of our current directors and executive officers as a group.

This table is based upon the information supplied by our Named Executive Officers, directors and principal stockholders and from Schedules 13D and 13G filed with the SEC. Except as indicated in footnotes to this table, the persons named in this table have sole voting and investment power with respect to all shares of common stock shown, and their address is c/o CorMedix Inc., 745 Route 202-206, Suite 303, Bridgewater, New Jersey 08807. As of December 31, 2014, we had 22,461,668 shares of common stock outstanding. Beneficial ownership in each case also includes shares issuable upon exercise of outstanding options that can be exercised within 60 days after December 31, 2014 for purposes of computing the percentage of common stock owned by the person named. Options owned by a person are not included for purposes of computing the percentage owned by any other person.

Name and Address of Beneficial Owner	Common Stock Beneficially Owned (1)	
	Shares	%
<b>5% or Greater Stockholders:</b>		
Kingsbrook Partners LP (2)	1,212,955	5.1
Elliott Associates, L.P. (3)	3,004,085	9.9
<b>Directors and Named Executive Officers:</b>		
Randy Milby (4)	1,367,541	5.8
Matthew P. Duffy (5)	520,723	2.3
Steve Lefkowitz (6)	998,712	4.3
Antony E. Pfaffle, M.D.(7)	751,725	3.2
Michael W. George(8)	45,000	*
Cora Tellez (9)	98,386	*
Taunia Markvicka (10)	10,000	*
Harry O’Grady (11)	25,000	*
All executive officers and directors as a group (8 persons) (12)	2,484,097	10.0

\*Less than 1%

(1)Based upon 22,461,668 shares of our common stock outstanding on December 31, 2014 and, with respect to each individual holder, rights to acquire our common stock exercisable within 60 days of December 31, 2014.



- (2) Due to the Ownership Limitation (as defined below), Kingsbrook Partners LP (“Kingsbrook”) may be deemed the beneficial owner of 1,212,955 shares of our common stock through securities held by it and by Kingsbrook Opportunities Master Fund LP (the “Fund”), for which Kingsbrook serves as the investment manager. Notwithstanding the above, Kingsbrook beneficially holds: (i) March 2014 warrants held by the Fund exercisable for 518,000 shares of our common stock, (ii) May 2013 warrants held by the Fund exercisable for 467,779 shares of our common stock, (iii) October 2013 warrants held by the Fund exercisable for 750,000 shares of our common stock, and (iv) 2,817 shares of our Series E non-voting convertible preferred stock held by the Fund convertible into 61,598 shares of our common stock (the March 2014 warrants, the May 2013 warrants, the October 2013 warrants and the Series E preferred stock shall collectively be referred to herein as the “Convertible Securities”). However, in accordance with Rule 13d-4 under the Exchange Act, the number of shares of our common stock into which the Convertible Securities are convertible or exercisable, as applicable, are limited pursuant to the terms of the Convertible Securities to that number of shares of our common stock which would result in Kingsbrook having aggregate beneficial ownership of, with the respect to the March 2014 warrants, 4.99% of the total issued and outstanding shares of our common stock, and with respect to the May 2013 warrants, the October 2013 warrants and the Series E preferred stock, 9.99% of the total issued and outstanding shares of our common stock (the "Ownership Limitation"). Kingsbrook disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Convertible Securities if such conversion or exercise would cause Kingsbrook’s aggregate beneficial ownership to exceed or remain above the applicable Ownership Limitation (as is currently the case). Therefore, Kingsbrook disclaims beneficial ownership of any of our common stock other than 1,212,955 shares, issuable upon any conversion or exercise of the May 2013 warrants, the October 2013 warrants and the Series E preferred stock. The business address of Kingsbrook is 689 Fifth Avenue, 12th Floor, New York, New York 10022. Based solely on information contained in a Schedule 13G filed with the SEC on March 25, 2014 by Kingsbrook Partners and other information known to us.
- (3) Due to the Ownership Limitation (as defined below), Elliott Associates, L.P. (“Elliott Associates”) may be deemed the beneficial owner of 3,004,085 shares of our common stock through securities held by it and by Manchester Securities Corp., a wholly-owned subsidiary of Elliott Associates (“Manchester”), and Elliott International, L.P., a wholly-owned subsidiary of Elliott Associates (“Elliott International”). Notwithstanding the above, Elliott Associates beneficially holds: (i) 781,440 shares of our common stock held by Manchester, (ii) 2010 warrants held by Manchester exercisable for 390,720 shares of our common stock, (iii) 2012 warrants exercisable for 1,000,000 shares of our common stock, (iv) May 2013 warrants exercisable for 500,000 shares of our common stock, (v) 52,500 shares of our Series C-2 non-voting convertible preferred stock convertible into 525,000 shares of our common stock, (vi) October 2013 warrants exercisable for 262,500 shares of our common stock, (vii) 97,500 shares of our Series C-2 non-voting convertible preferred stock held by Elliott International convertible into 975,000 shares of our common stock, (viii) October 2013 warrants held by Elliott International exercisable for 487,500 shares of our common stock, (ix) 73,962 shares of our Series D non-voting convertible preferred stock held by Manchester convertible into 1,479,240 shares of our common stock, and (x) 89,623 shares of our Series E non-voting convertible preferred stock held by Manchester convertible into 1,959,759 shares of our common stock (the 2012 warrants, the May 2013 warrants and the October 2013 warrants shall collectively be referred to herein as the “Convertible Securities”). However, in accordance with Rule 13d-4 under the Exchange Act, the number of shares of our common stock into which the Convertible Securities are convertible or exercisable, as applicable, are limited pursuant to the terms of the Convertible Securities to that number of shares of our common stock which would result in Elliott Associates having aggregate beneficial ownership of (a) with respect to the 2012 warrants, 4.999% of the total issued and outstanding shares of our common stock, and (b) with respect to the May 2013 warrants, the October 2013 warrants, the Series C-2 preferred stock, the Series D preferred stock and the Series E preferred stock, 9.99% of the total issued and outstanding shares of our common stock (the "Ownership Limitation"). Elliott Associates disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Convertible Securities if such conversion or exercise would cause Elliott Associates’ aggregate beneficial ownership to exceed or remain above the applicable Ownership Limitation (as is



currently the case). Therefore, Elliott Associates disclaims beneficial ownership of any of our common stock issuable upon any conversion or exercise of the 2012 warrants, and any shares of our common stock, other than 2,222,105 shares, issuable upon any conversion or exercise of the May 2013 warrants, the October 2013 warrants, the Series C-2 preferred stock, the Series D preferred stock and the Series E preferred stock. The business address of Elliott Associates is 40 West 57th Street, 30th Floor, New York, New York 10019. Based solely on information contained in a Schedule 13G/A filed with the SEC on February 14, 2014 by Elliott Associates and other information known to us.

- (4) Consists of (i) 46,298 shares of common stock held by Mr. Milby, (ii) 196,243 shares of our common stock held by MW Bridges LLC, of which Mr. Milby is Managing Partner, (iii) 687,500 shares of our common stock issuable upon exercise of stock options, (iii) 62,500 shares of our common stock issuable upon exercise of 2012 warrants held by MW Bridges LLC, (iv) 237,000 shares of our common stock issuable upon conversion of 23,700 shares of our Series C-3 non-voting convertible preferred stock, (v) 13,000 shares of our common stock issuable upon conversion of 1,300 shares of our Series C-3 non-voting convertible preferred stock held by MW Bridges LLC, (vi) 118,500 shares of our common stock issuable upon exercise of 2014 warrants, and (vii) 6,500 shares of our common stock issuable upon exercise of 2014 warrants held by MW Bridges LLC. The 2012 warrants identified in clause (iii) above prohibit conversion or exercise if after such conversion or exercise Mr. Milby and his affiliates would beneficially own more than 4.9% of our outstanding common stock, and the Series C-3 preferred stock and 2014 warrants identified in clauses (iv) through (vii) above prohibit conversion or exercise if after such conversion or exercise Mr. Milby and his affiliates would beneficially own more than 9.9% of our outstanding common stock (together with the limitation imposed upon the conversion of the 2012 warrants, the “Milby Ownership Limitation”). In accordance with Rule 13d-4 under the Exchange Act, Mr. Milby disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Milby Convertible Securities if such conversion or exercise would cause Mr. Milby’s aggregate beneficial ownership to exceed or remain above the Milby Ownership Limitation.
- (5) Consists of (i) 38,339 shares of our common stock, (ii) 452,500 shares of our common stock issuable upon exercise of stock options, (iii) 25,000 shares of our common stock issuable upon exercise of 2012 warrants, and (iv) 4,884 shares of our common stock issuable upon conversion of 2010 warrants. The warrants identified in clause (iii) above prohibit conversion or exercise if after such conversion or exercise Mr. Duffy and his affiliates would beneficially own more than 4.9% of our outstanding common stock.
- (6) Consists of (i) 124,035 shares of our common stock held by Mr. Lefkowitz individually, (ii) 10,000 shares of our common stock held by Mr. Lefkowitz’s spouse, (iii) 174,741 shares of our common stock held by Wade Capital Corporation, an entity for which Mr. Lefkowitz has voting and investment control, (iv) 545,000 shares of our common stock issuable upon exercise of stock options, (v) 45,000 shares of our common stock issuable upon conversion of 4,500 shares of our Series C-3 convertible preferred stock held by Mr. Lefkowitz individually, (vi) 30,000 shares of our common stock issuable upon conversion of 3,000 shares of our Series C-3 convertible preferred stock held by Wade Capital Corporation, (vii) 22,500 shares of our common stock issuable upon exercise of 2014 warrants held by Mr. Lefkowitz individually, (viii) 15,000 shares of our common stock issuable upon exercise of 2014 warrants held by Wade Capital Corporation, and (ix) 32,436 shares of our common stock issuable upon exercise of 2010 warrants held by Mr. Lefkowitz individually. The number of shares of our common stock into which the Series C-3 preferred stock and 2014 warrants are convertible or exercisable, as applicable, are limited pursuant to their terms to that number of shares of our common stock which would result in Mr. Lefkowitz having aggregate beneficial ownership of 9.99% of the total issued and outstanding shares of our common stock (the “Lefkowitz Ownership Limitation”). In accordance with Rule 13d-4 under the Exchange Act, Mr. Lefkowitz disclaims beneficial ownership of any and all shares of our common stock issuable upon any conversion or exercise of the Lefkowitz Convertible Securities if such conversion or exercise would cause Mr. Lefkowitz’s aggregate beneficial ownership to exceed or remain above the Lefkowitz Ownership Limitation.



- (7) Consists of (i) 16,725 shares of our common stock, and (ii) 735,000 shares of our common stock issuable upon exercise of stock options.
- (8) Consists of 45,000 shares of our common stock issuable upon exercise of stock options.
- (9) Consists of (i) 63,386 shares of our common stock, (ii) 10,000 shares of our common stock issuable upon exercise of stock options, and (iii) 25,000 shares of our common stock issuable upon exercise of 2014 warrants.
- (10) Consists of 10,000 shares of our common stock issuable upon the exercise of stock options.
- (11) Consists of 25,000 shares of our common stock issuable upon the exercise of stock options.
- (12) Consists of (i) 1,368,808 shares of our common stock, (ii) 2,210,000 shares of our common stock issuable upon exercise of stock options, (iii) 825,000 shares of our common stock issuable upon conversion of Series C-3 convertible preferred stock, and (iv) 625,420 shares of our common stock issuable upon exercise of warrants, as referenced in footnotes 4 through 8. However, pursuant to the various ownership limitations discussed in footnotes 4, 6 and 7, in accordance with Rule 13d-4 under the Exchange Act, an aggregate of 571,207 shares of our common stock issuable upon conversion or exercise of certain shares of Series C-3 preferred stock and warrants to purchase common stock are excluded from the table.

## EXECUTIVE COMPENSATION AND DIRECTOR COMPENSATION

## DIRECTOR COMPENSATION

## Director Compensation in Fiscal 2014

The following table shows the compensation earned by each non-employee director of our company for the year ended December 31, 2014.

Name	Fees		Option	Total
	Earned		Awards (1)	
	(\$)		(\$)	(\$)
Cora Tellez	32,637	(3)	44,640	77,277
Michael W. George	30,075	(3)	83,745	113,820
Taunia Markvicka	28,073		44,640	72,713
Gary A. Gelbfish, M.D.(4)	20,100		339,250	359,350
Antony E. Pfaffle, M.D.(5)	-		-	-
Steven Lefkowitz (6)	-		-	-
Matthew P. Duffy	37,818		265,500	303,318

(1) The amounts included in this column are the dollar amounts representing the full grant date fair value of each stock option award calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the directors upon option exercise. For information on the valuation assumptions used in calculating this amount, see Note 2 to our audited financial statements included in this Annual Report on Form 10-K.

(2) As of December 31, 2014, the number of shares underlying options held by each non-employee director was as follows: 30,000 shares for Ms. Tellez, 45,000 shares for Mr. George, 30,000 shares for Ms. Markvicka, no shares for Dr. Gelbfish; and 465,000 shares for Mr. Duffy. For information on options held by Dr. Pfaffle and Mr. Lefkowitz, see the “Outstanding Equity Awards at Fiscal Year End” table below.

(3) Includes fees of \$15,786 for Ms. Tellez and \$6,040 for Mr. George that were deferred. See “Directors Compensation Plan” below for a description of the deferral plan pursuant to which the deferrals were made.

(4) Dr. Gelbfish resigned on June 13, 2014.

(5) On July 21, 2014, Antony Pfaffle was appointed our Chief Scientific Officer. All compensation paid to Dr. Pfaffle as an officer and a director is set forth in the “Summary Compensation Table” below.

(6) On August 15, 2013, Steven Lefkowitz was appointed our Interim Chief Financial Officer, which position he resigned on July 20, 2014. All compensation paid to Mr. Lefkowitz as an officer and a director is set forth in the “Summary Compensation Table” below.

## Directors Compensation Plan

The following director cash and equity compensation policies were in effect prior to October 20, 2014. Non-employee directors are entitled to receive the following cash compensation: (i) a \$20,000 annual retainer,

except that the Chairman of the Board receives \$30,000, (ii) \$5,000 annually for service on the Audit Committee, except that the Chairman of the Audit Committee receives \$12,000, (iii) \$4,000 annually for service on the Nominating and Corporate Governance Committee, except that the Chairman of the Nominating and Corporate Governance Committee receives \$5,000, (iv) \$4,000 annually for service on the Compensation Committee, except that the Chairman of the Compensation Committee receives \$5,000, (v) \$1,000 for each in-person meeting of the Board attended, and (vi) \$500 for each telephonic meeting of the Board attended. Employee directors do not receive any compensation for their services on the Board. Non-employee directors are entitled to receive: (i) an annual grant to each non-employee director at the first Board meeting of the calendar year of an option to purchase 30,000 shares of our common stock at an exercise price equal to the closing price of the common stock on the grant date, which option vests on the first anniversary of the grant date; and (ii) a one-time grant to each new non-employee director in connection with his or her initial election to the Board of an option to purchase 30,000 shares of our common stock at an exercise price equal to the closing price of the common stock on the grant date, which option vests in equal installments on each of the grant date, the first anniversary of the grant date and the second anniversary of the grant date.

Effective October 20, 2014, we adopted the following cash and equity compensation policies for non-employee directors. Each director receives an annual cash fee of \$25,000, the Board Chair receives an additional \$5,000 and committee Chairs receive an additional \$5,000. Upon a director's first election to the Board, he or she will be granted an option to purchase 50,000 shares of our common stock. After election to the Board, in the next calendar year after his or her election and annually thereafter, each director will be granted an option to purchase 50,000 shares of our common stock for his or her service on the Board. Vesting for all option grants will be 25% on the second anniversary of grant and an additional 25% on the third, fourth and fifth anniversaries of grant, provided the director remains a member of the Board on the respective anniversary date.

In July 2014, we adopted a Deferred Compensation Plan for Directors, pursuant to which our non-employee directors may defer all of their cash director fees. Any cash fees due a participating director will be converted into a number of shares of our common stock by dividing the dollar amount of fees payable by the closing price of our common stock on the date such fees would be payable, and the director's unfunded account would be credited with the shares. The shares that accumulate in a director's account will be paid to the director on the tenth business day in January following the year in which the director's service terminates for whatever reason, other than death, in which case the account will be paid within 30 days of the date of death to the designated beneficiaries, if any. If there are no designated beneficiaries, the account will be paid out the same as with any other termination of service. In the event of a change in control of our company, the director would receive cash in an amount equal to the number of shares in the account multiplied by the fair market value of our common stock on the change in control date, and the payment would be accelerated to five business days after the effective date of the change in control.

## EXECUTIVE COMPENSATION

### Compensation Objectives and Philosophy

The Compensation Committee is responsible for reviewing and approving the compensation payable to our named executive officers and other key employees. As part of such process, the Compensation Committee seeks to accomplish the following objectives with respect to our executive compensation programs:

motivate, recruit and retain executives capable of meeting our strategic objectives;

provide incentives to ensure superior executive performance and successful financial results for our company; and

align the interests of the named executive officers with the long-term interests of our stockholders.

The Compensation Committee seeks to achieve these objectives by:

establishing a compensation structure that is both market competitive and internally fair;

linking a substantial portion of compensation to our achievement of financial objectives and the individual's contribution to the attainment of those objectives;

providing upward leverage for overachievement of goals; and

providing long-term equity-based incentives.

In order to achieve the above goals, our total compensation package includes base salary and annual bonus, all paid in cash, as well as long-term compensation in the form of stock options and/or restricted stock. We believe that appropriately balancing the total compensation package is necessary in order to provide market-competitive

compensation.

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## Setting Executive Compensation

The Compensation Committee oversees the design, development and implementation of the compensation program for the Chief Executive Officer and the other named executive officers. The Compensation Committee evaluates the performance of the Chief Executive Officer and determines the Chief Executive Officer's compensation in light of the goals and objectives of the compensation program. The Chief Executive Officer and the Compensation Committee together assess the performance of the other named executive officers and determine their compensation, based on initial recommendations from the Chief Executive Officer. Our Chief Executive Officer provided the Compensation Committee with a detailed review of the performance of the other named executive officers and made recommendations to the Compensation Committee with respect to the compensation packages for those officers for 2014.

The other named executive officers do not play a role in their own compensation determination, other than discussing individual performance objectives and results with the Chief Executive Officer.

We did not use the services of any compensation consultant in matters affecting the compensation of named executive officers or directors during 2013 or 2014. In the future, we, or the Compensation Committee, may engage or seek the advice of a compensation consultant.

The Compensation Committee has structured our annual and long-term incentive-based cash and non-cash executive compensation to motivate executives to achieve the business goals set by the Board and reward the executives for achieving such goals. At the end of the year, the Compensation Committee reviews the performance of each named executive officer in achieving the established objectives. These results are included with the overall performance review provided by the Chief Executive Officer, after which the Compensation Committee votes upon any recommendations for salary adjustments, stock option grants and cash incentives. The Chief Executive Officer then executes the actions approved by the Compensation Committee with respect to such matters.

## Components of Compensation

The key components of our executive compensation package are cash compensation (salary and annual bonuses), long-term equity incentive awards and change in control and other severance agreements. These components are administered with the goal of providing total compensation that recognizes meaningful differences in individual performance, is competitive, varies the opportunity based on individual and corporate performance, and is valued by our named executive officers.

## Base Salary

It is the Compensation Committee's objective to set a competitive rate of annual base salary for each named executive officer. The Compensation Committee believes competitive base salaries are necessary to attract and retain top quality executives, since it is common practice for public companies to provide their named executive officers with a guaranteed annual component of compensation that is not subject to performance risk. The Compensation Committee, on its own or with outside consultants, may establish salary ranges for the named executive officers, with minimum to maximum opportunities that cover the normal range of market variability. The actual base salary for each named executive officer is then derived from those salary ranges based on his responsibility, tenure and past performance and market comparability. Annual base salaries for the named executive officers are reviewed and approved by the Compensation Committee in the first quarter following the end of the previous performance year. Changes in base salary are based on the scope of an individual's current job responsibilities, individual performance in the previous performance year, target pay position relative to the peer group, and our salary budget guidelines. The Compensation Committee reviews established goals and objectives, and determines an individual's achievement of those goals and



objectives and considers the recommendations provided by the Chief Executive Officer to assist it in determining appropriate salaries for the named executive officers other than the Chief Executive Officer. For any given performance year, actual salary increases may range from 0% to 10% of the salary guidelines based on individual performance. This broad range allows for meaningful differentiation on a pay for performance basis.

The base salary information for our named executive officers for 2014 is set forth in the Summary Compensation Table below. In May 2014, we entered into an employment agreement with our Chief Executive Officer, Randy Milby, and in July 2014, we entered into a letter agreement with each of Dr. Anthony Pffafle, our Chief Scientific Officer, and Harry O'Grady, our Chief Financial Officer, that provides terms of employment. These agreements provide for a salary for each officer and are described under the caption "Employment Agreements and Arrangements."

#### Annual Bonuses

As part of their compensation package, our named executive officers generally have the opportunity to earn annual bonuses under our Short Term Incentive Plan. Annual bonuses are designed to reward superior executive performance while reinforcing our short-term strategic operating goals. The Compensation Committee establishes each year a target award for each named executive officer based on a percentage of base salary, and based on any applicable terms in any individual employment agreements. Annual bonus targets as a percentage of salary increase with executive rank so that for the more senior executives, a greater proportion of their total cash compensation is contingent upon annual performance.

At the beginning of the performance year, each named executive officer, in conjunction with the Chief Executive Officer, establishes annual goals and objectives. Actual bonus awards are based on an assessment against the pre-established goals for each named executive officer's individual performance, the performance of the business function for which he is responsible, and/or our overall performance for the year. For any given performance year, proposed annual bonuses may range from 0% to 100% of target, or higher under certain circumstances, based on corporate and individual performance. Corporate and individual performance has a significant impact on the annual bonus amounts because the Compensation Committee believes it is a precise measure of how the named executive officer contributed to business results.

As a result of our financial condition, our Interim Chief Executive Officer and the Compensation Committee determined not to grant bonuses to the named executive officers for 2013 or 2014.

#### Long-Term Incentive Equity Awards

We believe that long-term performance is achieved through an ownership culture that encourages high performance by our named executive officers through the use of stock-based awards. Our 2006 Stock Plan and 2013 Stock Plan were each established to provide our employees, including our named executive officers, with incentives to help align employees' interests with the interests of our stockholders. Effective upon the approval by our stockholders of our 2013 Stock Plan, we are no longer able to issue any award under the 2006 Stock Plan. The Compensation Committee believes that the use of stock-based awards offers the best approach to achieving our compensation goals. We have historically elected to use stock options as the primary long-term equity incentive vehicle; however, the Compensation Committee has used restricted stock in the past and may in the future utilize restricted stock as part of our long-term incentive program. We have selected the Black-Scholes method of valuation for share-based compensation. Due to the early stage of our business and our desire to preserve cash, we expect to provide a greater portion of total compensation to our named executive officers through stock options and restricted stock grants than through cash-based compensation. The Compensation Committee generally oversees the administration of our 2006 Stock Plan.

#### Stock Options

Our 2013 Stock Plan (and formerly our 2006 Stock Plan) authorizes us to grant options to purchase shares of common stock to our employees, directors and consultants.

The Compensation Committee reviews and approves stock option awards to named executive officers based upon a review of competitive compensation data, its assessment of individual performance, a review of each named executive officer's existing long-term incentives, and retention considerations. Periodic stock option grants are made at the discretion of the Compensation Committee to eligible employees and, in appropriate circumstances, the Compensation Committee considers the recommendations of Randy Milby, our Chief Executive Officer.

Stock options granted to employees have an exercise price equal to the fair market value of our common stock on the day of grant, typically vest over a time or upon the achievement of certain performance-based milestones and are based upon continued employment, and generally expire 10 years after the date of grant. The fair value of the options granted to the named executive officers in the Summary Compensation Table is determined in accordance with the Black-Scholes method of valuation for share-based compensation. Incentive stock options also include certain other terms necessary to ensure compliance with the Internal Revenue Code of 1986.

We expect to continue to use stock options as a long-term incentive vehicle because:

Stock options align the interests of our named executive officers with those of our stockholders, supporting a pay-for performance culture, foster employee stock ownership, and focus the management team on increasing value for our stockholders.

Stock options are performance-based. All of the value received by the recipient of a stock option is based on the growth of the stock price. In addition, stock options can be issued with vesting based on the achievement of specified milestones.

Stock options help to provide balance to the overall executive compensation program as base salary and annual bonuses focus on short-term compensation, while the vesting of stock options increases stockholder value over the longer term.

The vesting period of stock options encourages executive retention and the preservation of stockholder value. In determining the number of stock options to be granted to our named executive officers, we take into account the individual's position, scope of responsibility, ability to affect profits and stockholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual named executive officer's total compensation.

Restricted Stock. Our 2013 Stock Plan (and formerly our 2006 Stock Plan) authorizes us to grant restricted stock. No restricted stock grants were awarded during 2013 or 2014. In order to implement our long-term incentive goals, we may grant shares of restricted stock in the future.

#### Restricted Stock

Our 2013 Stock Plan (and formerly our 2006 Stock Plan) authorizes us to grant restricted stock. No restricted stock grants were awarded during 2013 or 2014. In order to implement our long-term incentive goals, we may grant shares of restricted stock in the future.

#### Executive Benefits and Perquisites

Our named executive officers, some of whom may be parties to employment or consulting agreements, will continue to be parties to such agreements in their current form until the expiration or termination of the employment or consulting agreement or until such time as the Compensation Committee determines in its discretion that revisions to such agreements are advisable. In addition, consistent with our compensation philosophy, we intend to continue to maintain our current benefits for our named executive officers, including medical, dental and life insurance and the ability to contribute to a 401(k) plan; however, the Compensation Committee in its discretion may revise, amend or add to the officer's executive benefits if it deems it advisable. We believe these benefits are currently comparable to benefit levels for comparable companies.

#### Employment Agreements and Arrangements

On May 9, 2014, we entered into an employment agreement, effective March 31, 2014, with our Chief Executive Officer, Randy Milby. Unless renewed pursuant to the terms thereof, the agreement will expire on March 31, 2016. Pursuant to the agreement, we must use best efforts to cause Mr. Milby to be elected as a member of our Board of Directors and we must include him in the management slate for election as a director at every stockholders meeting during the term of the agreement at which his term as a director would otherwise expire. Mr. Milby will not receive additional compensation for his services as a member of our Board of Directors.



In exchange for his service as our Chief Executive Officer, Mr. Milby will receive an annual base salary of \$300,000.00, up to 50% of which may be paid in the form of unregistered common stock at the discretion of Mr. Milby and subject to specified limitations. Mr. Milby will be eligible for an annual target bonus, the cash portion of which may equal up to 100% of his base salary then in effect, as determined by our Board or compensation committee. In determining such bonus, our Board or compensation committee will take into consideration the achievement of specified company objectives, predetermined by the Board, and specified personal objectives, predetermined by the Board and Mr. Milby. Mr. Milby's annual bonus, if any, will be paid in cash or a combination of cash and equity, provided that the equity portion will make up no more than 50% of the value of such annual bonus. Mr. Milby is eligible to participate in all employee benefits available to our senior executives from time-to-time, and we must designate Mr. Milby as a named insured on our directors' and officers' liability insurance policy. Pursuant to the agreement, Mr. Milby is eligible for up to four weeks of paid vacation per year and may be reimbursed for specified business-related expenses.

If we terminate Mr. Milby's employment for Cause (as defined below), Mr. Milby will be entitled to receive only the accrued compensation due to him as of the date of such termination, all shares of restricted stock then held by him will be forfeited to us as of such date, and all unexercised options to purchase shares of our capital stock, whether or not vested, will immediately terminate. If Mr. Milby resigns for other than Good Reason, he will be entitled only to payment of his accrued compensation as of such date. If we terminate Mr. Milby's employment other than for Cause, death or disability, or if Mr. Milby resigns for Good Reason (as each such term is defined below), Mr. Milby will continue to receive his base salary and benefits for a period of 12 months following the effective date of the termination of his employment, or, in the case of benefits, until such time as he receives equivalent coverage and benefits under plans and programs of a subsequent employer. All shares of restricted stock and all unvested options to purchase shares of our capital stock then held by Mr. Milby will be accelerated and deemed to have vested as of the effective date of the termination of his employment. To the extent any of the aforementioned benefits cannot be provided to former employees, we will pay Mr. Milby a lump-sum payment in the amount necessary to allow Mr. Milby to purchase the equivalent benefits. Upon a Change of Control of our company (as defined in the agreement), all shares of our company's restricted stock and all unvested options to purchase shares of our capital stock then held by Mr. Milby will be accelerated and deemed to have vested as of the date of such Change of Control.

For purposes of the agreement, "Cause" is defined as: (a) the willful failure, disregard or refusal by Mr. Milby to perform his material duties or obligations under the agreement; (b) any willful, intentional, or grossly negligent act by Mr. Milby having the effect of materially injuring (whether financial or otherwise and as determined reasonably and in good-faith by a majority of the members of our Board of Directors) the business or reputation of our company or any of our affiliates (provided, however, that this provision will not apply to any company affiliate that is engaged in a business competitive with our company's business); (c) Mr. Milby's conviction of any felony involving moral turpitude (including entry of a guilty or nolo contendere plea); (d) a good faith determination by the Board and/or any government representative or agency that Mr. Milby is a "bad actor" as defined by 17 CFR 230.506(a); (e) the good faith determination by our Board of Directors, after a reasonable and good-faith investigation by our company following any allegation by another employee of our company, that Mr. Milby engaged in some form of harassment prohibited by law (including, without limitation, harassment on the basis of age, sex, or race) unless Mr. Milby's actions were specifically directed by the Board; (f) any material misappropriation or embezzlement by Mr. Milby of the property of our company or our affiliates (whether or not a misdemeanor or felony); or (g) any breach by Mr. Milby of any material provision of the agreement that is not cured by him to our reasonable satisfaction within 30 days after written notice thereof.

For purposes of the agreement, "Good Reason" is defined as: (a) any material breach of the agreement by our company if Mr. Milby has provided us with written notice of the breach within 90 days of the breach and we have not cured such breach within 30 days from such notice; (b) without Mr. Milby's express written consent, we materially reduce his duties, responsibilities, or authority as Chief Executive Officer including, without limitation, a change in the line

of reporting between him and our Board of Directors, that causes his position with us to become of less responsibility or authority than his position as of the effective date of the agreement; (c) a relocation of our principal place of business outside the New York metropolitan area or to a location more than 50 miles from the immediately preceding location without Mr. Milby's written consent; (d) a material reduction in his annual base salary unless all officers and/or members of our executive management team experience an equal or greater percentage reduction in annual base salary and/or total compensation; or (e) our failure to include Mr. Milby in our management's slate for election to the Board.

On July 21, 2014, we entered into a letter agreement with each of our Chief Scientific Officer, Dr. Antony Pfaffle, and our Chief Financial Officer, Harry O'Grady. Pursuant to their respective agreements, we agreed to pay a base salary of \$230,000 to Mr. O'Grady and \$200,000 to Dr. Pfaffle. Additionally, we agreed to review each of Mr. O'Grady and Dr. Pfaffle's (each, an "Executive") salary in early 2015 with the goal of achieving market value for a CFO or CSO, respectively, with such Executive's experience operating in a company of similar size and with revenue similar to ours, but in any event not less than \$230,000 and \$200,000, respectively. Mr. O'Grady was eligible to participate in the Short Term Incentive Plan (STIP) beginning January 1, 2015, with a target award opportunity equal to 40% of his base salary. Dr. Pfaffle was eligible to participate in the STIP beginning on his employment date. His 2015 target award opportunity is equal to 30% of his base salary.

Upon a change of control of our company, as defined in each Executive's employment agreement, all shares of our capital stock held by such Executive that are subject to vesting ("Restricted Stock") and all options to purchase shares of capital stock of the Company ("Options") will be accelerated and deemed to have vested as of the date of the change of control.

If the Executive's employment is terminated, we will pay him his base salary and benefits otherwise payable to him through the last day of his actual employment, including any earned but unpaid bonuses. In addition, if the Executive's employment is terminated as a result of his death or disability, we will pay him or his estate, as applicable (i) his base salary for 180 days after the termination of his employment, and (ii) additional benefits, if any, as may be provided under our applicable employee benefit plans, programs and arrangements. All shares of Restricted Stock and Options that are scheduled to vest on or before the next succeeding anniversary of the date of his employment agreement will be accelerated and deemed to have vested as of the termination date. All other shares of Restricted Stock and Options that have not vested or been deemed to have vested will be forfeited.

If we terminate the Executive's employment without "cause" (as defined in the Executive's agreement) or the Executive terminates his employment for "good reason" (as defined in the agreement), then we will (i) pay the Executive his then-current salary for 12 months, and (ii) provide the Executive such other benefits, if any, as may be provided under applicable employee benefit plans, programs and arrangements of the Company. In addition, any all Restricted Shares and unvested Options will be accelerated and deemed to have vested as of the termination date.

## Summary Compensation Table

The following table sets forth information with respect to compensation earned by our named executive officers in the years ended December 31, 2014 and 2013:

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (1) (\$)	All Other Compensation (\$)	Total (\$)
Randy Milby (2) Chief Executive Officer	2014	287,500	-	147,500	-	435,000
	2013	223,500	-	368,500	-	592,000
Steven W. Lefkowitz (3) Interim Chief Financial Officer	2014	60,000	-	339,250	26,483 (4)	425,733
	2013	30,000	-	88,440	39,650 (4)	158,090
Antony E. Pfaffle (5) Acting Chief Scientific Officer	2014	219,800	30,000	356,550	16,928 (4)	623,728
	2013	120,000	-	154,770	37,500 (4)	312,270
Harry O'Grady (6) Chief Financial Officer	2014	103,795	-	111,000	-	214,795
	2013	-	-	-	-	-

(1) The amounts included in this column are the dollar amounts representing the full grant date fair value of each stock option award calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the named executive officers upon option exercise.

(2) Mr. Milby became our Chief Executive Officer on January 1, 2013, but was a consultant until becoming an employee on April 1, 2013. The amount of salary reported for 2013 includes \$36,000 paid in consulting fees to MW Bridges LLC, of which Mr. Milby is Managing Partner.

(3) Mr. Lefkowitz served as our Interim Chief Financial Officer from August 15, 2013 until July 20, 2014.

(4) Consists of director fees.

(5) Dr. Pfaffle became our Acting Chief Scientific Officer on January 1, 2013 and our Chief Scientific Officer effective July 1, 2014.

(6) Mr. O'Grady became our Chief Financial Officer on July 21, 2014.



Outstanding Equity Awards at Fiscal Year-End 2013

The following table contains certain information concerning unexercised options for the Named Executive Officers as of December 31, 2014.

Name	Number of Shares Underlying Unexercised Options (#) – Exercisable	Number of Shares Underlying Unexercised Options (#) - Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Randy Milby	50,000	-	0.29	5/14/2022
	100,000	-	0.68	12/05/2022
	437,500	-	0.90	3/20/2023
	100,000	-	2.02	1/09/2024
Steven W. Lefkowitz	30,000	-	1.10	8/11/2021
	30,000			