

CorMedix Inc.
Form S-3/A
March 28, 2013

As filed with the Securities and Exchange Commission on March 28, 2013

Registration Statement No. 333-185970

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2 to

FORM S-3

REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

CORMEDIX INC.

(Exact name of registrant as specified in its charter)

Delaware

20-5894890

(State or other jurisdiction

(I.R.S. Employer

of incorporation or organization) 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)

Copies to:

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

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. "

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

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

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

If this Form is a post-effective amendment filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. "

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

Accelerated filer

Non-accelerated filer (Do not check if smaller reporting company)

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.

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

Subject to completion, dated March 28, 2013

Prospectus

2,500,000

SHARES OF COMMON STOCK

This prospectus relates to the sale of an aggregate of 2,500,000 shares of our common stock, \$0.001 par value per share, issuable upon the exercise of convertible notes held by the selling stockholders identified in this prospectus, including their transferees, pledgees, donees or successors. The selling stockholders may sell the common stock from time to time in public transactions or in privately negotiated transactions, without limitation, through any means described in the section hereof entitled "Plan of Distribution", at market prices prevailing at the time of sale or at negotiated prices. The timing and amount of any sale are within the sole discretion of the selling stockholders. We will not receive any proceeds from the sale of shares registered under this prospectus.

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

Our common stock trades on the NYSE MKT under the trading symbol "CRMD." On March 27, 2013, the last reported sale price of our common stock was \$0.81 per share.

You should read carefully this prospectus and any prospectus supplement, including the information incorporated by reference herein and therein, before you invest. See “Where You Can Find More Information” 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 5 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 , 2013.

TABLE OF CONTENTS

| | |
|---|----|
| About This Prospectus | 1 |
| Prospectus Summary | 2 |
| Risk Factors | 5 |
| Special Note Regarding Forward-Looking Statements | 22 |
| Use of Proceeds | 23 |
| Selling Stockholders | 23 |
| Plan of Distribution | 30 |
| Certain Provisions of Delaware Law and of Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws | 32 |
| Legal Matters | 33 |
| Experts | 33 |
| Where You Can Find More Information | 33 |
| Incorporation of Documents by Reference | 33 |

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. Prospectus supplements may also add, update or change information contained or incorporated by reference in this prospectus. This prospectus, together with any prospectus supplement and the documents incorporated by reference into this prospectus and any prospectus supplement, includes all material information relating to this offering. You should carefully read this prospectus, any prospectus supplement, the information and documents incorporated herein and therein by reference and the additional information under the heading “Where You Can Find More Information” before making an investment decision.

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

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

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it might not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including “Risk Factors” beginning on page 5 and our financial statements and related notes thereto incorporated by reference herein, before making an investment decision.

Overview

We are a development stage pharmaceutical and medical device company that seeks to in-license, develop and commercialize therapeutic products for the treatment of cardiac and renal dysfunction, specifically in the dialysis and non-dialysis areas. As of the date of this prospectus, we have 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, that 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 candidate in development is Neutrolin for the prevention of catheter-related infections in the dialysis and non-dialysis markets, which we believe addresses a medical need and a potentially large market opportunity. 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 plan for use in hemodialysis catheters. There are approximately 780,000 hemodialysis patients in the United States and the European Union. We believe the patients undergoing hemodialysis using a tunneled central vein catheter will be our initial target market. We project 91,000 patients in the European Union and 104,000 patients in the United States. 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. 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 this 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. We also have successfully completed our stage 2 audit with TÜV SÜD which resulted in our receipt of the ISO 13485:2003 certification from TÜV SÜD on October 10, 2012. 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.

We anticipate receiving a CE Mark approval in the second quarter of 2013. If we obtain CE Mark approval in Europe, we intend to launch Neutrolin for the prevention of catheter-related bloodstream infections, or CRBI, and maintenance of catheter patency in hemodialysis patients in Europe during 2013. However, we cannot be assured of CE Mark approval of Neutrolin or the planned commercialization on that timeline or at all.

We are currently exploring the various methods of launching Neutrolin in Europe, whether through a distributorship or partnership arrangement, or otherwise, and plan to initially launch in Germany. To that end, on January 10, 2013, we entered into an Agreement for Work on Pharmaceutical Advertising with MKM Co-Pharma GmbH, or MKM, regarding Neutrolin, for which we anticipate receiving a CE Mark approval in Europe in the second quarter of 2013. Pursuant to the agreement, MKM hired a national sales manager, Joachim Petrak, to market Neutrolin in Germany according to a negotiated work plan. While the plan may be revised, it currently provides that the sales manager will market Neutrolin in three phases. In the first phase, from January to March 2013, the sales manager will visit hemodialysis centers and doctors to, among other things, provide them information and promotional materials. The sales manager will also produce a market review of our product, conduct test sales of Neutrolin in Germany, negotiate wholesaler relationships for initial orders of our product and determine sales projections for launching Neutrolin. In the second phase, from April to May 2013, assuming receipt of CE Mark approval, the sales manager will launch Neutrolin, generating sales on a best efforts basis, and supervise sales representatives. After that time, the sales manager will be responsible for growing Neutrolin sales and expanding the advertising plan. Additionally, to lead the commercialization of Neutrolin in the European Union, we have formed a European subsidiary, CorMedix Europe GmbH. Assuming the receipt of a CE Mark and the launch of Neutrolin, we intend to meet with the FDA to determine the pathway for U.S. approval of Neutrolin, which we expect will entail a Phase 3 trial.

Our other product candidate is CRMD004, which is the gel formulation of Neutrolin that we intend to develop for the prevention of catheter-related blood stream infections and maintenance of catheter patency in hemodialysis patients who are asymptomatic for catheter-related blood stream infections using both incident and prevalent catheters with any brand of central venous catheter. CRMD004 is in the pre-clinical stage. However, at this time, we intend to defer the development of CRMD004 until after we receive the CE Mark for Neutrolin in the European Union and have commenced the FDA regulatory approval process for Neutrolin.

During 2011, we completed a phase II study of CRMD001 (deferiprone) an oral formulation of the drug deferiprone which we in-licensed from Shiva Biomedical in 2006. The phase II study was designed for the prevention of Contrast-Induced Nephropathy, or CIN, which is a common and potentially serious complication arising from the use of iodinated contrast media used in X-ray procedures to identify the status of blood vessels in the heart. A total of 61 patients (32 deferiprone, 29 placebo) were enrolled in the study. A variety of biomarkers of kidney injury and function were measured. Clinical events and safety parameters, including Serious Adverse Events or SAEs were followed through day 90. Top-line results were reviewed and interpreted internally, by the principal investigator and by three external academic biomarker experts. In the placebo group, most of the kidney injury biomarkers increased after contrast administration, as expected. Deferiprone tended to reduce acute elevations of the injury biomarkers, particularly in the first 8 hours. Measures of glomerular filtration (serum cystatin C, serum creatinine and Estimated Glomerular Filtration Rate, or EGFR) unexpectedly trended in the opposite direction over the first 8 days, as there was little change in the placebo group and small decreases in renal function in the deferiprone group. Analysis of SAEs indicated no safety signal. Based upon these top-line results, along with the extensive review of our CIN intellectual property position, the review of biomarker expert opinions, and among other factors such as our current cash position, we decided against pursuing further development of CRMD001. On December 1, 2011 we issued a notice of termination to the Shiva Biomedical license agreement.

Recent Developments

On February 1, 2013, we received notice from the NYSE MKT LLC, or NYSE MKT, that it granted us an extension until April 15, 2013 to regain compliance with the continued listing standards of the NYSE MKT. The NYSE MKT is continuing our listing pursuant to the extension. The NYSE MKT had previously notified us on April 20, 2012 that we were not in compliance with Section 1003(a)(iv) of the NYSE MKT Company Guide in that we had sustained losses which are so substantial in relation to our overall operations or our existing financial resources, or our financial condition had become so impaired that it appeared questionable, in the opinion of the NYSE MKT, as to whether we will be able to continue operations and/or meet our obligations as they mature. We were afforded an opportunity to submit a plan of compliance to the NYSE MKT and, on May 17, 2012, we presented a plan to the NYSE MKT. On June 27, 2012, the NYSE MKT accepted our plan to regain compliance with its continued listing standards and granted us an extension until August 22, 2012. On September 21, 2012, the NYSE MKT granted us another extension until January 31, 2013 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 extension to April 15, 2013. Failure to make progress consistent with the plan or to regain compliance with continued listing standards by the end of the extension period could result in us being delisted from the NYSE MKT.

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On February 19, 2013, we sold to an existing institutional investor 761,429 shares of our newly created Series A Non-Voting Convertible preferred stock and a warrant to purchase up to 400,000 shares of our common stock for gross proceeds of \$533,000. The Series A shares and the warrant were sold together at a price of \$0.70 per share for each share of Series A stock.

Each share of Series A Stock is convertible into one share of our common stock at any time at the holder's option. However, the holder will be prohibited from converting Series A Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of our common stock then issued and outstanding. In the event of our liquidation, dissolution, or winding up, holders of the Series A Stock will receive a payment equal to \$0.001 per share of Series A Stock before any proceeds are distributed to the holders of common stock. Shares of the Series A Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors, and will rank:

- senior to all common stock;

- senior to any class or series of capital stock hereafter created specifically by its terms junior to the Series A Stock;

- on parity with our Series A Preferred Stock and any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series A Stock; and

- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A Stock.

The warrant is exercisable immediately upon issuance and has an exercise price of \$1.50 per share and a term of five years. However, the holder will be prohibited from exercising the warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of our common stock then issued and outstanding.

We intend to use the net proceeds of the offering for general corporate purposes, including the development and commercialization of Neutrolin®, and working capital and capital expenditures.

In a separate transaction, on February 19, 2013, we purchased from the same institutional investor outstanding warrants to purchase an aggregate of 220,000 shares of our common stock at a purchase price of \$0.15 per share underlying the warrant. The warrants were issued in our initial public offering and had an exercise price of \$3.4375. The warrants have been cancelled.

On February 22, 2013, an aggregate of 474,105 shares of this Series A non-voting convertible preferred stock was converted into 474,105 shares of our common stock.

Corporate History and Information

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

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

The Offering

The selling stockholders identified beginning on page 23 of this prospectus are offering on a resale basis a total of 2,500,000 shares of our common stock issuable upon the conversion of convertible notes issued in connection with our 2012 private placement of convertible notes and warrants.

| | |
|--|-------------------|
| Common stock offered by the selling stockholders | 2,500,000 shares |
| Common stock outstanding before the offering ⁽¹⁾ | 11,882,379 shares |
| Common stock to be outstanding after the offering ⁽²⁾ | 14,382,379 shares |
| Common stock NYSE MKT Symbol | CRMD |

(1) Based on the number of shares outstanding as of February 28, 2013.

Does not include: (i) 2,300,000 shares reserved for issuance under our Amended and Restated 2006 Stock Incentive Plan, of which 2,135,630 shares are issuable upon exercise of outstanding options with a weighted average exercise price of \$1.26; and (ii) an aggregate of 8,228,534 shares of common stock issuable upon outstanding warrants with exercise prices of between \$0.40 and \$10.66.

The selling stockholders acquired the convertible notes on September 20, 2012 and November 13, 2012 in a private placement by us of units, with each unit consisting of \$1,000 in principal amount of our one-year 9% Senior Convertible Notes and a five-year warrant to purchase 2,500 shares of our common stock. This financing is referred to as the 2012 Financing. For more details on the 2012 Financing and the selling stockholders, see "Selling Stockholders" beginning on page 23.

Use of Proceeds

The shares of common stock offered by this prospectus are being registered for the account of the selling stockholders named in this prospectus. As a result, all proceeds from the sales of the common stock will go to the selling stockholders and we will not receive any proceeds from the resale of the common stock by the selling stockholders. We will incur all costs associated with this registration statement and prospectus.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. In addition, pursuant to the terms of the subscription agreements executed with the investors in our 2012 convertible note private placement, we agreed not to declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of the convertible notes remain unpaid or unconverted and outstanding. We anticipate that any earnings will be retained for development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Our board of directors has sole discretion to pay cash dividends based on our financial condition, results of operations, capital requirements, contractual obligations and other relevant factors.

RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its audit report for the year ended December 31, 2012 and may do so again in the future.

In their report accompanying our audited financial statements for the year ended December 31, 2012, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern. A “going concern” opinion could impair our ability to finance our operations through the sale of debt or equity securities or through bank financing. We believe our recent decision to focus the majority of our resources, including our research and development efforts, primarily on the CE Mark approval and commercialization of Neutrolin in Europe will result in our currently available capital resources being sufficient to meet our operating needs only into the second quarter of 2013, after giving effect to our receipt of approximately \$1,324,000 in aggregate gross proceeds from the sale of our Senior Convertible Notes in September and November 2012 and the gross proceeds of \$533,000 received from the private placement of our Series A non-voting convertible preferred stock during the first quarter of 2013. Our ability to continue as a going concern will depend, in large part, on our ability to obtain additional financing. Thereafter, our ability to generate positive cash flow from operations will depend on our ability to receive a CE Mark for and launch Neutrolin in Europe. None of these undertakings are certain. 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.

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

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 net losses of approximately \$6.7 million and \$3.4 million for the years ended December 31, 2011 and 2012, respectively. As of December 31, 2012, we had an accumulated deficit of approximately \$46.4 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. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products unless and until we receive a CE Mark for and launch Neutrolin in Europe, and might never generate revenues from the sale of products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: successful completion of the development of our product candidates, particularly Neutrolin; obtaining necessary regulatory approvals for Neutrolin from the applicable European agencies, other foreign agencies and the FDA and from the FDA and international regulatory agencies for any other products; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing Neutrolin or other product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue to undertake development 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 for the foreseeable future 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 no approved product on the market and have generated no product revenues. Unless and until we receive applicable regulatory approval for Neutrolin and any other product candidates, we cannot sell our products and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants.

We believe that existing cash will be sufficient to enable us to fund our projected operating requirements only into the first quarter of 2013, based upon our recent decision to focus the majority of our resources, including our research and development efforts, primarily on the CE Marking approval and commercialization of Neutrolin in Europe. 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 increased 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.

Risks Related to the Development and Commercialization of Our Product Candidates

Our product candidates are still in development.

We are a development stage pharmaceutical and medical device company with product candidates 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 have elected to delay our other product candidates' development until we have obtained CE Marking approval in Europe for Neutrolin. Our product candidates are currently at the following stages:

- CRMD003 (Neutrolin) - submitted a CE Mark application for approval in Europe; 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. Our product candidates will require significant additional development, clinical trials, regulatory clearances and/or investment by us or our collaborators before they can be commercialized. Specifically, if we receive a CE Mark for Neutrolin, we will need to commercially launch it in Europe either on our own or through a third party, which will take time and capital.

Successful development of our products is uncertain.

Our development 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, pre-clinical and 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 current Good Manufacturing Practices requirements, referred to as cGMP, for use in clinical trials;

- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients;
- modification of clinical trial protocols;
- changes in regulatory requirements for clinical trials;
- lack of effectiveness during clinical trials;
- emergence of unforeseen safety issues;

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

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

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

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

Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of our product candidates. As an example in late 2011, we terminated development of CRMD001 due to disappointing data from our phase II study. 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 New Drug Application, or 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, 30 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 have contracted with TÜV SÜD, a European Union notified body, to handle the CE Marking process for Neutrolin. In October 2012, TÜV SÜD awarded the ISO 13485:2003 certification for Neutrolin, an important step in the CE Marking process. However, certain individual countries within the European Union require further approval by their national regulatory agencies. Failure to receive or maintain the right to affix the CE Mark or other requisite approvals could prohibit us from marketing and selling Neutrolin in the European Economic Area or elsewhere.

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

We have filed a design dossier submission with TÜV SÜD, the European Union notified body, as part of the regulatory CE Marking approval process in Europe for Neutrolin and have received ISO 13485:2003 certification. However, there cannot be any assurance that Neutrolin will receive a CE Mark that would allow it to be sold in 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 a NDA or PMA to the FDA for any product.

It is possible that none of our product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, especially for Neutrolin in Europe, would adversely affect the successful commercialization of it or any other drugs or biologics 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.

Physicians and patients may not accept and use our products.

Even if we receive FDA or foreign regulatory approval for one or more of our product candidates, physicians and patients may not accept and use it. 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 our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and would require us to seek additional financing.

Risks Related to Our Business and Industry

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

We compete with established pharmaceutical and biotechnology 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 any of our product candidates 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 biotechnology industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith 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 does not include the sale of commercial products. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any 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 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 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, Richard Cohen (our former Interim Chief Executive Officer, former Interim Chief Financial Officer and, effective January 1, 2013, our Chief Financial Officer), Randy Milby (our former Chief Operating Officer and, effective January 1, 2013, our Chief Executive Officer) and Dr. Antony Pfaffle, our director and, effective January 1, 2013, our Acting Chief Scientific Officer. While we have a consulting agreement, as amended, with MW Bridges LLC, of which Randy Milby is Managing Partner, consulting and employment agreements cannot ensure our retention of the persons covered by such agreements. 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.

Recent changes in our management may lead to instability and may negatively affect our business.

In September 2011, John Houghton, our former President and Chief Executive Officer, left the Company and, in April 2012, Brian Lenz, our former Chief Financial Officer and Chief Operating Officer resigned. In May 2012, our board of directors appointed director Richard Cohen to serve as our Interim Chief Executive Officer and Interim Chief Financial Officer. In May 2012, the board of directors also engaged Randy Milby to serve as our Chief Operating Officer. On December 21, 2012, we appointed Mr. Milby as our Chief Executive Officer, effective January 1, 2013. At that time, Mr. Milby's responsibilities as our Chief Operating Officer terminated. Effective January 1, 2013, we also appointed Mr. Cohen as our Chief Financial Officer and one of our directors, Dr. Antony Pfaffle, as our Chief Scientific Officer. Dr. Mark Klausner, our former part-time Chief Medical Officer, ceased employment on February 28, 2013. We cannot be certain that the changes in management will not negatively affect our business in the future or that additional changes in management and in the composition of our board of directors will not occur. Additionally, we may be negatively impacted by a lack of accounting expertise, lack of internal control processes (which include lack of segregation of duties over financial reporting), lack of accuracy and timeliness of financial reporting as a result of the resignation of our former Chief Financial Officer and Chief Operating Officer

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.

If we receive CE Mark approval for Neutrolin, our success will depend upon the expansion of our operations to commercialize Neutrolin and the effective management of our 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. 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 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. 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 most material to our business are as follows:

U.S. Registration No. 7,696,182 (expiring in May 2025) - use of Neutrolin for preventing infection and maintenance of catheter patency in hemodialysis catheters (for CRMD003);

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

European Registration No. 1442753 (expiring February 2023) - use of a thixotropic gel as a catheter locking composition, and method of locking a catheter (for CRMD004).

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 patent applications in our patent portfolio are exclusively licensed to us. To support our patent strategy, we have engaged in a review of patentability and 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.

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 additional proceedings initiated by third parties or the PTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. The defense and prosecution of 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. 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. An adverse determination in litigation or PTO or foreign proceedings to which we may become a party could subject us to significant liabilities, 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 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 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 described in the Lehner patent. 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 the date of this prospectus, 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 Sodemann patent covering Neutrolin, but remanded the proceeding to the lower court to consider restricting certain of the Sodemann patent claims. We believe we will receive the Appeals Board final written decision sometime in the first quarter of 2013. We intend to continue to vigorously defend the patent. However, we can provide no assurances

regarding the outcome of this matter.

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 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 pharmaceutical products; for other products we may also rely on such marketing collaborations or out-licensing or our product candidates. Specifically, for Neutrolin, assuming we receive applicable regulatory approval, we plan to enter into distribution agreements with one or more third parties for the sale of Neutrolin in various European and other markets. However, there can be no assurance that we will be able to successfully establish marketing, sales, or distribution relationships, that such relationships, if established, such as with MKM Co-Pharma GmbH, 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 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.

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 our product candidates 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, 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 our product candidates 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

Our 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 March 27, 2013, 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:

· our need for additional capital;

· the receipt of CE Mark approval for Neutrolin;

- results of clinical trials of our product candidates 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 biotechnology 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 biotechnology 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 securities 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 February 28, 2013, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

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 and 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;

warrants for 503,034 shares of our common stock issued in our 2009 private placement, which warrants have an exercise price of \$3.4375 per share and expire on October 29, 2014;

warrants for 18,250 shares of common stock with an exercise price of \$7.84 per share issued to co-placement agents in connection with our previous convertible note financings;

options to purchase an aggregate of 2,135,630 shares of our common stock issued to our officers, directors, employees and non-employee consultants under our Amended and Restated 2006 Stock Incentive Plan, or the 2006 Stock Plan, with a weighted average exercise price of \$1.26 per share;

outstanding Senior Convertible Notes issued in our 2012 private placement with an aggregate face value of \$1,324,000, convertible into an aggregate of 3,782,857 shares of our common stock;

warrants issued to investors in our 2012 private placement to purchase an aggregate of 3,310,000 shares of our common stock with an exercise price of \$0.40 per share;

warrants issued to the placement agent for our 2012 private placement to purchase an aggregate of 331,000 shares of our common stock with an exercise price of \$0.40 per share;

287,324 shares of our common stock issuable upon the conversion of 287,324 shares of our Series A Non-Voting Convertible preferred stock issued on February 19, 2013; and

400,000 shares of our common stock issuable upon the exercise of a warrant issued on February 19, 2013.

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.

In addition, we have agreed to register the shares issuable upon the conversion of the Senior Convertible Notes issued in our 2012 private placement under the Securities Act of 1933, or the Securities Act. The resale of those shares will be covered by this prospectus if the registration statement of which this prospectus is a part is declared effective. If those shares are issued, the effectiveness of the registration of those shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock. Even without registration, the shares issuable upon conversion of the Senior Convertible Notes generally will be freely tradable beginning in late March and mid-May of 2013, depending on the date of issuance of the Senior Convertible Notes except for shares held by our affiliates.

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.

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

In the preparation of our Annual Report on Form 10-K for the year ended December 31, 2012, we identified a material weakness in our internal control over financial reporting process with respect to lack of accounting expertise related to non-routine, complex accounting matters. This material weakness did not have any impact on our financial statements for the year ended December 31, 2012 but did result in a restatement of the financial statements in our September 30, 2012 Quarterly Report on Form 10-Q.

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.

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 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 February 28, 2013, options to purchase 2,135,630 shares of common stock issued under our 2006 Stock Plan at a weighted average exercise price of \$1.26 per share, were outstanding. In addition, at February 28, 2013, there were outstanding warrants to purchase an aggregate of 8,610,665 shares of our common stock at prices ranging from \$0.40 to \$10.66, an aggregate of 287,324 shares of Series A preferred stock convertible into an aggregate of 287,324 shares of our common stock, and convertible notes convertible into an aggregate of 3,782,857 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 options issued under our 2006 Stock Plan are exercised or any warrants are exercised, or Series A non-voting convertible preferred shares on convertible notes 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, as was done in February 2013 when we issued shares of Series A non-voting convertible preferred stock

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.

We received notice from the NYSE MKT that we fail to comply with certain of its continued listing standards, which 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. On April 20, 2012, the NYSE MKT notified us that we were not in compliance with certain listing standards relating to our financial condition and we had to submit a plan to regain compliance with the listing standards by August 22, 2012, which we submitted on May 17, 2012. On June 27, 2012, the NYSE MKT notified us that it had accepted our plan to regain compliance with the continued listing standards of NYSE MKT by August 22, 2012. On August 20, 2012, we requested an extension of the plan period. On September 21, 2012, NYSE MKT notified us that it was granting us an extension until January 31, 2013 to regain compliance with the continued listing standards of the NYSE MKT. The NYSE MKT determined that in accordance with Section 109 of the Company Guide, we made reasonable demonstration of our ability to regain compliance with Section 1003(a)(iv) of the Company Guide by the end of the extended plan period. On February 1, 2013, we received notice from the NYSE MKT that it granted us an extension until April 15, 2013 to regain compliance with the continued listing standards of the NYSE MKT. The NYSE MKT is continuing our listing pursuant to the extension. We will be subject to periodic review by the NYSE MKT during the extended plan period to April 15, 2013. Although we believe that, to date, we are making progress with the plan and that we will be in compliance with the continued listing standards, unless we can raise capital through various potential sources, such as equity, debt financing, strategic relationships, out-licensing or distribution arrangements of our products, we may receive further notice from the

NYSE MKT informing us that we are not in compliance with the listing standards. If we are not in compliance with the listing standards at the end of the extended plan period, or if we do not make progress consistent with the plan during the extended plan period, the NYSE MKT staff may initiate delisting proceedings. We may appeal a staff determination to initiate delisting proceedings in accordance with Section 1010 and Part 12 of the NYSE MKT Company Guide.

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 is low, 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 is low, 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 regulation 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. As a result, our common stock is 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.

Our management is aware of the abuses that have occurred historically in the penny stock market.

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. In addition, pursuant to the terms of the subscription agreements executed with the investors in our 2012 convertible note private placement, we agreed not to declare or pay any dividends or make any distributions on any of our shares or other equity securities as long as any of the convertible notes remain unpaid or unconverted and outstanding. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors. Any return to holders of our common stock will be limited to the value of their common stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

Words such as "may," "might," "should," "anticipate," "estimate," "expect," "projects," "intends," "plans," "believes" and words of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management's current judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to: our ability to obtain FDA and foreign approval of our product candidates, especially Neutrolin; our need to obtain additional funding and our ability to obtain future funding on acceptable terms, or at all; 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" above and contained in any supplements to this prospectus, and in our most recent annual report on Form 10-K, as revised or supplemented by our most recent quarterly report on Form 10-Q, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference.

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

USE OF PROCEEDS

The shares of common stock offered by this prospectus are being registered for the account of the selling stockholders named in this prospectus. As a result, all proceeds from the sales of the common stock will go to the selling stockholders and we will not receive any proceeds from the resale of the common stock by the selling stockholders. We will incur all costs associated with this registration statement and prospectus.

SELLING STOCKHOLDERS

The following table sets forth the shares beneficially owned, as of February 28, 2013, by the selling stockholders (based on information in our records or information available from brokerage firms or other third-party entities) prior to the offering contemplated by this prospectus, the number of shares the selling stockholders are offering by this prospectus and the number of shares which they would own beneficially if all such offered shares are sold.

Beneficial ownership is determined in accordance with the rules of the SEC and includes generally voting and/or investment power with respect to securities. Shares of common stock subject to warrants, options or convertible securities currently exercisable or convertible, or exercisable or convertible within 60 days of January 31, 2013, are deemed outstanding for the purpose of computing the percentage beneficially owned by the person holding such warrants, options or convertible stock but are not deemed outstanding for the purpose of computing the percentage beneficially owned by any other person. The percentage of beneficial ownership for the following table is based on 11,882,379 shares of common stock outstanding as of February 28, 2013.

Except as indicated in the footnotes to this table, the persons named in the table have sole voting and investment control with respect to all shares of our common stock shown as beneficially owned by them.

| Name of Selling Stockholder ⁽¹⁾ | Shares of Common Stock Beneficially Owned Prior to Any Sale | | Number of Shares of Common Stock Being Offered by this Prospectus | Shares of Common Stock Beneficially Owned After Sale of All Shares of Common Stock Offered Pursuant to this Prospectus | |
|---|---|------------|---|---|------------|
| | Number | Percentage | | Number | Percentage |
| Bruce D. Walck R/O IRA | 535,714 | (3) 4.5 % | 188,822 | 346,892 | 3.0 % |
| Lindsay A. Rosenwald, M.D. | 845,011 | (4) 7.2 % | 94,411 | 750,600 | 6.4 % |
| Steven W. Lefkowitz ⁽³⁰⁾ | 477,665 | (5) 3.9 % | 94,411 | 383,254 | 3.1 % |

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| | | | | | | | | |
|---|-----------|------|------|---|-----------|-----------|------|---|
| Oliver Buck | 535,714 | (6) | 4.5 | % | 188,822 | 346,892 | 3.0 | % |
| Randy Milby ⁽³¹⁾ | 377,857 | (7) | 3.0 | % | 94,411 | 283,446 | 2.4 | % |
| Paul Schneider | 80,357 | (8) | * | | 28,323 | 52,034 | * | |
| Gary A. Gelbfish, M.D. ⁽³²⁾ | 982,954 | (9) | 7.8 | % | 188,822 | 794,132 | 6.4 | % |
| Elliot Associates, L.P. | 3,315,017 | (10) | 22.5 | % | 755,287 | 2,559,730 | 20.0 | % |
| Matthew P. Duffy ⁽³³⁾ | 180,723 | (11) | 1.5 | % | 18,882 | 161,841 | 1.4 | % |
| Philip S. Forte R/O IRA | 535,714 | (12) | 4.5 | % | 188,822 | 346,892 | 3.0 | % |
| Kingsbrook Opportunities Master Fund LP | 133,929 | (13) | 1.2 | % | 47,206 | 86,723 | * | |
| Gregory Martino | 133,929 | (14) | 1.2 | % | 47,206 | 86,723 | * | |
| Patrick Caldwell | 26,786 | (15) | * | | 9,441 | 17,345 | * | |
| Roy Whitehead | 187,500 | (16) | 1.6 | % | 66,088 | 121,412 | * | |
| Janet Ballard | 133,929 | (17) | 1.2 | % | 47,206 | 86,723 | * | |
| Mark Livingston | 53,571 | (18) | * | | 18,882 | 34,689 | * | |
| Alvin L. Gray Trust | 133,929 | (19) | 1.2 | % | 47,206 | 86,723 | * | |
| Lori Shapero | 187,500 | (20) | 1.6 | % | 66,088 | 121,412 | * | |
| Ricky McKnight | 96,429 | (21) | * | | 33,987 | 62,442 | * | |
| Jonathan Stanney | 267,857 | (22) | 2.3 | % | 94,411 | 173,446 | 1.5 | % |
| Collace Services Limited | 133,929 | (23) | 1.2 | % | 47,206 | 86,723 | * | |
| Bowden Transportation Services RET Ltd. | 37,500 | (24) | * | | 13,218 | 24,282 | * | |
| Ronald Globus | 53,571 | (25) | * | | 18,882 | 34,689 | * | |
| Elbow Canyon Estates LLC | 107,143 | (26) | * | | 37,763 | 69,380 | * | |
| Jack Steven Jacobsen | 107,143 | (27) | * | | 37,763 | 69,380 | * | |
| Justin Bagnato-Schulte IRA | 21,429 | (28) | * | | 7,552 | 13,877 | * | |
| George B. Wright III | 53,571 | (29) | * | | 18,882 | 34,689 | * | |
| Total | 9,456,371 | | 46.4 | % | 2,500,000 | 6,956,371 | 38.9 | % |

*Less than 1%.

- (1) Based on the information we received from the selling stockholders, except as disclosed below, no selling stockholder is an affiliate of any registered broker-dealer.

(2) The selling stockholders may offer and sell all or a part of the common stock pursuant to this prospectus, but no estimates can be made as to the amount of shares of common stock that will be held by the selling stockholders after the completion of this offering.

(3) Consists of (i) 285,714 shares of common stock issuable upon conversion of convertible notes issued in our 2012 private placement, referred to as the 2012 Notes, and (ii) 250,000 shares of common stock issuable upon exercise of warrants issued in our 2012 private placement, referred to as the 2012 Warrants.

(4) Consists of (i) 382,257 shares of common stock held directly by Dr. Rosenwald, (ii) 103,400 shares of common stock issuable upon exercise of warrants held directly by Dr. Rosenwald, (iii) 142,857 shares of common stock issuable upon conversion of 2012 Notes held directly by Dr. Rosenwald, (iv) 125,000 shares of common stock issuable upon exercise of 2012 Warrants held directly by Dr. Rosenwald, (v) 60,998 shares of common stock held by Paramount Biosciences LLC, or PBS, of which Dr. Rosenwald is sole member, and (vi) 30,499 shares of common stock issuable upon exercise of warrants held by PBS.

(5) Consists of (i) 55,272 shares of common stock, (ii) 125,000 shares of common stock issuable upon exercise of stock options, (iii) 10,000 shares of common stock held by Mr. Lefkowitz's spouse, (iv) 100,000 shares of common stock issuable upon conversion of 2012 Notes held by Wade Capital Corporation, an entity for which Mr. Lefkowitz has voting and investment control, (v) 42,857 shares of common stock issuable upon conversion of 2012 Notes held directly by Mr. Lefkowitz, (vi) 19,536 shares of common stock issuable upon exercise of warrants, (vii) 87,500 shares of common stock issuable upon exercise of 2012 Warrants held by Wade Capital Corporation, and (viii) 37,500 shares of common stock issuable upon exercise of 2012 Warrants held directly by Mr. Lefkowitz.

(6) Consists of (i) 285,714 shares of common stock issuable upon conversion of 2012 Notes held directly by Mr. Buck, and (ii) 250,000 shares of common stock issuable upon exercise of 2012 Warrants held directly by Mr. Buck.

(7) Consists of (i) 100,000 shares of common stock issuable upon exercise of options, (ii) 142,857 shares of common stock issuable upon conversion of 2012 Notes held by MW Bridges LLC, of which Mr. Milby is Managing Partner, and (iii) 125,000 shares of our common stock issuable upon exercise of 2012 Warrants held by MW Bridges LLC.

(8) Consists of (i) 42,857 shares of common stock issuable upon conversion of 2012 Notes held directly by Mr. Schneider, and (ii) 37,500 shares of common stock issuable upon exercise of 2012 Warrants held directly by Mr. Schneider.

(9) Consists of (i) 115,000 shares of common stock issuable upon exercise of stock options held by Dr. Gelbfish individually, (ii) 94,496 shares of common stock held jointly by Dr. Gelbfish and his wife, (iii) 70,872 shares of common stock held by Dr. Gelbfish as custodian for certain of his children, (iv) 70,872 shares of common stock held by Landmark Foundation, of which Dr. Gelbfish and his wife are trustees, (v) 285,714 shares of common stock issuable upon conversion of 2012 Notes held directly by Dr. Gelbfish, (vi) 250,000 shares of common stock issuable upon exercise of 2012 Warrants held directly by Dr. Gelbfish, (vii) 38,400 shares of common stock issuable upon exercise of warrants held jointly by Dr. Gelbfish and his wife, (viii) 28,800 shares of common stock issuable upon exercise of warrants held by Dr. Gelbfish as custodian for certain of his children, and (ix) 28,800 shares of common stock issuable upon exercise of warrants held by Landmark Foundation.

(10) Consists of (i) 781,440 shares of common stock held by Manchester Securities Corp., or Manchester, a wholly-owned subsidiary of Elliott Associates, L.P., or Elliott Associates, (ii) 1,142,857 shares of common stock issuable upon conversion of 2012 Notes held by Manchester, (iii) 390,720 shares of common stock issuable upon exercise of warrants held by Manchester, and (iv) 1,000,000 shares of common stock issuable upon exercise of 2012 Warrants held by Manchester. Paul E. Singer (“Singer”), Elliott Capital Advisors, L.P., a Delaware limited partnership (“Capital Advisors”), which is controlled by Singer, and Elliott Special GP, LLC, a Delaware limited liability company (“Special GP”), which is controlled by Singer, are the general partners of Elliott Associates, with voting and dispositive power over the shares being offered by this prospectus.

(11) Consists of (i) 9,768 shares of common stock, (ii) 112,500 shares of common stock issuable upon exercise of stock options, (iii) 4,884 shares of common stock issuable upon exercise of warrants, (iv) 28,571 shares of common stock issuable upon conversion of 2012 Notes, and (v) 25,000 shares of common stock issuable upon exercise of 2012 Warrants.

(12) Consists of (i) 285,714 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 250,000 shares of common stock issuable upon exercise of 2012 Warrants.

(13) Consists of (i) 71,429 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 62,500 shares of common stock issuable upon exercise of 2012 Warrants. Kingsbrook Opportunities GP LLC is the general partner of Kingsbrook Opportunities Master Fund LP. Adam J. Chill is the managing member of Kingsbrook Opportunities GP LLC, with voting and dispositive power over the shares being offered by this prospectus.

(14) Consists of (i) 71,429 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 62,500 shares of common stock issuable upon exercise of 2012 Warrants.

(15) Consists of (i) 14,286 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 12,500 shares of common stock issuable upon exercise of 2012 Warrants.

(16) Consists of (i) 100,000 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 87,500 shares of common stock issuable upon exercise of 2012 Warrants.

(17) Consists of (i) 71,429 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 62,500 shares of common stock issuable upon exercise of 2012 Warrants.

(18) Consists of (i) 28,571 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 25,000 shares of common stock issuable upon exercise of 2012 Warrants.

Consists of (i) 71,429 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 62,500 shares of
(19) common stock issuable upon exercise of 2012 Warrants. Alvin L. Gray is the trustee of the Alvin L. Gray Trust, with voting and dispositive power over the shares being offered by this prospectus.

(20) Consists of (i) 100,000 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 87,500 shares of common stock issuable upon exercise of 2012 Warrants.

(21) Consists of (i) 51,429 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 45,000 shares of common stock issuable upon exercise of 2012 Warrants.

(22) Consists of (i) 142,857 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 125,000 shares of common stock issuable upon exercise of 2012 Warrants.

(23) Consists of (i) 71,429 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 62,500 shares of common stock issuable upon exercise of 2012 Warrants. Darren Toudic are directors of Collace Services Limited, with voting and dispositive power over the shares being offered by this prospectus.

(24) Consists of (i) 20,000 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 17,500 shares of common stock issuable upon exercise of 2012 Warrants. Peter Bowden is trustee of Bowden Transportation Services RET Ltd. and has voting and dispositive power over the shares being offered by this prospectus.

(25) Consists of (i) 28,571 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 25,000 shares of common stock issuable upon exercise of 2012 Warrants.

(26) Consists of (i) 57,143 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 50,000 shares of common stock issuable upon exercise of 2012 Warrants. Russell and Susan Bergstrom are members of Elbow Canyon Estates LLC with voting and dispositive power over the shares being offered by this prospectus.

(27) Consists of (i) 57,143 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 50,000 shares of common stock issuable upon exercise of 2012 Warrants.

(28) Consists of (i) 11,429 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 10,000 shares of common stock issuable upon exercise of 2012 Warrants.

(29) Consists of (i) 28,571 shares of common stock issuable upon conversion of 2012 Notes, and (ii) 25,000 shares of common stock issuable upon exercise of 2012 Warrants.

(30) Mr. Lefkowitz has been a director of our company since August 2011.

(31) Mr. Milby served as our Chief Operating Officer from May through December 2012 and currently serves as our Chief Executive Officer.

(32) Dr. Gelbfish has been a director of our company since December 2009.

(33) Mr. Duffy has been a director of our company since November 2011.

Certain Relationships and Transactions with the Selling Stockholders

Several of the selling stockholders have a material relationship with us, based on their position as either a director or executive officer of our company or their beneficial ownership of 5% or more of our common stock, as determined by SEC rules. We also disclose below any prior transactions between our company and these individuals.

Matthew P. Duffy, Gary Gelbfish and Steven W. Lefkowitz are each a director of our company. In the 2012 Financing, Mr. Duffy purchased \$10,000 in principal amount of Notes and warrants to purchase 25,000 shares of common stock, Dr. Gelbfish purchased \$100,000 in principal amount of Notes and warrants to purchase 250,000 shares of common stock, and Mr. Lefkowitz directly purchased \$15,000 in principal amount of Notes and warrants to purchase 37,500 shares of common stock and indirectly purchased through Wade Capital Corporation (an entity for which he has voting and investment power) \$35,000 in principal amount of Notes and warrants to purchase 87,500 shares of common stock.

Dr. Gelbfish also beneficially owned, as of February 28, 2013, approximately 7.8% of our outstanding common stock. In October 2009, Dr. Gelbfish and his wife (jointly) purchased 8% senior convertible notes in the principal amount of \$200,000, Dr. Gelbfish as custodian for certain of his children purchased 8% senior convertible notes in the aggregate principal amount of \$150,000, and Landmark Charity Foundation, of which Dr. Gelbfish and his wife are trustees, purchased 8% senior convertible notes in the aggregate principal amount of \$150,000. Upon the completion of our initial public offering, or IPO, on March 30, 2012, the outstanding principal amount of the 8% senior convertible notes and all accrued interest thereon automatically converted into 94,496 shares of our common stock held jointly by Dr. Gelbfish and his wife, 70,872 shares of our common stock held by Dr. Gelbfish as custodian for certain of his children, and 70,872 shares of our common stock held by Landmark Charity Foundation, of which Dr. Gelbfish and his wife are trustees. In connection with the issuance of the 8% senior convertible notes, Dr. Gelbfish and his wife (jointly), Dr. Gelbfish as custodian for certain of his children, and Landmark Charity Foundation also received warrants to purchase 38,400 shares, an aggregate of 28,800 shares, and 28,800 shares of our common stock, respectively, at an exercise price of \$3.4375.

Randy Milby is our Chief Executive Officer and purchased \$50,000 in principal amount of Notes and warrants to purchase 125,000 shares of common stock indirectly through MW Bridges LLC (an entity for which he has voting and investment power). Mr. Milby was our Chief Operating Officer at the time of the purchase.

Lindsay A. Rosenwald is a founder of our company and as of February 28, 2013, beneficially owned approximately 4.6% of our outstanding common stock. In the 2012 Financing, Dr. Rosenwald purchased \$50,000 in principal amount of Notes and warrants to purchase 125,000 shares of common stock. Prior to our initial public offering, or IPO, on March 30, 2010, we owed \$198,264, including accrued and unpaid interest, under a future advance promissory note held by Paramount BioSciences, LLC, or PBS, of which Dr. Rosenwald is the sole member, and \$452,007, including accrued and unpaid interest, was outstanding under a future advance promissory note held by various family trusts. Upon the completion of the IPO, the note held by PBS automatically converted into 30,499 units, consisting of 60,998 shares of our common stock and warrants to purchase 30,499 shares of our common stock at an exercise price of \$3.4375, and the note held by the family trusts automatically converted into 69,539 units, consisting of 139,078 shares of our common stock and warrants to purchase 69,539 shares of our common stock at an exercise price of \$3.4375. In September 2010, we entered into a board observer agreement with Dr. Rosenwald, pursuant to which he was entitled to attend meetings of our Board as a non-voting observer, subject to certain exceptions. This agreement was terminated by Dr. Rosenwald on January 3, 2012.

Elliott Associates, L.P., beneficially owned through its wholly owned subsidiary, Manchester Securities Corp., approximately 23.8%, of our common stock outstanding as of February 28, 2013. In the 2012 Financing, Elliott Associates, through Manchester Securities Corp., purchased \$400,000 in principal amount of Notes and warrants to purchase 1,000,000 shares of common stock.

All of the purchases made in the 2012 Financing by the above-named individuals and entities were purchased on the same terms as all other investors in the 2012 Financing.

The 2012 Financing

On September 20, 2012 and November 13, 2012, we entered into subscription agreements with the investors listed under the caption "Selling Stockholders," referred to as the Investors, to issue and sell an aggregate of \$1,324,000 of units to the Investors, referred to as the 2012 Financing. On September 20, 2012, we closed the initial portion of the 2012 Financing, referred to as the Initial Closing, for \$850,000 in gross proceeds, and on November 13, 2012, we closed the second and final portion of the 2012 Financing, referred to as the Subsequent Closing, for \$474,000 in gross proceeds. The Initial Closing and the Subsequent Closing are collectively referred to as the Closings. The total net proceeds of the 2012 Financing to us were \$1,196,600, including \$770,000 in net proceeds received by us at the Initial Closing and \$426,600 in net proceeds received by us in the Subsequent Closing.

The units we issued in the 2012 Financing to the Investors consisted of (i) a one-year \$1,000 aggregate principal amount 9% Senior Convertible Note, or the Notes, convertible into shares of our common stock, par value \$0.001 per share, at a conversion price of \$0.35 per share, and (ii) a five-year redeemable warrant, or the Warrants, to purchase 2,500 shares of common stock at an initial exercise price of \$0.40 per share. The maturity date of the Notes issued in the Initial Closing is September 20, 2013. The maturity date of the Notes issued in the Subsequent Closing is November 13, 2013. The conversion price of the Notes and the exercise price of the Warrants are subject to adjustment in the event of a stock dividend or a property distribution on, or a stock split or a combination or reclassification of, our common stock.

The Notes issued at the Closings are convertible into an aggregate of 3,782,857 shares of our common stock. The Notes accrue interest on their outstanding principal balances at a rate of 9% per annum payable quarterly in arrears. We have the right to prepay all (but not less than all, subject to the share ownership limitations discussed below) of the then outstanding Notes by paying 120% of the principal and accrued but unpaid interest through and including the date each Note is repaid. No portion of a Note may be converted into shares of our common stock if, as a result of such conversion, the holder of a Note would beneficially own either more than 4.999% or 9.999% of the total number of shares of our common stock then issued and outstanding unless the holder of a Note waives in writing such limitation and such written notice is provided to us at least 61 days prior to the effective date of such waiver.

The Investors represented that they are “accredited investors” and agreed that the securities issued in the 2012 Financing bear a restrictive legend against resale without registration under the Securities Act. The Notes and Warrants were sold pursuant to the exemption from registration afforded by Section 4(2) of the Securities Act and Regulation D thereunder.

In the Initial Closing, the Investors received Notes convertible into an aggregate of 2,428,570 shares of our common stock and Warrants to purchase an aggregate of 2,125,000 shares of our common stock.

| Investor | Total Number of Shares Underlying the Notes in the Initial Closing ⁽¹⁾ | Total Number of Shares Underlying Warrants in the Initial Closing ⁽²⁾ | Maximum Number of Shares that may be Issued Pursuant to the Initial Closing ⁽³⁾ |
|---|---|--|--|
| Bruce D. Walck R/O IRA | 285,714 | 250,000 | 535,714 |
| Lindsay A. Rosenwald, M.D. | 142,857 | 125,000 | 267,857 |
| Wade Capital Corporation Money Purchase Plan ⁽⁴⁾ | 100,000 | 87,500 | 187,500 |
| Oliver Buck | 285,714 | 250,000 | 535,714 |
| MW Bridges LLC ⁽⁵⁾ | 142,857 | 125,000 | 267,857 |
| Paul Schneider | 42,857 | 37,500 | 80,357 |
| Gary A. Gelbfish, M.D. ⁽⁶⁾ | 285,714 | 250,000 | 535,714 |
| Manchester Securities Corp. | 1,142,857 | 1,000,000 | 2,142,857 |
| Total | 2,428,570 | 2,125,000 | 4,553,570 |

(1) This represents the number of shares issuable upon conversion of the Notes at the conversion price of \$0.35 per share.

(2) This represents the number of shares issuable upon exercise of the Warrants at the exercise price of \$0.40 per share. The shares of common stock underlying the Warrants are not being registered under this registration statement, and will not be freely tradable.

(3) This represents the maximum number of shares that may be issued to the Investors.

(4) Wade Capital Corporation is an entity for which Steven W. Lefkowitz, a director of our company, has voting and investment power.

(5) Mr. Milby is our Chief Executive Officer; at the time of purchase, he was our Chief Operating Officer.

(6) Dr. Gelbfish is a member of our Board of Directors.

In the Subsequent Closing, the Investors received Notes to purchase 1,354,287 shares of our common stock, and Warrants to purchase 1,185,000 shares of our common stock.

| Investor | Total Number of Shares Underlying Convertible Notes in the Subsequent Closing ⁽¹⁾ | Total Number of Shares Underlying Warrants in the Subsequent Closing ⁽²⁾ | Maximum Number of Shares that may be Issued Pursuant to the Subsequent Closing ⁽³⁾ |
|---|--|---|---|
| Steven W. Lefkowitz ⁽⁴⁾ | 42,857 | 37,500 | 80,357 |
| Matthew P. Duffy ⁽⁵⁾ | 28,571 | 25,000 | 53,571 |
| Philip S. Forte R/O IRA | 85,714 | 75,000 | 160,714 |
| Kingsbrook Opportunities Master Fund LP | 71,429 | 62,500 | 133,929 |
| Gregory Martino | 71,429 | 62,500 | 133,929 |
| Patrick Caldwell | 14,286 | 12,500 | 26,786 |
| Roy Whitehead | 100,000 | 87,500 | 187,500 |
| Janet Ballard | 71,429 | 62,500 | 133,929 |
| Mark Livingston | 28,571 | 25,000 | 53,571 |
| Alvin Gray Trust | 71,429 | 62,500 | 133,929 |
| Lori Shapero | 100,000 | 87,500 | 187,500 |
| Ricky McKnight | 51,429 | 45,000 | 96,429 |
| Jonathan Stanney | 142,857 | 125,000 | 267,857 |
| Collace Services Limited | 71,429 | 62,500 | 133,929 |
| Bowden Transportation Services | 20,000 | 17,500 | 37,500 |
| Ronald Globus | 28,571 | 25,000 | 53,571 |
| Philip S. Forte IRA | 200,000 | 175,000 | 375,000 |
| Elbow Canyon Estates LLC | 57,143 | 50,000 | 107,143 |
| Jack Steven Jacobsen | 57,143 | 50,000 | 107,143 |
| Justin Schulte IRA | 11,429 | 10,000 | 21,429 |
| George B. Wright III | 28,571 | 25,000 | 53,571 |
| Total | 1,354,287 | 1,185,000 | 2,539,287 |

(1) This represents the number of shares issuable upon conversion of the Notes at the conversion price of \$0.35 per share. This amount does not include interest shares.

(2) This represents the number of shares issuable upon exercise of the Warrants at the exercise price of \$0.40 per share. Such shares of common stock underlying the Warrants are not being registered under this registration statement, and will not be freely tradable.

(3) This represents the maximum number of shares that may be issued to the Investors.

(4) Mr. Lefkowitz is member of our Board of Directors.

(5) Mr. Duffy is a member of our Board of Directors.

In connection with the 2012 Financing, we entered into a registration rights agreement with the Investors, pursuant to which we agreed to file a registration statement with the SEC to register the resale of all 3,782,857 shares of common stock issuable upon conversion of the Notes, referred to herein as the registrable shares, within 60 days of the Subsequent Closing. We met this obligation by filing a registration statement, of which this prospectus is a part, on January 11, 2013. We also agreed to use our reasonable commercial efforts to have the registration statement declared effective within 120 days of the Subsequent Closing, which is March 13, 2013. There is no guarantee that the SEC will declare this registration statement effective within that timeframe or at all. If the registration statement is not declared effective on or before March 13, 2013, we have agreed to pay as partial liquidated damages an amount equal to 1.0% of the aggregate purchase price paid by each Investor per month until the registration statement is declared effective, but these payments may not exceed 5% of the aggregate principal amount of the Notes outstanding, or \$66,200 in the aggregate. These registration rights will cease once the registrable shares are eligible for sale by the Investors without restriction under Rule 144.

The registration rights agreement allowed us to register a lesser amount of shares in the event the SEC affirmatively limited the number of shares that could be included in the registration statement. In such event, we could, and we did, reduce the number of shares on a pro rata basis applied to all Investors by an aggregate amount of 1,282,857 shares. As a result, the liquidated damages that we may be obligated to pay will not apply to the 1,282,857 shares that we remain obligated to register at a later date unless and until all shares are eligible for sale by the Investors without restriction under Rule 144. Liquidated damages, if any, would only be payable on the 2,500,000 shares registered under this registration statement. We expect the registration statement of which this prospectus is a part to be declared effective no later than April 12, 2013, in which event we will be obligated to pay aggregated liquidated damages of approximately \$745.00.

The following table summarizes the potential payments we are and may be required to pay to the Investors. We do not owe any payment to any Investor that is different from that owed to any other Investor other than the amount of interest and liquidated damages payable, which is based solely on the amount of principal of the Notes each Investor purchased. The table reflects all the payments due during the one-year term of the Notes, which consist of interest on the principal amount of the Notes and potential liquidated damages. Each note is due one year from the date of its issuance.

| Maximum Interest Payments ⁽¹⁾ | Maximum Liquidated Damages ⁽²⁾ | Total Net Proceeds to Company ⁽³⁾ |
|--|---|---|
| \$ 119,160 | \$ 43,750 | \$ 1,161,090 |

(1) Maximum amount of interest that can accrue assuming all the Notes remain outstanding until their respective maturity date of September 20, 2013 or November 13, 2013.

(2) Maximum amount of liquidated damages we may be required to pay.

(3) Total net proceeds to us assuming that we were required to make the full payment as described in footnote 2 and without deduction of any of the expenses of the 2012 Financing.

The following table sets forth the number of shares of our common stock issued and outstanding and issued and outstanding held by non-affiliates of our company, and the number of shares which have been registered for resale by Investors as a percentage of both numbers.

| Total Number of Shares Outstanding⁽¹⁾ | Total Number of Shares held by Non-Affiliates of the Company | Total Number of Shares Registered for Resale by Selling Security Holders | Resale Shares as a Percent of Outstanding | | Resale Shares as a Percent of Non-Affiliates | |
|---|---|---|--|---|---|---|
| 11,882,379 | 10,772,809 | 2,500,000 | 21.0 | % | 23.2 | % |

(1) As of February 28, 2013.

The value of 1,633,369 shares of common stock that we are registering and that are issuable upon the conversion of Notes sold on September 20, 2012, was approximately \$571,679 in the aggregate on September 20, 2012, based on the closing price per share of \$0.35 of our common stock on that date. The value of 866,631 shares of common stock that we are registering and that are issuable upon the conversion of Notes sold on November 13, 2012, was approximately \$407,317 in the aggregate on November 13, 2012, based on the closing price per share of \$0.47 of our common stock on that date.

The value of the 2,500,000 shares of common stock that we are registering, based on the closing price per share of \$0.98 of our common stock on February 20, 2013, is \$2,450,000, which is approximately 23.2% of the aggregate market value of our outstanding common stock held by non-affiliates of \$10,557,353, based on 11,882,379 shares of our common stock outstanding on February 28, 2013, of which 10,772,809 shares were held by non-affiliates, and a price of \$0.98 per share, the closing price for our common stock on February 20, 2013.

PLAN OF DISTRIBUTION

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

- ordinary brokerage transactions and transactions in which the broker solicits purchases;

- sales to one or more brokers or dealers as principal, and resale by those brokers or dealers for their account, including resales to other brokers and dealers;

- block trades in which a broker or dealer attempts to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

·
privately negotiated transactions with purchasers;

an exchange distribution in accordance with the rules of the applicable exchange;

settlement of short sales entered into after the date of this prospectus;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. No such broker-dealer will receive compensation in excess of that permitted by NASD Rule 2440 and IM-2440. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the selling stockholders. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that agent, dealer or broker-dealer under the Securities Act.

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

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

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

prospectus delivery requirements of the Securities Act.

We will file, during any period during which we are required to do so under our registration rights agreement with Lambda Investors, one or more post-effective amendments to the registration statement of which this prospectus is a part to describe any material information with respect to the plan of distribution not previously disclosed in this prospectus or any material change to such information in this prospectus.

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

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

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

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

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

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

Delaware Anti-takeover Law

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

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

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

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

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

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

Charter Documents

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

LEGAL MATTERS

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

EXPERTS

The balance sheets of CorMedix Inc. as of December 31, 2012 and 2011 and the related 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, 2012 have been audited by CohnReznick LLP, independent registered public accounting firm, as stated in their report, which includes an explanatory paragraph relating to our ability to continue as a going concern, which is incorporated herein by reference. Such financial statements have been incorporated herein by reference in reliance on the report of CohnReznick LLP given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Exchange Act and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC's web site at <http://www.sec.gov>. Our common stock is listed on the NYSE MKT, and you can read and inspect our filings at the offices of the NYSE MKT at 20 Broad Street, New York, NY 10005.

This prospectus is only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

INCORPORATION OF DOCUMENTS BY REFERENCE

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

our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the SEC pursuant to Section 13 of the Exchange Act on March 27, 2013;

our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on January 16, February 7, February 19, March 6 and March 22, 2013;

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

all of the filings pursuant to the Exchange Act after the date of the filing of the original registration statement and prior to the effectiveness of the registration statement.

In addition, all documents subsequently filed, but not furnished, by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act before the date our offering is terminated or completed are deemed to be incorporated by reference into, and to be a part of, this prospectus. In no event, however, will any of the information, including exhibits, that we disclose under Item 2.02 and Item 7.01 of any Current Report on Form 8-K that has been or may, from time to time, be furnished to the SEC be incorporated into or otherwise become a part of this Registration Statement.

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

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to CorMedix Inc., Attention: Secretary, 745 Route 202-206, Suite 303, Bridgewater, NJ 08807, (908) 517-9500.

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

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

We estimate that expenses payable by us in connection with the offering described in this registration statement will be as follows:

| | |
|------------------------------|-------------|
| SEC registration fee | \$ 524 |
| Legal fees and expenses | \$ 15,000 * |
| Accounting fees and expenses | \$ 12,000 * |
| Printing expenses | \$ 5,000 * |
| Miscellaneous | \$ 4,476 * |
| Total | \$ 37,000 * |

*Estimated as permitted under Item 511 of Regulation S-K.

Item 15. Indemnification of Directors and Officers.

Section 145 of the DGCL permits a corporation, under specified circumstances, to indemnify its directors, officers, employees or agents against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by them in connection with any action, suit or proceeding brought by third parties by reason of the fact that they were or are directors, officers, employees or agents of the corporation, if such directors, officers, employees or agents acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reason to believe their conduct was unlawful. In a derivative action, that is one by or in the right of the corporation, indemnification may be made only for expenses actually and reasonably incurred by directors, officers, employees or agents in connection with the defense or settlement of an action or suit, and only with respect to a matter as to which they will have acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made if such person will have been adjudged liable to the corporation, unless and only to the extent that the court in which the action or suit was brought will determine upon application that the defendant directors, officers, employees or agents are fairly and reasonably entitled to indemnity

for such expenses despite such adjudication of liability.

Pursuant to the DGCL, our Amended and Restated Certificate of Incorporation, as amended provides that no director will be personally liable to our company or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to our company or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived any improper personal benefit. Our Amended and Restated Bylaws provide that we will generally indemnify our directors, officers, employees or agents to the fullest extent permitted by the law against all losses, claims, damages or similar events. We have obtained liability insurance for each director and officer for certain losses arising from claims or charges made against them while acting in their capacities as directors or officers of our Company.

II-1

Item 16. Exhibits.

(a) The following exhibits are filed as part of this Registration Statement:

| Exhibit Number | Description of Document | Registrant's | | Exhibit Number | Filed Herewith |
|---------------------------|--|---------------------|--------------|---------------------------|---------------------------|
| | | Form | Dated | | |
| 4.1 | Specimen of Common Stock Certificate | S-1/A | 3/19/10 | 4.1 | |
| 4.2 | Specimen Unit certificate | S-1/A | 3/19/10 | 4.2 | |
| 4.3 | Specimen warrant certificate | S-1/A | 3/19/10 | 4.3 | |
| 4.4 | Form of warrant agreement | S-1/A | 3/19/10 | 4.4 | |
| 4.5 | Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC | S-1 | 11/25/09 | 4.6 | |
| 4.6 | Stockholder Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC | S-1 | 11/25/09 | 4.7 | |
| 4.7 | Form of Third Bridge Warrant | S-1/A | 1/20/10 | 4.18 | |
| 4.8 | Form of 9% Senior Convertible Note due 2013 | 10-Q | 11/13/12 | 4.1 | |
| 4.9 | Form of Purchaser Warrant | 10-Q | 11/13/12 | 4.2 | |
| 4.10 | Form of Placement Agent Warrant | 10-Q | 11/13/12 | 4.3 | |
| 4.11 | Form of Subscription Agreement | 10-Q | 11/13/12 | 4.4 | |
| 4.12 | Form of Registration Rights Agreement | 10-Q | 11/13/12 | 4.5 | |
| 4.13 | Form of Registered Direct Warrant | 8-K | 2/19/13 | 4.13 | |
| 5.1* | Opinion of Wyrick Robbins Yates & Ponton LLP. | S-3 | 1/11/13 | 5.1 | |
| 23.1 | Consent of CohnReznick LLP, Independent Registered Public Accounting Firm. | | | | x |
| 23.2* | Consent of Wyrick Robbins Yates & Ponton LLP (included as part of Exhibit 5.1). | S-3 | 1/11/13 | 23.2 | |
| 24.1* | Power of Attorney (included in the signature pages hereto). | S-3 | 1/11/13 | 24.1 | |

*Previously filed.

(b) None.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933 (the "Act");

To reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the (ii) most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information in this registration statement; and

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

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

That, for the purpose of determining any liability under the Act, each such post-effective amendment shall be (2) deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to (b) Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

- Insofar as indemnification for liabilities arising under the Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission, or SEC, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- (c)

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bridgewater, State of New Jersey, on March 28, 2013.

CORMEDIX INC.

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

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement on Form S-3 has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Capacity | Date |
|--|---|----------------|
| /s/ Richard M. Cohen Richard M. Cohen | Director and Chief Financial Officer (Principal Financial and Accounting Officer) | March 28, 2013 |
| /s/ Gary Gelbfish* Gary Gelbfish, M.D. | Director | March 28, 2013 |
| /s/ Matthew Duffy Matthew P. Duffy | Director | March 28, 2013 |
| /s/ Steven Lefkowitz Steven Lefkowitz | Director | March 28, 2013 |
| /s/ Antony E. Pfaffle, M.D.* Antony E. Pfaffle, M.D. | Director | March 28, 2013 |

* By: /s/ Randy Milby
 Randy Milby, Attorney-in-Fact

S-1