CorMedix Inc.
Form S-3/A
January 09, 2013

As filed with the Securities and Exchange Commission on January 9, 2013

Registration Statement No. 333-185737_____

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 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 of incorporation or organization)	**(I.R.S. Employer Identification No.)**

745 Route 202-206, Suite 303

Bridgewater, New Jersey 08807

Telephone: (908) 517-9500

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

Randy Milby

Chief Executive Officer

CorMedix Inc.

745 Route 202-206, Suite 303

Bridgewater, New Jersey 08807

Telephone: (908) 517-9500

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

Copies to:

ALEXANDER M. DONALDSON

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4101 Lake Boone Trail, Suite 300

Raleigh, North Carolina 27607

Telephone: (919) 781-4000

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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 x

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 January 9, 2013

Prospectus

$30,000,000 of

Common Stock,

Preferred Stock,

Warrants,

Debt Securities and/or

Units

From time to time, we may offer up to $30,000,000 of any combination of the securities described in this prospectus, either individually or in units, in one or more offerings in amounts, at prices and on the terms that we will determine at the time of offering. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

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

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

Our common stock trades on the NYSE MKT under the trading symbol "CRMD." On January 7, 2013, the last reported sale price of our common stock was $0.93 per share. We recommend that you obtain current market quotations for our common stock prior to making an investment decision.

As of January 7, 2013, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was approximately $9,587,095, which was calculated based on 10,308,704 shares of our outstanding common stock held by non-affiliates and on a price of $0.93 per share, the last reported sale price for our common stock on January 7, 2013. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our common stock in a public primary offering with a value exceeding one-third of our public float in any 12-month period unless our public float subsequently rises to $75.0 million or more. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

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

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

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

The date of this prospectus is , 2013.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this shelf registration process, we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of $30,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering.

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

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

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

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

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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 6 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. Specifically, our goal is to treat kidney disease by reducing the commonly associated cardiovascular and metabolic complications — in effect, "treating the kidney to treat the heart." 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.

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

We have successfully completed the stage 2 audit with TÜV SÜD. We anticipate receiving a CE Mark approval by the end of the fourth quarter of 2012 or in the first 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 in the first half of 2013. However, we cannot be assured of CE Mark approval of Neutrolin or the planned commercialization timeline.

We are currently exploring the various means of launching Neutrolin in Europe, whether through a distributorship or partnership arrangement, or otherwise, and plan to initially launch in Germany. 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.

Recent Developments

On September 20, 2012, we completed an initial closing of our private placement of 850 Units, each Unit consisting of (i) a one-year $1,000 principal amount 9% Senior Convertible Note, convertible into shares of our common stock at a conversion price of $0.35 per Note, and (ii) a five-year redeemable Warrant, to purchase 2,500 shares of our common stock at a purchase price of $0.40 per share. We received gross proceeds of $850,000 and net proceeds of approximately $689,000 in the September 20, 2012 initial closing. The maturity date of the Notes issued in the initial closing is September 20, 2013.

On November 13, 2012, we held the second and final closing of the private placement, and issued an additional 474 Units for a total gross amount of $474,000. The maturity date of the Notes issued in the final closing is November 13, 2013. Together with the sale of 850 Units at the initial closing, we issued and sold in the private placement an aggregate total of 1,324 Units for aggregate gross proceeds of $1,324,000. The total net proceeds (net of placement agent and legal fees) of the private placement to us were $1,095,600, including $689,000 net proceeds previously received by us at the initial closing and $406,600 net proceeds received by us in the final closing. We issued to the investors Warrants to purchase an aggregate of 3,310,000 shares of our common stock. We paid the placement agent for the private placement a total of $109,900 in fees and issued it warrants to purchase an aggregate of 331,000 shares. The placement agent warrants have the same terms as those issued to the investors.

We have agreed to file an initial registration statement with the SEC to register the resale of the shares of common stock issuable upon the conversion of the Notes and the exercise of the Warrants within 60 days after the final closing, which is January 11, 2013. Also, we have agreed to use our commercially reasonable efforts to have the registration statement declared effective within 120 days after the date of the final closing, which is March 13, 2013.

On December 24, 2012, we announced the following changes to our executive team.

- Randy Milby has been promoted to Chief Executive Officer, effective January 1, 2013. Mr. Milby previously served as our Chief Operating Officer.
- Richard M. Cohen will serve as Chief Financial Officer, effective January 1, 2013, and will continue as Executive Chairman and director of CorMedix. Mr. Cohen previously served as our Interim Chief Financial Officer and Interim Chief Executive Officer.

- Antony E. Pfaffle, M.D., a director on our board, joins the executive team as Acting Chief Scientific Officer, effective January 1, 2013.
- Mark Klausner, M.D., our current Chief Medical Officer, will depart CorMedix effective February 28, 2013 upon expiration of his employment agreement with CorMedix.

Mr. Milby will continue to work with the board and build the management team to drive our strategy forward with respect to the planned receipt of CE Mark approval for Neutrolin and subsequent commercial launch of Neutrolin in Europe and the planned expansion into countries beyond Europe. Dr. Pfaffle in this capacity will provide scientific support and will focus on the development of key opinion leader relationships throughout Europe.

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.

Offerings Under This Prospectus

We may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, with a total value of up to $30,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of any offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

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

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

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

· the names of those agents or underwriters;

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

· details regarding over-allotment options, if any; and

· the net proceeds to us.

Common Stock

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

Preferred Stock

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

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

Warrants

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

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

Debt Securities

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

With respect to any debt securities that we issue, we will issue such debt securities under an indenture, which we would enter into with the trustee named in the indenture. Any indenture would be qualified under the Trust Indenture Act of 1939.

Units

We may issue units consisting of common stock, preferred stock, debt securities and/or warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. In this prospectus, we have summarized

certain general features of the units. We urge you, however, to read the applicable prospectus supplement related to the series of units being offered, as well as the unit agreements that contain the terms of the units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference reports that we file with the SEC, the form of unit agreement and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

RISK FACTORS

Investing in our securities involves risk. The prospectus supplement applicable to each offering of our securities will contain a discussion of the risks applicable to an investment in our company. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed below and under the heading "Risk Factors" in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K and 10-K/A, 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

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 a net loss of approximately $2.2 million for the nine months ended September 30, 2012 and approximately $6.7 million for the year ended December 31, 2011. As of September 30, 2012, we had an accumulated deficit of approximately $45.2 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. 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.

Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its audited financial statements for the year ended December 31, 2011 and may do so again in the

future.

In their report accompanying our audited financial statements for the year ended December 31, 2011, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going a 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 first 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. 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 operation 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 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. We have recently 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:

- 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. 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 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.

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

There can be no assurance that 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 medical device 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 Acting Chief Scientific Officer. Dr. Mark Klausner, our current part-time Chief Medical Officer, will cease 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 for cash disbursements and cash reconciliations), 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 Form S-3, 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’s patent’s 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, 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 qualities 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 January 7, 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 medical device sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions;
- developments or disputes concerning patents or other proprietary rights;
- future sales or anticipated sales of our securities by us or our stockholders; and
- any other factors described in this "Risk Factors" section.

In addition, the stock markets in general, and the stock of pharmaceutical and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

For these reasons and others, you should consider an investment in our 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 January 7, 2013, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

- warrants for 4,263,569 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 17,869 shares of common stock with an exercise price of $10.66 per share and an expiration date of January 30, 2013 issued to consultants;

- 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 3,782,858 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; and

- 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.

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 and the exercise of the warrants issued in our 2012 private placement under the Securities Act of 1933, or the Securities Act. If those shares are issued, 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.

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

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

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

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may 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 January 7, 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. 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.

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

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

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting our stockholders from fixing the number of our directors; and
- establishing advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors.

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

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. We incurred a net loss of approximately $2.2 million for the nine months ended September 30, 2012 and as of September 30, 2012 we had a deficit accumulated during the development stage of approximately $45.2 million. On April 20, 2012, the NYSE MKT notified us that we were not in compliance with certain listing standards 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. We will be subject to periodic review by the NYSE MKT during the extended plan period. 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. 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 wor of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management's current judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to: 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 and 10-K/A, 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

We cannot assure you that we will receive any proceeds in connection with securities offered by us pursuant to this prospectus. Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of our securities by us under this prospectus for general corporate purposes, including the development and commercialization of Neutrolin, research and development of other product candidates, potential product acquisitions and/or potential acquisitions of complementary businesses, and working capital and capital expenditures. We will set forth in the applicable prospectus supplement our intended use for the net proceeds received from the sale of any securities by us. Pending the application of the net proceeds, we intend to invest the net proceeds generally in short-term, investment grade, interest bearing securities.

RATIO OF EARNINGS TO FIXED CHARGES

If we offer debt securities under this prospectus, then we will, if required at that time, provide a ratio of earnings to fixed charges in the applicable prospectus supplement for such offering

PLAN OF DISTRIBUTION

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

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

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

- the name or names of the underwriters, if any;
- the purchase price of the securities or other consideration therefor, and the proceeds, if any, we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;
- any public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

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

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

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

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

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

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

Any underwriter may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate-covering or other short-covering transactions involve purchases of the securities, either through exercise of the over-allotment option or in the open market after the distribution is completed, to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold

by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

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

In compliance with guidelines of the Financial Industry Regulatory Authority, or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker-dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

DESCRIPTION OF COMMON STOCK

Pursuant to our Amended and Restated Certificate of Incorporation, as amended we are authorized to issue 80,000,000 shares of common stock, $0.001 par value per share. As of January 7, 2013, we had 11,408,274 shares of common stock outstanding and 184 stockholders of record. In addition, we estimate that there were approximately 550 beneficial owners as of January 7, 2013.

The following summary of certain provisions of our common stock does not purport to be complete. You should refer to our Amended and Restated Certificate of Incorporation, as amended and our Amended and Restated Bylaws. We filed our Amended and Restated Certificate of Incorporation, as amended as an exhibit to our definitive proxy statement on Schedule 14A with the SEC on October 17, 2012 and filed our Amended and Restated Bylaws as an exhibit to the registration statement on Form S-1 filed with the SEC on March 1, 2010. The summary below is also qualified by provisions of applicable law.

General

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

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC. The transfer agent's address is 77 Spruce Street, Suite 201, Cedarhurst, New York 11516 and its telephone number is (212) 828-8436.

Listing on NYSE MKT

Our common stock is listed for quotation on the NYSE MKT under the symbol "CRMD." On January 7, 2013, the last reported sale price of our common stock was $0.93 per share.

DESCRIPTION OF PREFERRED STOCK

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

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

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;

- voting rights, if any, of the preferred stock;
- preemptive rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material or special United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

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

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

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

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provisions of any debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we may offer under a prospectus supplement may differ from the terms described below. For any debt securities that we may offer, an indenture (and any relevant supplemental indenture) will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement that includes this prospectus, or as an exhibit to reports that we file with the SEC and incorporated by reference in this prospectus.

With respect to any debt securities that we issue, we will issue such debt securities under an indenture, which we would enter into with the trustee named in the indenture. Any indenture would be qualified under the Trust Indenture Act of 1939.

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

· the title;

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

- any limit on the amount that may be issued;

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

- the maturity date;

- the principal amount due at maturity;

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

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

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

- whether or not the debt securities will be secured or unsecured by some or all of our assets, and the terms of any secured debt;
- the terms of the subordination of any series of subordinated debt;
- the place where payments will be payable;
- restrictions on transfer, sale or other assignment, if any;
- our right, if any, to defer payment or interest and the maximum length of any such deferral period;
- the date, if any, after which and the conditions upon which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemptions provisions;
- the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- whether the indenture will restrict our ability to pay dividends, or will require us to maintain any asset ratios or reserves;
- whether we will be restricted from incurring any additional indebtedness, issuing additional securities, or entering into a merger, consolidation or sale of our business;
- a discussion of any material or special United States federal income tax considerations applicable to the debt securities;
- information describing any book-entry features;
- any provisions for payment of additional amounts for taxes;
- whether the debt securities are to be offered at a price such that they will be deemed to be offered at an "original issue discount" as defined in paragraph (a) of Section 1273 of the Internal Revenue Code of 1986, as amended;

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

- events of default;

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

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

- description of the debenture trustee and paying agent, and the method of payments; and

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

DESCRIPTION OF WARRANTS

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

- the specific designation and aggregate number of, and the price at which we will issue, the warrants;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- if applicable, the exercise price for shares of our common stock or preferred stock and the number of shares of common stock or preferred stock to be received upon exercise of the warrants;
- in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at, and currency in which, this principal amount of debt securities may be purchased upon such exercise;
- the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;
- whether the warrants will be issued in fully registered form or bearer form, in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;
- any applicable material U.S. federal income tax consequences;
- the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;

- the proposed listing, if any, of the warrants or the common stock issuable upon exercise of the warrants on any securities exchange;
- if applicable, the date from and after which the warrants and the common stock will be separately transferable;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- the anti-dilution provisions of the warrants, if any;
- any redemption or call provisions;
- whether the warrants are to be sold separately or with other securities as parts of units; and
- any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

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

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

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

Transfer Agent and Registrar

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

DESCRIPTION OF UNITS

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

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

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

Certain provisions of DGCL and our Amended and Restated Certificate of Incorporation, as amended and 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.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information with respect to compensation earned by our named executive officers in the fiscal years ended December 31, 2011 and 2012.

Name and Principal Position	Year	Salary ($)	Bonus ($)	**Option Awards [1] ($)**	**All Other Compensation ($)**	Total ($)
Richard M. Cohen [2]	2012	86,250	-	39,200	-	125,450
Executive Chairman, Interim Chief Executive Officer and Interim Chief Financial Officer	2011	22,500	-	50,900	31,500	104,900
Randy Milby [3]	2012	58,800	-	67,750	-	126,550
Chief Operating Officer						
Mark A. Klausner, M.D. [4]	2012	180,833	-	-	7,556	188,389
Chief Medical Officer	2011	258,333	-	453,000	-	711,333
Brian Lenz [5]	2012	93,750	-	79,200	17,966	190,916
Former Chief Operating Officer and Chief Financial Officer, Treasurer and Secretary	2011	250,000	-	-	-	250,000

(1) The amounts included in this column are the dollar amounts representing the full grant date fair value of each stock option award, and in the case of Mr. Lenz, the incremental fair value of the modification to an outstanding option in 2012, calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the named executive officers upon option exercise. For information on the valuation assumptions used in calculating this amount, see Note 2 to our audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC; for 2012, the assumed risk-free interest rate was 0.27%-1.22% and the assumed expected volatility was 98%-120%.

(2) Mr. Cohen has been a director of CorMedix since December 2009, was appointed Executive Chairman in September 2011, our Interim Chief Executive Officer in November 2011 and our Interim Chief Financial Officer in May 2012. As compensation for serving as a director of CorMedix in 2011, Mr. Cohen received $31,500 in director fees, which is reflected in the "All Other Compensation" column in the table above, and was granted options to purchase 30,000 shares of our common stock, which is reflected in the "Option Awards" column in the table above. Effective upon his appointment as our Interim Chief Executive Officer, Mr. Cohen no longer received Board fees and Board stock options grants from the date thereof. On December 5, 2012, we granted Mr. Cohen options to purchase 70,000 shares of our common stock under our 2006 Stock Plan, which options vest (i) 50% on the date of issuance of a CE mark approval in Europe for Neutrolin® if the approval is received on or before March 31, 2013, and (ii) 50% on December 31, 2013. Effective January 1, 2013, the Board appointed Mr. Cohen as our Chief Financial Officer.

(3) Mr. Milby became our Chief Operating Officer in May 2012, pursuant to a consulting agreement described below under "Employment Agreements and Arrangements." On May 14, 2012, we granted Mr. Milby options to purchase 50,000 shares of our common stock under our 2006 Stock Plan, which options vest on the date of issuance of a CE mark approval in Europe for Neutrolin. On December 5, 2012, we granted Mr. Milby options to purchase 100,000 shares of our common stock under our 2006 Stock Plan, which options vest (i) 50% on the date of issuance of a CE mark approval in Europe for Neutrolin if the approval is received on or before March 31, 2013, and (ii) 50% on December 31, 2013. Effective January 1, 2013, the Board appointed Mr. Milby our Chief Executive Officer.

(4) Dr. Klausner became our Chief Medical Officer in March 2011. On March 1, 2011, we granted Dr. Klausner options to purchase 356,000 shares of our common stock under our 2006 Stock Plan with an exercise price of $1.61 per share. On February 29, 2012, we and Dr. Klausner agreed to amend Dr. Klausner's employment agreement effective March 1, 2012 which provides for a 50% reduction in both Dr. Klausner's services to our company and his compensation. The amount reflected in the "All Other Compensation" column represents life, long-term and short-term disability and health insurance premiums. Dr. Klausner will depart CorMedix effective February 28, 2013 upon expiration of his employment agreement.

(5) Mr. Lenz became our Chief Financial Officer and Treasurer in February 2010, our Secretary in January 2011 and our Chief Operating Officer in January 2012. On March 20, 2012, we granted Mr. Lenz options to purchase 180,000 shares of our common stock under our 2006 Stock Plan with an exercise price of $0.49 per share. The amount reflected in the "All Other Compensation" column represents life, dental, long-term and short-term disability and health insurance premiums. In April 2012, Mr. Lenz resigned all positions. In connection with his resignation, Mr. Lenz and we entered into a Memorandum of Understanding in May 2012, as described below under "Employment Agreements and Arrangements".

Compensation Objectives and Philosophy

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

- motivate, recruit and retain executives capable of meeting our strategic objectives;
- provide incentives to ensure superior executive performance and successful financial results for CorMedix; and
- align the interests of the named executive officers with the long-term interests of our stockholders.

The Compensation Committee seeks to achieve these objectives by:

- establishing a compensation structure that is both market competitive and internally fair;
- linking a substantial portion of compensation to our achievement of financial objectives and the individual's contribution to the attainment of those objectives;
- providing upward leverage for overachievement of goals; and
- providing long-term equity-based incentives.

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

Setting Executive Compensation

The Compensation Committee oversees the design, development and implementation of the compensation program for the Chief Executive Officer and the other named executive officers. The Compensation Committee evaluates the performance of the Chief Executive Officer and determines the Chief Executive Officer's compensation in light of the goals and objectives of the compensation program. The Chief Executive Officer and the Compensation Committee together assess the performance of the other named executive officers employed by us as of December 31 and determine their compensation, based on initial recommendations from the Chief Executive Officer. Our Interim Chief Executive Officer provided the Compensation Committee with a detailed review of the performance of the other named executive officers and made recommendations to the Compensation Committee with respect to the compensation packages for those officers for 2012.

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

We did not use the services of any compensation consultant in matters affecting the compensation of named executive officers or directors during 2011 or 2012. In the future, we, or the Compensation Committee, may engage or seek the advice of a compensation consultant.

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

Components of Compensation

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

Base Salary . It is the Compensation Committee's objective to set a competitive rate of annual base salary for each named executive officer. The Compensation Committee believes competitive base salaries are necessary to attract and retain top quality executives, since it is common practice for public companies to provide their named executive officers with a guaranteed annual component of compensation that is not subject to performance risk. The Compensation Committee, on its own or with outside consultants, may establish salary ranges for the named executive officers, with minimum to maximum opportunities that cover the normal range of market variability. The actual base salary for each named executive officer is then derived from those salary ranges based on his responsibility, tenure and past performance and market comparability. Annual base salaries for the named executive officers are reviewed and approved by the Compensation Committee in the first quarter following the end of the previous performance year. Changes in base salary are based on the scope of an individual's current job responsibilities, individual performance in the previous performance year, target pay position relative to the peer group, and our salary budget guidelines. The Compensation Committee reviews established goals and objectives, and determines an individual's achievement of those goals and objectives and considers the recommendations provided by the Chief Executive Officer to assist it in determining appropriate salaries for the named executive officers other than the Chief Executive Officer. For any given performance year, actual salary increases may range from 0% to 10% of the salary guidelines based on individual performance. This broad range allows for meaningful differentiation on a pay for performance basis.

The base salary information for our named executive officers for 2012 is set forth in the table above. As a result of our financial condition, the Interim Chief Executive Officer and the Compensation Committee recommended to the Board that no merit increases be granted to our named executive officers for 2012 or for 2013 due to changes in our management effective January 1, 2013.

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

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

As a result of our financial condition, our Interim Chief Executive Officer and the Compensation Committee determined not to grant bonuses to the named executive officers for 2011 or 2012.

Long-Term Incentive Equity Awards . We believe that long-term performance is achieved through an ownership culture that encourages high performance by our named executive officers through the use of stock-based awards. Our 2006 Stock Plan was established to provide our employees, including our named executive officers, with incentives to help align employees' interests with the interests of our stockholders. The Compensation Committee believes that the use of stock-based awards offers the best approach to achieving our compensation goals. We have historically elected to use stock options as the primary long-term equity incentive vehicle; however, the Compensation Committee has used restricted stock in the past and may in the future utilize restricted stock as part of our long-term incentive program. We have selected the Black-Scholes method of valuation for share-based compensation effective July 28, 2006. Due to the early stage of our business and our desire to preserve cash, we expect to provide a greater portion of total compensation to our named executive officers through stock options and restricted stock grants than through cash-based compensation.

Stock Options . Our 2006 Stock Plan authorizes us to grant options to purchase shares of common stock to our employees, directors and consultants. The Compensation Committee generally oversees the administration of our 2006 Stock Plan.

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

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

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

- Stock options align the interests of our named executive officers with those of our stockholders, supporting a pay-for performance culture, foster employee stock ownership, and focus the management team on increasing value for our stockholders.
- Stock options are performance-based. All of the value received by the recipient of a stock option is based on the growth of the stock price. In addition, stock options can be issued with vesting based on the achievement of specified milestones, such as options granted in December 2012, 50% of which vest if we receive a CE Mark for Neutrolin by March 31, 2013.
- Stock options help to provide balance to the overall executive compensation program as base salary and annual bonuses focus on short-term compensation, while the vesting of stock options increases stockholder value over the longer term.
- The vesting period of stock options encourages executive retention and the preservation of stockholder value. In determining the number of stock options to be granted to our named executive officers, we take into account the individual's position, scope of responsibility, ability to affect profits and stockholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual named executive officer's total compensation.

Restricted Stock . Our 2006 Stock Plan authorizes us to grant restricted stock. No restricted stock grants were awarded during 2011 or 2012. In order to implement our long-term incentive goals, we may grant shares of restricted stock in the future.

Executive Benefits and Perquisites

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

Employment Agreements and Arrangements

Mark A. Klausner

On February 25, 2011, we entered into an employment agreement with Mark A. Klausner, M.D., our Chief Medical Officer. Pursuant to his employment agreement, on March 1, 2011, we granted Dr. Klausner options to purchase 356,000 shares of our common stock under our 2006 Stock Plan with an exercise price of $1.61 per share. These options vest in equal installments on each of the first three anniversaries of the grant date.

On February 29, 2012, we and Dr. Klausner agreed to amend Dr. Klausner's employment agreement in order to reduce our overhead expenditures and help achieve our strategic focus of achieving CE Mark approval for Neutrolin. The amendment to the employment agreement, effective as of March 1, 2012, provides for a 50% reduction in both Dr. Klausner's services to our company and his compensation. Pursuant to the amendment, we pay Dr. Klausner an annual base salary equal to $155,000 and, at the sole discretion of the Board, we may pay Dr. Klausner a cash bonus each calendar year in an amount equal to up to 35% of the aggregate base salary. Dr. Klausner will depart our company on February 28, 2013 upon expiration of his employment agreement.

Brian Lenz

On March 20, 2012, the Compensation Committee awarded Brian Lenz, our former Chief Operating Officer and Chief Financial Officer, a cash bonus in the amount of $25,000. Payment of the bonus was contingent upon (i) the closing of a financing by us on or before December 31, 2012 with gross proceeds to us equal to or in excess $1.5 million, including the issuance by us of equity, debt or any combination thereof; and (ii) Mr. Lenz's continued employment. On April 30, 2012, Mr. Lenz resigned as our Chief Operating Officer and Chief Financial Officer. As such, no bonus was paid to Mr. Lenz.

On May 2, 2012, in connection with Mr. Lenz's resignation as our Chief Operating Officer, Treasurer, Secretary and Chief Financial Officer effective April 30, 2012, we and Mr. Lenz entered into a Memorandum of Understanding, or MOU, whereby Mr. Lenz provided certain transition services to us through May 31, 2012, and remained reasonably available to us from and after May 31, 2012. In exchange for providing such services to us, we agreed to compensate Mr. Lenz in the amount of $10,417, less applicable taxes and withholdings. Additionally, in consideration of Mr. Lenz's execution of the MOU and performance of the undertakings contained therein, on May 1, 2012, the Compensation Committee approved an extension of Mr. Lenz's right to exercise 45,000 of his vested stock options through and including May 31, 2014, which options had been granted to Mr. Lenz on March 20, 2012 and have an exercise price of $0.49. Mr. Lenz had 90 days from April 30, 2012 to exercise any other remaining vested options, all of which have expired. All unvested options were forfeited and cancelled on April 30, 2012.

Randy Milby

On May 2, 2012, we appointed Mr. Milby as Chief Operating Officer pursuant to a three-month consulting agreement with MW Bridges LLC, of which Mr. Milby is Managing Partner. As our Chief Operating Officer, in 2012 Mr. Milby rendered services to us as directed by Richard Cohen, our Executive Chairman, Interim Chief Executive Officer and Interim Chief Financial Officer. MW Bridges LLC receives a consulting fee of $6,400 per month for Mr. Milby’s services. Additionally, MW Bridges LLC was granted stock options to purchase 50,000 shares of our common stock at an exercise price of $0.29 per share. Such stock options will vest upon CE Mark approval for Neutrolin. On October 31, 2012, we and MW Bridges LLC entered into an amendment to the consulting agreement, which, among other things, (i) extended the then-current term for an additional three months, and (ii) increased Mr. Milby’s monthly retainer to $12,000, effective October 1, 2012. In addition, either party may terminate the consulting agreement, as amended, upon 30 days’ prior written notice.

Effective January 1, 2013, Mr. Milby was appointed our Chief Executive Officer.

Outstanding Equity Awards at Fiscal Year-End

The following table presents information regarding unexercised options for each named executive officer as of the end of the fiscal year ended December 31, 2012.

	Option Awards			
Name	Number of securities underlying	Number of securities underlying unexercised	Option exercise price ($)	Option expiration date

	unexercised options (#) exercisable	options (#) unexercisable		
Richard M. Cohen [1]	20,000	-	3.125	3/30/2020
	30,000	-	2.10	1/14/2021
	-	70,000	0.68	12/05/2022
Randy Milby [2]	-	50,000	0.29	5/14/2022
	-	100,000	0.68	12/05/2022
Brian Lenz [3]	45,000	-	0.49	5/31/2014
Mark A. Klausner, M.D. [4]	118,665	237,335	1.61	3/1/2021

(1) On December 5, 2012, we granted Mr. Cohen options to purchase 70,000 shares of our common stock under our 2006 Stock Plan, which options vest (i) 50% on the date of issuance of a CE mark approval in Europe for Neutrolin if the approval is received on or before March 31, 2013, and (ii) 50% on December 31, 2013.

(2) On May 14, 2012, we granted Mr. Milby options to purchase 50,000 shares of our common stock under our 2006 Stock Plan, which options vest on the date of issuance of a CE mark approval in Europe for Neutrolin. On December 5, 2012, we granted Mr. Milby options to purchase 100,000 shares of our common stock under our 2006 Stock Plan, which options vest (i) 50% on the date of issuance of a CE mark approval in Europe for Neutrolin if the approval is received on or before March 31, 2013, and (ii) 50% on December 31, 2013.

(3) On March 20, 2012, we granted Mr. Lenz options to purchase shares of our common stock under our 2006 Stock Plan, of which options only 45,000 had vested.

(4) On March 1, 2011, we granted Dr. Klausner options to purchase 356,000 shares of our common stock under our 2006 Stock Plan, which options vest in equal installments on each of the first three anniversaries of the grant date.

Director Compensation

The following table sets forth information with respect to compensation earned by or awarded to each of our non-executive directors who served on the Board during the fiscal year ended December 31, 2012.

Name	Fees Earned ($)	**Option Awards[1] [2] [3] ($)**	Total ($)
Richard M. Cohen[4]	-	-	-
Gary A. Gelbfish, M.D.	48,500	46,100	94,600
Antony E. Pfaffle, M.D.	48,500	146,900	195,400
Steven Lefkowitz	56,083	90,900	146,983
Matthew P. Duffy	30,667	76,900	107,567
Timothy M. Hofer[5]	46,083	24,596	70,679

(1) On January 10, 2012, each of our non-executive directors was granted an option to purchase 30,000 shares of our common stock.

(2) The amounts included in this column are the dollar amounts representing the full grant date fair value of each stock option award and in the case of Mr. Hofer, the incremental fair value of modifications to his outstanding options in November 2012, calculated in accordance with FASB ASC Topic 718 and do not represent the actual value that may be recognized by the directors upon option exercise. For information on the valuation assumptions used in calculating this amount, see Note 2 to our audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC; for 2012, the assumed risk-free interest rate was 0.27%-1.22% and the assumed expected volatility was 98%-120%.

(3) As of December 31, 2012, the number of shares underlying options held by each non-employee director was as follows: 150,000 shares for Dr. Gelbfish; 330,000 shares for Dr. Pfaffle; 210,000 shares for Mr. Lefkowitz; 185,000 shares for Mr. Duffy; and 80,000 shares for Mr. Hofer.

(4) On September 30, 2011 Richard Cohen was appointed our Interim Chief Executive Officer and Executive Chairman in a non-employee capacity, and as such, no longer received Board fees and stock options grants from the date thereof. Mr. Cohen's compensation is set forth in the "Summary Compensation Table" above.

(5) Mr. Hofer's term as a director ended on November 30, 2012.

The Compensation Committee has adopted the following director cash compensation policy. Employee directors do not receive any compensation for their services on the Board. Non-employee directors are entitled to receive the following cash compensation: (i) a $20,000 annual retainer, except that the Chairman of the Board receives $30,000, (ii) $5,000 annually for service on the Audit Committee, except that the Chairman of the Audit Committee receives $12,000, (iii) $4,000 annually for service on the Nominating and Corporate Governance Committee, except that the Chairman of the Nominating and Corporate Governance Committee receives $5,000, (iv) $4,000 annually for service on the Compensation Committee, except that the Chairman of the Compensation Committee receives $5,000, (v) $1,000 for each in-person meeting of the Board attended, and (vi) $500 for each telephonic meeting of the Board attended.

As an equity incentive, upon the consummation of our initial public offering in March 2010, we granted to each of our non-employee directors an option to purchase 20,000 shares of our common stock under our 2006 Stock Plan with an exercise price of $3.125 per share. These options vest in equal installments on each of the grant date and the first two anniversaries of the grant date.

In addition, the Board has adopted the following equity compensation plan for our non-employee directors: (i) an annual grant to each non-employee director at the first Board meeting of the calendar year of an option to purchase 30,000 shares of our common stock at an exercise price equal to the closing price of the common stock on the grant date, which option vests on the first anniversary of the grant date; and (ii) a one-time grant to each new non-employee director in connection with his or her initial election to the Board of an option to purchase 30,000 shares of our common stock at an exercise price equal to the closing price of the common stock on the grant date, which option vests in equal installments on each of the grant date, the first anniversary of the grant date and the second anniversary of the grant date.

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, 2011 and 2010 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, 2011 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 and Form 10-K/A for the fiscal year ended December 31, 2011, filed with the SEC pursuant to Section 13 of the Exchange Act on March 19 and April 26, 2012, respectively;

- our Quarterly Report on Form 10-Q for the three-month period ended March 31, 2012, filed with the SEC pursuant to Section 13 of the Exchange Act on May 15, 2012;

- our Quarterly Report on Form 10-Q and Form 10-Q/A for the six-month period ended June 30, 2012, filed with the SEC pursuant to Section 13 of the Exchange Act on August 13 and September 6, 2012, respectively;

- our Quarterly Report on Form 10-Q for the nine-month period ended September 30, 2012, filed with the SEC pursuant to Section 13 of the Exchange Act on November 13, 2012;

- our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on January 4, January 11, March 5, March 23, April 24, May 3, June 14, July 2, September 25, October 11, October 16, November 6, November 15, December 3, December 7 and December 26, 2012;

- our preliminary proxy statement and definitive proxy statement on Schedule 14A, filed with the SEC pursuant to Section 14 of the Exchange Act, for the 2012 annual meeting of stockholders on September 27 and October 17, 2012, respectively;

- 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	$4,092
Legal fees and expenses	$20,000*
Accounting fees and expenses	$8,000 *
Printing expenses	$5,000 *
Miscellaneous	$2,908 *
Total	$40,000*

*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.

Item 16. Exhibits.

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

Exhibit Number	**Description of Document**	**Registrant's Form**	**Dated**	Exhibit Number	Filed Herewith
1.1*	Form of Underwriting Agreement				
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*	Specimen Preferred Stock Certificate and Form of Certificate of Designation of Preferred Stock.				
4.14**	Form of Indenture.				
4.15*	Form of Note.				
4.16*	Form of Preferred Stock Warrant Agreement and Warrant Certificate.				
4.17*	Form of Debt Securities Warrant Agreement and Warrant Certificate.				
4.18*	Form of Unit Agreement.				
5.1**	Opinion of Wyrick Robbins Yates & Ponton LLP.				
12.1*	Computation of Ratio of Earnings to Fixed Charges.				
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).				
24.1**	Power of Attorney (included in the signature pages hereto).				
25.1*	Statement of Eligibility of Trustee.				

* To be filed by amendment or as an exhibit to a Current Report on Form 8-K and incorporated herein by reference, if applicable.
** 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;

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

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

provided, however, that paragraphs (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.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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

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

(i) Each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

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

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

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

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

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

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

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

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate

jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bridgewater, State of New Jersey, on January 9, 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)	January 9, 2013
/s/ Gary Gelbfish* Gary Gelbfish, M.D.	Director	January 9, 2013
/s/ Matthew P. Duffy* Matthew P. Duffy	Director	January 9, 2013
/s/ Steven Lefkowitz* Steven Lefkowitz	Director	January 9, 2013
/s/ Antony E. Pfaffle Antony E. Pfaffle, M.D.	Director	January 9, 2013

*By: /s/ Randy Milby

Randy Milby, Attorney-in-Fact

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een recognized since the Company s inception. The Company recognized stock-based compensation expense as follows for the three and nine months ended September 30, 2016 and 2015:

	Three Months ended September 30,		Nine Months ended September 30,	
	2016	2015	2016	2015
General and administrative	$ 288,000	$ 395,000	$ 1,571,000	$ 1,537,000
Research and development	288,000	396,000	1,786,000	1,440,000
	$ 576,000	$ 791,000	$ 3,357,000	$ 2,977,000

A summary of stock option activity for the nine months ended September 30, 2016 is as follows:

		Options Outstanding			
	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2015	135,484	515,690	85.60	7.46	
Authorized	101,857				
Granted	(259,721)	259,721	4.45		
Exercised		(403)	6.48		
Forfeited	65,781	(65,781)	41.00		
Balance, September 30, 2016	43,401	709,227	56.46	6.69	
Vested or expected to vest, September 30, 2016		697,004	57.29	4.82	
Exercisable, September 30, 2016		414,004	83.97	4.99	

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

8. Stock-Based Compensation (Continued)

Information with respect to stock options outstanding and exercisable at September 30, 2016 is as follows:

Exercise Price	Shares	Exercisable
$2.70 - $6.50	253,568	48,440
$14.80- $15.00	39,227	17,566
$23.20 - $39.80	107,237	63,770
$43.00 - $75.30	109,762	100,162
$132.80 - $151.20	193,083	178,591
$217.90 - $291.40	6,350	5,475
	709,227	414,004

Options granted after April 23, 2013

The Company accounts for all stock-based payments made after April 23, 2013 to employees and directors using an option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to the Company using the straight-line single option method. In accordance with authoritative guidance, the fair value of non-employee stock based awards is re-measured as the awards vest, and the resulting change in fair value, if any, is recognized in the period the related services are rendered.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company s common stock, assumptions related to the expected price volatility of the Company s stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company s stock.

As of September 30, 2016, there was $3,021,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through September 30, 2016, which is expected to be recognized over a weighted-average period of approximately 1.76 years.

The weighted-average assumptions underlying the Black-Scholes calculation of grant date fair value include the following:

	Nine months ended September 30, 2016
Risk-free interest rate	1.35%
Expected volatility	75.71%
Expected term	5.78 years
Expected dividend yield	0%
Weighted average grant date fair value	$2.87

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

8. Stock-Based Compensation (Continued)

The weighted-average valuation assumptions were determined as follows:

• Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

• Expected term of options: Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the simplified method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.

• Expected stock price volatility: Expected volatility is based on the historical volatility of the Company s common stock since its IPO in July 2013.

• Expected annual dividend yield: The Company has never paid, and does not expect to pay in the foreseeable future, dividends. Accordingly, the Company assumed an expected dividend yield of 0.0%.

• Estimated forfeiture rate: The Company s estimated annual forfeiture rate on stock option grants was 4.14% in 2016, 2015 and 2014, based on the historical forfeiture experience.

Options granted through April 23, 2013

At certain times throughout the Company s history, the chairman of the Company s board of directors, who is also a significant stockholder of the Company (the Significant Holder), afforded option holders the opportunity for liquidity in transactions in which options were exercised and the

shares of Common Stock issued in connection therewith were simultaneously purchased by the Significant Holder (each, a Purchase Transaction). Because the Company had established a pattern of providing cash settlement alternatives for option holders, the Company accounted for its stock-based compensation awards as liability awards, the fair value of which were then re-measured at each balance sheet date.

On April 23, 2013, the Company distributed a notification letter to all equity award holders under the Company s 2007 Equity Compensation Plan (the 2007 Plan) advising them that Purchase Transactions would no longer occur, unless, at the time of a Purchase Transaction, the option holder has held the Common Stock issued upon exercise of options for a period of greater than six months prior to selling such Common Stock to the Significant Holder and that any such sale to the Significant Holder would be at the fair value of the Common Stock on the date of such sale. Based on these new criteria for Purchase Transactions, the Company remeasured options outstanding under the 2007 Plan as of April 23, 2013 to their intrinsic value and reclassified such options from liabilities to stockholders deficit within the Company s consolidated balance sheets, which amounted to $14,482,000. As of September 30, 2016, there was $37,000 of unrecognized compensation expense related to these unvested awards, which is expected to be recognized over a weighted-average period of approximately 0.20 years.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

9. Research Agreements

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University (Temple), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through September 30, 2016 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple a percentage of any sublicensing fees received by the Company.

The Company signed a funding agreement with the Leukemia and Lymphoma Society (LLS) in May 2010, which was amended in January 2013, to fund the development of rigosertib (the LLS-funded Research Program). Under the LLS-funded Research Program, the Company was entitled to receive milestone payments of up to $8,000,000 through 2013 in connection with the proposed clinical trial to be conducted, ONTIME, after which LLS was not obligated to fund any further amounts. Under the terms of the funding agreement, if the LLS-funded Research Program lead to approval of rigosertib by the regulatory authorities, the Company would have been required to proceed with commercialization of the licensed product or repay the amount funded. LLS was entitled to receive regulatory and commercial milestone payments and royalties from the Company based on the Company s net sales of the licensed product after regulatory approval, with the amount of such milestone payments and royalties not to exceed three times the amount funded. During the year ended December 31, 2012, in connection with the execution of the Baxter agreement, the Company paid $1,000,000 to LLS. This payment reduced the maximum potential milestone and royalty payment obligation under this agreement to $23,000,000. No further payments would be due to LLS if the LLS-funded Research Program did not meet its clinical endpoints for safety and efficacy. As a result of the potential obligation to repay the funds under this arrangement, the $8,000,000 of milestone payments received was initially recorded as deferred revenue. The Company received guidance from regulatory authorities during 2015 that the LLS-funded Research Program was not sufficient to support a regulatory submission. Based on the guidance and the commencement of the INSPIRE trial during the fourth quarter of 2015, the company determined that the research program covered by the LLS funding agreement was unsuccessful and, as a result, the funding received non-repayable. Accordingly, the Company recognized the $8.0 million of deferred revenue during the quarter ended December 31, 2015.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements

Baxalta Agreement

In September 2012, the Company entered into a development and license agreement with Baxter Healthcare SA, the predecessor in interest to Baxalta GmbH (together with its affiliates, Baxalta), pursuant to which the Company granted an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe. In accordance with this agreement, the Company received an upfront cash payment of $50,000,000 in 2012. On March 3, 2016, the Company received a notification of Baxalta s election to terminate the development and license agreement based on a strategic reprioritization review, effective August 30, 2016, at which time, the rights licensed to Baxalta reverted to the Company at no cost. Additionally, any rights the Company had to funding, pre-commercial milestone payments and royalties from Baxalta terminated in accordance with the agreement.

Among other things, the Baxalta agreement contemplated development of rigosertib IV in higher-risk MDS patients, through the Company s ONTIME trial and, potentially, additional Phase 3 clinical trials. The ONTIME trial did not achieve its primary endpoint and the Company is continuing the development of rigosertib IV in higher-risk MDS patients through its INSPIRE trial. In accordance with the agreement, the Company elected to have Baxalta fund fifty percent of the costs of the INSPIRE trial, up to $15.0 million. The Company recorded revenue of $1,538,000 during the three months ended September 30, 2016 and $4,857,000 during the nine months ended September 30, 2016 related to Baxalta s funding of the INSPIRE trial. The funding from Baxalta terminated effective August 30, 2016. The Company has overall responsibility for the trial, including determination of the trial specifications, selection of third party service providers and payment for all services and materials.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements (Continued)

SymBio Agreement

In July 2011, the Company entered into a license agreement with SymBio, which has been subsequently amended, granting SymBio an exclusive, royalty-bearing license for the development and commercialization of rigosertib in Japan and Korea. Under the SymBio license agreement, SymBio is obligated to use commercially reasonable efforts to develop and obtain market approval for rigosertib inside the licensed territory and the Company has similar obligations outside of the licensed territory. The Company has also entered into an agreement with SymBio providing for it to supply SymBio with development-stage product. Under the SymBio license agreement, the Company also agreed to supply commercial product to SymBio under specified terms that will be included in a commercial supply agreement to be negotiated prior to the first commercial sale of rigosertib. The supply of development-stage product and the supply of commercial product will be at the Company s cost plus a defined profit margin. Sales of development-stage product have been de minimis. The Company has additionally granted SymBio a right of first negotiation to license or obtain the rights to develop and commercialize compounds having a chemical structure similar to rigosertib in the licensed territory.

Under the terms of the SymBio license agreement, the Company received an upfront payment of $7,500,000. The Company is eligible to receive milestone payments of up to an aggregate of $22,000,000 from SymBio upon the achievement of specified development and regulatory milestones for specified indications. Of the regulatory milestones, $5,000,000 is due upon receipt of marketing approval in the United States for rigosertib IV in higher-risk MDS patients, $3,000,000 is due upon receipt of marketing approval in Japan for rigosertib IV in higher-risk MDS patients, $5,000,000 is due upon receipt of marketing approval in the United States for rigosertib oral in lower-risk MDS patients, and $5,000,000 is due upon receipt of marketing approval in Japan for rigosertib oral in lower-risk MDS patients. Furthermore, upon receipt of marketing approval in the United States and Japan for an additional specified indication of rigosertib, which the Company is currently not pursuing, an aggregate of $4,000,000 would be due. In addition to these pre-commercial milestones, the Company is eligible to receive tiered milestone payments based upon annual net sales of rigosertib by SymBio of up to an aggregate of $30,000,000.

Further, under the terms of the SymBio license agreement, SymBio will make royalty payments to the Company at percentage rates ranging from the mid-teens to 20% based on net sales of rigosertib by SymBio.

Royalties will be payable under the SymBio agreement on a country-by-country basis in the licensed territory, until the later of the expiration of marketing exclusivity in those countries, a specified period of time after first commercial sale of rigosertib in such country, or the expiration of all valid claims of the licensed patents covering rigosertib or the manufacture or use of rigosertib in such country. If no valid claim exists covering the composition of matter of rigosertib or the use of or treatment with rigosertib in a particular country before the expiration of the royalty term, and specified competing products achieve a specified market share percentage in such country, SymBio s obligation to pay the Company royalties will continue at a reduced royalty rate until the end of the royalty term. In addition, the applicable royalties payable to the Company may be reduced if SymBio is required to pay royalties to third-parties for licenses to intellectual property rights necessary to develop,

use, manufacture or commercialize rigosertib in the licensed territory. The license agreement with SymBio will remain in effect until the expiration of the royalty term. However, the SymBio license agreement may be terminated earlier due to the uncured material breach or bankruptcy of a party, or force majeure. If SymBio terminates the license agreement in these circumstances, its licenses to rigosertib will survive, subject to SymBio s milestone and royalty obligations, which SymBio may elect to defer and offset against any damages that may be determined to be due from the Company. In addition, the Company may terminate the license agreement in the event that SymBio brings a challenge against it in relation to the licensed patents, and SymBio may terminate the license agreement without cause by providing the Company with written notice within a specified period of time in advance of termination.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements (Continued)

The Company determined that the deliverables under the SymBio agreement include the exclusive, royalty-bearing, sublicensable license to rigosertib, the research and development services to be provided by the Company and its obligation to serve on a joint committee. The Company concluded that the license did not have standalone value to SymBio and was not separable from the research and development services, because of the uncertainty of SymBio s ability to develop rigosertib in the SymBio territory on its own and the uncertainty of SymBio s ability to sublicense rigosertib and recover a substantial portion of the original upfront payment of $7,500,000 paid by SymBio to the Company.

The supply of rigosertib for SymBio s commercial requirements is contingent upon the receipt of regulatory approvals to commercialize rigosertib in Japan and Korea. Because the Company s commercial supply obligation was contingent upon the receipt of future regulatory approvals, and there were no binding commitments or firm purchase orders pending for commercial supply at or near the execution of the agreement, the commercial supply obligation is deemed to be contingent and is not valued as a deliverable under the SymBio agreement. If SymBio orders the supplies from the Company, the Company expects the pricing for this supply to equal its third-party manufacturing cost plus a pre-negotiated percentage, which will not result in a significant incremental discount to market rates.

Due to the lack of standalone value for the license, research and development services, and joint committee obligation, the upfront payment is being recognized ratably using the straight line method through December 2027, the expected term of the agreement.

11. Preclinical Collaboration

In December 2012, the Company agreed to form GBO, an entity owned by the Company and GVK. The purpose of GBO is to collaborate on and develop two programs through filing of an investigational new drug application and/or conducting proof of concept studies using the Company s technology platform. If a program failure occurs for one or both programs, the Company may contribute additional assets to GBO to establish a replacement program or programs.

During 2013, GVK made an initial capital contribution of $500,000 in exchange for a 10% interest in GBO, and the Company made an initial capital contribution of a sublicense to all the intellectual property controlled by the Company related to the two specified programs in exchange for a 90% interest. Under the terms of the agreement, GVK may make additional capital contributions. The GVK percentage interest in GBO may change from the initial 10% to up to 50%, depending on the amount of its total capital contributions. During November 2014, GVK made an additional capital contribution of $500,000 which increased its interest in GBO to 17.5%. The Company evaluates its variable interests in GBO on a quarterly basis and has determined that it is the primary beneficiary.

For thirty days following the 15-month anniversary of the commencement of either of the two programs, the Company will have an option to (i) cancel the license and (ii) purchase all rights in and to that program. There are three of these buy-back scenarios depending on the stage of development of the underlying assets. In addition, upon the occurrence of certain events, namely termination of the Company s participation in the programs either with or without a change in control, GVK will be entitled to purchase or obtain the Company s interest in GBO. GVK will have operational control of GBO and the Company will have strategic and scientific control.

The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

12. Related-Party Transactions

The Company is party to a research agreement, as amended, with Mount Sinai School of Medicine (Mount Sinai), with which a member of the Company s board of directors and a significant stockholder is associated. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in connection with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions. Payments to Mount Sinai under this research agreement for the three months ended September 30, 2016 and 2015 were $187,000 and $0, respectively and for the nine months ended September 30, 2016 and 2015 were $374,000 and $715,000, respectively. At September 30, 2016 and December 31, 2015, the Company had $88,000 and $0 payable to Mount Sinai under this agreement.

The Company has entered into a consulting agreement with a member of its board of directors, who is also a significant stockholder of the Company. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member for the three months ended September 30, 2016 and 2015 were $33,000 and $49,000, respectively and for the nine months ended September 30, 2016 and 2015 were $99,000 and $148,000, respectively. At September 30, 2016 and December 31, 2015, the Company had no outstanding amounts payable under this agreement.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements

In October 2014, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (Cantor) to create an at-the-market equity program under which the Company from time to time was able to offer and sell shares of its Common Stock through Cantor. A registration statement (Form S-3 No. 333-199219) covering the shares offered through the Cantor program and other securities was filed with the SEC on October 8, 2014 and became effective on November 20, 2014. During the year ended December 31, 2015, 271,517 shares were sold under the sales agreement for net proceeds of $6,018,000. The Cantor sales agreement was terminated on January 5, 2016, and there were no sales of Common Stock under this program during the nine months ended September 30, 2016.

On October 8, 2015, the Company entered into a purchase agreement and a registration rights agreement with Lincoln Park. A registration statement (Form S-1 No. 333-207533) covering the offer and resale by Lincoln Park of shares of Common Stock sold by the Company to Lincoln Park was filed with the SEC on October 20, 2015 and became effective on November 3, 2015.

Subject to the terms and conditions of the purchase agreement, including the effectiveness of a registration statement covering the resale of the shares, the Company may sell additional shares of its Common Stock, having an aggregate offering price of up to $15,000,000 to Lincoln Park from time to time until December 1, 2018.

Upon execution of the Lincoln Park purchase agreement, Lincoln Park made an initial purchase of 84,676 shares of the Company s Common Stock for $1,500,000. Subject to the terms and conditions of the purchase agreement, including the effectiveness of a registration statement covering the resale of the shares, the Company has the right to sell to and Lincoln Park is obligated to purchase up to an additional $15,000,000 of shares of Common Stock, subject to certain limitations, from time to time until December 1, 2018. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 10,000 shares of Common Stock on any business day, increasing to up to 25,000 shares depending upon the closing sale price of the Common Stock (such purchases, Regular Purchases). However, in no event shall a Regular Purchase be more than $1,000,000. The purchase price of shares of Common Stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a Regular Purchase the closing sale price of the Common Stock is not below the threshold price as set forth in the Purchase Agreement. The Company s sales of shares of Common Stock to Lincoln Park under the Purchase Agreement were limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 4.99% of the then-outstanding shares of the Common Stock, which limit increased to 9.99% on May 1, 2016.

Pursuant to the terms of the Lincoln Park purchase agreement and to comply with the listing rules of the NASDAQ Stock Market, the number of shares issued to Lincoln Park thereunder shall not exceed 19.99% of the Company s shares outstanding on October 8, 2015 unless the approval of the Company s stockholders is obtained. This limitation shall not apply if the average price paid for all shares issued and sold under the purchase agreement is equal to or greater than $15.56. The Company is not required or permitted to issue any shares of Common Stock under the Lincoln Park purchase agreement if such issuance would breach the Company s obligations under the listing rules of the NASDAQ Stock Market.

As consideration for entering into the purchase agreement, the Company issued to Lincoln Park 20,000 shares of Common Stock. Lincoln Park represented to the Company, among other things, that it was an accredited investor (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the Securities Act), and the Company sold the securities in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The net proceeds to the Company under the Lincoln Park purchase agreement will depend on the frequency and prices at which the Company may sell shares of Common Stock to Lincoln Park. The Company expects that the proceeds received from the initial purchase and any additional proceeds from future sales to Lincoln Park will be used to fund the development of the Company s clinical and preclinical programs, for other research and development activities and for general corporate purposes.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements (continued)

On January 5, 2016, the Company entered into the Securities Purchase Agreement with an institutional investor providing for the issuance and sale by the Company of 193,684 shares of the Company s Common Stock, at a purchase price of $9.50 per share and warrants to purchase up to 96,842 shares of the Company s Common Stock for aggregate gross proceeds of $1,840,000. The Warrants will be exercisable from July 11, 2016 through July 11, 2021 at an exercise price of $11.50 per share of Common Stock, subject to customary adjustments. Net proceeds from the sale of the Common Stock and Warrants (not including any future proceeds from the exercise of the Warrants) were approximately $1,609,000 after deducting certain fees due to the placement agent and the Company s estimated transaction expenses. The net proceeds received by the Company from the transactions will be used to fund the development of the Company s clinical and preclinical programs, for other research and development activities and for general corporate purposes.

The shares of Common Stock sold by the Company pursuant to the Securities Purchase Agreement were sold pursuant to an effective shelf registration statement on Form S-3, which was initially filed with the SEC on October 8, 2014 and subsequently declared effective on November 20, 2014 (File No. 333- 199219).

The Warrants were issued and sold without registration under the Securities Act in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the Warrants and the shares of Common Stock underlying the Warrants may not be offered or sold except pursuant to an effective registration statement under the Securities Act or pursuant to an available exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and in accordance with applicable state securities laws.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements (continued)

On July 8, 2016, the Company distributed to holders of its Common Stock and to holders of certain of outstanding warrants, at no charge, non-transferable subscription rights to purchase units. Each unit consisted of one share of Common Stock and 0.75 of a tradable warrant representing the right to purchase one share of Common Stock (Tradeable Warrants). The offering of units pursuant to the subscription rights is referred to as the Rights Offering. On July 7, 2016, the Company entered into a dealer-manager agreement (the Dealer-Manager Agreement) with Maxim Group LLC (Maxim), to engage Maxim as dealer-manager for the Rights Offering.

In the Rights Offering, holders received 1.5 subscription rights for each share of Common Stock, or each share of Common Stock underlying participating warrants owned on the record date, July 7, 2016. Subscribers whose subscriptions otherwise would have resulted in their beneficial ownership of more than 4.99% of the Company s Common Stock could elect to receive, in lieu of shares of Common Stock in excess of that threshold, pre-funded warrants to purchase the same number of shares of Common Stock for $0.01 (Pre-Funded Warrants), and the subscription price per unit consisting of a Pre-Funded Warrant in lieu of a share of Common Stock was reduced by the $0.01 exercise price.

The Rights Offering closed on July 29, 2016. Gross proceeds from the offering were $17.4 million, which represents the sale of all 4,256,186, units at approximately $4.10 per unit. Net proceeds were approximately $15.8 million. The Company issued 3,599,786 shares of Common Stock, 3,192,022 Tradable Warrants and 656,400 Pre-Funded Warrants in the Rights Offering. The Tradable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of $4.92 per share. After the one-year anniversary of issuance, we may redeem the Tradable Warrants for $0.001 per Tradable Warrant if the volume weighted average price of our Common Stock is above $12.30 for each of 10 consecutive trading days. On August 3, 2016, the Tradable Warrants were listed for trading on the NASDAQ Capital Market under the symbol ONTXW.

The Pre-Funded Warrants are exercisable for one share of Common Stock at an exercise price of $0.01. The exercise period for the Pre-Funded Warrants is seven years, which may be extended if an exercise would result in the holder s beneficial ownership of our Common Stock exceeding 4.99%.

In connection with the Rights Offering, the Company paid to Maxim a cash fee equal to (a) 4.5% of the dollar amount of the units sold to any holders of subscription rights who were beneficial owners of shares of the Company s common stock prior to July 30, 2013, and (b) 8.0% of the dollar amount of the units sold to any other holders of subscription rights, plus a non-accountable expense allowance of $100,000 for expenses incurred in connection with the Rights Offering.

Under the terms and subject to the conditions contained in the Dealer-Manager Agreement, the Company has agreed not to issue, agree to issue or announce the issuance of any shares of Common Stock or Common Stock equivalents until 90 days after the closing date of the Rights

Offering, without the consent of Maxim, subject to certain exceptions including a pre-existing agreement, equity awards, conversion of derivative securities and in connection with any acquisitions, partnerships or strategic transactions.

A registration statement on Form S-1, as amended (File No. 333-211769), relating to the securities being offered and sold in connection with the Rights Offering was declared effective by the SEC on July 7, 2016. A prospectus and prospectus supplement relating to and describing the terms of the Rights Offering has been filed with the SEC as a part of the registration statement and is available on the SEC s web site at http://www.sec.gov.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with interim unaudited condensed consolidated financial statements contained in Part I, Item 1 of this quarterly report, and the audited consolidated financial statements and notes thereto for the year ended December 31, 2015 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K filed with the SEC on March 28, 2016. As used in this report, unless the context suggests otherwise, we, us, our, the Company or Onconova refer to Onconova Therapeutics, Inc. and its consoli subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements. We may, in some cases, use terms such as believes, estimates, anticipates, expects, plans, intends, may, could, might, will, should, approximately or other words that convey uncertainty of outcomes to identify these forward-looking statements. Forward-looking statements appear in a number of places throughout this report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, protection of our intellectual property portfolio, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial and manufacturing functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this report, they may not be predictive of results or developments in future periods.

Actual results could differ materially from our forward-looking statements due to a number of factors, including risks related to:

- our need for additional financing for our INSPIRE trial and other operations, and our ability to obtain sufficient funds on acceptable terms when needed, and our plans and future needs to scale back operations if adequate financing is not obtained;
- our ability to continue as a going concern;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- the success and timing of our preclinical studies and clinical trials, including site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;

- our ability to enter into, maintain and perform collaboration agreements with other pharmaceutical companies, for funding and commercialization of our clinical product candidates or preclinical compounds, and our ability to achieve certain milestones under those agreements;

- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;

- our plans and ability to develop, manufacture and commercialize our product candidates;

- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;

- the size and growth of the potential markets for our product candidates and our ability to serve those markets;

- regulatory developments in the United States and foreign countries;

- the rate and degree of market acceptance of any of our product candidates;

- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;

- the successful development of our commercialization capabilities, including sales and marketing capabilities;

- recently enacted and future legislation and regulation regarding the healthcare system;

- the success of competing therapies and products that are or become available;

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- our ability to maintain the listing of our common stock on a national securities exchange;
- the potential for third party disputes and litigation; and
- the performance of third parties, including contract research organizations (CROs) and third-party manufacturers.

Any forward-looking statements that we make in this report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the Risk Factors in our most recent annual report on Form 10-K and quarterly reports on Form 10-Q, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any forward-looking statements.

All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-ten reverse stock split which was effective May 31, 2016.

Overview

Onconova Therapeutics, Inc., sometimes referred to as we or the Company, is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. Using our proprietary chemistry platform, we have created an extensive library of targeted anti-cancer agents designed to work against cellular pathways important to cancer cells. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers. We have one Phase 3 clinical-stage product candidate and two other clinical-stage product candidates (one of which is being developed for treatment of acute radiation syndromes) and several preclinical programs. Substantially all of our current effort is focused on our lead product candidate, rigosertib. Rigosertib is being tested in both intravenous and oral formulations as a single agent, and the oral formulation is also being tested in combination with azacitidine, in clinical trials for patients with myelodysplastic syndromes (MDS), and related cancers.

In December 2015, we enrolled the first patient in a randomized controlled Phase 3 clinical trial of rigosertib IV in a population of patients with higher-risk MDS after failure of hypomethylating agent (HMA) therapy. The trial, which we refer to as INSPIRE, is expected to enroll approximately 225 patients at more than 100 sites globally. The primary endpoint of INSPIRE is overall survival, and an interim analysis is anticipated. We anticipate reporting topline data from the INSPIRE trial in 2018.

In January 2016, we completed a sale of common stock and warrants for net proceeds of approximately $1.6 million. In July 2016, we completed a rights offering of units of common stock and warrants for net proceeds of $15.8 million. In the first half of 2016, we took significant

actions to conserve cash, including reduction in personnel and expenditures. While we will continue to take cash conservation actions where appropriate, our costs will increase in subsequent quarters as more INSPIRE sites open and more patients enroll in the INSPIRE trial. We believe that our cash and cash equivalents, together with anticipated contractual cost-sharing payments from Baxalta for a portion of the INSPIRE trial costs through August 31, 2016, will be sufficient to fund our ongoing trials and operations into the fourth quarter of 2017, although there is substantial doubt about our ability to continue as a going concern.

We are exploring various sources of funding for continued development of rigosertib in MDS and acute myelogenous leukemia (AML), as well as our ongoing operations. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, including rigosertib, or grant licenses on terms that are not favorable to us. There can be no assurance, however, that we will be successful in obtaining such financing in sufficient amounts, on terms acceptable to us, or at all. In addition, there can be no assurance that we will obtain approvals necessary to market our products or achieve profitability or sustainable, positive cash flow. If we are unable to successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements, we will not have sufficient cash to fund our ongoing trials and operations. Due to our ongoing losses and our accumulated deficit in combination with these factors, the opinion of our independent registered public accounting firm on our audited consolidated financial statements for our fiscal year ended December 31, 2015 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

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Rigosertib

Rigosertib is a small molecule that inhibits cellular signaling by acting as a Ras mimetic. This is believed to be mediated by the binding of rigosertib to the Ras-binding domain (RBD), found in many Ras effector proteins, including the Raf and PI3K kinases. This mechanism of action provides a new approach to block the interactions between Ras and its targets containing RBD sites. Rigosertib is being tested as a single agent and in combination with azacitidine, in clinical trials of patients with MDS and related cancers. We have enrolled more than 1,200 patients in rigosertib clinical trials. We were a party to a license and development agreement with Baxalta, which granted Baxalta certain rights to commercialize rigosertib in Europe. The Baxalta agreement was terminated on August 30, 2016, at which time the European rights reverted to us at no cost. We are party to a collaboration agreement with SymBio, which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. We have retained development and commercialization rights to rigosertib in the rest of the world, including in the United States and Europe, although we could consider licensing commercialization rights to other territories as we continue to seek additional funding.

Rigosertib IV for higher-risk MDS

In early 2014, we announced topline survival results from our ONTIME trial, a multi-center Phase 3 clinical trial of rigosertib IV as a single agent. The ONTIME trial did not meet its primary endpoint in the intent-to-treat population, although improvements in median overall survival were observed in various pre-specified and exploratory subgroups of higher-risk MDS patients.

During 2014 and 2015, we held meetings with the U.S. Food and Drug Administration (FDA) European Medicines Agency (EMA) and several European national regulatory authorities to discuss and seek guidance on a path for approval of rigosertib IV in higher-risk MDS patients whose disease had failed HMA therapy. After discussions with the FDA and EMA, we refined our patient eligibility criteria by defining a more homogenous patient population. After regulatory feedback, input from key opinion leaders in the U.S. and Europe and based on learnings from the ONTIME study, we designed a new randomized controlled Phase 3 trial, referred to as INSPIRE, with overall survival as a primary endpoint. The INSPIRE trial will enroll higher-risk MDS patients under 82 years of age who have progressed on, or failed to respond to, previous treatment with HMAs within the first nine months after initiation of HMA therapy, and had their last dose of HMA within six months prior to enrollment in the trial. The primary endpoint of this study is overall survival, and an interim analysis is anticipated. This randomized trial of approximately 225 patients is expected to be conducted at more than 100 sites globally. The first patient in the INSPIRE trial was enrolled at the MD Anderson Cancer Center in December 2015 and, as of October 3, 2016, 157 clinical sites are open and can recruit patients. The first patient in Europe was enrolled in March, 2016 and the first patient in Japan was enrolled in July, 2016.

Rigosertib oral in combination with azacitidine for MDS and AML

We have completed enrollment in the Phase 2 portion of an open label Phase 1/2 clinical trial testing rigosertib oral in combination with the approved dose of injectable azacitidine for patients with higher-risk MDS and AML. This study is based on our published preclinical data demonstrating synergistic activity of this combination. The Phase 2 portion of the trial was designed to assess whether treatment with rigosertib, in combination with the approved dose of injectable azacitidine, reduces the number of bone marrow blasts, improves peripheral blood counts and can resensitize the marrow blast cells to azacitidine for patients who were previously exposed to azacitidine. Patient enrollment in the Phase 2 portion of this trial was completed in the fourth quarter of 2015 and interim data were summarized by way of an oral presentation at the ASH Annual Meeting in December 2015 and updated at the European Hematology Association Congress in June 2016.

The Phase 2 trial included both patients with first-line MDS (that is, patients not previously treated with HMAs) and patients with second-line MDS (i.e. patients whose disease had failed prior HMA therapy). The presentation at ASH included results from a total of 37 MDS patients treated with the recommended Phase 2 dose of oral rigosertib (560 mg AM/280 mg PM) plus the full standard dose of injectable azacitidine. The combination of oral rigosertib and azacitidine was generally well tolerated, with a median duration of treatment of four months (range 1 to 27 months).

At the time of the ASH presentation, 30 MDS patients were evaluable for efficacy assessment per 2006 IWG criteria. Twenty-three of 30 patients (77%) responded to the combination therapy, including six patients who had complete remissions. Hematologic improvement was observed in 13 of 26 patients that were evaluable for this part of the analysis. Notably, 16 of 19 (84%) HMA-naïve patients had a response to the combination therapy and 7 of 11 (64%) patients whose disease had previously failed HMAs responded. Additional data collection on efficacy and safety will be presented at the ASH Annual Meeting in December 2016. In September 2016, we held an End-of-Phase 2 meeting with FDA on the use of oral rigosertib in combination with azacitidine for the treatment of patients with MDS. Based on these discussions, we plan to design a randomized, controlled Phase 3 clinical trial comparing the combination of oral rigosertib plus azacitidine to azacitidine plus placebo in 1st-line HR-MDS patients. The primary endpoint of this pivotal trial will be overall response rate

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(ORR); ORR will be a composite of complete remission (CR) and partial remission (PR). We may also pursue additional available paths from FDA for accelerated or enhanced review and further input on the development of a final trial protocol.

Rigosertib oral for lower-risk MDS

Higher-risk MDS patients suffer from a shortfall in normal circulating blood cells, or cytopenias, as well as elevated levels of cancer cells, or blasts in their bone marrow and peripheral blood, whereas lower-risk MDS patients suffer mainly from cytopenias, that is low levels of red blood cells, white blood cells or platelets. Thus, lower-risk MDS patients depend on transfusions and growth factors or other therapies to improve their low blood counts.

We have explored single agent rigosertib oral as a treatment for lower-risk MDS in two Phase 2 clinical trials, 09-05 and 09-07. In December 2013, we presented data at the Annual ASH Meeting from the 09-05 Phase 2 trial. To date, Phase 2 clinical data have shown encouraging signs of efficacy of single agent oral rigosertib in transfusion-dependent, lower-risk MDS patients. Rigosertib has been generally well tolerated, except for urinary side effects at higher dose levels. Future clinical trials will be needed to evaluate dosing and schedule modifications and their impact on efficacy and toxicity of oral rigosertib in lower-risk MDS patients.

Data presented from the 09-05 trial also suggested the potential of a genomic methylation assessment of bone marrow cells to prospectively identify lower-risk MDS patients likely to respond to oral rigosertib. We therefore expanded the 09-05 trial by adding an additional cohort of 20 patients to advance the development of this genomic methylation test. Enrollment in this expansion cohort has been completed. We are working with academic collaborators to refine this genomic methylation test.

Other Programs

The vast majority of the Company s efforts are now devoted to the advanced stage development of rigosertib for unmet medical needs of MDS patients. Other programs are either paused, inactive or require only minimal internal resources and efforts.

Briciclib

Briciclib, another of our product candidates, is a small molecule targeting an important intracellular regulatory protein, cyclin D1, which is often found at elevated levels in cancer cells. Cyclin D1 expression is regulated through a process termed cap-dependent translation, which requires the function of eukaryotic initiation factor 4E protein, or eIF4E. In vitro evidence indicates briciclib binds to eIF4E, blocking cap-dependent translation of cyclin D1 and other cancer proteins, such as c-MYC, leading to tumor cell death. We have been conducting a Phase 1 multisite dose-escalation trial of briciclib in patients with advanced solid tumors refractory to current therapies. Safety and efficacy assessments are complete in six of the seven dose-escalation cohorts of patients in this trial. As of December 2015, the briciclib IND is on full clinical hold following a drug product lot testing failure. We will be required to undertake appropriate remedial actions prior to re-initiating the clinical trial and completing the final dose-escalation cohort.

Recilisib

Recilisib is a product candidate being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. We have completed four Phase 1 trials to evaluate the safety and pharmacokinetics of recilisib in healthy human adult subjects using both subcutaneous and oral formulations. We have also conducted animal studies and clinical trials of recilisib under the FDA s Animal Efficacy Rule, which permits marketing approval for new medical countermeasures for which conventional human efficacy studies are not feasible or ethical, by relying on evidence from studies in appropriate animal models to support efficacy in humans. Ongoing studies of recilisib, focusing on animal models and biomarker development to assess the efficacy of recilisib are being conducted by third parties with government funding. We anticipate that any future development of recilisib beyond these ongoing studies would be conducted solely with government funding or by collaboration.

Preclinical Product Candidates

In addition to our three clinical-stage product candidates, we have several product candidates that target kinases, cellular metabolism or cell division in preclinical development. We may explore additional collaborations to further the development of these product candidates as we focus internally on our more advanced programs.

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Critical Accounting Policies and Significant Judgments and Estimates

This management s discussion and analysis of our financial condition and results of operations is based on our interim unaudited consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, deferred revenue and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe there have been no significant changes in our critical accounting policies as discussed in our annual report on Form 10-K filed with the SEC on March 28, 2016.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

	Three Months Ended September 30,		
	2016	2015	Change
Revenue	$ 1,651,000	$ 1,622,000	$ 29,000
Operating expenses:			
General and administrative	1,975,000	2,217,000	242,000
Research and development	3,991,000	5,282,000	1,291,000
Total operating expenses	5,966,000	7,499,000	1,533,000
Loss from operations	(4,315,000)	(5,877,000)	1,562,000
Change in fair value of warrant liability	2,706,000		2,706,000
Other income (expense), net	10,000	4,000	6,000
Net loss	$ (1,599,000)	$ (5,873,000)	$ 4,274,000

Revenues

Revenues increased by $29,000 for the three months ended September 30, 2016 when compared to the same period in 2015 primarily as a result of slightly higher contractual cost-sharing revenue from Baxalta for a portion of the costs of the INSPIRE trial in the 2016 period. The Baxalta agreement terminated as of August 31, 2016; therefore, we do not expect cost-sharing revenue from Baxalta to continue in future periods.

General and administrative expenses

General and administrative expenses decreased by $0.2 million, or 11%, to $2.0 million for the three months ended September 30, 2016 from $2.2 million for the three months ended September 30, 2015. The decrease was attributable primarily to a $0.1 million reduction in professional

fees as the company continued to focus on reducing non-core costs. The decrease was also caused by a reduction in stock-based compensation expense of $0.1 million in the 2016 period as a result of fewer outstanding options following the reductions in workforce. Personnel and related costs decreased $0.1 million as a result of a reduction in general and administrative headcount to 9 at September 30, 2016 from 12 at September 30, 2015. These decreases were partially offset by an increase of $0.1 million in meetings, investor relations, and other general and administrative costs during the 2016 period.

Research and development expenses

Research and development expenses decreased by $1.3 million, or 24%, to $4.0 million for the three months ended September 30, 2016 from $5.3 million for the three months ended September 30, 2015. This decrease was caused primarily by a $0.9 million decrease in clinical research, which was comprised of $0.6 million less expense in the 2016 period for the higher risk MDS studies which preceded INSPIRE, offset by $0.9 million higher clinical expense related to INSPIRE. The

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decrease was also attributable to $0.8 million less expense related to lower risk MDS and other legacy studies, and $0.4 million less preclinical and sponsored research in 2016. The decrease in research and development expenses in the 2016 period was also caused by $0.4 million decrease in active pharmaceutical ingredient manufacturing in the 2016 period. Stock-based compensation expense was $0.1 million lower in the 2016 period as a result of fewer outstanding options following the reductions in workforce. These decreases were partially offset by a $0.1 million increase in personnel costs resulting from severance expense related to the reduction in force during the 2016 period.

Change in fair value of warrant liability

The change in fair value of the warrant liability was $2.7 million for the three months ended September 30, 2016 compared to $0 for the three months ended September 30, 2015. The change in the fair value of the warrant liability in 2016 was related to the revaluation of the outstanding warrants issued in January 2016 and July 2016 to fair value at September 30, 2016.

Other income (expense), net

Other income (expense), net, increased by $6,000 for the three months ended September 30, 2016 compared to the three months ended September 30, 2015, due primarily to higher interest income partially offset by higher foreign exchange loss in the 2016 period.

Comparison of the Nine Months Ended September 30, 2016 and 2015

	Nine Months Ended September 30,		
	2016	**2015**	**Change**
Revenue	$ 5,373,000	$ 1,859,000	$ 3,514,000
Operating expenses:			
General and administrative	7,229,000	7,750,000	521,000
Research and development	15,377,000	21,292,000	5,915,000
Total operating expenses	22,606,000	29,042,000	6,436,000
Loss from operations	(17,233,000)	(27,183,000)	9,950,000
Change in fair value of warrant liability	2,985,000		2,985,000
Other income (expense), net	28,000	(32,000)	60,000
Net loss	$ (14,220,000)	$ (27,215,000)	$ 12,995,000

Revenues

Revenues increased by $3.5 million for the nine months ended September 30, 2016 when compared to the same period in 2014 primarily as a result of contractual cost-sharing revenue from Baxalta for a portion of the costs of the INSPIRE trial in the 2016 period. The Baxalta agreement terminated as of August 31, 2016; therefore, we do not expect cost-sharing revenue from Baxalta to continue in future periods.

General and administrative expenses

General and administrative expenses decreased by $0.5 million, or 7%, to $7.2 million for the nine months ended September 30, 2016 from $7.7 million for the nine months ended September 30, 2015. The decrease was primarily caused by a decrease in professional fees and consulting fees of $0.4 million as a result of the company s focus on reducing non-core costs. The decrease was also caused by a $0.3 million decrease in personnel and related costs related to a reduction in general and administrative headcount to 9 at September 30, 2016 from 12 at September 30, 2015, partially offset by a net increase of $0.2 million in other general and administrative expenses.

Research and development expenses

Research and development expenses decreased by $5.9 million, or 28%, to $15.4 million for the nine months ended September 30, 2016 from $21.3 million for the nine months ended September 30, 2015. This decrease was caused primarily by a $2.5 million decrease in pre-clinical and clinical development costs and a $0.9 million decrease in institutional research in the 2016 period, as our development efforts were focused on the INSPIRE trial and we worked to reduce expenses related to other programs and legacy studies. The decrease in research and development expenses in 2016 was also caused by a

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reduction of $1.7 million in API manufacturing costs and a reduction of $0.3 million in consulting expenses related to analyzing clinical trial results and preparing for meetings with regulatory authorities in the 2015 period. Personnel and related costs were $2.0 million lower as research and development headcount was down to 14 at September 30, 2016 from 23 at September 30, 2015, partially offset by $1.2 million of severance costs resulting from the reductions in workforce during 2016. Stock-based compensation expense was $0.3 million higher in the 2016 period as a result of acceleration of vesting and expense recognition in connection with our reduction in workforce in the first quarter of 2016.

Change in fair value of warrant liability

The change in fair value of the warrant liability was $3.0 million for the nine months ended September 30, 2016 compared to $0 for the nine months ended September 30, 2015. The change in the fair value of the warrant liability in 2016 was related to the revaluation of the outstanding warrants issued in January 2016 and July 2016 to fair value at September 30, 2016.

Other income (expense), net

Other income (expense), net, increased by $60,000 for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, primarily to $30,000 less foreign exchange loss and $30,000 higher interest income in the 2016 period.

Financial Condition

Total assets increased $4.6 million, or approximately 20%, from $23.4 million at December 31, 2015 to $28.1 million at September 30, 2016. The increase in total assets was due primarily to the net increase in cash and cash equivalents resulting from the completion of our registered direct offering during the first quarter and our rights offering during the third quarter of 2016, partially offset by decreases in receivables and prepaid expenses. Total liabilities increased from $12.6 million at December 31, 2015 to $18.1 million at September 30, 2016, an increase of $5.5 million, primarily as a result of the warrant liability arising from the issuance of warrants during 2016, and due to the timing of invoices from and payments to vendors. Total stockholders equity decreased from $10.8 million at December 31, 2015 to $10.1 million at September 30, 2016, a decrease of $0.8 million, or approximately 8%. This decrease was primarily due to the completion of our registered direct offering during the first quarter, our rights offering during the third quarter, and stock compensation of $3.4 million, offset by a net loss of $14.2 million for the nine months ended September 30, 2016.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of $14.2 million and $27.2 million for the nine months ended September 30, 2016 and 2015, respectively. Our operating activities used $11.5 million and $26.2 million of net cash during the nine months ended September 30, 2016 and 2015, respectively. At September 30, 2016, we had an accumulated deficit of $332.8 million, working capital of $18.9 million, and cash and cash equivalents of $25.8 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the fourth quarter of 2017.

Cash Flows

The following table summarizes our cash flows for the three months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	**2015**
Net cash (used in) provided by:		
Operating activities	$ (11,450,000)	$ (26,198,000)
Investing activities		
Financing activities	17,424,000	4,818,000
Effect of foreign currency translation	5,000	(5,000)
Net (decrease) increase in cash and cash equivalents	$ 5,979,000	$ (21,385,000)

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Net cash used in operating activities

Net cash used in operating activities was $11.5 million for the nine months ended September 30, 2016 and consisted primarily of a net loss of $14.2 million and change in fair value of warrant liability of $3.0 million, partially offset by $3.4 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of $2.3 million. Significant changes in operating assets and liabilities included a decrease in prepaid expenses and other current assets of $0.7 million as a result of the recognition of expense for clinical and manufacturing activities and insurance expense, a decrease in receivables of $0.6 million due to collections of receivables. Accounts payable and accrued liabilities increased by $1.4 million as a result of the timing of receipt and payment of vendor invoices, primarily related to our INSPIRE trial. Deferred revenue decreased $0.3 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash provided by investing activities

There was no net cash provided by or used in investing activities for the nine months ended September 30, 2016 or 2015.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2016 was $17.4 million, which resulted from the proceeds received from the sale of common stock in our registered direct offering and rights offering, as well as the exercise of stock options. Net cash provided by financing activities for the nine months ended September 30, 2015 was $4.8 million resulting from the issuance of common stock.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our net cash expenditures in 2016 to decrease from 2015 due to a reduction in cash expenses related to administrative expenses and non-core clinical trials, which will be partially offset by an increase in cash expenditures related to our INSPIRE trial. As part of our ongoing commitment to reduce costs and conserve cash, in February 2016, we eliminated six employee positions and in August 2016 we eliminated an additional six employee positions. Affected employees have been offered severance pay in accordance with our policy or, if applicable, their employment agreements. We recorded in the first quarter of 2016, a one-time severance-related charge totaling $2.8 million, which includes a non-cash charge of $1.6 million related to the accelerated vesting of the outstanding stock options for certain of the affected employees. We recorded in the third quarter of 2016, a one-time severance-related charge totaling $0.4 million. There was no accelerated vesting of stock options related to the August 2016 workforce reduction. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction.

We do not have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund our INSPIRE trial and to further develop rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may delay or pause our planned clinical trials, including the INSPIRE trial, until we secure adequate

additional funding. If we seek to proceed with a clinical trial without additional funding, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. Additionally, we plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials.

We are continuing to explore various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. However, we may not be able to obtain additional funding on favorable terms, if at all. If we are unable to secure adequate additional funding, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations and our business until such time as we are successful in securing adequate additional funding. As a result, our business, operating results, financial condition and cash flows may be materially and adversely affected. We will incur substantial costs beyond the present and planned clinical trials in order to file a New Drug Application (NDA) for rigosertib. The nature, design, size and cost of further studies will depend in large part on the outcome of preceding studies and discussions with regulators.

Our future capital requirements will depend on many factors, including:

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- timing and success of our clinical trials for rigosertib;
- continued progress of and increased spending related to our research and development activities;
- conditions in the capital markets and the biopharmaceutical industry, particularly with respect to raising capital or entering into strategic arrangements;
- progress with preclinical experiments and clinical trials, including regulatory approvals necessary for advancement and continuation of our development programs;
- changes in regulatory requirements and guidance of the FDA and other regulatory authorities, which may require additional clinical trials to evaluate safety and/or efficacy, and thus have significant impacts on our timelines, cost projections, and financial requirements;
- ongoing general and administrative expenses related to our reporting obligations under the Exchange Act;
- cost, timing, and results of regulatory reviews and approvals;
- costs of any legal proceedings, claims, lawsuits and investigations;
- success, timing, and financial consequences of any existing or future collaborative, licensing and other arrangements that we may establish, including potential granting of licenses to one or more of our programs in various territories, or otherwise monetizing one or more of our programs;
- cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- costs of commercializing any of our other product candidates;
- technological and market developments;
- cost of manufacturing development; and
- timing and volume of sales of products for which we obtain marketing approval.

If we are unable to successfully raise sufficient additional capital, through future debt or equity financings, product sales, or through strategic and collaborative ventures with third parties, we will not have sufficient cash flows and liquidity to fund our planned business operations. In that event, we may be forced to limit many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing to others the development and commercialization of products that we consider valuable and would otherwise likely develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders interests. The consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

For additional risks associated with our substantial capital requirements, please see Risk Factors previously disclosed in our annual report on Form 10-K filed with the SEC on March 28, 2016.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, the Company is not required to provide the information otherwise required by this Item.

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Item 4. Controls and Procedures

Managements Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial officers, evaluated any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive and principal financial officers concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not party to any pending material legal proceedings and are not aware of any such proceedings contemplated by governmental authorities.

Item 1A. Risk Factors

There have been no material changes from our risk factors as previously disclosed in our annual report on Form 10-K filed with the SEC on March 28, 2016.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit Number	Description
4.1	Form of Warrant Certificate issued pursuant to Warrant Agreement, dated as of July 27, 2016, by and between Onconova Therapeutics, Inc. and Wells Fargo Bank, N.A., as Warrant Agent (Incorporated by reference to Exhibit 4.1 to the Company s Quarterly Report on Form 10-Q, filed with the SEC on August 15, 2016)
4.2	Warrant Agreement, dated as of July 27, 2016, by and between Onconova Therapeutics, Inc. and Wells Fargo Bank, N.A., as Warrant Agent (Incorporated by reference to Exhibit 4.2 to the Company s Quarterly Report on Form 10-Q, filed with the SEC on August 15, 2016)
4.3	Form of Pre-Funded Warrants issued as of July 27, 2016 (Incorporated by reference to Exhibit 4.3 to the Company s Quarterly Report on Form 10-Q, filed with the SEC on August 15, 2016)
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ONCONOVA THERAPEUTICS, INC.

Dated: November 14, 2016

/s/ RAMESH KUMAR, Ph.D.
Ramesh Kumar, Ph.D.
President and Chief Executive Officer
(*Principal Executive and Principal Operating Officer*)

Dated: November 14, 2016

/s/ MARK GUERIN
Mark Guerin
Chief Financial Officer
(*Principal Financial Officer*)

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EXHIBIT INDEX

Exhibit Number	Description
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document