

CorMedix Inc.  
Form S-3  
August 19, 2011

As filed with the Securities and Exchange Commission on August 19, 2011.

Registration No. 333-[ ]

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM S-3

REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

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CORMEDIX INC.  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

20-5894890  
(I.R.S. Employer  
Identification No.)

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

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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John C. Houghton  
President and Chief Executive Officer  
CorMedix Inc.  
745 Route 202-206, Suite 303  
Bridgewater, NJ 08807  
(908) 517-9500

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

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Copies to:

Andrew P. Gilbert, Esq.

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DLA Piper LLP (US)  
300 Campus Drive, Suite 100  
Florham Park, New Jersey 07932  
(973) 520-2500

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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, as determined by market conditions.

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 (the "Securities Act"), other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

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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(e) under the Securities Act, check the following box. "

If this form is a post-effective amendment to a registration statement 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 "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer "                      Accelerated filer "  
 Non-accelerated filer "                      Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per share(2)	Proposed maximum aggregate offering price(2)	Amount of registration fee
Common Stock, par value \$0.001 per share	18,000,000(3)	\$ 1.12	\$ 20,160,000	\$2,342

(1) Pursuant to Rule 416(a) the number of shares being registered shall be adjusted to include any additional shares that may be issuable as a result of a distribution, split, combination or similar transaction.

(2) The proposed maximum aggregate offering price, estimated solely for the purpose of calculating the registration fee, has been computed pursuant to Rule 457(c) promulgated under the Securities Act of 1933 and is based on the average of the high and low prices of CorMedix Inc.'s common stock, par value \$0.001 per share on August 16, 2011, as reported by NYSE Amex LLC.

(3) Includes up to an aggregate of 17,488,923 shares of common stock offered by CorMedix Inc. and 511,077 shares of common stock offered by the Selling Stockholder.

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 or supplemented. No securities described in this prospectus can be sold until the registration statement that we filed to cover the securities has become effective under the rules of the Securities and Exchange Commission. This prospectus is not an offer to sell the securities, nor is it a solicitation of an offer to buy the securities in any state where an offer or sale of the securities is not permitted.

Subject to Completion, dated August 19, 2011

Prospectus

CORMEDIX INC.

18,000,000 Shares

Common Stock

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CorMedix Inc. may offer to sell up to an aggregate of 17,488,923 shares of our common stock and the Selling Stockholder named in this prospectus may offer up to an aggregate of 511,077 shares of our common stock.

Our common stock is listed on NYSE Amex LLC under the symbol "CRMD." The last reported sale price of our common stock on The NYSE Amex LLC on August 16, 2011 was \$1.12 per share. We may sell the shares of common stock through underwriters, through dealers, directly to one or more institutional purchasers or through agents.

Investing in shares of our common stock involves risk. See "Risk Factors" beginning on page 4 of this prospectus. You should read this document and any prospectus supplement carefully before you invest.

We will provide a prospectus supplement each time we issue any shares of common stock, which will inform you about the specific terms of that offering and may also supplement, update or amend information contained in this document.

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.

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The date of this Prospectus is , 2011.

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### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission using a “shelf” registration process. Under the shelf registration process, we or the Selling Stockholder may sell from time to time the shares of common stock described in the prospectus in one or more offerings. You should rely only on the information contained in this prospectus and the documents incorporated by reference. We have not authorized anyone to provide you with information different from that contained in this prospectus. Each time that we sell shares of common stock under this prospectus we will provide a prospectus supplement that will contain specific information about the terms of that offering. The Selling Stockholder may sell none, some or all of the shares of common stock offered by such Selling Stockholder under this prospectus. Each time that a Selling Stockholder sells shares of common stock under this prospectus we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add to, update or change information in this prospectus. The information in this prospectus is accurate as of its date. You should carefully read this prospectus, the prospectus supplement and the documents that we have incorporated by reference below.

Unless the context otherwise requires, references in this prospectus to “we,” “us” and “our” refer to CorMedix Inc. and its subsidiaries. To understand this offering fully, you should read this entire document carefully, particularly the “Risk Factors” section, as well as the documents identified in the section titled “Where You Can Find More Information.”

## ABOUT CORMEDIX INC.

We are a development stage pharmaceutical company that seeks to in-license, develop and commercialize therapeutic products for the treatment of cardiac and renal dysfunction, also known as “cardiorenal disease.” 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.” To date, we have licensed all of the products in our cardiorenal pipeline.

We have the worldwide rights to develop and commercialize several proprietary product candidates in clinical development that address significant market opportunities, including our most advanced product candidates, CRMD003 (Neutrolin®) and CRMD001 (a proprietary formulation of deferiprone).

CRMD003 is a liquid designed to prevent central venous Catheter Related Bloodstream Infections, or CRBI, and maintenance of catheter patency in central venous catheters (initially in hemodialysis catheters). We submitted an amendment to our Investigational Device Exemption application with the U.S. Food and Drug Administration, or the FDA, for CRMD003 during the first half of 2011, which if approved will enable us to start a pivotal clinical trial in the United States in 2011. We are seeking approval of Neutrolin® in Europe through a CE mark application. During the first half of 2011 we submitted our design dossier with the European notified body managing our CE mark application. Subject to the successful audit and approval of the design dossier and the implementation and successful audit of our quality management systems, we would anticipate being in a position to obtain a CE mark approval in the first half of 2012. If we obtain CE mark approval in Europe, we expect to be in a position to launch Neutrolin® for the prevention of CRBI and maintenance of catheter patency in hemodialysis patients in Europe during the first half of 2012. We cannot be assured of CE mark approval of Neutrolin® on that timeline or at all. We are currently exploring the various methods of marketing and selling Neutrolin® in Europe, whether through a distributorship or partnership arrangement.

CRMD001 is our oral formulation of the drug deferiprone, which we intend to develop for use in the prevention of Contrast-Induced Nephropathy, or CIN, which is a common and potentially serious complication arising from the use of iodinated contrast media used in X-ray procedures to identify the status of blood vessels in the heart. Following our assessment of the data generated in connection with our development of CRMD001 for the CIN indication, we will consider whether or not to also develop CRMD001 for use in the treatment of Chronic Kidney Disease, or CKD, based on the support such data provides for this additional indication as well as other factors, including our access to capital, clinical and regulatory considerations regarding development of CRMD001 for the CKD indication, and our assessment of the then-current state of our intellectual property estate in CRMD001 with respect to both the CIN and the CKD indications. In June 2010, we initiated patient dosing in a phase II biomarker “proof of concept” study for the CIN indication. As of June 2011, we completed the recruitment of our phase II biomarker study. We expect to have the results of the phase II biomarker study during the second half of 2011. We believe this study will generate supportive data on the ability of CRMD001 to reduce biomarker evidence of acute kidney injury and provide other information that will increase the likelihood of success of a later phase III trial for the CIN indication. We received a Special Protocol Assessment on the design of a pivotal phase III trial for CRMD001 in the prevention of CIN.

We are a development stage company. 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. Since our inception, we have had no revenue from product sales. 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. We have generated significant losses to date, and we expect to continue to generate losses as we progress towards the commercialization of our product candidates, including CRMD003 and CRMD001. As of June 30, 2011, we had an

accumulated deficit of \$40,688,430. Since we do not generate revenue from any of our product candidates, our losses will continue as we advance our product candidates toward regulatory approval and eventual commercialization. As a result, our operating losses are likely to be substantial over the next several years. We are unable to predict the extent of any future losses or when we will become profitable, if at all.



In March 2010, we completed our initial public offering (the “IPO”), whereby we sold 1,925,000 units, each unit consisting of two shares of our common stock and a warrant to purchase one share of common stock, each a “Unit”, at \$6.50 per Unit resulting in gross proceeds of \$12,512,500 and net proceeds to us of \$10,457,270 after deducting underwriting discounts and commissions and offering expenses payable by us. All of our convertible notes and accrued interest thereon and all of our outstanding shares of Non-Voting Subordinated Class A Common Stock automatically converted into Units or common stock upon the completion of the IPO.

From March 30, 2010 to May 13, 2010, the units issued in connection with the IPO were traded on NYSE Amex under the symbol “CRMD.U”, each unit consisting of two shares of our common stock and a warrant to purchase one share of our common stock at an exercise price of \$3.4375. These units separated and ceased to be traded independently on May 13, 2010, on which date the common stock and the warrants comprising the units commenced trading on NYSE Amex under the symbols “CRMD” and “CRMD.WS”, respectively.

Our principal executive office is located at 745 Route 202-206, Suite 303, Bridgewater, NJ 08807, and our telephone number is (908) 517-9500. Our website address is [www.cormedix.com](http://www.cormedix.com). The information on our website is not incorporated into this prospectus and should not be considered to be a part of this prospectus. We have included our website address as an inactive textual reference only.

## RISK FACTORS

You should carefully consider the following risk factors and the section entitled “Forward-Looking Statements” before you decide to buy our common stock.

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

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

We have a limited operating history and a history of substantial 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 their early stages of operations. We incurred net losses of approximately \$9.0 million, \$8.1 million and \$10.9 million for the years ended December 31, 2008, 2009 and 2010, respectively. We incurred a net loss of \$4.5 million for the six months ended June 30, 2011. As of June 30, 2011, we had an accumulated deficit of approximately \$40.7 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, and clinical trial 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 in the near future, 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; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more 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 our 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 may 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 approval from the FDA and other regulatory authorities for our 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 into the first quarter of 2012. 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 pharmaceutical company focused on the development of product candidates that are in various stages of development. Our products are currently at the following stages of development:

- CRMD003 (Neutrolin®) – during the fourth quarter of 2010 we submitted an Investigational Device Exemption, commenced the application process for CE Mark approval in Europe, and entered the final stages of manufacturing scale-up, and in 2011 we expect to begin a pivotal late stage clinical study in the U.S., and submit a Design Dossier to the European notified body as part of the CE mark application
- CRMD001 – we completed enrollment of our phase II clinical trial for the prevention of CIN, we have provided an interim analysis from such study in March 2011, and we expect the final results of the phase II study by the end of the second half of 2011, which will serve as the basis for a phase III clinical trial decision.
- CRMD004 – we anticipate starting pre-clinical animal studies during 2011 and will otherwise look to further development, which is currently in the pre-clinical phase
- CRMD002 – we have commenced pre-clinical assay development

Our product development methods 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 investment by us or our collaborators before they can be commercialized.

We may not proceed with the development of CRMD001 for the treatment of chronic kidney disease (CKD).

It is our present intention to proceed with the development of CRMD001 for the prevention of CIN. Despite data suggesting that CRMD001 may be useful in the treatment of CKD, and despite the issuance of the CKD Patents (as defined below), we do not intend to consider the development of CRMD001 for the CKD indication until after data is generated with respect to the use of CRMD001 in the prevention of CIN. Moreover, even after that data is generated, our determination to develop CRMD001 for the treatment of CKD will depend on other relevant factors, including our access to capital, clinical and regulatory considerations regarding development of CRMD001 for the CKD indication, and our assessment of the then-current state of our intellectual property estate in CRMD001 with respect to both the CIN and the CKD indications. If we determine not to proceed with the development of CRMD001 for the CKD indication, the size of the potential target population for CRMD001 will be reduced and our potential future revenues from CRMD001 may be adversely affected.

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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, clinical testing, or manufacturing;
- unplanned expenditures in product development, clinical testing, or manufacturing;
  - failure to receive regulatory approvals;
  - emergence of superior or equivalent products;
- inability to manufacture our product candidates on a commercial scale on our own, or in collaboration with third parties; and
  - failure to achieve market acceptance.

Because of these risks, our development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercialized successfully, our business, financial condition, and results of operations may 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 approval to market a new drug or device product, we must demonstrate proof of safety and effectiveness in humans. To meet these 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 herein 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;
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delays, suspension, or termination of clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and

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

The results from early clinical trials are not necessarily predictive of results to be obtained in later clinical trials. Accordingly, even if we obtain positive results from early 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 our New Drug Applications or Premarket Approval Applications 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.

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

We have not applied for or received the regulatory approvals required for the commercial sale of any of our products in the United States or in any foreign jurisdiction. None of our product candidates has been determined to be safe and effective, and we have not submitted a New Drug Application or Premarket Approval Application to the FDA or an equivalent application to any foreign regulatory authority for any of our product candidates.

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, may adversely affect the successful commercialization of any 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 receipt of revenues or royalties.

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

Once a product is approved, numerous post-approval requirements apply. 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 and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA 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 healthcare programs and private health insurers. Without the financial support of the government or 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 healthcare 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 healthcare products. Third-party payors may not reimburse sales of our products or enable our collaborators to sell them at profitable prices.

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Physicians and patients may not accept and use our products.

Even if the FDA approves 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 healthcare 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 payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing.

#### Risks Related to Our Business and Industry

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

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than we do, obtaining FDA 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 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. 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 our product(s) as a treatment of choice.

Furthermore, the pharmaceutical 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 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 harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, healthcare providers, pharmaceutical companies or others selling our products.



We currently carry product liability insurance that covers our clinical trial. 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.

Recent healthcare policy changes may have an adverse effect on our business, financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Healthcare 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 imposes 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 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 recently enacted 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.

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

We are highly dependent on the principal members of our management and scientific staff, specifically, John C. Houghton, our President and Chief Executive Officer; Brian Lenz, our Chief Financial Officer; and Dr. Mark Klausner, our Chief Medical Officer. While we have employment agreements with such persons, employment agreements cannot ensure our retention of the employees 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 workforce is located in the New York/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. Due to this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent former employees from competing with us.

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

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

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and our administrative, operational and financial resources. To manage this growth, we must 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. Particularly, our license agreement with Shiva (referred to herein as the “Shiva Contribution Agreement”) provides for a right of termination for, among other things, our failure to initiate patient dosing in a phase III pivotal trial on or before September 30, 2011. 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 a particular piece of technology (there are two) available to the market by the later of eight years after (i) the date of the Polaschegg License Agreement, and (ii) the priority date of any new patent. Our intellectual property licensed under the Shiva Contribution Agreement serves as the basis for CRMD001 and CRMD002, and our intellectual property licensed under the Polaschegg License Agreement serves as a basis for CRMD004. Should the licensor party to any of our license agreements exercise such a termination right, we would lose our right to the intellectual property under the license agreement at issue, 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)
- 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)
- U.S. Patent Nos. 6,933,104, 6,906,052, 6,908,733, 6,995,152, 6,998,396, 7,045,282, 7,037,643, and 7,235,542 (expiring April 2020) - family of patents related to the diagnosis and treatment of CKD and other kidney diseases and disorders (for CRMD001) (the “CKD Patents”)

We are currently seeking further patent protection for numerous 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 those stated below.

- 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.
- 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 (the “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 this information may be greatly reduced.

Patent protection and other intellectual property protection is important to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

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 to reexamine the patentability of our licensed or owned patents. The defense and prosecution of intellectual property suits, PTO 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 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.

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 our 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 successfully.

Our business strategy may rely on out-licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharmaceutical products. 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 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.

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. If, for any reason, we become unable to rely on our current sources for the manufacture of our product candidates, either for clinical trials or, at some future date, 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 approval before they can produce clinical material or commercial product, and any that are identified may not receive such approval. 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 can begin to commercially manufacture our product candidates, we must obtain regulatory approval of the manufacturing facility and process. Manufacturing 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 will require that we expend time, money, and effort in production, recordkeeping, and quality control to ensure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection may significantly delay FDA 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 may 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 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 these collaborations or similar relationships. However, there can be no assurance that we will be successful establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator. Replacement collaborators might not be available on attractive terms, or at all. 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 development and marketing of our proposed products and may not be able to develop and market such products effectively, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed 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 and this Offering

Our stock price has fluctuated considerably and is likely to remain volatile, in part due to the limited market for our common stock.

During the period from the completion of the IPO on March 30, 2010 through August 16, 2011, the high and low sales prices for our common stock were \$4.00 and \$1.06, 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:

- general economic conditions;
- economic conditions in our industry and in the industries that typically comprise our customers and suppliers;
- 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; and
- changes in key personnel.

If the prices of our securities are volatile, purchasers of our securities could incur substantial losses.

The prices of our securities are likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their securities at or above the price they paid for such securities. The market prices of our securities may be influenced by many factors, including but not limited to the following:

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

- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
  - general economic, industry and market conditions;
- developments or disputes concerning patents or other proprietary rights;

- future sales or anticipated sales of our securities by us or our stockholders; and
- any other factors described in this “Risk Factors” section.

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 become eligible for sale at a later date, and their sale could depress the market price of our common stock.

The Units we issued in the IPO and upon conversion of certain of our convertible notes in connection therewith consisted of two shares of common stock and a warrant to purchase one share of common stock. The warrants that were issued as part of the Units have an exercise price of \$3.4375 per share and expire on March 24, 2015. As of June 30, 2011, there were 4,263,569 of these warrants outstanding, which if executed, would result in the issuance of an additional 4,263,569 shares of common stock. In connection with the IPO, we also issued a warrant to purchase 2,406 Units to the underwriters of the IPO that, if executed, 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. From March 30, 2010 to May 13, 2010, the units issued in connection with the IPO were traded on NYSE Amex under the symbol “CRMD.U”, each unit consisting of two shares of our common stock and a warrant to purchase one share of our common stock at an exercise price of \$3.4375. These units separated and ceased to be traded independently on May 13, 2010, on which date the common stock and the warrants comprising the units commenced trading on NYSE Amex under the symbols “CRMD” and “CRMD.WS”, respectively.

In addition, in connection with our private placement of convertible notes in October and November 2009, we issued warrants to the investors in such private placement, which warrants have an exercise price of \$3.4375 per share and expire on October 29, 2014. As of June 30, 2011, the number of shares of common stock issuable upon exercise of these warrants was 503,034 shares.

As of June 30, 2011, we also had outstanding other warrants that, if exercised, would result in the issuance of an additional 17,869 shares of common stock at an exercise price of \$10.66 per share and 18,250 shares of common stock at an exercise price of \$7.84 per share.

As of June 30, 2011, options to purchase 2,089,716 shares of our common stock, which were issued to our officers, directors and employees, were outstanding under our Amended and Restated 2006 Stock Incentive Plan with a weighted average exercise price of \$2.20 per share. Options to purchase 458,808 of such shares are currently exercisable or will be exercisable within 60 days of the date of this report.

In addition, the Selling Stockholder named in this prospectus may offer up to 511,077 shares of common stock, for which we will not receive any proceeds, which may impact the market price of our common stock.

The sale or even the possibility of sale of the shares of common stock described above could substantially reduce the market price for our common stock or our ability to obtain future financing.

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 Amended and Restated 2006 Stock Incentive 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 and employees. As of June 30, 2011, options to purchase 2,089,716 shares of common stock issued under the Amended and Restated 2006 Stock Incentive Plan at a weighted average exercise price of \$2.20 per share, were outstanding. Stockholders will experience dilution in the event that additional shares of common stock are issued under the Amended and Restated 2006 Stock Incentive Plan, or options previously issued or to be issued under the Amended and Restated 2006 Stock Incentive Plan are exercised.



If our existing securityholders exercise their registration rights, they may substantially reduce the market price of our common stock. The existence of these rights may make it more difficult for us to effect future offerings.

Holders of 5,918,669 shares of common stock and warrants to purchase an additional 505,440 shares of common stock are entitled to certain “demand” and “piggyback” registration rights. If these holders exercise their registration rights, the presence of these additional shares of common stock eligible for trading in the public market may substantially reduce the market price of our common stock. In addition, the existence of these holders’ piggyback registration rights may make it more difficult for us to effect future public offerings and may reduce the amount of capital that we are able to raise for our own account in these offerings.

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 and Amended and Restated By-laws, as well as provisions of the General Corporation Law of the State of Delaware (“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:

- 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.

Additionally, Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. We have not opted out of the restrictions under Section 203.

#### FORWARD-LOOKING STATEMENTS

This prospectus, any prospectus supplement and the documents we incorporate by reference may contain “forward-looking statements” within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. These forward-looking statements may contain expectations regarding revenues, earnings, operations and other financial projections, and may include statements of future performance, positioning, plans and objectives. These forward-looking statements are usually preceded by the words “continue,” “intends,” “will,” “plans,” “expects,” “anticipates,” “estimates,” “believes,” or similar expressions. These forward-looking statements represent only our belief regarding future events and rely on assumptions and are subject to risks, uncertainties and other factors that could cause our actual results to differ materially from expectations. The following documents, among others, describe these assumptions, risks, uncertainties, and other factors. You should read and interpret any forward-looking statements together with the following documents:

- our most recent Annual Report on Form 10-K, including the sections entitled “Business”, “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”;
- our most recent Quarterly Report of Form 10-Q;
- the risk factors contained in this prospectus under the caption “Risk Factors”; and

- our other filings with the Securities and Exchange Commission.

Any forward-looking statement speaks only as to the date on which that statement is made. We assume no obligation to update any forward-looking statement to reflect events or circumstances that occur after the date on which the statement is made.

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### USE OF PROCEEDS

Unless the applicable prospectus supplement states otherwise, we will retain broad discretion in the allocation of the net proceeds of this offering. We currently intend to use the net proceeds of this and any future issuances for:

- research and development of current and additional product candidates;
- potential product acquisitions and/or potential acquisitions of complementary businesses; and
- other general corporate purposes, including principally working capital and capital expenditures.

We have not determined the amount of net proceeds to be used for each of the specific purposes indicated. The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our research and development efforts, technological advances and the competitive environment for our product candidates. Accordingly, we will have broad discretion to use the proceeds as we see fit. Pending such uses, we intend to invest the net proceeds in interest-bearing, investment grade or government securities. We will not receive the proceeds from any sale of our common stock made by the Selling Stockholder.

SELLING STOCKHOLDER

Shiva Biomedical, LLC may from time to time offer and sell, pursuant to this prospectus and any applicable prospectus supplement, up to an aggregate of 511,077 shares of our common stock which it owns pursuant to that certain Contribution Agreement, dated as of July 28, 2006, as amended. The following table sets forth, as of August 18, 2011, the number of shares of our common stock that the Selling Stockholder beneficially owns and the number of shares being registered for sale. The percentage of outstanding shares beneficially owned after the offering assumes that all of the shares offered by the Selling Stockholder will have been sold.

	Number of Shares Owned Prior to the Offering	Number of Shares Being Offered		Number and Percentage of Shares Owned After the Offering
Selling Stockholders				
Shiva Biomedical, LLC	511,077	511,077	0	0.0%

## PLAN OF DISTRIBUTION

We may sell the shares of common stock through underwriters, through dealers or agents or directly to purchasers. We will describe in the prospectus supplement, the particular terms of any offering of our shares of common stock, including the following:

- the names of any underwriters;
- the purchase price and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters' compensation;
- any initial public offering price and any discounts or concessions allowed or re-allowed or paid to dealers; and
- any other information that we think is important.

The Selling Stockholder may from time to time offer and sell, pursuant to this prospectus and any applicable prospectus supplement, up to an aggregate of 511,077 shares of our common stock. In addition, the Selling Stockholder may offer and sell shares of common stock in the open market pursuant to Rule 144.

If we use underwriters in the sale, the shares of common stock may either be offered to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. The shares of common stock will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, either at a fixed public offering price, or at varying prices determined at the time of sale. The underwriters will use this prospectus and the prospectus supplement to sell our common stock. Unless otherwise described in the prospectus supplement, the obligations of the underwriters to purchase shares of common stock will be subject to conditions precedent, and the underwriters will be obligated to purchase all the shares of common stock of a series if any are purchased. Underwriters may be deemed to have received compensation from us in the form of underwriting discounts or commissions and may also receive commissions from the purchasers of the shares of common stock for whom they may act as agent. Underwriters may sell these securities to or through dealers. If we use a dealer, such person, as principal, will sell our securities to the dealer. These dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they act as agent. Any initial offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

Shares of common stock may be sold directly by us or through agents designated by us from time to time. Any agent involved in the offer or sale of the common stock for which this prospectus is delivered will be named, and any commissions payable by us to that agent will be set forth, in the prospectus supplement. Unless otherwise indicated in the prospectus supplement, any agent will be acting on a best efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutions to purchase shares of common stock from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts. These contracts will provide for payment and delivery on a specified date in the future. The conditions to these contracts and the commissions payable for solicitation of such contracts will be set forth in the applicable prospectus supplement. We may also sell our securities upon the exercise of rights which we may issue.

In connection with an underwritten offering of the shares of common stock, the underwriters may engage in transactions that stabilize, maintain, or otherwise affect the price of the common stock during and after the offering. Specifically, the underwriters may over-allot or otherwise create a short position in the common stock for their own account by selling more shares than we have actually sold to them. The underwriters may elect to cover any short

position by purchasing shares in the open market or by exercising the over-allotment option granted to the underwriters. In addition, the underwriters may stabilize or maintain the price of the common stock by bidding for or purchasing shares in the open market and may impose penalty bids, under which selling concessions allowed to syndicate members or other broker-dealers participating in the offering are reclaimed if shares of common stock previously distributed in the offering are repurchased in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price at a level above that which might otherwise prevail in the open market, and these transactions may be discontinued at any time. The imposition of a penalty bid may also affect the price of the common stock to the extent that it discourages resales. No representation is made as to the magnitude or effect of these activities.

Agents, dealers and underwriters may be entitled to indemnification by us against civil liabilities arising out of this prospectus, including liabilities under the Securities Act of 1933, or to contribution for payments which the agents, dealers or underwriters may be required to make relating to those liabilities. Agents, dealers and underwriters may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

Underwriters, dealers and agents that participate in the distribution of our securities may be underwriters as defined in the Securities Act of 1933, and any discounts or commissions they receive and any profit they make on the resale of the offered securities may be treated as underwriting discounts and commissions under the Securities Act of 1933.

Any underwriter may make a market in the common stock, but will not be obligated to do so, and may discontinue any market making at any time without notice. We cannot and will not give any assurances as to the liquidity of the trading market for our common stock.

The Company has agreed to bear all of the expenses incurred by it in connection with the registration of the shares of common stock offered under this prospectus, except for any legal fees or similar expenses incurred by the Selling Stockholder.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file with the SEC at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC maintains a website at <http://www.sec.gov> that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. In addition, we maintain a website at <http://www.cormedix.com> and make available free of charge on this website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" much of the information we file with them under Commission File No. 001-34673, which means that we can disclose important information to you by referring you to those publicly available documents. All of the information that we incorporate by reference is considered to be part of this prospectus, and any of our subsequent filings with the SEC will automatically update and supersede this information. This prospectus incorporates by reference the documents listed below and any future filings made by CorMedix Inc. with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except for information furnished under Items 2.02 or 7.01 of Current Report on Form 8-K, or exhibits related thereto, until the filing of a post-effective amendment to this prospectus which indicates that all securities registered have been sold or which deregisters all securities then remaining unsold:

- our annual report on Form 10-K for the year ended December 31, 2010, filed on March 11, 2011;
- our proxy statement for our annual meeting of stockholders, filed on April 29, 2011;
- our quarterly reports on Form 10-Q for the quarters ended March 31, 2011, filed May 10, 2011 and June 30, 2011, filed August 9, 2011;
- our current reports on Form 8-K, filed January 5, 2011; filed on January 19, 2011; filed on March 3, 2011; ; filed on April 1, 2011; filed on June 6, 2011; filed on June 8, 2011; filed June 17, 2011; filed June 21, 2011; and filed June 23, 2011;
- our description of common stock contained in our registration statement on Form 8-A12B, filed on March 19, 2010, (File No. 000-34673); and
- all other reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act after the date of this registration statement and prior to the effectiveness of the registration statement.

We will provide, upon written or oral request, to each person to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in the prospectus but not delivered with the prospectus. You may request a copy of these filings, at no cost, by writing us at CorMedix Inc., 745 Route 202-206, Suite 303, Bridgewater, NJ 08807, and our telephone number is (908) 517-9500.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The Selling Stockholder will not make an offer of these shares in any jurisdiction where the offer is not permitted. You should not assume that information in

this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by DLA Piper LLP (US), Florham Park, New Jersey. Any underwriters will be advised about other issues relating to any offering by their own legal counsel.

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EXPERTS

The financial statements of CorMedix Inc. appearing in CorMedix's Annual Report on Form 10-K for the year ended December 31, 2010, have been audited by J.H. Cohn LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

CORMEDIX INC.

18,000,000 Shares

Common Stock

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Prospectus

, 2011

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## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

## Item 14. Other Expenses of Issuance and Distribution

The following table sets forth an estimate of the costs and expenses payable by CorMedix Inc. in connection with the offering described in this registration statement. All of the amounts shown are estimates except the Securities and Exchange Commission (“SEC”) registration fee:

Securities and Exchange Commission Registration Fee	\$2,342.00
Printing	\$50,000.00
Accounting Services	\$50,000.00
Legal Fees	\$75,000.00
Miscellaneous	\$3,000.00
<b>Total</b>	<b>\$180,342.00</b>

## Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law (the “DGCL”) provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending or completed actions, suits or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee or agent to the registrant. The DGCL provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any by-laws, agreement, vote of stockholders or disinterested directors or otherwise. Our Amended and Restated Certificate of Incorporation and Amended and Restated By-laws provide for indemnification of our directors, officers and employees to the fullest extent permitted by the DGCL. We refer you to our charter and by-laws which are filed as exhibits to our Registration Statement on Form S-1 (File No. 333-163380).

We have entered into indemnification agreements with each of our directors and certain executive officers pursuant to which we have agreed to indemnify each such director and officer to the fullest extent permitted by applicable law.

We have an insurance policy which insures our directors and officers, within the limits and subject to the limitations of the policy, against certain expenses in connection with the defense of actions, suits or proceedings, and certain liabilities that might be imposed as a result of such actions, suits or proceedings, to which they are parties by reason of being or having been directors or officers.

Item 16. Exhibits

The exhibits filed as part of this registration statement are as follows:

Exhibit Number	Description
4.1	Amended and Restated Certificate of Incorporation of the Company. (Incorporated by reference to Exhibit 3.3 to the Registration Statement on Form S-1 of the Company filed March 1, 2010, File No. 333-163380).
4.2	Amended and Restated By-Laws of the Company. (Incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1 of the Company filed March 1, 2010, File No. 333-163380).
5.1	Opinion of DLA Piper LLP (US) (filed herewith).
23.1	Consent of DLA Piper LLP (US) (included in Exhibit 5.1).
23.2	Consent of J. H. Cohn LLP (filed herewith).
24.1	Powers of Attorney (filed herewith).

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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;

(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 Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent 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 (1)(i), (1)(ii) and (1)(iii) do not apply if the registration statement is on Form S-3 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Sections 13 or 15(d) of the Exchange Act 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, 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.

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(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, 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 Exchange Act) 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 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 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 Securities Act and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.



SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, 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 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bridgewater, State of New Jersey, on this 19th day of August, 2011.

CORMEDIX INC.

By:

/s/ John C. Houghton  
John C. Houghton  
President and Chief Executive  
Officer

KNOW BY ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John C. Houghton and Brian Lenz, and each of them, the undersigned's true and lawful attorneys-in-fact and agents, with full power of substitution and revocation, for and in the undersigned's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratify and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1933, as amended, this registration statement has been signed below by the following persons on behalf of the registrant and in the capacities indicated on the date listed below.

	Signature	Title	Date
By:	/s/ John C. Houghton John C. Houghton	President, Chief Executive Officer and Director (principal executive officer)	August 19, 2011
By:	/s/ Brian Lenz Brian Lenz	Chief Financial Officer, Treasurer and Secretary (principal financial and accounting officer)	August 19, 2011
By:	/s/ Richard M. Cohen Richard M. Cohen	Director	August 19, 2011
By:	/s/ Gary Gelbfish Gary Gelbfish	Director	August 19, 2011
By:	/s/ Steven W. Lefkowitz Steven W. Lefkowitz	Director	August 19, 2011
By:	/s/ Anthony E. Pfaffle Anthony E. Pfaffle	Director	August 19, 2011
By:	/s/ Timothy Hofer Timothy Hofer	Director	August 19, 2011

INDEX TO EXHIBITS

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