CorMedix Inc.
Form 10-K
March 11, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: December 31, 2010

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-34673

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

Delaware	20-5894890
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
745 Rt. 202-206, Suite 303, Bridgewater, NJ	08807
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (908) 517-9500

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 Par Value	NYSE Amex LLC
Units, each consisting of two shares of Common Stock and a Warrant	NYSE Amex LLC
Warrants, exercisable for Common Stock at an exercise price of $3.4375 per share	NYSE Amex LLC

Securities registered pursuant to Section 12(g) of the Act: none

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ¨ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulations S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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. (Check one):

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant, based upon the closing price of the registrant's common stock on the last business day of the registrant's most recently completed second fiscal quarter ($2.20) was $24,417,523. Solely for the purpose of this calculation, shares held by directors and executive officers of the registrant have been excluded. Such exclusion should not be deemed a determination or an admission by the registrant that such individuals are, in fact, affiliates of the registrant.

The number of outstanding shares of the registrant's common stock was 11,408,274 as of March 10, 2011.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Items 10, 11, 12, 13 and 14 of Part III of this report is incorporated by reference from the registrant's definitive proxy statement relating to its 2011 annual meeting of stockholders. Such proxy statement will be filed with the Securities and Exchange Commission within the period permitted under General Instruction G(3) of Form 10-K.

CORMEDIX INC.

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Annual Report on Form 10-K that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "will," "plan," "project," "seek," "would," and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below in the section titled "Risk Factors." Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Item 1. Business.

Overview

CorMedix Inc., incorporated in July 2006 under the laws of the State of Delaware (referred to herein as "we," "us," "our" and the "Company"), is a 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."

We have several proprietary product candidates in clinical development that address large market opportunities, including our most advanced product candidates, CRMD003 (Neutrolin®) and CRMD001. CRMD003 is a liquid designed to prevent central venous catheter infection and maintenance of catheter patency in central venous catheters (initially in hemodialysis catheters). CRMD001 is our 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 different parts of the body. 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.

We submitted an Investigational Device Exemption for CRMD003 in the fourth quarter of 2010, which if approved will enable us to start a pivotal clinical trial. For CRMD001, we started a phase II biomarker "proof of concept" study for the CIN indication in June 2010. 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.

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, 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. We believe that the net proceeds from the IPO and existing cash will be sufficient to fund our projected operating requirements into the first quarter of 2012.

We also effected a 1 for 7.836 reverse stock split of our common stock on February 24, 2010 in connection with the IPO. All shares and per share amounts, except as noted, have been retroactively adjusted to give effect to the reverse stock split.

Platforms and Products

We have two foundational platforms. Our first foundational platform seeks to utilize liquid and gel formulations of Neutrolin® (CRMD003 and CRMD004, respectively) to prevent the infection and maintenance of catheter patency in central venous catheters and peripherally inserted central catheters. These catheters are frequently used for vascular access in hemodialysis (a form of dialysis where the patient's blood is circulated through a dialysis filter), for cancer chemotherapy, long term antibiotic therapy, total parenteral nutrition (complete or partial dietary support via intravenous nutrients) and intensive care patients. Our second foundational platform seeks to reduce excess free (catalytic) iron, which is toxic to cells and tissues, using CRMD001, our formulation of the drug deferiprone.

Over the past two years we have made rapid and significant progress, including the following:

- CRMD001 received a Special Protocol Assessment ("SPA") from the Food and Drug Administration ("FDA") for a single phase III study as the basis of a New Drug Application for reducing the serious kidney damage and associated morbidity and mortality arising from contrast-induced nephropathy ("CIN")

- we published early proof of concept studies for the use of CRMD001 in slowing the progression of chronic kidney disease ("CKD");

- in June 2010, we initiated patient enrollment in our phase II biomarker study of CRMD001 (Deferiprone) and we enrolled our 30th patient in February 2011, which we expect will provide information sufficient for an interim analysis by the end of the first quarter of 2011;

- in the fourth quarter of 2010, we manufactured a clinical trial batch of CRMD003 and began stability testing;

- in December 2010, we commenced the application process for submitting a CE Mark in Europe for CRMD003, and

- in December 2010, we filed an Investigational Device Exemption application with the FDA for CRMD003 for the prevention of Catheter Related Bloodstream Infection ("CRBI") and Maintenance of Catheter Patency in Hemodialysis Patients.

Provided that an Investigational Device Exemption is approved by the FDA for CRMD003 (which is not assured) and successful results from the CRMD001 phase II biomarker proof of concept study, both CRMD003 and CRMD001 will be poised to enter pivotal studies. Both products have the benefit of significant market experience outside of the United States and defined FDA regulatory pathways, potentially reducing development risk.

The following table summarizes our product candidates.

Product	Intended Indication	Status of Clinical Programs	Commercial Rights
CRMD003 (Neutrolin®)	Prevention of catheter-related blood stream infections and maintenance of catheter patency in hemodialysis patients who are asymptomatic for catheter-related blood stream infections using both incident and prevalent catheters with any brand of central venous catheter	In Europe, Neutrolin® (taurolidine 1.35%, citrate 3.5% and heparin 1,000 u/mL) is considered to be a Class III device requiring submission and approval of a CE mark for marketing of the product. We commenced the application process for CE Mark approval in Europe during the fourth quarter 2010. In the U.S., Neutrolin® is considered to be a device/drug combination product, requiring submission and approval of a Premarket Approval application for marketing of the product. We submitted an Investigational Device Exemption for Neutrolin® during the fourth quarter of 2010.	Worldwide
CRMD004	Prevention of catheter-related blood stream infections and maintenance of catheter patency in hemodialysis patients who are asymptomatic for catheter-related blood stream infections using both incident and prevalent catheters with any brand of central venous catheter	In Europe, CRMD004 is considered to be a Class III device requiring submission and approval of a CE mark for marketing of the product. In the U.S., CRMD004 is considered to be a device/drug combination product, requiring submission and approval of a Premarket Approval application for marketing of the product. CRMD004 is in the pre-clinical phase of development. We anticipate starting pre-clinical animal studies in 2011.	Worldwide
CRMD001 for CIN	Prevention (decrease in the rate of incidence) of morbidity and mortality in subjects with moderate to severe chronic kidney disease and other risk factors undergoing interventional cardiac procedures and receiving an iodinated radiocontrast agent	We currently have an approved Investigational New Drug application in the U.S. and final approval for marketing will be obtained following approval of a New Drug Application. We are continuing to enroll patients in a phase II biomarker proof of concept study commenced during the second quarter of 2010 which we expect will provide information sufficient for an interim analysis by the end of the first quarter of 2011.	Worldwide
CRMD001 for CKD	Prevention of progressive loss of kidney function in patients with CKD	We currently have an approved Investigational New Drug Application in the U.S. and final approval for marketing would occur after approval of a New Drug Application.	Worldwide
CRMD002			Worldwide

Urine diagnostic test for "toxic labile iron" that could be used to diagnose chronic kidney disease, identify patients at risk for the disease, identify likely treatment responders and monitor response to therapy with CRMD001	We commenced pre-clinical assay development.

Lead Product Candidates

The market opportunity, development strategy, sales and marketing strategy and competitive landscape of our lead product candidates, CRMD003 (Neutrolin®) and CRMD001.

CRMD003 (CorMedix Neutrolin®)

Market Opportunity

Patients undergoing hemodialysis require access to the vascular system in order to perform treatments on a multiple scheduled basis each week. According to U.S. Renal Data System 2008 Annual Data Report, approximately 80,000 hemodialysis patients relied on a central venous catheter in 2008. One of the major complications in the use of a central venous catheter for hemodialysis treatment is catheter-related blood stream infections and the inflammatory complications associated with them. Catheter-related blood stream infections and inflammatory complications are a primary cause of morbidity in the end-stage renal disease hemodialysis patient population, and the second most common cause of mortality. Recent data from the United States Renal Data System (USRDS, 2008) indicates nearly 2 catheter infection events per-patient year or 5.37 per 1000 catheter days.

Prevention of catheter-related blood stream infections and inflammatory complications requires decontamination of the internal surface of the catheter to prevent the systemic dissemination of organisms contained within the biofilm and an anticoagulant to retain patency. Biofilm forms when bacteria adhere to surfaces in aqueous environments and begin to excrete a slimy, glue-like substance that can anchor them to various types of materials, including intravenous catheters. The presence of biofilm has many adverse effects, including the ability to release bacteria into the bloodstream. The current standard of catheter care is to instill a heparin lock solution at a concentration of 1,000 – 5,000 u/mL into each catheter lumen immediately post treatment, in order to prevent clotting between dialysis treatments. However, a heparin lock solution provides no protection from the risk of infection. Currently, there are no pharmacologic agents approved for the prevention of catheter-related blood stream infections in central venous catheters.

There is a significant unmet need for prevention of catheter-related blood stream infections in the hemodialysis patient population as well as for other patient populations utilizing central venous catheters, such as oncology/chemotherapy, total parenteral nutrition and intensive care unit patients.

CRMD003, or Neutrolin®, is a broad-spectrum antimicrobial/antifungal and anticoagulant combination that is active against common microbes including antibiotic-resistant strains and in addition may prevent biofilm formation. We believe that using Neutrolin® as a catheter lock solution will significantly reduce the incidence of catheter-related blood stream infections, thus reducing the need for local and systemic antibiotics while prolonging catheter life.

Development Strategy

Our strategy is to obtain worldwide approval for Neutrolin® solution, and to obtain “Orphan” designation and qualify for FDA grants (of up to $400,000). Orphan status is a designation used by the FDA to encourage development of drugs and devices for rare diseases or indications. Achieving this status conveys significant benefits to the developer. An Orphan Device grant request was submitted in February 2009. Projected key regulatory submissions/communications for both the United States and European Union in the next 12 months include:

- selection of E.U. Notified Body and discussions/agreements with them for Class III CE marking and Quality System Regulation (QSR) certification;

- submission of the CTA (if EU studies are necessary) and approval of Class III CE mark;

- obtaining Investigational Device Exemption approval from the FDA for the trial required to achieve registration

If we obtain CE mark approval, 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 by the end of 2011. However, we cannot be assured of CE Mark approval of Neutrolin® on that timeline or at all. We are currently exploring the various methods of launching Neutrolin® in Europe, whether through a distributorship or partnership arrangement.

If we obtain FDA Premarket Approval by the end of the first half of 2013, we would expect to launch Neutrolin® for the prevention of CRBI and maintenance of catheter patency in hemodialysis patients in the U.S. before the end of the second half of 2013. However, we cannot be assured of FDA approval of Neutrolin® on that timeline or at all.

We plan to conduct a prospective, multicenter, double-blind, randomized, active comparator (heparin, which is the current standard of care) controlled study of approximately 400 patients to demonstrate the safety and effectiveness of Neutrolin® (1.35% taurolidine, 3.5% citrate and heparin 1,000 u/mL) in preventing catheter-related blood stream infections and maintaining catheter patency in patients receiving hemodialysis therapy as treatment for End Stage Renal Disease three times a week with a tunneled silicone or polyurethane hemodialysis catheter that has demonstrated the ability to deliver sufficient blood flow to enable successful hemodialysis. Patients can be enrolled with either incident catheters (catheters placed less than one week prior to entry into the trial) or prevalent catheters.

Subjects will be randomized in a 1:1 ratio to receive either Neutrolin® or the active comparator heparin (1,000 u/ml) as a catheter locking solution. CorMedix Neutrolin® or heparin will be instilled into central venous hemodialysis catheters following all dialysis sessions and will be withdrawn prior to the initiation of the next dialysis session. All subjects will receive standard of care consistent with current dialysis clinical practice guidelines for the placement, care and use of central venous catheters for hemodialysis therapy.

A total of approximately 400 randomized subjects are currently planned for this trial, which will have co-primary endpoints (two separate endpoints, both of which have to be achieved for the trial to be considered successful). Calculation of the sample size was based upon the assumption that the cumulative event rate for catheter-related blood stream infections would be 22.6% at 180 days. Although published data have consistently demonstrated an 80 – 90% reduction in catheter-related blood stream infections with Neutrolin®, we calculated sample size based upon an assumed 80% reduction in catheter-related blood stream infections. Conservative standard statistical sample size calculations for the first endpoint suggest that the required sample size would be approximately 200 patients in each arm. The patency endpoint tests the hypothesis that the use of Neutrolin® is superior to the heparin comparator for the composite endpoint of requirement for catheter intervention (including use of a tissue plasminogen activator) or requirement for catheter replacement due to catheter thrombosis/dysfunction. A superiority margin of 43% was assumed as was an event rate of 36%. Conservative standard statistical sample size calculations suggest that the required sample size is approximately 200 patients per arm to meet these assumptions. As is normal, the superiority endpoint will drive the required number of patients for the trial, which is a total sample of approximately 400 patients. The planned treatment duration for all patients is 180 days.

The total cost for the trial is estimated to be approximately $10 million. We expect that our existing cash resources will be sufficient to fund the development costs of, and complete patient enrollment in, this trial. We will require additional funds to complete this trial and submit the Premarket Approval application to the FDA.

Sales and Marketing Strategy

If we obtain FDA Premarket Approval, we would expect to launch Neutrolin® for the prevention of catheter-related blood stream infections and maintenance of catheter patency in hemodialysis patients in the U.S. approximately three months afterwards. The sales model will primarily be one of achieving formulary listing and inclusion as policy and

procedure with the key customers (Fresenius and Davita, as dialysis providers, cover 70% of dialysis patients). Key account managers will be required as well as medical liaison specialists.

It is anticipated that the costs of Neutrolin® will be added to the dialysis "bundle", which will transition in from 2011 – 2014. In the interim, for those centers not participating in the bundle, we expect that the product will be billable on the basis of a separate billing "J" code. In any future model of full capitation reimbursement for dialysis services, the value proposition for Neutrolin® would be even stronger. Clear demonstration of cost-effectiveness will be important for CMS, private payers and users of Neutrolin®.

After we launch Neutrolin®, we will consider developing it for indications for prevention of catheter-related blood stream infections associated with any chronic central venous catheter and peripherally inserted central catheter use, such as cancer chemotherapy, intensive care and total parenteral nutrition.

Competitive Landscape

Products in development in the United States for the prevention and treatment of catheter-related blood stream infections are listed below.

Product	Company	Mechanism	Estimated Launch	Differentiation
Zuragen	Ash Access	Antimicrobial and anticoagulant Methylene blue + parabens + citrate 7%	Unknown	First potential approvable treatment for catheter-related blood stream infections in the U.S. Potentially need to undertake a 2nd pivotal trial which will delay launch
B-Lock	Great Lakes Pharmaceuticals Inc.	Minocycline + EDTA + ethanol combinations	Pre Investigational Device Exemption discussions with the FDA	Contains an antibiotic which may be prone to resistance development

Antibiotic or antimicrobial coated catheters have been launched by some device companies as short term prevention of catheter infection. These are not effective for hemodialysis catheters due to long term use and high blood flow.

CRMD001 — Prevention of Morbidity and Mortality Associated with Contrast Induced Nephropathy (CIN)

Market Opportunity

Contrast-induced nephropathy, or CIN, 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 different parts of the body. CIN is most commonly defined as a new onset or exacerbation of renal dysfunction after contrast administration without other identifiable causes. There are an estimated 150,000 cases per year in the United States. It is the third most common cause of hospital-acquired renal insufficiency (11% of cases) after low blood pressure and major surgery, and is associated with increased mortality, cardiovascular complications (myocardial infarction, stroke, heart failure, etc.), in-hospital and long term, increased dialysis, permanent kidney damage, and delayed discharge/re-hospitalization. In addition, CIN, or the risk of developing CIN, disrupts the workflow of the catheterization laboratory — a key profit center of many hospitals. Any decrease in case load potentially reduces revenue. The most important risk factor for a patient developing CIN is the presence of chronic kidney disease, or CKD.

Currently, the standard of care to prevent CIN in high risk patients with CKD is hydration before and after the procedure with saline (e.g., 1 – 1.5 mL/kg/h of 0.9% saline given 3 – 12 hours before and 6 – 24 hours after contrast procedure) or bicarbonate (3 mL/kg/h given for 1 hour before and 3 – 6 hours afterwards). Additional methods to reduce the risk of developing CIN include minimizing the volume of contrast used, utilizing low or iso-osmolar contrast agents, and withholding potentially nephrotoxic drugs.

There is no single therapeutic intervention that has conclusively and consistently proven to be effective in the prevention of CIN, and there are no FDA-approved preventative treatments. N-acetylcysteine (NAC — Mucomyst), an antioxidant and free radical scavenger, has been extensively studied in the prevention of CIN, but study results are conflicting. Other therapies that have suggested some efficacy in studies include vitamin C, Prostaglandin E1, theophylline, statins and bicarbonate.

We expect that the incidence of CIN will increase as the number of procedures requiring contrast grows with the ever-expanding scope of image-guided radiological interventions and the burgeoning older population.

There is accumulating evidence that iron plays an important role in the pathogenesis of CIN and the progression of CKD. The mechanism by which iron causes tissue injury in these renal diseases likely involves the generation of reactive oxygen species which cause damage to cell membranes, proteins and deoxyribonucleic acid. Reactive oxidants have the ability to cause both local tissue damage and also to instigate toxic effects distant from their site of generation. We believe that deferiprone, which binds or chelates iron, reducing oxidative stress and cellular injury, will be an effective treatment for the prevention of morbidity and mortality associated with CIN.

Deferiprone is a logical choice for evaluation of the potential therapeutic effect of iron chelation in these renal and cardiovascular diseases for a variety of reasons. There is clear experimental and clinical evidence of the efficacy of deferiprone as an oral iron chelator, complimented by an extensive safety database gathered from the administration of deferiprone for long periods of time and often at considerably higher drug exposure levels than is likely to be required for the suggested renal indications. Deferiprone is able to mobilize iron from multiple tissue and cellular sites, including reticuloendothelial, liver and heart, from the intracellular proteins ferritin and hemosiderin, and from transferrin and non-transferrin bound iron present in the serum. Due to its small size and neutral charge, deferiprone is able to access multiple intracellular iron pools and shuttle iron to acceptor molecules in the extracellular space. Deferiprone is also known to be partially excreted in an active form in the urine.

Development Strategy

Our current regulatory strategy for deferiprone is to obtain approval in the United States for the marketing of deferiprone for the prevention (decrease in the rate of incidence) of morbidity and mortality associated with acute kidney injury in subjects with moderate to severe CKD and risk factors undergoing interventional cardiac procedures and receiving an iodinated radiocontrast agent. Our goal is to be the first company to obtain this approval. As a second step, we plan to develop a strategy for the approval of deferiprone for the above indication in the rest of the world, with Europe as the next region of interest. Our current expectation is that completion of the New Drug Application for deferiprone for the desired indication will require completion of the following: a single, phase III safety and efficacy clinical trial (DEFEND-AKI), a thorough QT/QTc study and a drug-drug interaction study. The total cost to file the New Drug Application is anticipated to be approximately $20-30 million (DEFEND-AKI study, pharmacology studies, manufacturing/CMC and regulatory filing costs).

Prior to commencement of the phase III trial, we decided to perform a phase II biomarker “proof of concept” study, which we commenced in second quarter 2010. We expect that the trial will generate specific data on the ability of our formulations of deferiprone to reduce biomarker evidence of acute kidney injury, consequently reducing the risk of the phase III trial, potentially enhancing the primary endpoint and providing pharmacokinetic data that is required for our patent continuation filing. This study will include exactly the same population as the SPA single phase III study and will recruit 60 patients over approximately 12 months and cost approximately $1 million. The primary endpoint will be a reduction in a panel of sensitive biomarkers of acute kidney injury by CRMD001 compared with placebo (NGAL, Cystatin C, creatinine, liver fatty acid binding protein, Kidney injury molecule-1, glutathione-S-transferase). We enrolled our 30th patient in the study in February 2011, which we expect will provide information sufficient for an interim analysis by the end of the first quarter of 2011.

The phase III clinical trial is already designed and would be the largest pharmaceutical trial ever conducted for the prevention of CIN. In addition, the patient population will also be the highest-risk population ever studied. Currently there is no proven pharmaceutical therapy that prevents or reduces the frequency/severity of CIN. Given this need, and the clear relationship between the development of CIN (defined as a change in renal function) and important clinical outcomes, the FDA has allowed us a unique opportunity to register CRMD001 following the successful completion of a single phase III trial.

The trial will be a randomized, double-blind, placebo-controlled, parallel-arm, multicenter study. The entry criteria for the trial includes the requirement for moderate to severe CKD as determined by an eGFR (estimated glomerular filtration rate, a marker of kidney function) of less than 60 mL/min, and at least one additional risk factor (diabetes, age greater than or equal to 75 years or heart failure). The patients will receive either low or iso-osmolar radiocontrast dye for a cardiac interventional procedure. Standard of care will be provided to all patients. This includes the avoidance of nephrotoxic medications, limiting contrast volume as much as clinically possible and hydration both before and after the procedure.

CRMD001 will be given as one immediate release tablet and two extended release tablets (total dose 2.7 g) 1 – 3 hours before angiography and given twice daily for a total of eight days. This dose is close to the initial starting dose for treatment of iron-overload disorders. Eight days of dosing was selected as contrast may be retained in patients with CKD for an extended period and oxidative stress is also present for at least 72 hours in some patients. Patients will be monitored for 90 days following the procedure and the composite endpoint includes any of the following: death, myocardial infarction, dialysis, stroke/TIA, heart failure or re-hospitalization. Given the known safety profile of deferiprone, no significant toxicity or safety issues are anticipated during the trial. From a statistical perspective, the trial is powered (to define the required sample size) to demonstrate a 1/3 reduction of the composite event rate (30% to 20%).

Sales and Marketing Strategy

The primary target audience for the CIN indication will be catheterization laboratory-based interventional cardiologists and secondarily nephrologists and interventional radiologists. There are 6,300 interventional cardiologists and approximately 2,200 catheterization labs in the United States of which 1,000 “target” labs conduct the majority of procedures.

We believe that a “sales” force of approximately 50 people, including medical liaisons, sales representatives and management, would be adequate to support the product. The rapid inclusion in relevant guidelines would be important to accelerate uptake. Given the medical safety issue surrounding the use of radiocontrast in at-risk patients and the anticipated morbidity-mortality label for deferiprone, we expect the ramp-up to peak sales and penetration to be faster (3 years) and larger (up to 90%) than for a typical new product launch.

We conducted a formal value-based pricing analysis based on expected events avoided. This analysis shows that the product is cost-neutral at a per-treatment cost of $3,500 (using a threshold cost per-QALYG (Quality Adjusted Life Year, a standard health economic tool) less than $50,000) and, we believe, highly cost-effective at a cost of $1,000 per treatment (cost per QALYG of only $3,500). The actual cost-effectiveness will ultimately depend on the results of the DEFEND-AKI trials and the chosen sales price.

Given the largely in-patient nature of this high-risk patient group, reimbursement is expected to be via specific Diagnosis Related Groups that cover these high-risk patients.

All in all, we believe that the disease area known as CIN represents a reasonably fast-to-market opportunity — with significant sales potential.

Competitive Landscape

There are only three other iron chelators, or chelators, currently marketed. We believe that none are suited for use in cardiorenal disease and that our patents would preclude the marketing of any iron chelator for cardiorenal indications without a cross-license with us.

The Ferriprox® brand of deferiprone is sold in Europe and Asia as a 500mg immediate release formulation with a high Cmax (associated with nausea) that must be given three times daily, exhibiting a completely different pharmacokinetic profile from the CorMedix formulations.

Deferoxamine (Desferal®) has been available for the longest period of time. It is given intravenously or subcutaneously and due to the large size of the molecule, it does not adequately penetrate cells. Further, we believe the parenteral delivery system will preclude its use in our targeted indications and that multiple days of therapy are likely required.

Desferasirox (Exjade®) is an oral iron trap that was recently launched in the United States and European Union. It has a different pharmacokinetic profile than CRMD001 and is excreted primarily in the feces. Post-marketing experience has revealed frequent and significant renal adverse events (increasing proteinuria and creatinine) including cases of fatal renal failure. This has led to a black box warning in the U.S. and makes it unlikely, in our opinion, that this product could be used for cardiorenal indications.

A comparison of CRMD001 with the other three currently marketed iron chelators is found below:

	Deferiprone CRMD001 (CorMedix)	Deferiprone Ferriprox®(1)	Desferasirox Exjade®(2)	Deferoxamine(3) Desferal®
Route	Oral IR/ER (b.i.d)	Oral IR (t.i.d)	Oral daily	I.V./S.C.
Renal Toxicity	No	No	Yes	No
Active drug in urine	Yes	Yes	No	Yes
Method of use patents in cardiorenal disease	Yes	No	No	No
Effective at redistributing iron/ membrane permeable	Yes	Yes	Yes	No
Launch date	N/A	2000 EU	2006	1970s

(1) Registered Trademark of Apopharma Inc.

(2) Registered Trademarks of Novartis

(3) Also known as desferrioxamine, desferoxamine

We do not believe that currently available iron chelators are suited for development for the prevention (decrease in the rate of incidence) of morbidity and mortality associated with CIN either because of an intravenous form of delivery in the case of deferoxamine or because of documented renal toxicity in the case of desferasirox (Exjade®).

We do not believe there are any late stage investigational new drugs currently in development for this indication. Off-label studies continue to be conducted for N-acetyl cysteine and sodium bicarbonate, but results are inconclusive.

However, there are a number of device-based approaches currently under development by our competitors, including those listed below.

- Reprieve® Endovascular Temperature Therapy — cooling system for core body temperature
- Benephit® CV Infusion System — renal artery infusion catheter for targeted drug delivery or fluids
- RenalGuard® Therapy — matched fluid replacement device

We believe that none of these approaches will match the efficacy and simplicity of a short course of deferiprone tablets given before and after contrast administration.

Manufacturing

All of our manufacturing processes currently are, and we expect them to continue to be, outsourced to third parties. We rely on third-party manufacturers to produce sufficient quantities of drug product for use in clinical trials. We intend to continue this practice for any future clinical trials and commercialization of our products.

Navinta LLC, a U.S.-based Active Pharmaceutical Ingredient ("API") developer, provides Active Pharmaceutical Ingredient manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to a supply agreement dated December 7, 2009 (the "Navinta Agreement"). The Navinta Agreement provides that Navinta supply taurolidine (the API for CRMD003) to us on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as we purchased a minimum of $350,000 of product from Navinta by December 30, 2010, which we achieved, and following our first commercial sale of a product incorporating taurolidine, purchase a minimum of $2,250,000 of product on an annual basis for five years. We are also required to make certain cash payments to Navinta upon the achievement of certain sales-based milestones. The maximum aggregate amount of such payments, assuming achievement of all milestones, is $1,975,000. The Navinta Agreement has a term of five years, but may be terminated by either party upon 30 days written notice.

The deferiprone drug substance for CRMD001 is sourced from a company based in India, with which we have a supply agreement. This site has received previous FDA audits and was also audited by us. No significant issues were identified. The finished product is manufactured by Emcure Pharmaceuticals USA, Inc., a United States company ("Emcure"), which was also audited by the FDA without citations in 2010. Emcure manufactures the finished product pursuant to a manufacture and development agreement with us, dated March 5, 2007, and the first phase III commercial-sized batch has been produced. Emcure is also performing stability studies in PVC and ACLAR blisters and bottles and no substantive stability issues have been identified as of December 31, 2010. Additional API is available for production of the second and third batches required for the New Drug Application. In order to meet the requirements for 18 months stability, production of these batches will commence when the phase III trial is about to start.

We are confident that there exist a sufficient number of potential sources for the drug substances required to produce our products, as well as third-party manufacturers, that we will be able to find alternate suppliers and third-party manufacturers in the event that our relationship with any supplier or third-party manufacturer deteriorates.

Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. Because certain of our product candidates are considered as medical devices and others are considered as drugs for regulatory purposes, we intend to submit applications to regulatory agencies for approval or clearance of both medical devices and pharmaceutical product candidates.

In the United States, the FDA regulates drugs and medical devices under the Federal Food, Drug, and Cosmetic Act and the agency's implementing regulations. If we fail to comply with the applicable United States requirements at any time during the product development process, clinical testing, and the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

Our products may be classified by the FDA as a drug or a medical device depending upon the indications for use or claims.

Drug Approval Process

The research, development, and approval process in the United States and elsewhere is intensive and rigorous and generally takes many years to complete. The typical process required by the FDA before a therapeutic drug may be marketed in the United States includes:

- preclinical laboratory and animal tests performed under the FDA's Good Laboratory Practices regulations;
- submission to the FDA of an Investigational New Drug Application, which must become effective before human clinical trials may commence;
- preliminary human clinical studies to evaluate the drug's safety and effectiveness for its intended uses;
- FDA review of whether the facility in which the drug is manufactured, processed, packed, or held meets standards designed to assure the product's continued quality; and
- submission of a marketing application to the FDA, and approval of the application by the FDA.

During preclinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. These studies are subject to GLP requirements. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. An Investigational New Drug Application must be submitted to the FDA and become effective before studies in humans may commence.

Clinical trial programs in humans generally follow a three-phase process. Typically, phase I studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase I studies are conducted to determine the metabolic and pharmacological action of the product candidate in humans and the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In phase II, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product candidate and optimal dosing. This phase also helps determine further the safety profile of the product candidate. In phase III, large-scale clinical trials are generally conducted in patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate as required by United States and foreign regulatory agencies.

In the case of products for certain serious or life-threatening diseases, the initial human testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will also provide results traditionally obtained in phase II studies. These studies are often referred to as "phase I/II" studies. However, even if patients participate in initial human testing and a phase I/II study carried out, the sponsor is still responsible for obtaining all the data usually obtained in both phase I and phase II studies.

Before proceeding with a study, sponsors may seek a written agreement known as a special protocol assessment ("SPA") from the FDA regarding the design, size, and conduct of a clinical trial. Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product's efficacy. SPAs help establish up-front agreement with the FDA about the adequacy of a clinical trial design to support a regulatory approval, but the agreement is not binding if new circumstances arise. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

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United States law requires that studies conducted to support approval for product marketing be “adequate and well controlled.” In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice requirements, and informed consent must be obtained from all study subjects.

The clinical trial process for a new compound can take ten years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional review boards, who must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product’s use and, potentially, withdrawal of the product from the market.

Following the completion of clinical trials, the data are analyzed to determine whether the trials successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the United States, if the product is regulated as a drug, a New Drug Application must be submitted and approved before commercial marketing may begin. The New Drug Application must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal, and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers CorMedix may decide to use, must be listed in the New Drug Application and must be registered with the FDA. The application generally will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug product, and determines that the facility is in compliance with cGMP requirements.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing an New Drug Application and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. For fiscal year 2010, the New Drug Application review fee alone is $1,405,500, although certain limited deferral, waivers, and reductions may be available.

Each New Drug Application submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will “file” the New Drug Application, thereby triggering substantive review of the application. The FDA can refuse to file any New Drug Application that it deems incomplete or not properly reviewable. The FDA has established performance goals for the review of New Drug Applications — six months for priority applications and 10 months for standard applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an “action letter” that describes additional work that must be done before the application can be approved. The FDA’s review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval.

Significant legal and regulatory requirements also apply after FDA approval to market under a New Drug Application. These include, among other things, requirements related to adverse event and other reporting, product advertising and promotion and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental

applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

The regulatory framework applicable to the production, distribution, marketing, and/or sale, of our products may change significantly from the current descriptions provided herein in the time that it may take for any of its products to reach a point at which a New Drug Application is approved.

Overall research, development, and approval times depend on a number of factors, including the period of review at FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA's questions, the severity or life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials, and the risks and benefits demonstrated in the clinical trials.

Drugs for Serious or Life-Threatening Illnesses

The Federal Food, Drug, and Cosmetic Act, as amended, and FDA regulations provide certain mechanisms for the accelerated "Fast Track" approval of products intended to treat serious or life-threatening illnesses which have been studied for safety and effectiveness and which demonstrate the potential to address unmet medical needs. The procedures permit early consultation and commitment from the FDA regarding the preclinical and clinical studies necessary to gain marketing approval. Provisions of this regulatory framework also permit, in certain cases, New Drug Applications to be approved on the basis of valid surrogate markets of product effectiveness, thus accelerating the normal approval process. Where the FDA approves a product on the basis of a surrogate market, it requires the sponsor to perform post-approval, or Phase 4, studies as a condition of approval, and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the product. Special rules would also apply to the submission to the FDA of advertising and promotional materials prior to use.

Controlled Substances

Compounds that have a potential for patient dependence and abuse are classified as controlled substances under the Controlled Substances Act, regulations of the DEA, and similar state and foreign laws. In the United States, for new chemical entities under development for medicinal use, designated staff at the FDA make recommendations about whether a drug should be scheduled as a controlled substance, and the Drug Enforcement Administration ("DEA") makes the final determination. States then either follow the federal classification or make their own determination. In the case of a new drug approved by the FDA, the final DEA scheduling determination generally occurs several months or longer after the FDA's approval.

Drugs that are scheduled as controlled substances are subject to stringent regulatory requirements, including requirements for registering manufacturing and distribution facilities, security controls and employee screening, recordkeeping, reporting, product labeling and packaging, import and export. There are five federal schedules for controlled substances, known as Schedule I, II, III, IV and V. The regulatory requirements that apply to a drug vary depending on the particular controlled substance schedule into which a drug is placed, based on consideration of its potential for dependence and abuse and its medicinal uses. Schedules I and II contain the most stringent restrictions and requirements, and Schedule V the least. No products with recognized medicinal uses are in Schedule I. For substances in Schedule I and II, quotas must be obtained from the DEA in order to manufacture, procure, and distribute inventory. For all controlled substances, there are potential criminal and civil penalties that apply for the failure to meet applicable legal requirements. Healthcare professionals must have special DEA licenses in order to prescribe controlled substances.

Other United States Regulatory Requirements

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state, and local authorities in addition to the FDA, including the

Centers for Medicare and Medicaid Services (formerly the Heath Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provision of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

Moreover, CorMedix is now, and may become subject to, additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Foreign Regulatory Requirements

CorMedix and its collaborative partners may be subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacture, product registration and approval, and pharmaceutical sales. Whether or not FDA approval has been obtained, CorMedix or its collaboration partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

Reimbursement and Pricing Controls

In many of the markets where CorMedix or its collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms. Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supposed by one or more citations in the American Hospital Formulary Service Drug Information the American Medical Association Drug Evaluations, or the United States Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

Medical Device Approval Process

We expect some of our products to be regulated as medical devices. Unless an exception applies, each medical device we wish to commercialize in the United States will require either prior 510(k) clearance or premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring premarket approval application, or PMA.

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Pre-Approval Requirements

510(k)

When a 510(k) clearance is required, the device sponsor must submit a premarket notification demonstrating that their proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution. The evidence required to prove substantial equivalence varies with the risk posed by the device and its complexity. By regulation, the FDA is required to complete its review of a 510(k) within 90 days of submission of the notification. As a practical matter, clearance often takes longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not "substantially equivalent," the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous pre-marketing requirements, as required in a Premarket Approval ("PMA") (see discussion below).

After a device receives 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, will require a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or a PMA is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Premarket Approval Application (PMA)

If an applicant is unable to demonstrate that a product candidate is substantially equivalent to a marketed device, the FDA will require the submission and approval of a PMA before marketing of the product. The FDA will approve a PMA only if the applicant provides the FDA with reasonable assurance that the product is safe and effective when used in accordance with its proposed labeling. The PMA review process includes analysis of manufacturing processes, inspection of manufacturing facilities, and a comprehensive review of pre-market data.

A PMA must be supported by extensive data, including data from preclinical studies and human clinical trials, and must contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling.

After the FDA determines that a PMA is sufficiently complete to permit a substantive review, the FDA will file the application and begin an in-depth review. The FDA, by statute, has 180 days to review a PMA, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the FDA's Quality System Regulations, or QSR. New PMAs or supplemental PMAs are required for significant modifications to the manufacturing process, labeling, intended use and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA, and may not require as extensive clinical data or the convening of an advisory panel.

A clinical trial is almost always required to support a PMA and, to a much lesser extent, to support a 510(k) pre-market notification. When FDA approval of a device requires human clinical trials, and if the clinical trial presents a “significant risk” to human health, the device sponsor is required to file an investigational device exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the institutional review boards, or IRB, overseeing the clinical trial. If the product is deemed a “non-significant risk” device, FDA approval is not required, but informed consent and approval from the IRB overseeing the clinical trial is required. Clinical trials are subject to extensive recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an IRB at the relevant clinical trials site and in accordance with applicable regulations and policies including, but not limited to, the FDA’s good clinical practice, or GCP, requirements. The applicant, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. The results of clinical testing may not be sufficient to obtain approval of a product.

Humanitarian Device Exemption (HDE)

A third approval process requires that an application for a Humanitarian Device Exemption, or HDE, be made to the FDA for the use of a Humanitarian Use Device, or HUD. A HUD is intended to benefit patients by treating or diagnosing a disease or condition that affects, or is manifested in, fewer than 4,000 individuals in the U.S. per year. The application submitted to the FDA for an HDE is similar in both form and content to a PMA, but is exempt from the effectiveness requirements of a PMA. This approval process demonstrates there is no comparable device available to treat or diagnose the condition, the device will not expose patients to unreasonable or significant risk, and the benefits to health from use outweigh the risks. The HUD provision of the regulation provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting small patient populations.

Post-Approval Requirements

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. Medical device manufacturers are subject to periodic inspections by the FDA and state agencies. If the FDA believes that a company is not in compliance with applicable laws or regulations, it can take any of the following actions: issue a warning or other letter notifying the particular manufacturer of improper conduct; impose civil penalties; detain or seize products; issue a recall; ask a court to seize products; enjoin future violations; withdraw clearances or approvals; or assess civil and criminal penalties against us, our officers or our employees.

In addition, regulations regarding the development, manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances, seizures or recalls of products, operating restrictions and/or criminal prosecution. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products or the withdrawal of product approval by the FDA could have a material adverse effect on our business, financial condition or results of operations.

Medical device manufacturers are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA’s QSR requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require medical device manufacturers to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA.

We cannot assure you that we or our collaborators will be able to meet the FDA’s requirements or receive FDA clearance for our products. Moreover, even if we are exempt from approval or even if we receive clearance, the FDA may impose restrictions on our marketing efforts. Finally, delays in the approval process may cause us to introduce our products into the market later than anticipated. Any failure to obtain regulatory approval, restrictions on our ability to market our products, or delay in the introduction of our products to the market could have a serious adverse effect on our business, financial condition and results of operations.

Foreign Regulatory Requirements

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

In the European Union, we are required to comply with the Medical Devices Directive and obtain CE mark certification in order to market medical devices. The CE Mark certification, granted following approval from an independent notified body, is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. Manufactures are also required to maintain certain International Organization for Standardization, or ISO, certifications in order to sell their products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. We are also required to comply with other foreign regulations such as the requirement that we obtain Ministry of Health, Labor and Welfare approval before we can launch new products in Japan. The time required to obtain these foreign approvals to market our products may vary from U.S. approvals, and requirements for these approvals may differ from those required by the FDA.

Medical device laws and regulations are in effect in many of the countries in which we may do business outside the United States. These laws and regulations range from comprehensive device approval requirements for our medical device product to requests for product data or certifications. The number and scope of these requirements are increasing. We may not be able to obtain regulatory approvals in such countries and we may be required to incur significant costs in obtaining or maintaining our foreign regulatory approvals. In addition, the export of certain of our products which have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Any failure to obtain product approvals in a timely fashion or to comply with state or foreign medical device laws and regulations may have a serious adverse effect on our business, financial condition or results of operations.

Intellectual Property

CRMD001 and CRMD002

On July 28, 2006, we entered into a license agreement with Shiva Biomedical, LLC (Shiva), which was amended on October 6, 2009 and on February 22, 2010 (the Shiva Contribution Agreement). Pursuant to the Shiva Contribution Agreement, Shiva contributed to us its kidney products business and granted us an exclusive, worldwide license agreement for a patent estate covering proprietary formulations of deferiprone and a biomarker diagnostic test for measuring levels of labile iron (the Shiva Technology). The Shiva Technology served as the basis for CRMD001 and CRMD002, respectively. In addition to an initial licensing fee and equity stake in us consisting of 511,077 shares of our common stock as of December 31, 2010 provided to Shiva under the Shiva Contribution Agreement, we are also required to make cash payments to Shiva upon the achievement of certain clinical and regulatory-based milestone and the maximum aggregate amount of such payments, assuming achievement of all milestones, is $10,000,000. Events that trigger milestone payments include but are not limited to the reaching of various stages of applicable clinical trials and regulatory approval processes. Under the terms of the Shiva Contribution Agreement, in the event that the Shiva

Technology is commercialized, we are also obligated to pay to Shiva annual royalties on sales of the products, on a country-by-country basis, equal to a percentage of net sales in the single-digit range. In the event that we sublicense Shiva Technology to a third party, we are obligated to pay to Shiva a portion of the royalties in the single-digit range, fees or other lump-sum payments we receive from the sublicense, subject to certain deductions. As of December 31, 2010, no milestone payments or royalty payments have been earned by or paid to Shiva.

The Shiva Contribution Agreement will expire on a country-by-country basis upon the later of (i) the date the last claim under the patent rights covering a licensed product expires in a particular country, or (ii) 10 years from the first commercial sale of an applicable licensed product in such country. Following the date the last claim under the patent rights covering a licensed product expires in a particular country, we will have an irrevocable, paid-up, royalty-free license to the Shiva Technology in such country. The Shiva Contribution Agreement also may be terminated by Shiva if we fail to make payments due in accordance with the Shiva Contribution Agreement within 45 days after written notice of such failure is given to us, or if we fail to meet certain funding and developmental progress requirements, including but not limited to initiating patient dosing in a pivotal trial on or before September 30, 2011. We have the right to terminate the Shiva Contribution Agreement for any reason upon 30 days prior written notice. Should the Shiva Contribution Agreement be terminated by either party, we are obligated to reassign to Shiva all our intellectual property rights with respect to the Shiva Technology.

Pursuant to the Shiva Contribution Agreement, we have licensed worldwide rights to “Kidney Disease” use patents for deferiprone as well as certain related patents and patent applications. Two significant patent families for deferiprone were developed and filed by Shiva and licensed by CorMedix. Both families are directed to the application of iron chelators in kidney disease. The earliest patent family, originally filed in 2000 (now issued in the United States and by the European Patent Office), includes claims related to the diagnosis (based on urine catalytic iron) and treatment of progressive kidney disease (all forms of glomerulonephritis and other nephropathies). The family covers the use of any iron chelator (including deferoxamine and desferasirox) in this setting and will expire in 2020. The second patent family, focused on the prevention of acute renal failure associated with iodinated radiocontrast dyes (CIN), was filed in August 2005, and is still undergoing prosecution. This application also seeks the broad application of all iron chelators and, together with the contemplated filing of a continuation-in-fact application, this family is targeted to have a significant formulation element (drug product claims) as well as method of treatment claims in the United States and if issued, will expire in 2025.

In addition to the above two patent families, an additional patent application, filed by us in November 2006, seeks to apply iron chelators and catalytic iron in the treatment of and diagnosis of gadolinium-induced toxicity. Gadolinium is a contrast agent commonly used for magnetic resonance imaging. This application is pending in the United States, Canada, before the European Patent Office, and in Australia.

CRMD003 and CRMD004

On January 30, 2008, we entered into a License and Assignment Agreement (the “NDP License Agreement”) with ND Partners, LLC (“NDP”). Pursuant to the NDP License Agreement, NDP granted us exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the “NDP Technology”). We acquired such licenses and patents through our assignment and assumption of NDP’s rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann, and Dr. Johannes Reinmueller. NDP also granted us exclusive licenses, with the right to grant sublicenses, to use and display certain trademarks in connection with the NDP Technology. As consideration in part for the rights to the NDP Technology, we paid NDP an initial licensing fee of $325,000 and granted NDP an equity interest in us consisting of 365,534 shares of common stock as of December 31, 2010. In addition, we are required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones and the number of shares held in escrow is 145,543 shares of common stock as of December 31, 2010. The maximum aggregate amount of cash payments upon achievement of milestones is $3,000,000. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval processes and certain worldwide net sales amounts. As of December 31, 2010, no milestone payments have been earned by or paid

to NDP.

The NDP License Agreement will expire on a country-by-country basis upon the earlier of (i) the expiration of the last patent claim under the NDP License Agreement in a given country, or (ii) the payment of all milestone payments and release of all shares of our common stock held in escrow under the NDP License Agreement. Upon the expiration of the NDP License Agreement in each country, we will have an irrevocable, perpetual, fully paid-up, royalty-free exclusive license to the NDP Technology in such country. The NDP License Agreement also may be terminated by NDP if we materially breach or default under the NDP License Agreement and that breach is not cured within 60 days following the delivery of written notice to us, or by us on a country-by-country basis upon 60 days prior written notice. If the NDP License Agreement is terminated by either party, our rights to the NDP Technology will revert back to NDP.

On January 30, 2008, we also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg. Pursuant to the Polaschegg License Agreement, Dr. Polaschegg granted us an exclusive, worldwide license for a gel lock invention and certain taurolidine treatments and the corresponding United States patent applications, the Polaschegg Technology. The Polaschegg Technology serves as a basis for CRMD004. As consideration for the rights to the Polaschegg Technology, in addition to an initial fee of $5,000, we agreed to pay Dr. Polaschegg certain royalty payments ranging from 1% to 3% of the net sales of the Polaschegg Technology. The Polaschegg License Agreement also sets forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from $10,000 to $90,000. Additional minimum royalty payments will become payable to Dr. Polaschegg if he develops new intellectual property that is applied to the Polaschegg Technology. As of December 31, 2010, Dr. Polaschegg has received an aggregate of approximately $378,000 in licensing and minimum royalty payments under the Polaschegg License Agreement.

We may terminate the Polaschegg License Agreement with respect to the gel lock invention or taurolidine treatments (individually or together) upon 60 days notice. Dr. Polaschegg has a right to terminate the Polaschegg License Agreement with respect to the gel lock invention and/or taurolidine treatments if no product based on the particular portion of Polaschegg Technology has been made 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. If the Polaschegg License Agreement is terminated with respect to any piece of Polaschegg Technology by either party, all rights with respect to such portion of Polaschegg Technology will revert to Dr. Polaschegg.

We believe that the patents and patent applications we have licensed pursuant to the NDP License Agreement and the Polaschegg License Agreement cover effective solutions to the various problems discussed previously when using taurolidine in clinical applications, and specifically in hemodialysis applications. We intend to file additional patent applications to cover any additional related subject matter we develop.

Employees

As of March 10, 2011, we employed 6 full-time employees. Of the full-time employees, 3 were engaged in research and development activities and 3 were engaged in executive management, finance and other administrative activities. We plan to continue to expand our product development programs. To support this growth, we will need to expand managerial, operations, development, regulatory, sales, marketing, finance and other functions. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Corporate Information

We were organized as a Delaware corporation on July 28, 2006 under the name “Picton Holding Company, Inc.” and we changed our corporate name to “CorMedix Inc.” on January 18, 2007. Our principal executive offices are located at 745 Rt. 202-206, Suite 303, Bridgewater, NJ 08807. Our telephone number is (908) 517-9500.

Item 1A. Risk Factors.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of escalating 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. As of December 31, 2010, we had an accumulated deficit of approximately $36.2 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, create an interim analysis from such study, and submit a CE mark application

- 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

- CRMD001 – we are continuing to enroll patients in our phase II clinical trial for the treatment of CIN, (with eight active sites enrolling patients), we expect to create an interim analysis from such study by the end of the first quarter of 2011, and we expect the final results of the phase II study in the second half of 2011, which will serve as the basis for a phase III clinical trial decision.

- 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.

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;
- delays, suspension, or termination of clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

The results from early 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 health care 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 health care system in the United States have included measures that would limit or eliminate payments for medical products and services or subject the pricing of medical treatment products to government control. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors may not reimburse sales of our products or enable our collaborators to sell them at profitable prices.

Physicians and patients may not accept and use our products.

Even if 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 health care community, including physicians, about the safety and effectiveness of our drug or device product;

- cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our product from government or other healthcare 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, health care 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 Health Care and Education Reconciliation Act of 2010, or collectively, the Healthcare Reform Act, substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. We anticipate that if we obtain approval for our products, some of our revenue may be derived from U.S. government healthcare programs, including Medicare. Furthermore, beginning in 2011, the Healthcare Reform Act will impose 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.

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 Houghton, our 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 insure 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 work force 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. Because of this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent

former employees from competing with us.

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

Over time, we 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 current Good Manufacturing Practices, referred to herein as 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 assure 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

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 March 10, 2011, the high and low sales prices for our common stock were $4.00 and $1.08, 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 December 31, 2010, 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.

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 December 31, 2010, the number of shares of common stock issuable upon exercise of these warrants was 503,034 shares.

As of December 31, 2010 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 December 31, 2010, options to purchase 1,662,827 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 $3.15 per share. Options to purchase 477,853 of such shares are currently exercisable or will be exercisable within 60 days of the date of this report.

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 December 31, 2010, options to purchase 1,662,827 shares of common stock issued under the Amended and Restated 2006 Stock Incentive Plan at a weighted average exercise price of $3.15 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.

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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 6,429,746 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices are located in approximately 3,500 square feet of office space in Bridgewater, New Jersey. We lease this office space pursuant to a lease agreement dated March 18, 2010 with UA Bridgewater Holdings, LLC (the "Lease Agreement"). The Lease Agreement has an initial term of 60 months, commencing on April 1, 2010 and expiring on March 31, 2015, and lease payments began on July 1, 2010. We have a one-time right to terminate the lease after two years from the commencement date, provided we give the landlord notice of our election to exercise this option on or before 18 months after April 1, 2010. If we elect to exercise the early termination option, we will pay an early cancellation fee to the landlord in an amount equal to the sum of the following: (i) the remaining balance of the unamortized leasing costs incurred by the landlord; (ii) the brokerage commissions; (iii) the landlord's legal fees associated with this lease; and (iv) $18,474, representing three months base rent. We also have been granted the option to extend the lease term for one additional period of three years, commencing the day following the then-current expiration date of the term, March 31, 2015, provided we deliver notice to the landlord no later than nine months prior to March 31, 2015. The total 60 month lease obligation is approximately $389,000. The Company's total remaining lease obligation was approximately $347,000 as of December 31, 2010.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 4. (Removed and Reserved)

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market for Common Equity

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. Based upon information furnished by our transfer agent, at March 10, 2011, we had approximately 113 holders of record of our common stock. The following table sets forth the high and low sales prices for our common stock for the periods indicated as reported by NYSE Amex:

Fiscal Year 2011	High	Low
First Quarter (1)	$ 2.50	$ 1.47

Fiscal Year 2010	High	Low
Second Quarter (2)	$ 4.00	$ 1.87
Third Quarter	2.01	1.08
Fourth Quarter	2.08	1.10

(1) From January 1, 2011 through March 10, 2011.
(2) From May 13, 2010 through June 30, 2010.

Dividend Policy

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors.

Equity Compensation Plan Information

The following table provides information as of December 31, 2010 about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans (including individual arrangements):

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
	1,662,827	$ 3.15	637,173

Equity compensation plans approved by security holders (1)				
Equity compensation plans not approved by security holders	—		—	—
Total	1,662,827	$	3.15	637,173

(1) Our Amended and Restated 2006 Stock Incentive Plan was approved by our stockholders on February 19, 2010.

Use of Proceeds from the Sale of Registered Securities

Our IPO was effected through a Registration Statement on Form S-1, as amended (Registration No. 333-163380), that was declared effective by the U.S. Securities and Exchange Commission (the "SEC") on March 24, 2010. The net offering proceeds to us, after deducting underwriting discounts, commissions and offering expenses payable by us, were approximately $10.5 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. Of the net proceeds of $10.5 million, we have used approximately $2.3 million for research and development ("R&D") expenditures and approximately $2.0 million for general working capital expenditures through the end of the fourth quarter of 2010. We have invested the unused proceeds from the IPO in an interest bearing savings account.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis together with our audited financial statements and the accompanying notes. This discussion contains forward-looking statements, within the meaning of Section 27A of Securities Act, Section 21E of the Exchange Act, and the Private Securities Litigation Reform Act of 1995, including statements regarding our expected financial position, business and financing plans. These statements involve risks and uncertainties. Our actual results could differ materially from the results described in or implied by these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this report, particularly under the headings "Forward-Looking Statements" and "Risk Factors."

Overview

We are a 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." 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 large market opportunities, including our most advanced product candidates, CRMD003 (Neutrolin®) and CRMD001.

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 Investigational Device Exemption for CRMD003 in the fourth quarter of 2010, which if approved will enable us to start a pivotal clinical trial in 2011.

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. During February 2011, we enrolled our 30th patient which we expect will provide information sufficient for an interim analysis by the end of the first quarter 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 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 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 since our inception and we expect to continue to generate losses as we progress towards the commercialization of our product candidates, including CRMD003 and CRMD001. As of December 31, 2010, we had an accumulated deficit of $36,236,279. Because we do not generate revenue from any of our product candidates, our losses will continue as we advance our product candidates towards 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 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, 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. We believe that the net proceeds from the IPO and existing cash will be sufficient to fund our projected operating requirements into the first quarter of 2012.

We also effected a 1 for 7.836 reverse stock split of our common stock on February 24, 2010 in connection with the IPO. All shares and per share amounts, except as noted, have been retroactively adjusted to give effect to the reverse stock split.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception. As of December 31, 2010, we have funded our operations primarily through debt financings and the IPO, and our receipt of a total of approximately $490,000 from federal grants under the Qualifying Therapeutic Discovery Project program and a total of approximately $280,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program.

If our product development efforts result in clinical success, regulatory approval and successful commercialization of any of our products, we could generate revenue from sales or licenses of any such products.

Research and Development Expense

R&D expense consists of: (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, investigative sites, and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, stock-based compensation, benefits, travel and related costs for the personnel involved in drug development; (vi) activities relating to regulatory filings and the advancement of our product candidates through preclinical studies and clinical trials; and (vii) facilities and other allocated expenses, which include direct and allocated expenses for

rent, facility maintenance, as well as laboratory and other supplies. All R&D is expensed as incurred.

Conducting a significant amount of development is central to our business model. Through December 31, 2010, we incurred $18,038,746 in R&D expenses since our inception in July 2006. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our R&D expenses for the foreseeable future in order to complete development of our two most advanced product candidates, CRMD003 and CRMD001, and our earlier-stage R&D projects.

The following table summarizes the percentages of our R&D payments related to our two most advanced product candidates and other projects. The percentages summarized in the following table reflect payments directly attributable to each development candidate, which are tracked on a project basis. A portion of our internal costs, including indirect costs relating to our product candidates, are not tracked on a project basis and are allocated based on management's estimate.

	Year Ended December 31,		Period from July 28, 2006 (Inception) through December 31, 2010
	2010	2009	
CRMD001	44%	55%	62%
CRMD002	1%	4%	1%
CRMD003	53%	34%	34%
CRMD004	2%	7%	3%

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates.

Development timelines, probability of success and development costs vary widely. We are currently focused on developing our two most advanced product candidates, CRMD003 for the prevention of CRBI and CRMD001 for the CIN indication. We expect to raise additional funds at a later date in order to fully complete the development of CRMD003 for CRBI and CRMD001 for the CIN indication, to further develop CRMD002 or CRMD004 through and beyond the pre-clinical stage, to develop CRMD001 for the CKD indication (should we decide to pursue such development) or to develop any new product candidates.

General and Administrative Expense

General and administrative ("G&A") expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, finance and accounting functions. Other G&A expense includes facility-related costs not otherwise included in R&D expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services and accounting services. We expect that our G&A expenses will increase if we add personnel and as a result of the reporting obligations applicable to public companies. From our inception on July 28, 2006 through December 31, 2010, we incurred $7,788,898 of G&A expense.

Other Income

Other income consists of federal research grants awarded, net of application fees. From our inception on July 28, 2006 through December 31, 2010, we received $391,168 of other income, net of application fees and related filing costs.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents. Interest expense consists of interest incurred on our convertible notes up to their automatic conversion into units or common stock upon the completion of the IPO on March 30, 2010, as well as the amortization and write-off of deferred financing costs and debt discounts and a charge for the beneficial conversion relating to certain of our convertible notes. From our inception on July 28, 2006 through December 31, 2010, we received $112,305 of interest income through interest bearing savings accounts and incurred $11,193,028 of interest expense, which consists of interest incurred in debt issued to noteholders, amortization and write-off of deferred financing costs and debt discounts and a beneficial conversion feature charge related to the conversion of certain of our convertible notes.

Results of Operations

Comparison of the Years Ended December 31, 2010 and December 31, 2009

Research and Development ("R&D") Expense. R&D expense was $5,494,297 for the year ended December 31, 2010, an increase of $605,759, from $4,888,538 for the year ended December 31, 2009. The increase was primarily attributable to our issuance of 828,024 shares of our common stock on March 30, 2010, of which 118,288 shares are held in escrow, to our licensors valued at $3.125 per share, or $2,217,924 as a result of anti-dilution adjustments in connection with the conversion of our outstanding convertible debt to common stock upon the closing of the IPO, which anti-dilution provisions have expired. The increase in R&D expense was partially offset by higher stock-based licensor expenses in 2009 versus 2010, as a result of our issuance of 98,739 shares of common stock to Shiva in exchange for Shiva surrendering its rights to our Series B-F Common Stock, resulting in $3,164,502 of expense in 2009. The increase was also attributable to stock-based compensation expense of $480,381 related to all stock options granted to our Chief Medical Officer and a portion of the stock options granted to our Chief Executive Officer in connection with the IPO. Also contributing to the higher R&D expense were the clinical development costs related to our Phase II clinical trial of CRMD001 that began in June 2010, higher manufacturing costs related the development of CRMD003 and costs related to the hiring of two employees in the areas of clinical operations and product development during the third quarter of 2010.

General and Administrative ("G&A") Expense. G&A expense was $3,012,706 for the year ended December 31, 2010, an increase of $1,845,861 from $1,166,845 for the year ended December 31, 2009. The increase was primarily attributable to stock-based compensation expense of $686,700 related to a portion of the stock options granted to our Chief Executive Officer, and all of the stock options granted to our Chief Financial Officer and Board members in connection with the IPO, in addition to the issuance of 4,059 shares of our common stock to a consultant valued at $32.05 per share or $130,091. The increase in G&A expense also reflects the increased costs of operating as a publicly-traded company following the IPO in March 2010, which include filing fees related to the listing of our common stock, as well as increased legal, accounting, investor relations consulting fees and increased compensation expense as a result of our hiring a Chief Financial Officer in February 2010.

Other Income. Other income was $391,168 for the year ended December 31, 2010 and $0 for the year ended December 31, 2009. Other income during 2010 represented federal grants, net of filing and application fees we received under the Qualifying Therapeutic Discovery Project program.

Interest Income and Interest Expense. Interest income was $23,442 for the year ended December 31, 2010, an increase of $21,312, from $2,130 for the year ended December 31, 2009. The increase was attributable to having higher interest-bearing cash balances during the year ended December 31, 2010 compared to the year ended December 31, 2009 as a result of the funds received from the completion of our IPO in March 2010.

Interest expense was $3,093,763 for the year ended December 31, 2010, compared to $2,068,202 for the year ended December 31, 2009. The increase of $1,025,561 was primarily attributable to charges related to the conversion of all our convertible notes, of which the aggregate amount of principal and accrued interest as of March 30, 2010 was $18,897,167, in connection with the IPO. The increase was partially offset by lower interest accrued on our convertible notes during 2010 compared to 2009, as a result of a full year of interest in 2009 compared to approximately three months of interest in 2010. The interest expense charges consisted primarily of a beneficial conversion feature charge of $1,137,762 related to the 30% discount at which the 8% senior convertible notes we issued in October and November 2009 in the aggregate principal amount of $2,619,973 (the “Third Bridge Notes”), converted into common stock, a write-off of debt discount of $1,135,076 in 2010 compared to the amortization of debt discount of $539,064 in 2009, a write-off of the remaining amortization of deferred financing fees of $358,495 in 2010 compared to amortization of deferred financing fees of $153,642 in 2009.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in July 2006. Prior to the IPO, we had funded our operations principally with $14,364,973 in convertible notes sold in private placements and $625,464 in related party notes, which were also convertible. We received net proceeds of $10,457,270 from the IPO, after deducting underwriting discounts, commissions and offering expenses payable by us upon the closing of the IPO on March 30, 2010. All of our convertible notes were automatically converted into 1,237,293 shares of common stock and 2,338,569 units comprised of 4,677,138 shares of common stock and 2,338,569 warrants at an exercise price of $3.4375. We also received a total of approximately $490,000 from federal grants under the Qualifying Therapeutic Discovery Project rogram and a total of approximately $280,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program.

Net Cash Used in Operating Activities

Net cash used in operating activities was $3,668,404 for the year ended December 31, 2010. The net loss of $10,905,236 for the year ended December 31, 2010 was higher than cash used in operating activities by $7,236,832. The primary reasons for the difference are the stock issued in connection with our license agreements' anti-dilution provision of stock issuances of $2,217,924, which provisions expired upon the completion of our IPO in March 2010, the charge for the beneficial conversion feature related to the Third Bridge Notes of $1,137,762, non-cash interest expense of $462,431 on our outstanding debt during the first quarter of 2010, the write-offs of debt discount and deferred financing costs of $1,135,076 and $358,495, respectively, as a result of the conversion of our notes, stock-based compensation charges of $1,167,081, an increase in accounts payable and accrued expenses of $589,638 and $361,367, respectively, relating primarily to clinical research organization costs, manufacturing costs, patent fees, accrued legal fees, accounting fees, bonuses and filing fees.

Net Cash Used in Investing Activities

Net cash used in investing activities was $10,361 for the year ended December 31, 2010. Net cash used in investing activities consisted of leasehold improvements made to our corporate headquarters located in Bridgewater, New Jersey, in addition to purchases of computer equipment and accounting software, which are being amortized over the term of the lease and depreciated over the expected life of the equipment and software. Net cash used in investing activities was $0 for the year ended December 31, 2009.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $10,457,270 for the year ended December 31, 2010. Net cash provided by financing activities consisted of the sale of equity securities issued in our IPO, through which we received gross proceeds of $12,512,500. The gross proceeds of $12,512,500 were offset by underwriting discounts and commissions of $1,063,563, corporate finance fees of $225,250, and reimbursable legal fees for counsel to the underwriters of $90,000, in addition to other offering costs and expenses of $676,417, consisting primarily of legal, accounting, printing and filing fees. Net cash provided by financing activities was $2,271,621 for the year ended December 31, 2009.

Funding Requirements

Our total cash on hand as of December 31, 2010 was $8,283,684, compared to $1,505,179 at December 31, 2009. Because our business does not generate positive operating cash flow, we will need to either raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, including our long-term plans for clinical trials and new product development, as well as to fund operations generally. Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity, debt financing, strategic relationships, or out-licensing of our products. Through December 31, 2010, all of our financing has been through our recent IPO, previous debt financings and our receipt of a total of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program and a total of approximately $280,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program. We expect to continue to fund operations from cash on hand and through either capital raising sources as previously described, which may be dilutive to existing stockholders, or through generating revenues from the licensing of our products or strategic alliances. We plan to seek additional debt and/or equity financing, but can provide no assurances that such financing will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness in connection with a debt financing would result in increased fixed obligations and could also result in covenants that would restrict our operations. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including the changes in the focus and direction of our research and development programs, the acquisition and pursuit of development of new product candidates, competitive and technical advances, costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

We do not anticipate that we will generate significant product sales revenue for 2011. In the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters.

Based on our cash resources at December 31, 2010, and our current plan of expenditure on continuing development of our current products, we believe that we have sufficient capital to fund our operations into the first quarter of 2012, and will need additional financing until we can achieve profitability, if ever. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, or we could be required to delay, scale back or eliminate some or all of our research and development programs. Each of these alternatives would likely have a material adverse effect on the prospects of our business.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 2 to our financial statements included with this report, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

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Stock-Based Compensation

We account for stock options according to the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") No. 718, "Compensation — Stock Compensation" ("ASC 718"). Under ASC 718, share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis.

We account for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method in accordance with ASC 718. The non-cash charge to operations for non-employee options with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and amortized to consulting expense over the related vesting period.

For the purpose of valuing options and warrants granted to our employees, non-employees and directors and officers during the year ended December 31, 2010, we used the Black-Scholes option pricing model. We granted options to purchase 1,639,215 shares of common stock to our employees, non-employees and directors and officers during the year ended December 31, 2010. No options were issued during the year ended December 31, 2009. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of our awards. We estimated the expected term of the options granted to employees is based on anticipated exercises in future periods assuming the success of our business model as currently forecasted. For non-employee consultants, we used the contractual terms of the options and warrants. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options was calculated by examining historical volatilities for publicly traded industry peers, although we do not have any trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for our common stock becomes available. Given that the stock options currently outstanding are primarily held by our senior management and directors, we do not currently expect to experience any forfeitures with respect to such options and, as such, compensation expense for stock-based awards does not include an estimate for forfeitures.

Accounting Standards Updates

In April 2010, the FASB issued Accounting Standards Update ("ASU") 2010-17 related to revenue recognition under the milestone method. The objective of the accounting standard update is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. This update is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this standard did not have a significant impact on our results of operations, cash flows, or financial position.

In February 2010, the FASB issued ASU 2010-09 to amend certain recognition and disclosure requirements. Under this update, an entity that is either (1) an SEC filer or (2) a conduit bond obligor for conduit debt securities that are traded in a public market, must evaluate subsequent events through the date the financial statements are issued. All other entities are required to evaluate subsequent events through the date the financial statements are available to be issued. In addition, SEC filers are not required to disclose in their financial statements the date through which subsequent events have been evaluated. However, all other entities, including conduit bond obligors, must both disclose that date and indicate whether it is when the financial statements were issued or were available to be issued. The adoption of this standard did not have a significant impact on our results of operations, cash flows or financial position.

Accounting Standards Updates Not Yet Effective

In December 2010, the FASB issued ASU 2010-27 to address questions concerning how pharmaceutical manufacturers should recognize and classify in their income statements fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act. The legislation imposes an annual fee on the pharmaceutical manufacturing industry for each calendar year beginning on or after January 1, 2011. An entity's portion of the annual fee is payable no later than September 30 of the applicable calendar year and is not tax deductible. Pharmaceutical manufacturers and importers with less than $5 million in annual sales are exempt from the annual fee. The adoption of this standard is not expected to have a significant impact on our results of operations, cash flows or financial position.

Other ASUs not effective until after December 31, 2010 are not expected to have a significant effect on our financial position or results of operations.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

See the financial statements included at the end of this report beginning on page F-1.

ItemChanges in and Disagreements With Accountants on Accounting and Financial Disclosure.
9.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on their evaluation of our disclosure controls and procedures, our management, including our principal executive officer and principal financial officer, have concluded that our disclosure controls and procedures were effective as of December 31, 2010 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (b) accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow for timely decisions regarding required disclosure.

Management's Annual Report on Internal Controls Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during our fourth quarter ended December 31, 2010, or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors and Executive Officers and Corporate Governance.

The information required by this Item 10 will be furnished on or prior to May 2, 2011 (and is hereby incorporated by reference) by an amendment hereto or pursuant to a definitive proxy statement in connection with our 2011 Annual Meeting of Stockholders.

Item 11. Executive Compensation.

The information required by this Item 11 will be furnished on or prior to May 2, 2011 (and is hereby incorporated by reference) by an amendment hereto or pursuant to a definitive proxy statement in connection with our 2011 Annual Meeting of Stockholders.

Item 12. Security Ownership Of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be furnished on or prior to May 2, 2011 (and is hereby incorporated by reference) by an amendment hereto or pursuant to a definitive proxy statement in connection with our 2011 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be furnished on or prior to May 2, 2011 (and is hereby incorporated by reference) by an amendment hereto or pursuant to a definitive proxy statement in connection with our 2011 Annual Meeting of Stockholders.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be furnished on or prior to May 2, 2011 (and is hereby incorporated by reference) by an amendment hereto or pursuant to a definitive proxy statement in connection with our 2011 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) List of documents filed as part of this report:

1. Financial Statements:

The financial statements of the Company and the related report of the Company's independent registered public accounting firm thereon have been filed under Item 8 hereof.

2. Financial Statement Schedules:

None.

3. Exhibit Index

The following is a list of exhibits filed as part of this Form 10-K:

Exhibit No.	Description
3.1	Form of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
3.2	Form of Amended and Restated By-laws (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.2	Specimen Unit certificate (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.3	Specimen warrant certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.4	Form of warrant agreement (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.5	Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC (incorporated by reference to Exhibit 4.6 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.6	Stockholder Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).

4.7	Form of Stock Purchase Agreement for former stockholders of Picton Pharmaceuticals, Inc (incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).

4.8	Form of Note and Warrant Purchase Agreement for First Bridge Notes (incorporated by reference to Exhibit 4.11 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.9	Form of Note and Warrant Purchase Agreement for Second Bridge Notes (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.10	Form of Note and Warrant Purchase Agreement for Third Bridge Notes (incorporated by reference to Exhibit 4.16 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.11	Form of Third Bridge Warrant (incorporated by reference to Exhibit 4.18 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on January 20, 2010).
10.1	Contribution Agreement, dated as of July 28, 2006, by and between Shiva Biomedical, LLC, Picton Pharmaceuticals, Inc., Picton Holding Company, Inc., and the stockholders of Picton Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.2	Amendment to Contribution Agreement, dated as of October 6, 2009, by and between Shiva Biomedical, LLC and CorMedix, Inc. (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.3	Amendment No. 2 to Contribution Agreement, dated as of February 22, 2010, by and between the Company and Shiva Biomedical, LLC (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.4	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC. (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.5	Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.6	Exclusive License and Consulting Agreement, dated as of January 30, 2008, between the Company and Hans-Dietrich Polaschegg (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).‡
10.7	Amended and Restated Consulting Agreement, dated as of January 10, 2008, between the Company and Sudhir V. Shah, M.D. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.8	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.9	

Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).‡

10.10	Manufacture and Development Agreement, dated as of March 5, 2007, by and between the Company and Emcure Pharmaceuticals USA, Inc. (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.11	Amended and Restated Employment Agreement, dated as of November 25, 2009, between the Company and John Houghton (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.12	Amendment to Amended and Restated Employment Agreement, dated as of January 14, 2011, by and between the CorMedix Inc. and John C. Houghton (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on January 19, 2011.
10.13	Employment Agreement, dated as of February 4, 2010, between the Company and Brian Lenz (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010.
10.14	Amendment to Employment Agreement, dated as of January 14, 2011, by and between CorMedix Inc. and Brian Lenz (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed with the SEC on January 19, 2011.
10.15	Employment Agreement, dated as of February 25, 2011, between the Company and Mark A. Klausner M.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 3, 2011.
10.16	Amended and Restated 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.17	Form of Indemnification Agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
23.1	Consent of Independent Registered Public Accounting Firm.*
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

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* filed herewith

‡ Confidential treatment has been granted for portions of this document. The omitted portions of this document have been filed separately with the SEC.

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SIGNATURES

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

CORMEDIX INC.

March 11, 2011	By:	/s/ John C. Houghton John C. Houghton President and Chief Executive Officer (Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ John C. Houghton John C. Houghton	President, Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2011
/s/ Brian Lenz Brian Lenz	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	March 11, 2011
/s/ Richard M. Cohen Richard M. Cohen	Director	March 11, 2011
Gary A. Gelbfish	Director	
/s/ Bamdad Bastani Bamdad Bastani	Director	March 11, 2011
/s/ Antony E. Pfaffle Antony E. Pfaffle	Director	March 11, 2011
/s/ Timothy Hofer Timothy Hofer	Director	March 11, 2011

CORMEDIX, INC.
(A Development Stage Company)

FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
CorMedix Inc.

We have audited the accompanying balance sheets of CorMedix Inc. (A Development Stage Company) as of December 31, 2010 and 2009, and the related statements of operations, changes in stockholders' equity (deficiency) and cash flows for the years then ended, and the period from July 28, 2006 (Inception) to December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of CorMedix Inc. (A Development Stage Company) as of December 31, 2010 and 2009, and its results of operations and cash flows for the years then ended, and the period from July 28, 2006 (Inception) to December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

/s/ J.H. Cohn LLP

Roseland, New Jersey
March 11, 2011

CORMEDIX INC.
(A Development Stage Company)

BALANCE SHEETS

	December 31, 2010	December 31, 2009
ASSETS		
Current assets		
Cash and cash equivalents	$ 8,283,684	$ 1,505,179
Prepaid research and development expenses	205,404	175,000
Other prepaid expenses and current assets	323,060	3,114
Total current assets	8,812,148	1,683,293
Property and equipment, net	22,310	24,116
Deferred financing fees, net	-	506,510
Security deposit	13,342	11,733
TOTAL ASSETS	$ 8,847,800	$ 2,225,652
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities		
Accounts payable	$ 1,139,276	$ 549,638
Accrued expenses	436,367	75,000
Senior convertible notes, net of discount	-	12,229,897
Interest payable – senior convertible notes	-	2,393,132
Notes payable – related parties	-	535,428
Interest payable – related parties	-	97,456
Notes payable – Galenica, Ltd.	-	1,000,000
Interest payable – Galenica, Ltd.	-	54,000
Total current liabilities	1,575,643	16,934,551
Deferred rent	16,759	-
TOTAL LIABILITIES	1,592,402	16,934,551
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIENCY)		
Common stock - $0.001 par value: 40,000,000 shares authorized, 11,408,274 shares issued and outstanding at December 31, 2010; 33,000,000 shares authorized, 787,010 shares issued and outstanding at December 31, 2009	11,408	787
Common stock – Non-Voting Subordinated Class A, $0.001 par value: none authorized, issued or outstanding at December 31, 2010; 5,000,000 shares authorized, 193,936 shares issued and outstanding at December 31, 2009	-	194
Deferred stock issuances	(146)	(27)
Additional paid-in capital	43,480,415	10,621,190
Deficit accumulated during the development stage	(36,236,279)	(25,331,043)
TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)	7,255,398	(14,708,899)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	$ 8,847,800	$ 2,225,652

See Notes to Financial Statements

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CORMEDIX INC.
(A Development Stage Company)

STATEMENTS OF OPERATIONS

	Year Ended December 31, 2010	Year Ended December 31, 2009	Cumulative Period from July 28, 2006 (inception) Through December 31, 2010
OPERATING EXPENSES			
Research and development	$ 5,494,297	$ 4,888,538	$ 18,038,746
General and administrative	3,012,706	1,166,845	7,788,898
Total Operating Expenses	8,507,003	6,055,383	25,827,644
LOSS FROM OPERATIONS	(8,507,003)	(6,055,383)	(25,827,644)
OTHER INCOME (EXPENSE)			
Other income	391,168	-	391,168
Interest income	23,442	2,130	112,305
Interest expense, including amortization and write-off of deferred financing costs and debt discounts	(3,093,763)	(2,068,202)	(11,193,028)
LOSS BEFORE INCOME TAXES	(11,186,156)	(8,121,455)	(36,517,199)
State income tax benefit	280,920	-	280,920
NET LOSS	$ (10,905,236)	$ (8,121,455)	$ (36,236,279)
NET LOSS PER SHARE – BASIC AND DILUTED	$ (1.15)	$ (9.48)	
WEIGHTED AVERAGE SHARES OUTSTANDING – BASIC AND DILUTED	9,473,259	856,646	

See Notes to Financial Statements

CORMEDIX INC.
(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2010

	Common Stock		Non-Voting Common Stock – Class A		Common Stock – Series B - F		Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount				
Common stock issued to founders at $0.008 per share in July 2006	510,503	$510						$3,490		$4,000
Common stock issued and held in escrow to licensor at $0.008 per share in August 2006					1,000,000	$1,000	$(1,000)			-
Common stock issued to employee at $0.008 per share in November 2006	53,743	54						367		421
Stock-based compensation								4,726		4,726
Net loss									$(975,317)	(975,317)
Balance at December 31, 2006	564,246	564			1,000,000	1,000	(1,000)	8,583	(975,317)	(966,170)
Common stock issued to employees at	27,056	27						185		212

$0.008 per share in January and March 2007										
Common stock issued to technology finders at $0.008 per share in March 2007			193,936	$194						194
Warrants issued in connection with senior convertible notes								748,495		748,495
Debt discount on senior convertible notes								2,993,981		2,993,981
Stock-based compensation								64,875		64,875
Net loss									(7,237,526)	(7,237,526)
Balance at December 31, 2007	591,302	591	193,936	194	1,000,000	1,000	(1,000)	3,816,119	(8,212,843)	(4,395,939)

See Notes to Financial Statements

CORMEDIX INC.
(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2010

	Common Stock		Non-Voting Common Stock – Class A		Common Stock – Series B - F		Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2007 (carried forward)	591,302	$591	193,936	$194	1,000,000	$1,000	$(1,000)	$3,816,119	$(8,212,843)	$(4,395,939)
Common stock issued to licensor at $8.23 per share in January 2008	39,980	40						328,908		328,948
Common stock issued to licensor and held in escrow in January 2008	15,992	16					(125)	109		-
Common stock issued to consultant at $8.23 per share in May 2008	939	1						7,720		7,721
Debt discount on senior convertible notes								747,215		747,215
Stock-based compensation								281,652		281,652
Net loss									(8,996,745)	(8,996,745)
	648,213	648	193,936	194	1,000,000	1,000	(1,125)	5,181,723	(17,209,588)	(12,027,148)

Balance at December 31, 2008								
Common stock issued to consultant at $32.05 per share in July 2009	639	1				20,449		20,450
Common stock issued to licensor at $32.05 per share in exchange for Series B-F common stock in October 2009	98,739	99	(1,000,000)	(1,000)	1,186	3,164,217		3,164,502
Common stock issued to licensor at $32.05 per share in October 2009	28,156	28				902,316		902,344
Common stock issued to licensor and held in escrow in October 2009	11,263	11			(88)	77		-
Debt discount on senior convertible notes						1,238,265		1,238,265
Stock-based compensation						114,143		114,143
Net loss							(8,121,455)	(8,121,455)
Balance at December 31, 2009	787,010	787	193,936	194	(27)	10,621,190	(25,331,043)	(14,708,899)

See Notes to Financial Statements

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CORMEDIX INC.
(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
Period from July 28, 2006 (Inception) to December 31, 2010

	Common Stock Shares	Common Stock Amount	Non-Voting Common Stock – Class A Shares	Non-Voting Common Stock – Class A Amount	Non-Voting Common Stock – Series B Shares	Non-Voting Common Stock – Series B Amount	Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficiency)
Balance at December 31, 2009 (carried forward)	787,010	$787	193,936	$194			$(27)	$10,621,190	$(25,331,043)	$(14,708,899)
Common stock issued to consultant at $32.05 per share in February 2010	4,059	4						130,087		130,091
Common stock issued upon conversion of Class A Non-Voting Common Stock at a 1 for 7.836 conversion rate in February 2010	24,750	25	(193,936)	(194)				169		-
Common stock issued from debt conversion to noteholders in March 2010	5,914,431	5,914						18,891,253		18,897,167
Common stock issued to licensors at $3.125 per share in	828,024	828					(119)	2,217,215		2,217,924

March 2010									
Common stock issued in initial public offering at $3.125 per share in March 2010, net of issuance costs	3,850,000	3,850					10,453,420		10,457,270
Stock-based compensation							1,167,081		1,167,081
Net loss								(10,905,236)	(10,905,236)
Balance at December 31, 2010	11,408,274	$11,408	-	$-	-	$-	$(146)	$43,480,415	$(36,236,279)	$7,255,398

See Notes to Financial Statements

CORMEDIX INC.
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STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2010	Year Ended December 31, 2009	Period from July 28, 2006 (Inception) To December 31, 2010
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (10,905,236)	$ (8,121,455)	$ (36,236,279)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,167,081	114,143	1,632,477
Stock issued in connection with license agreements	2,217,924	4,066,846	6,613,718
Stock issued in connection with consulting agreement	130,091	20,450	158,262
Amortization of deferred financing costs	358,495	153,642	2,047,881
Amortization of debt discount	1,135,076	539,064	4,979,461
Non-cash charge for beneficial conversion feature	1,137,762	-	1,137,762
Non-cash interest expense	462,431	1,373,014	3,007,018
Expenses paid on behalf of the Company satisfied through the issuance of notes	-	-	51,253
Depreciation	12,167	9,945	37,774
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(350,350)	(104,673)	(528,464)
Security deposits	(1,609)	-	(13,342)
Accounts payable	589,638	(63,665)	1,139,276
Accrued expenses	361,367	(133,765)	436,367
Deferred rent	16,759	-	16,759
Net cash used in operating activities	(3,668,404)	(2,146,454)	(15,520,077)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of equipment	(10,361)	-	(60,084)
Net cash used in investing activities	(10,361)	-	(60,084)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from notes payable to related parties	-	190,749	2,465,749
Proceeds from senior convertible notes	-	2,619,973	13,364,973
Proceeds from Galenica, Ltd. promissory note	-	-	1,000,000
Deferred financing costs	-	(539,101)	(1,447,400)
Repayment of amounts loaned under related party notes	-	-	(1,981,574)
Proceeds from sale of equity securities, net of issuance costs	10,457,270	-	10,457,270
Proceeds from receipt of stock subscriptions and issuances of common stock	-	-	4,827
Net cash provided by financing activities	10,457,270	2,271,621	23,863,845
NET INCREASE IN CASH AND CASH EQUIVALENTS	6,778,505	125,167	8,283,684
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	1,505,179	1,380,012	-

CASH AND CASH EQUIVALENTS – END OF PERIOD	$ 8,283,684	$ 1,505,179	$ 8,283,684
Cash paid for interest	$ -	$ -	$ 18,425
Supplemental Disclosure of Non-Cash Financing Activities:			
Conversion of notes payable and accrued interest to common stock	$ 18,897,167	$ -	$ 18,897,167
Reclassification of deferred financing fees to additional paid-in capital	$ 148,015	$ -	$ 148,015
Stock issued to technology finders and licensors	$ -	$ 11	$ 155
Warrants issued to placement agent	$ -	$ -	$ 748,495
Debt discount on senior convertible notes	$ -	$ 1,238,265	$ 4,979,461

See Notes to Financial Statements

CORMEDIX INC.
(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

CorMedix Inc. (f/k/a Picton Holding Company, Inc.) ("CorMedix" or the "Company") was incorporated in the State of Delaware on July 28, 2006. CorMedix is a development stage biopharmaceutical company that seeks to fulfill selected, significant unmet medical needs in the therapeutic areas at the crossroads of cardiac and kidney (renal) disease. On January 18, 2007, the Company changed its name from Picton Holding Company, Inc. to CorMedix Inc.

Basis of Presentation:

The Company's primary activities since incorporation have been organizational activities, including recruiting personnel, establishing office facilities, acquiring licenses for its pharmaceutical compound pipeline, performing business and financial planning, performing research and development and raising funds through the issuance of debt and common stock. The Company has not generated any revenues and, accordingly, the Company is considered to be in the development stage.

The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments through the normal course of business. For the year ended December 31, 2010 and the period from July 28, 2006 (inception) to December 31, 2010, the Company incurred net losses of $10,905,236 and $36,236,279, respectively. The Company has stockholders' equity as of December 31, 2010 of $7,255,398. Management believes that the Company will continue to incur losses for the foreseeable future and will need additional equity or debt financing or will need to generate revenue from the licensing of its products or by entering into strategic alliances to be able to sustain its operations until it can achieve profitability and positive cash flows, if ever. Management plans to seek additional debt and/or equity financing for the Company, but cannot assure that such financing will be available on acceptable terms, or at all. Management believes that the currently available capital resources will be sufficient to meet the Company's operating needs into the first quarter of 2012. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On February 24, 2010, the Company effected a 1 for 7.836 reverse stock split of its common stock. All share and per-share information in these financial statements have been adjusted to give effect to the reverse stock split.

Note 2 — Summary of Significant Accounting Policies:

Cash:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. The Company maintains its cash in bank deposit and other interest bearing accounts, the balances of which, at times, may exceed federally insured limits.

Use of Estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

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NOTES TO FINANCIAL STATEMENTS

Deferred Financing Fees

Deferred financing fees are associated with obtaining long and short-term debt financing which have been deferred and were amortized to interest expense over the expected term of the related debt, and have been fully amortized upon the conversion of the Company's convertible notes in connection with the Company's initial public offering ("IPO") in March 2010. See Notes 6 and 8. Deferred financing fees as of December 31, 2010 and 2009 were $0 and $506,510, respectively, net of amortization of $358,495 in deferred financing fees and $148,015 in additional paid-in capital in 2010 and amortization of $153,642 in deferred financing fees in 2009.

Prepaid Expenses

Prepaid expenses consist of payments made in advance to vendors relating to service contracts for clinical trial development, manufacturing, preclinical development and insurance policies. These advanced payments are amortized to expense either as services are performed or over the relevant service period using the straight-line method.

Property and Equipment

Property and equipment consist primarily of furnishings, fixtures, leasehold improvements, office equipment and computer equipment which are recorded at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. Property and equipment, net as of December 31, 2010 and 2009 were $22,310 and $24,116, respectively, net of accumulated depreciation of $37,775 and $25,608, respectively.

Description	Estimated Useful Life
Office equipment and furniture	5 years
Leasehold improvements	5 years
Computer equipment	5 years
Computer software	3 years

Stock-Based Compensation:

The Company accounts for stock options granted to employees according to the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") No. 718 ("ASC 718"), "Compensation — Stock Compensatio Under ASC 718, share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis.

The Company accounts for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method in accordance with ASC 718. The initial non-cash charge to operations for non-employee options with vesting are revalued at the end of each reporting period based upon the change in the fair value of the

options and amortized to consulting expense over the related vesting period.

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NOTES TO FINANCIAL STATEMENTS

For the purpose of valuing options and warrants granted to employees, non-employees and directors and officers of the Company during the year ended December 31, 2010, the Company used the Black-Scholes option pricing model utilizing the assumptions noted in the following table. No options were issued during the year ended December 31, 2009. The Company estimated the expected term of the stock options granted based on anticipated exercises in future periods assuming the success of the Company's business model as currently forecasted. For non-employee consultants, the Company used the contractual term of the options and warrants. Given the Company's short period of publicly-traded stock history, management's estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including: industry, stage of life cycle, size and financial leverage. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The expected dividend yield reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. Given that the stock options currently outstanding are primarily held by senior management and directors of the Company, management does not currently expect to experience any forfeitures with respect to such options and, as such, compensation expense for stock-based awards does not include an estimate for forfeitures.

	2010
Risk-free interest rate	1.5% – 2.6%
Expected volatility	112% – 114%
Expected life of options in years	5
Expected dividend yield	0.0%

Research and Development:

Research and development costs are charged to expense as incurred. Research and development includes fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated executive, human resources and facilities expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in the period when actual costs become known. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development expense.

Income Taxes:

Under ASC 740, "Income Taxes" ("ASC 740"), deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.

Loss per Common Share:

Basic earnings (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per common share reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity. Since the Company has only incurred losses, basic and diluted loss per share are the same. The amount of potentially dilutive securities excluded from the calculation was 6,472,767 and 2,883,084 shares of common stock underlying warrants and options at December 31, 2010 and 2009, respectively. Additionally, there were 145,543 and 27,255 shares of common stock being held in escrow at December 31, 2010 and 2009, respectively, pending the achievement of certain regulatory and sales-based milestones as part of the license agreement with ND Partners LLC.

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NOTES TO FINANCIAL STATEMENTS

Accounting Standards Updates

In April 2010, the FASB issued ASU 2010-17 related to revenue recognition under the milestone method. The objective of the accounting standard update is to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. This update is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this standard did not have a significant impact on the Company's results of operations, cash flows, or financial position.

In February 2010, the FASB issued ASU 2010-09 to amend certain recognition and disclosure requirements. Under this update, an entity that is either (1) a Securities and Exchange Commission ("SEC") filer or (2) a conduit bond obligor for conduit debt securities that are traded in a public market, must evaluate subsequent events through the date the financial statements are issued. All other entities are required to evaluate subsequent events through the date the financial statements are available to be issued. In addition, SEC filers are not required to disclose in their financial statements the date through which subsequent events have been evaluated. However, all other entities, including conduit bond obligors, must both disclose that date and indicate whether it is when the financial statements were issued or were available to be issued. The adoption of this standard did not have a significant impact on the Company's results of operations, cash flows or financial position.

Accounting Standards Updates Not Yet Effective

In December 2010, the FASB issued ASU 2010-27 to address questions concerning how pharmaceutical manufacturers should recognize and classify in their income statements fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act. The legislation imposes an annual fee on the pharmaceutical manufacturing industry for each calendar year beginning on or after January 1, 2011. An entity's portion of the annual fee is payable no later than September 30 of the applicable calendar year and is not tax deductible. Pharmaceutical manufacturers and importers with less than $5 million in annual sales are exempt from the annual fee. The adoption of this standard is not expected to have a significant impact on the Company's results of operations, cash flows or financial position.

Other ASUs not effective until after December 31, 2010 are not expected to have a significant effect on the Company's financial position or results of operations.

Note 3 — Related Party Transactions:

Consulting Services:

Effective August 1, 2006, the Company began accruing monthly fees for consulting services at a rate of $25,000 per month payable to Paramount Corporate Development, LLC ("Paramount"), an affiliate of a significant stockholder of the Company, pursuant to a services agreement with Paramount. This agreement was terminated as of August 31, 2008 and, accordingly, there was no consulting services expense under this agreement for the years ended December 31, 2010 and 2009. For the period from July 28, 2006 (inception) to December 31, 2010, consulting services expense under this agreement was $625,000, of which $75,000 was accrued for as of December 31, 2009. No amounts were due to Paramount pursuant to this agreement as of December 31, 2010.

Notes Payable:

On July 28, 2006, the Company issued a 5% promissory note payable to Paramount BioSciences, LLC (“PBS”), an affiliate of a significant stockholder of the Company. This note and all accrued interest was originally scheduled to mature on July 28, 2008, or earlier if certain events occurred. This note was subsequently amended to, among other things, extend the maturity date until July 31, 2010 and increase the annual interest rate to 8% per year. The note was issued to PBS for expenses that PBS has paid on behalf of the Company. On March 30, 2010, in conjunction with the closing of the Company’s initial public offering (the “IPO”) of units, each consisting of two shares of the Company’s common stock and a warrant to purchase one share of the Company’s common stock at an exercise price of $3.4375 (Units), the principal and accrued interest amount outstanding under this note, which was $198,264 on such date, converted into 30,499 Units, consisting of 60,998 shares of common stock and warrants to purchase 30,499 shares of common stock at an exercise price of $3.4375. See Note 8.

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NOTES TO FINANCIAL STATEMENTS

On August 11, 2006, the Company issued a 5% promissory note payable to an entity related to the sole member of PBS. This note and all accrued interest was originally scheduled to mature on August 11, 2009, or earlier if certain events occurred. This note was subsequently amended to, among other things, extend the maturity date until July 31, 2010 and increase the annual interest rate to 8% per year. On March 30, 2010, in conjunction with the closing of the IPO, the principal and accrued interest amount under this note which was $452,007 on such date, converted into 69,539 Units, consisting of 139,078 shares of common stock and warrants to purchase 69,539 shares of common stock at an exercise price of $3.4375. See Note 8.

Note 4 — Income Taxes:

There was no current or deferred income tax provision for the years ended December 31, 2010 and 2009.

The Company's deferred tax assets as of December 31, 2010 and 2009 consist of the following:

	2010	2009
Net operating loss carryforwards – Federal	$ 5,962,000	$ 3,910,000
Net operating loss carryforwards – state	821,000	662,000
Intangible assets	1,436,000	1,545,000
Other	54,000	46,000
Totals	8,273,000	6,163,000
Less valuation allowance	(8,273,000)	(6,163,000)
Deferred tax assets	$ -	$ -

At December 31, 2010, the Company had potentially utilizable Federal and state net operating loss tax carryforwards of approximately $17,535,000 and $13,678,000, respectively. The net operating loss tax carryforwards will start to expire in 2026 for Federal purposes and 2013 for state purposes.

The utilization of the Company's net operating losses may be subject to a substantial limitation due to the "change of ownership provisions" under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation may result in the expiration of the net operating loss carryforwards before their utilization.

The effective tax rate varied from the statutory rate as follows:

	December 31,	
	2010	2009
Statutory Federal tax rate	(34.0)%	(34.0)%
State income tax rate (net of Federal)	(1.3)%	(6.0)%
Debt discount amortization	4.9 %	2.0 %
Stock issued to licensor and consultant	7.1 %	
Federal Qualified Therapeutic Discovery Project grant	(1.2)%	
Other permanent differences	3.3 %	
Sale of State of New Jersey net operating losses (net of federal)	(1.7)%	
Effect of valuation allowance	20.4 %	38.0 %

Effective tax rate	(2.5)%	- %

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NOTES TO FINANCIAL STATEMENTS

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2010 and 2009 and for the period from July 28, 2006 (inception) to December 31, 2010 was $2,110,000, $608,000 and $8,273,000, respectively. The tax benefit assumed the Federal statutory tax rate of 34% and a state tax rate of 6% and has been fully offset by the aforementioned valuation allowance.

In July 2006, the Company adopted guidance under ASC Topic 740-10 which clarifies the accounting and disclosure for uncertainty in income taxes. The adoption of this interpretation did not have a material impact on the Company's financial statements.

Management believes that the Company does not have any tax positions that will result in a material impact on the Company's financial statements because of the adoption of ASC 740-10. However management's conclusion may be subject to adjustment at a later date based on ongoing analyses of tax laws, regulations and related Interpretations. The Company's tax returns from inception to 2009 remain open.

Note 5 — Commitments:

Operating Lease:

On March 18, 2010, the Company entered into a lease agreement with UA Bridgewater Holdings, LLC for office space located in Bridgewater, New Jersey, for an initial term of 60 months, with a commencement date of April 1, 2010, an expiration date of March 31, 2015, and lease payments beginning on July 1, 2010. In accordance with the lease agreement, the Company has deposited $13,342 with the landlord, the equivalent of two months' rent. The Company has a one-time right to terminate the lease after two years from the commencement date, provided the Company gives the landlord notice of its election to exercise this option on or before 18 months after April 1, 2010. If the Company elects to exercise the early termination option, the Company will pay an early cancellation fee to the landlord in an amount equal to the sum of the following: the remaining balance of the unamortized leasing costs incurred by the landlord; the brokerage commissions; the landlord's legal fees associated with this lease; and $18,474, representing three months base rent. The Company also has been granted the option to extend the lease term for one additional period of three years, commencing the day following the then-current expiration date of the term, March 31, 2015, provided the Company delivers notice to the landlord no later than nine months prior to March 31, 2015. The total 60 month lease obligation is approximately $389,000. The Company's total remaining lease obligation is $347,281 as of December 31, 2010, as set forth below:

Schedule of Future Minimum Lease Payments

Years Ending December 31,	Amount
2011	$ 80,057
2012	80,057
2013	82,697
2014	83,576
2015	20,894
Total	$ 347,281

Employment Agreements:

As of December 31, 2010, the Company has employment agreements with its executive officers which have an aggregate financial obligation through the end of their respective agreements of approximately $455,000.

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NOTES TO FINANCIAL STATEMENTS

Other:

The Company has entered into various contracts with third parties in connection with the development of the licensed technology described in Note 10.

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of December 31, 2010. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Note 6 — Convertible Notes:

In connection with the closing of the IPO, which occurred on March 30, 2010, all of the Company's outstanding convertible notes converted into Units or shares of common stock, as described below, in accordance with the terms of such notes. See Note 8.

In July and September 2007, the Company issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $8,645,000 (the "First Bridge Notes") with an original maturity date of July 31, 2008, which was subsequently extended to July 31, 2009. The First Bridge Notes were amended on June 5, 2009 to extend the maturity date to July 31, 2010 and to provide for an annual interest rate of 10% from June 5, 2009 until July 31, 2009, and 12% per annum from and after August 1, 2009. On March 30, 2010, the aggregate amount of principal and accrued interest outstanding under the First Bridge Notes was $11,036,837 and the First Bridge Notes converted into an aggregate of 1,697,966 Units, which consist of 3,395,932 shares of common stock and warrants to purchase 1,697,966 shares of common stock at an exercise price of $3.4375, in conjunction with the IPO.

In August 2008, the Company issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $2,100,000 (the "Second Bridge Notes") with an original maturity date of July 31, 2009. The Second Bridge Notes were amended on June 5, 2009 to extend the maturity date to July 31, 2010 and to provide for an interest rate of 10% per annum from June 5, 2009 until July 31, 2009, and 12% per annum from and after August 1, 2009. On March 30, 2010, the aggregate amount of principal and accrued interest outstanding under the Second Bridge Notes was $2,440,368 and the Second Bridge Notes converted into an aggregate of 375,437 Units, consisting of 750,874 shares of common stock and warrants to purchase 375,437 shares of common stock at an exercise price of $3.4375, in conjunction with the IPO.

On December 10, 2008, the Company issued a promissory note with no stated interest rate to Galenica, Ltd., a pharmaceutical company ("Galenica"), in the principal amount of $1,000,000, in connection with a proposed purchase agreement between the Company and Galenica. As a result of the termination of the proposed purchase agreement, on April 30, 2009, this promissory note was cancelled and the Company issued to Galenica a new promissory note in the principal amount of $1,000,000, with an interest rate of 8% and a maturity date of July 31, 2010 (the "Galenica Note"). Except for the interest rate, the terms of the Galenica Note were consistent with the terms of the Second Bridge Notes. On March 30, 2010, the amount of principal and accrued interest outstanding under the Galenica Note was $1,073,333 and the Galenica Note converted into 165,128 Units, consisting of 330,256 shares of common stock and warrants to purchase 165,128 shares of common stock at an exercise price of $3.4375, in conjunction with the IPO.

In October and November 2009, the Company issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $2,619,973 (the “Third Bridge Notes”) with a maturity date of October 29, 2011. Under the terms of the Third Bridge Notes, the aggregate amount of principal and accrued interest automatically converted into shares of the Company’s common stock upon completion of the IPO at a price equal to 70% of the portion of the offering price of the Units sold in the IPO that was allocated to the common stock, which was $3.125. Accordingly, on March 30, 2010, the aggregate amount of principal and accrued interest outstanding under the Third Bridge Notes, which was $2,706,594, converted into 1,237,293 shares of common stock in conjunction with the IPO. The beneficial conversion feature of the Third Bridge Notes as a result of the 30% discount at which the Third Bridge Notes converted into shares of common stock upon the IPO was valued at $1,137,762, which was recorded to interest expense on March 30, 2010.

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In addition, in connection with the private placement of the Third Bridge Notes, each noteholder received 503,034 warrants to purchase such number of shares of the Company's common stock equal to 60% of the principal amount of the Third Bridge Notes purchased divided by $3.125, the portion of the offering price of the Units sold in the IPO that was allocated to the common stock. These warrants have an exercise price of $3.4375, the same exercise price as the warrants underlying the Units sold in the IPO, and are exercisable for a period of five years.

Note 7 — Stockholders' Equity (Deficiency):

Common Stock:

During July 2006, the Company issued 510,503 shares of Common Stock to its founders for proceeds of $4,000 or $0.008 per share.

In accordance with the Shiva Contribution Agreement (see Note 10), during August 2006, the Company issued 800,000 shares of Series B Common Stock, 50,000 shares of Series C Common Stock, 50,000 shares of Series D Common Stock, 50,000 shares of Series E Common Stock and 50,000 shares of Series F Common Stock to Shiva Biomedical, LLC at $0.008 per share. These shares of Series B-F Common Stock were subsequently surrendered by Shiva in exchange for Common Stock in October 2009, as described below, and were eliminated from the Company's certificate of incorporation pursuant to an amendment effected in connection with such exchange. During 2006, the Company recorded $1,000 in deferred stock issuances for these shares of Series B-F Common Stock which were issued but were held in escrow until achievement of certain future clinical milestones (see Note 10).

During November 2006, the Company issued 53,743 shares of Common Stock to an employee in connection with an employment agreement for proceeds of $421 or $0.008 per share which vest equally over a three year period. In connection with this stock issuance, the Company recorded compensation expense at $1.72 per share for a total of $0, $25,736 and $92,649 of compensation expense for the years ended December 31, 2010 and 2009 and the period from July 28, 2006 (inception) to December 31, 2010, respectively. As of December 31, 2010, the total compensation expense has been recognized.

During January and March 2007, the Company issued 27,056 shares of Common Stock to employees in connection with employment agreements for proceeds of $212 or $0.008 per share which vest equally over a three year period. In connection with this stock issuance, the Company recorded compensation expense at $1.72 per share for a total of $1,296, $15,547 and $46,641 of compensation expense for the years ended December 31, 2010 and 2009 and the period from July 28, 2006 (inception) to December 31, 2010, respectively. As of December 31, 2010, the total compensation expense has been recognized.

During March 2007, the Company issued 193,936 shares of Non-Voting Subordinated Class A Common Stock to technology finders for proceeds of $194 or $0.008 per share which vest equally over a three year period. In connection with this stock issuance, the Company recorded compensation expense at $1.72 per share for a total of $0, $14,222 and $42,666 of compensation expense for the years ended December 31, 2010 and 2009 and the period from July 28, 2006 (inception) to December 31, 2010, respectively. As of December 31, 2010, the total compensation expense has been recognized.

In accordance with the NDP License Agreement (see Note 10), during January 2008, the Company issued 39,980 shares of Common Stock to ND Partners LLC at $8.23 per share. During 2008, the Company recorded $328,948 in research and development expense in connection with this issuance. In addition, under the NDP License Agreement, the Company issued an additional 15,992 shares of Common Stock which are being held in escrow pending the achievement of certain regulatory and sales-based milestones. During 2008, the Company recorded $125 in deferred stock issuances for this common stock which was issued but is being held in escrow (see Note 10).

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During May 2008, the Company issued 939 shares of Common Stock to a consultant in lieu of payment for consulting services at $8.23 per share. During 2008, the Company recorded $7,721 in research and development expense in connection with this issuance.

During July 2009, the Company issued 639 shares of Common Stock to a consultant as partial payment for consulting services at $32.05 per share. During 2009, the Company recorded $20,450 in research and development expense in connection with this issuance.

Pursuant to an amendment to the Shiva Contribution Agreement, dated as of October 6, 2009, and a corresponding common stock exchange and stockholder agreement of the same date (the “Exchange Agreement”), during October 2009, the Company issued 98,739 shares of Common Stock to Shiva Biomedical, LLC at $32.05 per share in exchange for the surrender by Shiva of all rights to the Series B-F Common Stock. During 2009, the Company recorded $3,164,502 in research and development expense in connection with the issuance. See Note 10.

During October 2009, the Company issued 28,156 shares of Common Stock to ND Partners LLC at $32.05 per share in accordance with the NDP License Agreement as a result of anti-dilution adjustments in connection with the issuance of shares to Shiva Biomedical, LLC under the Exchange Agreement. During 2009, the Company recorded $902,344 in connection with the issuance. See Note 10.

During October 2009, the Company issued 11,263 shares of Common Stock into escrow for the benefit of ND Partners LLC at $32.05 per share in accordance with the NDP License Agreement as a result of anti-dilution adjustments in connection with the issuance of shares to Shiva Biomedical, LLC under the Exchange Agreement. See Note 10.

During February 2010, the Company issued 4,059 shares of Common Stock to a consultant as payment for consulting services at $32.05 per share. During 2010, the Company recorded $130,091 in general and administrative expense in connection with this issuance.

During February 2010, the Company issued 24,750 shares of Common Stock to technology finders as a result of the conversion of Non-Voting Subordinated Class A Common Stock to Common Stock.

During March 2010, the Company issued a total of 5,914,431 shares of Common Stock to the holders of its convertible notes has a result of the conversion of such notes into Common Stock in conjunction with the IPO. See Notes 6 and 8.

During March 2010, the Company issued a total of 828,024 shares of Common Stock to Shiva Biomedical, LLC and ND Partners LLC at $3.125 per share, as a result of anti-dilution adjustments pursuant to their respective agreements, of which 145,543 shares are being held in escrow for ND Partners LLC pending the achievement of certain regulatory and sales-based milestones. The anti-dilution provisions under these agreements were terminated upon the completion of the Company’s IPO in March 2010. See Note 10.

During March 2010, the Company issued 3,850,000 shares of Common Stock in connection with the Company’s IPO at a per share price of $3.125.

Common Stock Options:

In 2006, the Company established a stock incentive plan (the “Plan”) under which restricted stock, stock options and other awards based on the Company’s common stock could be granted to the Company’s employees, directors, consultants, advisors and other independent contractors. On January 28, 2010, the Company amended and restated the Plan to, among other things, increase the shares of common stock issuable under the Plan from 925,000 to 2,300,000. Options issuable under the Plan have a maximum term of ten years, vest over a period to be determined by the Company’s Board of Directors (the “Board”), and have an exercise price at or above the fair market value on the date of grant.

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During the year ended December 31, 2010, the Company granted options to purchase 1,639,215 shares of common stock under the Plan to various employees, officers and directors, including options to purchase 1,589,215 shares at an exercise price of $3.125 per share and options to purchase 50,000 shares at an exercise price of $1.57 per share. Each option granted to employees during the year ended December 31, 2010 has a ten-year term and vests equally over a three-year period. The options granted to directors during the year ended December 31, 2010 have ten-year terms and vested one-third on March 30, 2010, the date of grant, and the remaining two-thirds will vest equally over a two-year period. The Company recorded $1,167,081, $114,143 and $1,632,477 of compensation expense during the years ended December 31, 2010 and 2009 and the period from July 28, 2006 (inception) to December 31, 2010, respectively, in accordance with ASC 718. There were no options granted during year ended December 31, 2009.

A summary of the Company's stock options activity under the Plan and related information is as follows:

	Year Ended December 31, 2010		Year Ended December 31, 2009	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	23,612	$8.23	29,993	$8.23
Granted	1,639,215	$3.08	-	$-
Cancelled	-	-	6,381	$8.23
Outstanding at end of period and expected to vest	1,662,827	$3.15	23,612	$8.23
Options exercisable	57,231	$4.66	8,720	$8.23
Weighted-average fair value of options granted during the period		$2.47		$6.82

The weighted average remaining contractual life of stock options outstanding at December 31, 2010 is 9.1 years. The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company as of December 31, 2010 for those options that have an exercise price below the quoted closing price. As of December 31, 2010, there were options to purchase an aggregate of 1,612,827 shares with an exercise price above the quoted closing price of $1.82 of the common stock of the Company, resulting in $0 intrinsic value, and 50,000 shares with an exercise price of $1.57 resulting in $12,500 of intrinsic value.

As of December 31, 2010, the total compensation expense related to non-vested options not yet recognized totaled $2,946,933. The weighted-average vesting period over which the total compensation expense related to non-vested options not yet recognized at December 31, 2010 was approximately 2.2 years.

Warrants

As of December 31, 2010, there were warrants issued in 2008 to consultants to purchase 17,869 shares with an exercise price of $10.66 and 18,250 warrants to purchase shares with an exercise price of $7.84 which have been issued to placement agents in connection with the Company's previous Convertible Note financings. The warrants are fully vested.

See Note 6 for a discussion of warrants issued in connection with the Third Bridge Notes. See Note 8 for a discussion of warrants issued in connection with the Company's IPO.

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Note 8 — Initial Public Offering:

In March 2010, the Company completed its IPO, whereby the Company sold 1,925,000 Units, each Unit consisting of two shares of its common stock and a warrant to purchase one share of common stock, at $6.50 per Unit resulting in gross proceeds of $12,512,500. In connection with the IPO, the Company paid underwriting discounts and commissions of $1,063,563, corporate finance fees of $225,250 and reimbursable legal expenses of counsel for the underwriters of $90,000, and the Company incurred other offering costs and expenses, including legal, accounting, printing and filing fees totaling $678,284.

All of the Company's convertible notes and all of the Company's outstanding shares of Non-Voting Subordinated Class A Common Stock automatically converted into Units or common stock upon the completion of the IPO. Management believes that the net proceeds from the IPO and existing cash will be sufficient to fund the Company's projected operating requirements into the first quarter of 2012.

Note 9 — Fair Value Measurements:

The fair value of the Company's cash and cash equivalents, accounts payable and other accrued liabilities at December 31, 2010 are estimated to approximate their carrying values due to the relative liquidity and short term nature of these instruments.

Note 10 — License Agreements:

On July 28, 2006, the Company entered into a contribution agreement (as amended on October 6, 2009 and on February 22, 2010) (the "Shiva Contribution Agreement") with Shiva Biomedical, LLC, a New Jersey limited liability company ("Shiva"), and certain other parties. Pursuant to the Shiva Contribution Agreement, Shiva contributed to the Company its kidney products business and granted the Company an exclusive, worldwide license agreement for a patent estate covering proprietary formulations of the first "iron chelator" for kidney diseases, specifically deferiprone (the "Compound"), and a biomarker diagnostic test for measuring levels of labile iron (the "Test"). Specifically, the Company licensed treatment, formulation and dosing regimens and methods of using the Compound and the Test, for the treatment and diagnosis of diseases and disorders, and the corresponding United States and foreign patents and applications in all fields of use (collectively, the "Shiva Technology"). As consideration in part for the rights to the Shiva Technology, the Company paid Shiva an initial licensing fee of $500,000 and granted Shiva up to a 20% equity interest in the Company consisting of shares of the Company's Series B, C, D, E and F Common Stock which were placed in escrow to be released upon the achievement of certain clinical milestones. Pursuant to the October 2009 amendment and corresponding Exchange Agreement, Shiva surrendered all rights to such shares in exchange for 7.0% of the outstanding shares of Common Stock as of the date of exchange, or 98,739 shares (see Note 7). The Company was also obligated to issue additional shares of Common Stock to Shiva sufficient to maintain its ownership percentage at 7.0% of the outstanding Common Stock on a fully diluted basis, and the Company issued an additional 412,338 shares to Shiva at a price of $3.125 per share as a result this obligation in connection with the Company's IPO; however, such anti-dilution obligation terminated upon the completion of the IPO. In addition, the Company will be required to make substantial payments to Shiva upon the achievement of certain clinical and regulatory based milestones. The maximum aggregate amount of such milestone payments, assuming achievement of all milestones, is $10,000,000. Events that trigger milestone payments include, but are not limited to, the reaching of various stages of clinical trials and regulatory approval processes. In the event that the Shiva Technology is commercialized, the

Company is obligated to pay to Shiva annual royalties based upon net sales of the product. In the event that the Company sublicenses the Shiva Technology to a third party, the Company is obligated to pay to Shiva a portion of the royalties, fees or other lump-sum payments it receives from the sublicense, subject to certain deductions. Through December 31, 2010, no milestone payments or royalty payments have been earned by or paid to Shiva.

The Company has the right to terminate the Shiva Contribution Agreement for any reason upon 30 days prior written notice. Should the Shiva Contribution Agreement be terminated by either party, the Company is obligated to reassign to Shiva all of the Company's intellectual property rights with respect to the Shiva Technology.

On February 22, 2010, the Company and Shiva entered into an amendment to the Shiva Contribution Agreement, pursuant to which the Company's deadline for meeting a certain development progress requirement was extended from April 30, 2010 to June 30, 2010 and the Company paid $25,000 to Shiva following completion of the Company's IPO, as partial reimbursement for Shiva's expenses in connection with such amendment and prior amendments to the Shiva Contribution Agreement.

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During the years ended December 31, 2010 and 2009 and the period from July 28, 2006 (Inception) to December 31, 2010, the Company expensed $1,288,556, $3,011,464 and $4,820,310, respectively, in connection with the Shiva Contribution Agreement.

In connection with the Shiva Contribution Agreement, on July 28, 2006, the Company entered into a Consulting Agreement with Dr. Sudhir Shah, which was amended and restated on January 10, 2008 (the "Shah Consulting Agreement"). Pursuant to the Shah Consulting Agreement, as amended, for a period of one year commencing on January 10, 2008, Dr. Shah provides the Company with consulting services involving areas mutually agreed to by Dr. Shah and the Company for up to 40 hours per month and serves on one of the Company's Scientific Advisory Boards. On April 1, 2010, this agreement has been renewed on an annual basis in the amount of $5,000. During the years ended December 31, 2010 and 2009 and the period from July 28, 2006 (Inception) to December 31, 2010, the Company expensed $84,000, $84,000 and $196,000, respectively, in connection with the Shah Consulting Agreement.

On January 30, 2008, the Company entered into a License and Assignment Agreement (the "NDP License Agreement") with ND Partners LLC, a Delaware limited liability company ("NDP"). Pursuant to the NDP License Agreement, NDP granted the Company exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). The Company acquired such licenses and patents through our assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann and Dr. Johannes Reinmueller. NDP also granted the Company exclusive licenses, with the right to grant sublicenses, to use and display certain trademarks in connection with the NDP Technology. As consideration in part for the rights to the NDP Technology, the Company paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest in the Company, consisting of 39,980 shares of the Company's Common Stock. In connection with this stock issuance, the Company recorded $328,948 of research and development expense in 2008. In addition, the Company is required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The Company was also obligated to issue additional shares of common stock to NDP sufficient to maintain its ownership percentage at 5.0% of the outstanding common stock (7.0%, including the escrow shares) on a fully diluted basis, until such time that the Company has raised $25 million through the sale of its equity securities or until an initial public offering, reverse merger or a sale of the Company. As a result of this obligation, in October 2009, the Company issued an additional 28,156 shares to NDP and an additional 11,263 shares into the escrow, at a price of $32.05 per share, in connection with the issuance of shares to Shiva under the Exchange Agreement as described above, and in March 2010 the Company issued an additional 297,398 shares to NDP and an additional 118,288 shares into the escrow, at a price of $3.125 per share, in connection with the Company's IPO; however, such anti-dilution obligation terminated upon the completion of the IPO. The maximum aggregate number of shares issuable upon achievement of milestones and the number of shares held in escrow as of December 31, 2010 is 145,543 shares of common stock. The maximum aggregate amount of cash payments upon achievement of milestones is $3,000,000. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval processes and certain worldwide net sales amounts. Through December 31, 2010, no milestone payments have been earned by or paid to NDP.

The NDP License Agreement may be terminated by the Company on a country-by-country basis upon 60 days prior written notice. If the NDP License Agreement is terminated by either party, the Company's rights to the NDP

Technology will revert back to NDP.

During the years ended December 31, 2010 and 2009 and the period from July 28, 2006 (Inception) to December 31, 2010, the Company expensed $929,367, $902,468 and $2,515,782, respectively, in connection with the NDP License Agreement.

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On January 30, 2008, the Company also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg (the "Polaschegg License Agreement"). The Polaschegg License Agreement replaced the original license agreement between NDP and Dr. Polaschegg that the Company was assigned and the Company assumed under the NDP License Agreement. Pursuant to the Polaschegg License Agreement, Dr. Polaschegg granted the Company an exclusive, worldwide license for a certain antimicrobial solution and certain taurolidine treatments and the corresponding United States patent applications (the "Polaschegg Technology"), and agreed to provide the Company with certain consulting services. As consideration for the rights to the Polaschegg Technology, the Company paid Dr. Polaschegg an initial payment of $5,000 and agreed to pay Dr. Polaschegg certain royalty payments ranging from 1% to 3% of the net sales of the Polaschegg Technology. The Polaschegg License Agreement also sets forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from $10,000 to $90,000. As compensation for Dr. Polaschegg's consulting services to be provided under the Polaschegg License Agreement, Dr. Polaschegg is being paid €200 per hour for services consisting of scientific work and €250 per hour for services consisting of legal work.

The Company may terminate the Polaschegg License Agreement with respect to any piece of the Polaschegg Technology upon 60 days notice. If the Polaschegg License Agreement is terminated with respect to any piece of the Polaschegg Technology by either party, all rights with respect to such portion of the Polaschegg Technology will revert to Dr. Polaschegg.

During the years ended December 31, 2010, and 2009 and the period from July 28, 2006 (Inception) to December 31, 2010, the Company expensed approximately $132,000, $132,000 and $378,000, respectively, in connection with the Polaschegg License Agreement.

Note 11 – Other Income

During November 2010, the Company received approximately $490,000 from the Qualifying Therapeutic Discovery Project ("QTDP") program which was recorded as other income of approximately $391,000, net of application and filing fees. The QTDP program was established as a result of the Patient Protection and Affordable Care Act of 2010 to provide tax credits or grants to taxpayers with no more than 250 employees in an amount equal to 50% of eligible 2009 and 2010 expenses related to a QTDP. The QTDP program targeted projects that show potential to produce new therapies to treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions, reduce long-term health care costs in the United States, or significantly advance the goal of curing cancer within the next 30 years. As part of the review process for research projects, the Department of Health and Human Services evaluated each project and only projects that show a reasonable potential to meet these goals were certified as eligible for the credit or grant. Allocation of the credit also took into consideration which projects show the greatest potential to create and sustain high-quality, high-paying U.S. jobs and to advance U.S. competitiveness in life, biological and medical sciences. The grant amounts were further limited because the QTDP program was oversubscribed resulting in the Company receiving significantly less than 50% of its qualifying expenditures.

Note 12 – Retirement Plan:

On May 1, 2010, the Company adopted a 401(k) savings plan (the "401(k) Plan") for the benefit of its employees. Under the 401(k) Plan, the Company is required to make contributions equal to 3% of eligible compensation for each eligible employee whether or not the employee contributes to the 401(k) Plan. For the year ended December 31, 2010, the

Company has recorded $9,703 of matching contributions to the 401(k) Plan.

Note 13 — Subsequent Events:

On January 4, 2011, the Company received $280,920, net of expenses, from the sale of its unused Net Operating Losses ("NOLs"), through the State of New Jersey's Economic Development Authority ("NJEDA") Technology Business Tax Certificate Transfer Program. As of December 31, 2010, $992,017 of NOLs have been approved for future sale under the NJEDA program. In order to realize these benefits, the Company must apply to the NJEDA each year and must meet various requirements for continuing eligibility. In addition, the program must continue to be funded by the State of New Jersey and there are limitations based on the level of participation by other companies. Any future tax benefits will be recognized in the financial statements as specific sales are approved.

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On January 14, 2011, the Company entered into an amendment to the employment agreement, effective January 1, 2011, with its President and Chief Executive Officer, John C. Houghton (the "Houghton Amendment"). The Houghton Amendment amended that certain Amended and Restated Employment Agreement, dated as of November 25, 2009, by and between the Company and Mr. Houghton to (i) increase Mr. Houghton's annual base salary to $350,000 and (ii) increase the amount of the discretionary bonus Mr. Houghton may receive upon the achievement of certain Milestones (as defined under the Houghton Amendment), at the sole discretion of the Company's Board, to up to 40% of Mr. Houghton's annual base salary.

On January 14, 2011, the Company also entered into an amendment to the employment agreement, effective January 1, 2011, with its Chief Financial Officer, Brian Lenz (the "Lenz Amendment"). The Lenz Amendment amended that certain Employment Agreement, dated as of February 4, 2010, by and between the Company and Mr. Lenz to (i) increase Mr. Lenz's annual base salary to $250,000 and (ii) eliminate Mr. Lenz's annual guaranteed bonus.

On January 14, 2011, the Board adopted revisions to its director compensation policy (the "Director Compensation Policy") based on recommendations from an independent compensation consultant retained by the Compensation Committee of the Board. The Board revised the Director Compensation Policy to provide for an increase in the amount of the annual retainer paid to non-employee directors to $20,000, except that the Chairman of the Board will be paid $30,000. Under the revised Director Compensation Policy, each non-employee director will be granted annually, at the first Board meeting of the calendar year, an option to purchase 30,000 shares of the Company's common stock at an exercise price equal to the closing price of the common stock on the grant date, which option will vest on the first anniversary of the grant date. In addition, pursuant to the revised Director Compensation Policy, each new non-employee director will be granted, in connection with his or her initial election to the Board, an option to purchase 30,000 shares of the Company's common stock at an exercise price equal to the closing price of the common stock on the grant date, which option will vest as follows: one-third on the grant date; an additional one-third on the first anniversary of the grant date; and the remaining one-third on the second anniversary of the grant date.

On February 25, 2011, the Company entered into an employment agreement with Mark A. Klausner, M.D. (the "Klausner Employment Agreement"). Pursuant to the Klausner Employment Agreement, Dr. Klausner will serve as the Company's Chief Medical Officer for an initial term of two years commencing on March 1, 2011, which term will extend automatically for additional one-year periods unless appropriate notice is given by one of parties. Dr. Klausner will receive an annual base salary of $310,000, and will be eligible for annual bonus payments of up to 35% of his base salary, based upon the achievement of certain milestones as established annually by the Company's Chief Executive Officer, in consultation with the Company's Board of Directors and Dr. Klausner.

Pursuant to the Klausner Employment Agreement, if the Company terminates Dr. Klausner as a result of his death or Disability (as defined under the Klausner Employment Agreement), Dr. Klausner or his estate, as applicable, will receive his base salary and any accrued but unpaid benefits through the termination date (the "Accrued Compensation"), plus his base salary for a period of 90 days, and all his unvested restricted shares and stock options that are scheduled to vest on or before the next succeeding anniversary of March 1, 2011 will be accelerated and vest as of the termination date. If the Company terminates Dr. Klausner for Cause (as defined under the Klausner Employment Agreement), if Dr. Klausner terminates his employment other than for Good Reason (as defined under the Klausner Employment Agreement), or if Dr. Klausner's employment terminates by expiration of the term of the Klausner Employment Agreement, Dr. Klausner will receive the Accrued Compensation only. If the Company terminates Dr. Klausner within two months prior to or six months following the occurrence of a Change of Control (as defined under

the Klausner Employment Agreement), and on the date of termination the fair market value of the Company's common stock on a fully-diluted basis is more than $50 million (as determined by the Board of Directors in good faith), Dr. Klausner will receive the Accrued Compensation, his base salary and benefits for a period of three months following his termination, and all his unvested restricted shares and stock options will be accelerated and vest as of the termination date. If the Company terminates Dr. Klausner for reasons other than those stated above or Dr. Klausner terminates his employment for Good Reason, Dr. Klausner will receive the Accrued Compensation and his base salary and benefits for a period of six months following his termination, and all his unvested restricted shares and stock options that are scheduled to vest within the 12 months following his termination will be accelerated and vest as of the termination date.

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On March 1, 2011, in connection with the Klausner Employment Agreement, the Company issued to Dr. Klausner an option to purchase 356,000 shares of the Company's common stock at an exercise price of $1.61 per share. Such option will vest in equal installments on each of the first three anniversaries of the grant date. The stock option had an approximate fair value of approximately $453,100 at the date of grant based on the Black-Scholes option-pricing model.

The employment term of Dr. Mark Houser, the Company's former Chief Medical Officer, expired on February 28, 2011 in accordance with the terms of his employment agreement. As of March 10, 2011, the Company has accrued for Dr. Houser's discretionary 2010 bonus of $51,084, which is expected to be paid to Dr. Houser by March 15, 2011.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Form of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
3.2	Form of Amended and Restated By-laws (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.2	Specimen Unit certificate (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.3	Specimen warrant certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.4	Form of warrant agreement (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 19, 2010).
4.5	Common Stock Exchange and Stockholder Agreement, dated as of October 6, 2009, by and between CorMedix Inc. and Shiva Biomedical, LLC (incorporated by reference to Exhibit 4.6 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.6	Stockholder Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.7	Form of Stock Purchase Agreement for former stockholders of Picton Pharmaceuticals, Inc (incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).
4.8	Form of Note and Warrant Purchase Agreement for First Bridge Notes (incorporated by reference to Exhibit 4.11 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.9	Form of Note and Warrant Purchase Agreement for Second Bridge Notes (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.10	Form of Note and Warrant Purchase Agreement for Third Bridge Notes (incorporated by reference to Exhibit 4.16 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
4.11	

	Form of Third Bridge Warrant (incorporated by reference to Exhibit 4.18 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on January 20, 2010).
10.1	Contribution Agreement, dated as of July 28, 2006, by and between Shiva Biomedical, LLC, Picton Pharmaceuticals, Inc., Picton Holding Company, Inc., and the stockholders of Picton Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡

10.2	Amendment to Contribution Agreement, dated as of October 6, 2009, by and between Shiva Biomedical, LLC and CorMedix, Inc. (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.3	Amendment No. 2 to Contribution Agreement, dated as of February 22, 2010, by and between the Company and Shiva Biomedical, LLC (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.4	License and Assignment Agreement, dated as of January 30, 2008, between the Company and ND Partners LLC. (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.5	Escrow Agreement, dated as of January 30, 2008, among the Company, ND Partners LLC and the Secretary of the Company, as Escrow Agent (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.6	Exclusive License and Consulting Agreement, dated as of January 30, 2008, between the Company and Hans-Dietrich Polaschegg (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).‡
10.7	Amended and Restated Consulting Agreement, dated as of January 10, 2008, between the Company and Sudhir V. Shah, M.D. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.8	Consulting Agreement, dated as of January 30, 2008, between the Company and Frank Prosl (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-163380), filed with the SEC on November 25, 2009).
10.9	Supply Agreement, dated as of December 7, 2009, between the Company and Navinta, LLC (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).‡
10.10	Manufacture and Development Agreement, dated as of March 5, 2007, by and between the Company and Emcure Pharmaceuticals USA, Inc. (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on December 31, 2009).‡
10.11	Amended and Restated Employment Agreement, dated as of November 25, 2009, between the Company and John Houghton (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.12	Amendment to Amended and Restated Employment Agreement, dated as of January 14, 2011, by and between CorMedix Inc. and John C. Houghton (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on January 19, 2011).
10.13	Employment Agreement, dated as of February 4, 2010, between the Company and Brian Lenz (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).

10.14	Amendment to Employment Agreement, dated as of January 14, 2011, by and between CorMedix Inc. and Brian Lenz (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed with the SEC on January 19, 2011).

10.15	Employment Agreement, dated as of February 25, 2011, between the Company and Mark Klausner, M.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on March 3, 2011).
10.16	Amended and Restated 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
10.17	Form of Indemnification Agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1/A (File No. 333-163380), filed with the SEC on March 1, 2010).
23.1	Consent of Independent Registered Public Accounting Firm.*
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

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* filed herewith

† Confidential treatment has been granted for portions of this document. The omitted portions of this document have been filed separately with the SEC.