CorMedix Inc. (“CorMedix” or “the Company”) is focused on treating cardiorenal† diseases, which entails addressing kidney dysfunction and its cardiovascular complications. CorMedix’s lead product candidates are Neutrolin® and deferiprone. Neutrolin® is a catheter lock solution for chronic central venous catheters (CVCs), which are a type of catheter commonly used by hemodialysis patients, among other individuals. Neutrolin®, which has antimicrobial, antifungal, and anticoagulant properties, has been shown to reduce the likelihood of contracting a catheter-related bloodstream infection (CRBSI) by approximately 90% in hemodialysis patients. To CorMedix’s knowledge, there is no approved combined antimicrobial and anticoagulant catheter-locking solution for the prevention of CRBSI in the U.S. today. The Company is working to submit an Investigational Device Exemption (IDE) by the end of 2010, which would enable the start of clinical trials for Neutrolin® in early 2011. CorMedix is also developing proprietary formulations of deferiprone, a generic pharmaceutical that is commercially available in over 50 countries for removing iron from the body. However, it is not yet marketed in the U.S. CorMedix believes that it possesses novel formulations of immediate and extended-release deferiprone that are not available elsewhere. The FDA has approved Investigational New Drug (IND) applications for deferiprone to prevent contrast-induced nephropathy (CIN) and to treat chronic kidney disease (CKD). The Company commenced a Phase II biomarker proof-of-concept study of deferiprone in June 2010. In March 2010, CorMedix completed an initial public offering (IPO) on the NYSE Amex for approximately $10.4 million in net proceeds, which the Company primarily intends to use in further clinical development of Neutrolin® and deferiprone.

Recent Financial Data

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* Units issued in the IPO separated on 05/13/10; see entry 05/07/10 on pg. 54 for more detail. ** At 05/11/10.

Key Points

- Both Neutrolin® and deferiprone have previously shown safety and efficacy, which CorMedix believes may mitigate some of the risk associated with drug development. While neither product is yet approved for use in the U.S., taurolidine (the active antimicrobial component in Neutrolin®) has been employed for nearly 10 years in Europe and deferiprone has a 15-year history.
- Roughly six million people in the U.S. have simultaneous heart problems and CKD, which increases their risk of death and other complications, such as CIN.
- U.S. physicians insert more than five million CVCs every year, which are prone to infection and blood clots and can lead to patient illness, limited catheter life, and increased healthcare costs.
- CorMedix holds exclusive rights to more than 20 patents and patent applications globally.
- The Company’s leadership blends science and commercial expertise, which CorMedix believes is necessary to bring its products to market. Management is supported by a Board of Directors skilled in investment, commercial, and clinical fields, as well as multiple Advisory Boards.
- CorMedix had cash and cash equivalents of $11.7 million at March 31, 2010.
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Executive Overview

CorMedix Inc. ("CorMedix" or "the Company") is a pharmaceutical company working to transform medicine at the cardiorenal crossroads. All of the Company’s technologies seek to address unmet medical needs in the area of cardiorenal disease, which is essentially the interface between cardiovascular and kidney disease. CorMedix’s two most advanced product candidates are as follows: (1) Neutrolin®, a drug/device combination that serves as a catheter lock solution to prevent catheter-related bloodstream infection (CRBSI) and blood clots; and (2) deferiprone, a pharmaceutical approach to reduce the morbidity and mortality of contrast-induced nephropathy (CIN) in high-risk chronic kidney disease (CKD) patients. Both products have demonstrated safety and efficacy and are supported by broad intellectual property. While neither product is yet approved for use in the U.S., taurolidine (the active antimicrobial component in Neutrolin®) has been employed for nearly 10 years in Europe and deferiprone has a 15-year history.

Cardiorenal Disease

Cardiorenal disease encompasses a range of interrelated heart, kidney, and metabolic problems. CorMedix’s operations are based on the belief that much of the illness and death attributed to renal disease is actually cardiovascular in nature and may be preventable. Thus, CorMedix is focused on addressing kidney dysfunction and the associated cardiovascular and metabolic complications. This platform is known by the Company as “treating the kidney to treat the heart.”

Kidney disease can represent either a cause or a consequence of cardiovascular disease (Source: the American Heart Association). A primary renal defect can produce severe cardiovascular problems, hypertension (as the kidney is important in maintaining a constant effective blood volume), and can alter the composition of plasma and extracellular fluid. Primary kidney diseases have been associated with accelerated cardiac atherosclerosis (hardening of the arteries), left ventricular hypertrophy and remodeling, and myocardial microangiopathy (disease of certain of the heart’s blood vessels). Renal-associated electrolyte imbalances may lead to cardiac arrhythmias and hyperlipidemia, a major risk factor for coronary artery disease. Conversely, malignant and severe hypertension can cause extensive and progressive renal damage, and congestive heart failure (CHF) can cause kidney failure.

Approximately six million people in the U.S. have simultaneous cardiovascular dysfunctions and chronic kidney disease (CKD), the combination of which increases patients’ risks and may present treatment challenges (Source: International Urology and Nephrology 2005). Factors contributing to this prevalence of cardiorenal disorders include obesity, high blood pressure, diabetes, and an aging population. The risk of cardiovascular disease is higher in patients with renal insufficiency than in the general population. People afflicted with severe kidney failure, called end-stage renal disease (ESRD), are 30 times more likely to die of cardiovascular disease (Source: the American Heart Association).

As cardiorenal disease extends beyond just cardiovascular disorders or just renal disease, its management may require unique strategies separate from treating the heart or kidney individually (Source: Nephrology Dialysis Transplantation 2005). CorMedix’s primary platform technologies aim to prevent and treat cardiorenal disease by reducing oxidative stress, which is a common denominator in both cardiovascular and renal disease. CorMedix’s Neutrolin® is intended to prevent catheter-related infections and clots, which can be severe consequences of the hemodialysis treatment that kidney disease patients must undergo.

Table 1 (page 4) summarizes CorMedix’s product pipeline, followed by an overview of the lead candidates.
CorMedix’s objective is to establish Neutrolin® (also referred to as “CRMD003”) as the standard of care for hemodialysis patients with central venous catheters (CVCs). A CVC is a thin, flexible tube inserted into a large vein in the arm or chest that is used to pass blood out of and into the body during hemodialysis, which is the process of cleansing blood of harmful wastes, salts, and fluid—a task normally performed by the kidneys. Hemodialysis is typically initiated when 10% to 15% of kidney function is remaining, before a patient’s kidneys have completely shut down. In this treatment, blood is drawn from the body and filtered by an external machine connected to the patient’s vascular system. While some individuals are taught how to perform dialysis at home, hemodialysis is a life-long therapy that usually requires visits to a hospital or dialysis center three times a week. Each visit may average three to five hours.

The use of a chronic CVC in hemodialysis patients, among others, is associated with two severe complications: catheter-related bloodstream infection (CRBSI) and low blood flow due to blood clots forming within the catheter. CRBSI is a considerable source of morbidity and mortality in hemodialysis patients. The risk of developing CRBSI is proportionate to the duration of CVC use. Infection is estimated to occur in 35% of patients within three months of CVC use, and in 48% of patients within six months (Source: American Journal of Kidney Diseases February 2008). CorMedix estimates that there are over 160,000 infections each year due to CRBSI among hemodialysis patients and approximately 6,000 related deaths annually. CorMedix views the prevention of CRBSI and clotting in CVCs as an urgent, unmet medical need important to patients, dialysis providers, and nephrologists.

Initially, CorMedix is targeting Neutrolin® toward the CVCs used in hemodialysis; however, CVCs are used in a wide range of applications beyond just hemodialysis. In the U.S., physicians insert more than five million CVCs every year (Source: New England Journal of Medicine 2003). Additional indications, which may represent future secondary markets for Neutrolin®, include chemotherapy, chronic antibiotic therapy, total parenteral nutrition, and intensive care. It is estimated that a CRBSI requires approximately 12 days of hospitalization, and the average cost to the healthcare system is $18,000 per episode (Source: Journal of the American Medical Association March 2009).
To enhance the safety and efficacy of CVCs, CorMedix is developing a catheter lock solution called Neutrolin®, which is designed to prevent CRBSI and clotting from occurring between hemodialysis sessions. Initial studies with Neutrolin® have found that when this solution is placed into both chambers of a CVC at the conclusion of each hemodialysis session, it may reduce the risk of infection by approximately 90%. Consequently, Neutrolin® could decrease patients’ need for local and systemic antibiotics and may prolong catheter life.

CorMedix's catheter lock solution has been shown to overcome common and antibiotic-resistant microbes, including strains of methicillin-resistant Staphylococcus aureus (MRSA), methicillin-resistant Staphylococcus epidermidis (MRSE), and vancomycin-resistant enterococcus (VRE). These microbes occur most frequently in patients at healthcare facilities (e.g., dialysis centers) due to the weakened immune systems of these individuals and their need for a chronic CVC or other internal medical device.

The key features of Neutrolin® as CorMedix views the product are as follows: (1) it is a broad-spectrum antimicrobial that is not likely to produce antibiotic cross-resistance; (2) it prevents buildup of biofilm (microscopic disease-causing bacteria); (3) it contains two anticoagulants to prevent clotting; and (4) it has been shown to have low toxicity and be well tolerated. The composition of Neutrolin® includes 1.35% taurolidine (the antimicrobial and antifungal agent) as well as 4% citrate and 1,000 u/mL heparin (the anti-clotting components). To the Company’s knowledge, there is no approved antimicrobial and anticoagulant catheter-locking solution for the prevention of CRBSI in the U.S. today.

CorMedix intends to submit an Investigational Device Exemption (IDE) by late 2010 to support a pivotal clinical trial for Neutrolin®. To CorMedix’s knowledge, Neutrolin® is associated with favorable preliminary data demonstrating safety and efficacy—factors that the Company believes lower the risk of this candidate’s clinical program. Also in development is a lifecycle management tool for Neutrolin®—a thixotropic gel formulation of a catheter lock (“CRMD004”)—that may provide further benefits as a catheter lock and may extend the anticipated benefits of Neutrolin®.

Deferiprone (CRMD001)

CorMedix is also advancing a cardio renal treatment approach that uses novel formulations of the generic pharmaceutical deferiprone (which the Company refers to as “CRMD001”) to reduce the tissue-damaging oxidative stress caused by labile (toxic) iron in the body. Deferiprone is a known oral iron chelator. It is available as Ferriprox® from ApoPharma Inc. in 58 countries. However, it is not yet approved for use in the U.S. ApoPharma estimates that thousands of individuals with iron overload are being treated with Ferriprox® (deferiprone). CorMedix hopes to capitalize on deferiprone’s beneficial characteristics, including efficacy at reducing cardiovascular disease and iron overload and being generally well tolerated. Further, similar to Neutrolin®, CorMedix believes that it can direct deferiprone toward indications where there is considerable unmet need.

The first deferiprone indication is prevention of contrast-induced nephropathy (CIN), which is a common problem for CKD patients. CKD patients have a high likelihood of developing cardiovascular disease. The laboratory tests for heart disease require radiographic contrast (a solution containing iodine that can be visualized on an X-ray) to be injected into the area being viewed. In certain high-risk patients, the use of radiographic contrast can cause injury to the kidneys and can increase cardiovascular morbidity and mortality. The cardiovascular events associated with CIN include heart attacks and strokes, and CIN has been noted as the third leading cause of hospital-acquired renal failure (Source: Catheterization and Cardiovascular Interventions 2007).

CorMedix is studying specific formulations of immediate and extended-release deferiprone that it believes are not available elsewhere. These novel compositions are designed to enable twice daily dosing rather than three times a day and are anticipated to reduce nausea. CorMedix holds patent rights for deferiprone in the area of kidney diseases, with methods of use patents entailing the application of iron chelators in CKD patients. CorMedix expects to obtain five years of market exclusivity in the U.S. for deferiprone as a new chemical entity (NCE) and may also pursue orphan drug registration for the compound, which could provide other advantages.
CorMedix’s licensor conducted human clinical studies of deferiprone, through which it established proof of concept and determined that deferiprone has potential to become a new therapy for slowing the progression of CKD and its metabolic and cardiovascular complications. The FDA has approved IND applications for the use of deferiprone in both the prevention of CIN and in the treatment of CKD.

In June 2010, the first patient was dosed in CorMedix’s Phase II biomarker proof-of-concept study, which is anticipated to support a future Phase III trial for deferiprone to prevent CIN. This ongoing Phase II study is expected to enroll approximately 60 high-risk CKD patients at two centers in the U.S. The Company aims to prevent CIN in these patients by administering deferiprone orally for eight days total, with the first dose between one and three hours prior to coronary angiography. The study is also evaluating the safety and tolerability of the candidate in short-term use.

Subsequently, the Company may also study deferiprone in clinical trials as a potential treatment to slow the progression of CKD. In April 2008, CorMedix entered into an agreement with Afferix Ltd., a closely held specialized diagnostic company, for a diagnostic labile iron biomarker test called CRMD002. CRMD002 may support the use of deferiprone in CKD by identifying patients at risk for CKD, diagnosing CKD patients, and monitoring patients’ responses to therapy.

Headquarters and Employees

CorMedix was formed around deferiprone in 2006. In July 2007, CorMedix established its corporate headquarters in Summit, New Jersey, 20 miles from midtown Manhattan, where the Company had begun operations in August 2006. CorMedix moved executive offices in March 2010, from Summit to Bridgewater, New Jersey. Since its formation, CorMedix has identified and licensed several new product candidates in addition to deferiprone, including Neutrolin®.

Following the completion of CorMedix’s initial public offering (IPO) in March 2010, the Company’s Common Stock is now traded on the NYSE Amex under the primary ticker symbol “CRMD.” The IPO provided CorMedix with net proceeds of approximately $10.4 million. As depicted in Figure 1, Mr. John C. Houghton, the Company’s president and chief executive officer (CEO) (biography on page 11), rang the closing bell of the NYSE on March 25, 2010.

CorMedix believes that it employs a cost-effective approach to its operation. Management has kept the internal headcount to a minimum by leveraging consultants and external resources. At present, the Company employs five full-time individuals. The Company also retains full-time consultants for regulatory, manufacturing, and intellectual property support functions.
Growth Strategy

While simultaneously developing its existing product pipeline, CorMedix will likely seek to license additional therapeutic product candidates for the treatment of diseases related to cardiac and renal dysfunction. These may be small molecules, biologicals, therapeutic devices, or therapy-enabling diagnostics. In an effort to reduce potential development risks, the Company selectively licenses candidates that have been previously studied or marketed either outside of the U.S. or for different indications, which provides an initial indication of the candidate's safety and efficacy. By operating at the crossroads of the renal and cardiovascular markets, CorMedix anticipates that it is positioned to capitalize on further emerging cardiorenal opportunities going forward.

CorMedix's current clinical objectives are focused on advancing development of Neutrolin® and deferiprone. The Company intends to develop Neutrolin® and the thixotropic gel (CRMD004) independently; however, CorMedix may elect to enter into a strategic partnership for continued development of deferiprone based on the results of deferiprone’s Phase II biomarker study.

Use of Proceeds from CorMedix’s Recent IPO

The Company’s IPO, completed in March 2010, was intended to help accomplish the following:

- fund development activities, including clinical trials for Neutrolin® and deferiprone and preclinical development of CRMD004 and CRMD002;

- increase working capital;

- create a public market for the Company’s Common Stock;

- increase CorMedix’s ability to access the capital markets in the future;

- facilitate general corporate purposes; and

- provide liquidity for existing stockholders.

CorMedix believes that the net proceeds from its IPO, in combination with existing cash resources, are sufficient to fund development costs and complete patient enrollment for a clinical trial of Neutrolin® as well as to develop deferiprone through completion of the Phase II biomarker study and advance the preclinical research of CRMD004 and CRMD002, as described below.

CorMedix anticipates using approximately $5.3 million of the IPO’s net proceeds to support development of Neutrolin®, which includes funding creation of the final formulation for clinical trials, regulatory filing costs, clinical trial costs, and patent maintenance fees. A further $1 million of the proceeds were earmarked for deferiprone’s development in the CIN indication, comprising regulatory as well as clinical trial costs for the Phase II biomarker study.

For the thixotropic gel (CRMD004), CorMedix intends to use approximately $100,000 to optimize a gel formulation and support initial preclinical animal studies. For the diagnostic labile iron biomarker test (CRMD002), $100,000 is expected to support the preclinical development costs associated with identifying and validating an assay methodology to establish a reproducible test.

Neutrolin®

CorMedix’s commercial strategy for Neutrolin® in the U.S. is to initially launch the product for CVCs in hemodialysis settings using a focused specialty care sales force. At present, hemodialysis is the primary focus because it fits with CorMedix’s corporate strategy and since this area was included in a prior IDE for Neutrolin®. Going forward, the Company intends to pursue other indications as well, which comprise any setting that uses a central venous or peripherally inserted catheter. CorMedix is keeping both internal
commercialization and outlicensing options open for these added indications. Greater details of the product line extensions for Neutrolin® are provided on page 28.

In terms of obtaining reimbursement for Neutrolin®, CorMedix’s objective is to establish the candidate as the standard of care for hemodialysis patients with CVCs. To do so, the Company would need to receive quality of care endorsements from relevant entities, including the End Stage Renal Disease (ESRD) Network Program, which consists of a national network of 18 ESRD Networks under the direction of the U.S. Centers for Medicare and Medicaid Services (CMS); the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative (KDOQI); the Medicare Payment Advisory Commission (MedPAC), which is an independent agency established to advise the U.S. Congress on issues affecting Medicare; the American Association of Kidney Patients (AAKP); and chief medical officers of private insurance companies, among others. CorMedix believes that receiving a standard of care designation is a viable option due to positive political influences in the current administration that include a focus on preventive care.

In Europe, CorMedix hopes to receive a **CE Mark** for Neutrolin® and progress with a product launch.

**Deferiprone**

CorMedix’s strategy for deferiprone initially entails obtaining U.S. marketing approval for the candidate in the CIN indication, followed by approval in Europe and other locations globally. The Company is also seeking an orphan designation for deferiprone.

CorMedix believes that deferiprone may be targeting a favorable market opportunity, as the Company estimates that there are approximately 165,000 high-risk patients in the U.S. who could benefit from deferiprone and who have few alternatives. If successfully commercialized, CorMedix expects to experience a rapid uptake of deferiprone, potentially reaching peak levels within three years, due to the compound’s anticipated benefits on the morbidity and mortality of CIN patients. Similarly to Neutrolin®, the Company intends to use a focused and guideline-driven sales and marketing approach directed at specialty care.

Going forward, deferiprone may have possibilities in areas of diagnostic, cardiac, and peripheral angiography as well as gadolinium or other renal toxicities. Gadolinium is used as a contrast agent in magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). Certain patients with acute or chronic kidney insufficiency or renal dysfunction who receive gadolinium may develop a toxic complication called **nephrogenic systemic fibrosis**.
As CorMedix advances development of its lead product candidates, the Company also emphasizes its intellectual property protection and exclusivity position. The Neutrolin® (CRMD003) patents were licensed from ND Partners LLC, and CorMedix holds an exclusive worldwide license with ND Partners to develop Neutrolin® for the prevention of CRBSI. Likewise, Shiva Biomedical, LLC has granted CorMedix an exclusive, worldwide license to intellectual property for proprietary formulations of deferiprone and a biomarker diagnostic test for measuring levels of labile iron, which serves as the basis for the deferiprone (CRMD001) and CRMD002 programs. Table 2 summarizes the Company’s licensed patent estate, followed by a brief overview of the ND Partners and Shiva agreements on page 10.

It is important to note that one of CorMedix’s cornerstone patents has withstood challenges in the EU and won. As such, the Company believes it possesses a solid patent portfolio that is enhanced by its remaining patents and patent applications.

### Table 2
**CorMedix Inc.**

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* Referred to as the CKD Patents.

** Issued by the European Patent Office and validated in Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, Greece, France, Great Britain, Ireland, Italy, Luxembourg, the Netherlands, Monaco, Portugal and Sweden.

Source: CorMedix Inc.
License Agreement with ND Partners LLC

In January 2008, CorMedix entered into a license agreement with ND Partners that granted the Company exclusive, worldwide rights to U.S. and foreign patents and applications for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system, and a taurolidine delivery apparatus. As well, CorMedix received exclusive licenses, with the right to grant sublicenses, for the use and display of certain trademarks in connection with this technology.

Also in January 2008, CorMedix licensed from Dr. Hans-Dietrich Polaschegg exclusive, worldwide rights to U.S. patent applications for a gel lock invention and certain taurolidine treatments. The Polaschegg Technology serves as a basis for the thixotropic gel candidate (CRMD004).

The Company believes that its patent portfolio for Neutrolin® and CRMD004 entails solutions to issues that have been previously encountered when using taurolidine in clinical applications, specifically for hemodialysis.

License Agreement with Shiva Biomedical, LLC

Under CorMedix’s license agreement with Shiva, the Company holds worldwide rights to kidney disease use patents for deferiprone as well as certain method of use patents for iron chelators in CKD treatment and CIN prevention, which are filed in non-U.S. markets such as Japan, Europe, Australia, and Canada. CorMedix also holds worldwide rights to the U.S. CKD Patents and a corresponding issued patent from the European Patent Office and additional pending patent applications relating to extensions of the technology—contrast nephropathy, methods to treat erythropoietin (EPO) resistance, and gadolinium toxicity. The Shiva Technology serves as the basis for CRMD001 and CRMD002.
Company Leadership

Management

CorMedix’s leadership has experience developing, registering, negotiating pricing and reimbursement, and selling medicines, biologicals, and medical devices. Table 3 summarizes CorMedix’s key management, followed by detailed biographies.

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<thead>
<tr>
<th>Name</th>
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<tr>
<td>John C. Houghton</td>
<td>President, Chief Executive Officer, and Director</td>
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<tr>
<td>Brian Lenz, MBA, CPA</td>
<td>Chief Financial Officer and Treasurer (Principal</td>
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<td>Mark T. Houser, M.D., MBA</td>
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<td>Timothy M. Hofer</td>
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Source: CorMedix Inc.

John C. Houghton, President, Chief Executive Officer, and Director (Principal Executive Officer)

Mr. Houghton is a business executive whose 20 years of experience has spanned global strategic and affiliate tactical roles covering the full product lifecycle from research through generics, including drugs, biologicals, and devices. Prior to assuming the role of president and chief executive officer (CEO), he was the chief business officer (CBO) for CorMedix. Before joining CorMedix, Mr. Houghton established the global sales and marketing infrastructure for the Biotech division of Stryker Corp. (SYK-NYSE). Highlights of his experience there include the following: (1) building EU and U.S. sales and marketing infrastructure; (2) managing the development and launch of OP-1® (BMP7) in over 30 countries; (3) leading the global launch of Calstrux®, and (4) directing a global team. Prior to Stryker Biotech, he worked with Aventis (now Sanofi-Aventis SA [SNY-NYSE]) and predecessor companies for more than 14 years. Highlights of his experience with Aventis include the following: (1) leading the global launch of Nasacort® (a $100 million brand); (2) serving as commercial lead on the Aventis-Millennium inflammation collaboration; (3) serving as global new products commercialization head for respiratory, inflammation, cardiovascular, and metabolism; and (4) leading the commercial business development outside of core therapeutic areas.

Brian Lenz, MBA, CPA, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)

Mr. Lenz joined CorMedix as chief financial officer (CFO) on February 16, 2010. Previously, he served as the CFO of Arno Therapeutics, Inc., a development-stage pharmaceutical company, from July 2008 to February 2010. Mr. Lenz served as CFO and treasurer of VioQuest Pharmaceuticals, Inc. (VOQP-OTC) from April 2004 to July 2008, and prior to that served as its controller beginning in October 2003. Mr. Lenz was a controller with Smiths Detection Group, a provider of threat detection and screening technologies, from 2000 to 2003, and a senior auditor with KPMG LLP, a provider of audit, tax, and advisory services, from 1998 to 2000. Mr. Lenz holds a B.S. in accounting from Rider University and received an MBA from Saint Joseph’s University. He is a certified public accountant (CPA) licensed in the State of New Jersey.

Mark T. Houser, M.D., MBA, Chief Medical Officer

As an experienced academic and clinical nephrologist with a strong basic science, clinical research, and management background, Dr. Houser has a skill set that suits CorMedix’s cardiorenal aspirations. During his tenure at Johnson & Johnson (JNJ-NYSE) (Ortho Biotech Products, L.P.), Dr. Houser had diverse responsibilities, including leading clinical development projects in oncology and critical care; leading business development projects primarily focused on cardiorenal areas (over 50 projects accessed);
serving as internal nephrology consultant to the J&J family of companies, including Cordis Corp., Ethicon, Inc., Veridex, LLC, Centocor, Inc., and J&J Pharmaceutical Research & Development, L.L.C.; and entailing regional medical affairs management for Procrit®. As a clinical and academic nephrologist, his achievements include being clinical medical director of a large dialysis network and basic research in the areas of oxidative stress in acute and chronic renal injury. He completed an MBA, majoring in marketing and management, in 2002.

Timothy M. Hofer, Secretary and Director

Mr. Hofer has been a director of CorMedix since February 2007 and was appointed secretary in November 2006. He is senior vice president, legal affairs for Paramount BioCapital, Inc. and Paramount Biosciences, LLC, where he has been employed since April 2005. Mr. Hofer also serves as an officer and director of several closely held development-stage biotechnology companies. From July 2000 until March 2005, he was an associate in the Mergers & Acquisitions/Private Equity practice group of the New York office of the law firm O’Melveny & Myers LLP, and its predecessor, O’Sullivan Graev & Karabell, LLP.

Board of Directors

The Board of Directors oversees the conduct of and supervises the Company’s management. Table 4 summarizes the members of CorMedix’s Board of Directors, followed by detailed biographies.

<table>
<thead>
<tr>
<th>Russell H. Ellison, M.D., M.Sc.</th>
<th>Chairman</th>
</tr>
</thead>
<tbody>
<tr>
<td>John C. Houghton</td>
<td>President, Chief Executive Officer, and Director (Principal Executive Officer)</td>
</tr>
<tr>
<td>Timothy M. Hofer</td>
<td>Secretary and Director</td>
</tr>
<tr>
<td>Richard M. Cohen, MBA, CPA</td>
<td>Director</td>
</tr>
<tr>
<td>Gary A. Gelbfish, M.D.</td>
<td>Director</td>
</tr>
<tr>
<td>Bamdad (Bami) Bastani, M.S., Ph.D.</td>
<td>Director</td>
</tr>
<tr>
<td>Antony E. Pfaffle, M.D.</td>
<td>Director</td>
</tr>
</tbody>
</table>

Source: CorMedix Inc.

Russell H. Ellison, M.D., M.Sc., Chairman

Dr. Ellison has been a director of the Company and chairman of the Board since July 2007. Dr. Ellison is executive vice president of Paramount BioSciences, LLC, where he began working in July 2007. From October 2005 until June 2007, Dr. Ellison served as the vice president of clinical development of FibroGen, Inc., a closely held biotechnology company based in San Francisco, California, engaged in the development of novel therapeutics for fibrotic disorders, diabetic complications, anemia, ischemic disease, cancer, and other areas of unmet medical need. From August 2002 to December 2004, Dr. Ellison served as vice president of medical affairs and chief medical officer (CMO) of Sanofi-Synthelabo, USA (now part of Sanofi-Aventis), based in New York, New York. From May 1997 to August 2002, Dr. Ellison served as vice president, medical affairs and CMO of Hoffman–La Roche, Inc. Prior thereto, Dr. Ellison held senior management positions focused on drug development at Roche Canada, Glaxo Canada Inc. (part of GlaxoSmithKline plc [GSK-NYSE]), and Hoechst Canada Inc. In addition, Dr. Ellison has also served as international medical director at Ciba-Geigy (now Novartis AG [NVS-NYSE]). Dr. Ellison holds an M.D. from the University of British Columbia and an M.Sc. (with distinction) from the London School of Tropical Medicine and Hygiene.
Richard M. Cohen, MBA, CPA, Director

Mr. Cohen has been a director of CorMedix since December 2009. Since 2002, Mr. Cohen has served as a managing director of Encore/Novation, a company that purchases and securitizes settlement assets. He also served as CFO of Dune Energy, an oil and gas exploration and production company, from 2003 to 2005. Mr. Cohen is a member of the Board of Directors of Dune Energy, a member of the Board of Directors and the Audit Committee of Rodman & Renshaw, a public investment bank, and a member of the Board of Directors of Pinpoint Recovery Systems, a public payroll tax recovery company. Mr. Cohen holds a CPA designation from the State of New York, received an MBA from Stanford University, and received a B.S. from the Wharton School of the University of Pennsylvania.

Gary A. Gelbfish, M.D., Director

Dr. Gelbfish has been a director of CorMedix since December 2009. Dr. Gelbfish has been in private practice as a vascular surgeon since 1990. He has practiced vascular surgery at Beth Israel Hospital since 1990 and at New York University Downtown Hospital since 2003. Since 1997, Dr. Gelbfish has served as an assistant clinical professor of surgery at Mt. Sinai Hospital. Dr. Gelbfish received a B.S. from Brooklyn College, holds an M.D. from Columbia University, and completed his fellowship in vascular surgery at Maimonides Medical Center.

Bamdad (Bami) Bastani, M.S., Ph.D., Director

Dr. Bastani has been a director of CorMedix since February 9, 2010. Dr. Bastani is the chairman of VSSB Medical Nanotechnology Inc., a medical device company specializing in radiofrequency devices, and chairman of B 2 Global Consulting, a consulting firm. Dr. Bastani was the president and CEO of ANADIGICS, Inc. (ANAD-NASDAQ), a provider of semiconductor solutions, from October 1998 to August 2008, and executive vice president of the System LSI Group of Fujitsu Microelectronics, Inc., an electronics manufacturer, from 1996 to 1998. He currently serves on the Boards of Directors of Amelio Solar, Inc., a producer of solar energy technology, and Nitronex Corporation, a producer of power transistors. Dr. Bastani received a B.S.E.E. from the University of Arkansas and an M.S. and a Ph.D. in electrical engineering from the Ohio State University.

Antony E. Pfaffle, M.D., Director

Dr. Pfaffle has been a director of CorMedix since February 2007. He is a managing director at Paramount and senior vice president of business development at Paramount BioSciences. Dr. Pfaffle was a principal and founder of Black Diamond Research, LLC from 2001 to 2006 and has been a healthcare consultant to Goldman Sachs Group, Inc. (GS-NYSE) since 2001. Dr. Pfaffle is an internist who practiced nephrology at New York Hospital, Lenox Hill Hospital, and Memorial Sloan-Kettering. Dr. Pfaffle received an M.D. from New York Medical College in 1989.
Scientific Advisory Boards

CorMedix's Cardiorenal Advisory Board comprises a panel of physicians who have expertise in cardiorenal disease. These individuals are skilled in an array of fields, including nephrology, diabetes and endocrinology, and cardiology. The Cardiorenal Board is intended to provide feedback and advice regarding unmet medical needs and new therapeutic options that can significantly improve the outcomes and quality of life for patients with cardiorenal diseases. The Board also offers guidance on the design and conduct of clinical studies, medical and scientific data on cardiorenal diseases and treatment breakthroughs, and product development strategies and in-licensing opportunities.

CorMedix also maintains a Ferroscience Advisory Board, which provides expertise in support of the Company's development of treatments for iron-related diseases. The Ferroscience Board provides advice regarding the role of iron and oxidative stress in tissue injury and cardiorenal disease as well as feedback on the current and potential future uses of iron chelation therapy. Table 5 summarizes the members of CorMedix's Scientific Advisory Boards, followed by brief biographies.

<table>
<thead>
<tr>
<th>Scientific Advisors</th>
<th>Expertise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vivian Fonseca, M.D.</td>
<td>Professor of Medicine, Director of the Diabetes Program, Tulane University Medical Center; Expertise in the prevention and treatment of diabetic complications and cardiovascular disease</td>
</tr>
<tr>
<td>Charles Herzog, M.D.</td>
<td>Professor of Medicine at the University of Minnesota and Director of the Cardiovascular Studies Center for the U.S. Renal Data System; Expertise in cardiovascular disease in patients with CKD</td>
</tr>
<tr>
<td>Joseph Bonventre, M.D., Ph.D.</td>
<td>Robert H. Ebert Professor of Medicine and Health Sciences Technology, Harvard Medical School; Director of the Renal Division, Brigham and Women's Hospital; Expertise in acute kidney injury and the use of predictive biomarkers</td>
</tr>
<tr>
<td>Giuseppe Remuzzi, M.D.</td>
<td>Professor and Director of the Negri Bergamo Laboratories and of the Mario Negri Institute for Pharmacological Research in Bergamo, Italy; International expertise in renal disease</td>
</tr>
<tr>
<td>Sudhir V. Shah, M.D.</td>
<td>Professor of Medicine and Director, Division of Nephrology, University of Arkansas for Medical Sciences (UAMS); Expertise in iron-mediated oxidative stress</td>
</tr>
<tr>
<td>Z. Ioav Cabantchik, M.D., Ph.D.</td>
<td>Professor of Biological Chemistry at the Hebrew University of Jerusalem, Israel; Expertise in the pathophysiology of labile or catalytic iron and iron chelation</td>
</tr>
</tbody>
</table>

Source: CorMedix Inc.

Vivian Fonseca, M.D.

At Tulane University Medical Center, Dr. Fonseca is a professor of medicine, director of the diabetes program, and Tullis-Tulane Alumni Chair in diabetes. He is a recognized expert in the prevention and treatment of diabetic complications and cardiovascular disease. He has authored or co-authored more than 200 professional publications, is editor-in-chief of *Diabetes Care*, and is on the Editorial Board of *Metabolic Syndrome and Related Disorders*.
Charles Herzog, M.D.

Dr. Herzog is director of the Cardiovascular Special Studies Center, U.S. Renal Data System. He has been a cardiologist at Hennepin County Medical Center (HCMC) in Minneapolis. As a University of Minnesota faculty member for 23 years, he has been professor of medicine since 2004. Since 1985, he has been the cardiology consultant to the end-stage renal disease (ESRD) program at HCMC (dialysis and renal transplantation). He founded the program in interventional cardiology and served as director of the Cardiac Catheterization Laboratory at HCMC from 1985 to 1991. Since 1997, he has been director of the HCMC Cardiac Ultrasound Laboratory. Dr. Herzog is a Fellow of the American College of Cardiology. His areas of research or special interest include cardiac disease, ESRD, and echocardiography. He is a member of the Editorial Boards of American Heart Journal, Journal of Nephrology, and Clinical Journal of the American Society of Nephrology. He is a liaison editor (cardiology) for Nephrology Dialysis Transplantation.

Joseph Bonventre, M.D., Ph.D.

Dr. Bonventre is the Robert H. Ebert Professor of Medicine at the Harvard Medical School, and is director of the Renal Division, Brigham and Women’s Hospital. He has expertise in acute kidney injury and the use of biomarkers to define tissue injury and predict clinical outcomes.

Giuseppe Remuzzi, M.D.

Professor Remuzzi is director of the Negri Bergamo Laboratories of the Mario Negri Institute for Pharmacological Research and director of the Department of Immunology and Clinical Transplantation of the Ospedali Riuniti di Bergamo, Italy. In these positions, he leads a diverse team of clinicians and researchers studying human renal diseases and experimental models for pathophysiological study and therapeutic intervention. Professor Remuzzi is recognized as an international expert in renal disease. An author or co-author of more than 920 scientific articles, he serves on the Editorial Boards of many journals, including the New England Journal of Medicine.

Sudhir V. Shah, M.D.

Dr. Shah is professor of Internal Medicine and director, Division of Nephrology at the University of Arkansas for Medical Sciences (UAMS), where he has been on the faculty since 1990. Dr. Shah is also chief of the Nephrology Section at the John L. McClellan Memorial Veterans Hospital. Prior to joining UAMS, Dr. Shah was on the teaching faculty in the Section of Nephrology at Tulane University School of Medicine from 1979 to 1990, most recently as professor of medicine. Dr. Shah has served as a member of the Pathology A Study Section of the National Institutes of Health (NIH) and was chairman of the program committee for the National Kidney Foundation. He has been on the Editorial Boards of Kidney International, Journal of the American Society of Nephrology, American Journal of Kidney Disease, and American Journal of Physiology. He has served as chairman of the Acute Renal Failure Advisory Group for the American Society of Nephrology (ASN) and also on the ASN Board of Advisors. He is currently president of the International Federation of Kidney Foundations. He recently completed a year of service on CorMedix’s Board of Directors.

Z. Ioav Cabantchik, M.D., Ph.D.

Dr. Cabantchik is professor of biological chemistry at the Hebrew University of Jerusalem, Israel. A research hematologist, Dr. Cabantchik spent his early career studying membrane transport in acid-base metabolism. Over the past decade, he has studied iron metabolism in health and disease. He has expertise in the pathophysiology of labile or catalytic iron and iron chelation. His recent research has focused on the role of labile iron as a mediator of cellular injury in diseases of regional iron accumulation.
# Neutrolin® Executive Committee

CorMedix also maintains an Executive Committee for Neutrolin®, one of the Company’s chief product candidates. Table 6 summarizes the members of this committee, followed by brief biographies.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael Allon, M.D.</td>
<td>Professor of Medicine, University of Alabama</td>
</tr>
<tr>
<td>Alfred K. Cheung, M.D.</td>
<td>Professor of Medicine, Chief of Division of Nephrology and Hypertension, and Executive Director of the Dialysis Program at the University of Utah</td>
</tr>
<tr>
<td>Charmaine Lok, M.D.</td>
<td>Medical Director of the Renal Management and Hemodialysis Vascular Access Programs, University of Toronto Health Network</td>
</tr>
<tr>
<td>Michele Mokrzycki, M.D.</td>
<td>Professor of Clinical Medicine, Albert Einstein College of Medicine</td>
</tr>
</tbody>
</table>

Source: CorMedix Inc.

**Michael Allon, M.D.**

Dr. Allon is professor of medicine at the University of Alabama. Dr. Allon was the principal investigator of the pilot Neutrolin® study in the U.S. and has expertise in hemodialysis vascular access and CRBSI. He was also a member of the Infectious Disease Society of America Working Group on CRBSI and an author of the practice guidelines.

**Alfred K. Cheung, M.D.**

Dr. Cheung is professor of medicine, chief of the Division of Nephrology and Hypertension, and executive director of the Dialysis Program at the University of Utah. Dr. Cheung has expertise in hemodialysis and as a clinical trialist in CKD and hemodialysis. He also has an active laboratory interest focused on the development of therapeutics to prevent hemodialysis vascular access stenosis.

**Charmaine Lok, M.D.**

Dr. Lok is medical director of the Renal Management and Hemodialysis Vascular Access Programs, University of Toronto Health Network. Dr. Lok has expertise in hemodialysis vascular access and CRBSI.

**Michele Mokrzycki, M.D.**

Dr. Mokrzycki is professor of clinical medicine, Albert Einstein College of Medicine. Dr. Mokrzycki has expertise on the use and outcomes of CVCs in hemodialysis patients as well as CRBSI.
Core Story

CorMedix Inc. ("CorMedix" or "the Company") is a biopharmaceutical company developing product candidates to address aspects of cardiorenal disease, which is the intersection of cardiovascular and kidney (renal) disease. Research has indicated that cardiovascular and kidney disease share common characteristics, including the presence of oxidative stress as well as endothelial dysfunction. The Company’s operations are based on the belief that much of the illness and death attributed to renal disease is actually cardiovascular in nature and may be preventable. Thus, CorMedix is focused on addressing kidney dysfunction and the associated cardiovascular and metabolic complications. This platform is known by the Company as “treating the kidney to treat the heart.”

CARDIORENAL DISEASE

Cardiorenal disease encompasses a range of interrelated heart, kidney, and metabolic problems, as depicted in Figure 2. Initially, cardiorenal syndromes were thought to entail a heart condition that causes a secondary deterioration of kidney function. However, research in recent years has identified that the inverse also occurs (Source: *Kidney International* 2009). Primary kidney diseases can cause severe cardiovascular problems, including accelerated cardiac atherosclerosis (hardening of the arteries), left ventricular hypertrophy (enlargement) and remodeling, and myocardial microangiopathy (disease of certain of the heart’s blood vessels).

Approximately six million people in the U.S. have simultaneous cardiovascular dysfunctions and chronic kidney disease (CKD), the combination of which increases patients’ risks and may present treatment challenges (Source: *International Urology and Nephrology* 2005). Factors contributing to the prevalence of cardiorenal disorders include obesity, high blood pressure, diabetes, and an aging population.
The section below provides a brief overview of cardiovascular disease, followed by a summary of renal disease on pages 19-22. As highlighted in Figure 2 (page 17), cardiorenal diseases involve interrelated dysfunctions of both the renal and cardiovascular systems. However, as cardiorenal disease extends beyond just cardiovascular disorders or just renal disease, its management may require unique strategies separate from treating the heart or kidney individually (Source: *Nephrology Dialysis Transplantation* 2005). CorMedix’s primary platform technologies aim to prevent or treat cardiorenal disease by reducing oxidative stress (detailed on pages 22-23), which is a common denominator in both cardiovascular and renal disease.

### Cardiovascular Disease

The term cardiovascular disease references a group of disorders of the heart and blood vessels, as summarized in Table 7. Collectively, these disorders represent the leading cause of death in the U.S.—as many as 40% of fatalities—which surpasses all cancers combined (Source: the Mayo Clinic). Cardiovascular disease is also the most common cause of sudden cardiac arrest (when the heart unexpectedly stops beating), which kills approximately 330,000 U.S. adults each year before they reach an emergency room (Source: the American Heart Association). Globally, cardiovascular diseases are the number one cause of death, claiming approximately 17.1 million lives a year (Source: the World Health Organization [WHO]). These afflictions are expected to remain the leading cause of mortality going forward, and over 23 million people are projected to die of cardiovascular diseases by 2030.

<table>
<thead>
<tr>
<th>Table 7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A SELECTION OF CARDIOVASCULAR DISEASES</strong></td>
</tr>
<tr>
<td>• Coronary Heart Disease (CHD): disease of the blood vessels supplying the heart muscle</td>
</tr>
<tr>
<td>• Cerebrovascular Disease: disease of the blood vessels supplying the brain</td>
</tr>
<tr>
<td>• Peripheral Arterial Disease (PAD): disease of blood vessels supplying the arms and legs</td>
</tr>
<tr>
<td>• Rheumatic Heart Disease: damage to the heart muscle and heart valves from rheumatic fever, caused by streptococcal bacteria</td>
</tr>
<tr>
<td>• Arrhythmias: heart rhythm problems</td>
</tr>
<tr>
<td>• Congenital Heart Disease: malformations of heart structure existing at birth</td>
</tr>
<tr>
<td>• Deep Vein Thrombosis (DVT) and Pulmonary Embolism: blood clots in the leg veins, which can dislodge and move to the heart and lungs</td>
</tr>
</tbody>
</table>

*Source: the World Health Organization (WHO).*

Heart attacks and strokes are two of the most common cardiovascular events and may be brought on due to complications of chronic kidney disease ([CKD] as described on page 19). In the U.S., approximately 1.1 million people have a heart attack each year, and almost 50% are fatal (Source: the National Heart, Lung, and Blood Institute). Typically, heart attacks occur as a result of coronary heart disease ([CHD] also called coronary artery disease). In CHD, plaque accumulates in the coronary arteries (those supplying blood to the heart) over many years. When the plaque ruptures, it causes a blood clot that can become large enough to block the flow of blood to the heart, causing a heart attack.

Roughly 15 million people worldwide suffer from a stroke annually, of which approximately five million strokes are fatal and another five million cause permanent disability (Source: WHO). Strokes occur when blood vessels carrying blood to the brain are blocked by a clot or break open, causing blood to leak into the brain. When blood and oxygen flow to the brain stops as a result of either of these events, brain cells can die, which often leads to permanent damage. Atherosclerosis and a type of arrhythmia called atrial fibrillation both contribute to the likelihood of a stroke.
Chronic Kidney Disease (CKD)

Healthy kidneys serve critical bodily functions, as highlighted below:

- removing waste, fluid, drugs, and toxins from the body;
- regulating water and other chemicals in the blood, such as sodium, potassium, phosphorus, and calcium;
- releasing hormones and regulating blood pressure;
- producing red blood cells; and
- promoting strong bones.

However, there are many diseases, obstructions, and infections that can prevent these organs from performing properly. Diabetes and high blood pressure cause the majority of renal disorders. Impaired kidney function often occurs in one of two manners: (1) as an acute kidney injury, which entails a rapid loss of renal function (e.g., within 48 hours); or (2) as chronic kidney disease (CKD), which progresses over the course of several months to years. The National Kidney Foundation estimates that the U.S. CKD population exceeds 26 million people, up from approximately 20 million people in 2002.

There are a number of complications of CKD, including waste buildup in the body, anemia, weak bones, poor nutritional health, nerve damage, and increased risks for developing heart and blood vessel problems. Medical research suggests that kidney disease can both result from cardiovascular changes as well as negatively affect the cardiac system. For instance, CKD patients have an increased likelihood of accelerated atherosclerosis, heart attack, congestive heart failure (CHF), atrial and ventricular arrhythmias, and cardiac death (Source: *International Urology and Nephrology* and *Cardiology Clinics* 2005). As such, heart disease is a leading cause of death for CKD patients. People afflicted with severe kidney failure, called end-stage renal disease (ESRD), are 30 times more likely to die of cardiovascular disease than the general population (Source: the American Heart Association).

As CKD progresses, it typically leads to early cardiovascular death or ESRD. ESRD is characterized by 10% or less remaining kidney function. At present, treatment options for advanced kidney disease are limited to either a transplant or dialysis. Without one of these options, ESRD is fatal due to the buildup of fluids and waste in the body. However, transplantation is a lengthy and unsure process due to a shortage that exists between the large number of people on transplant waiting lists and the small number of available organs. Table 8 shows this discrepancy, noting that over 80,000 people were waiting for a kidney transplant in November 2009. As of June 30, 2010, over 108,000 people were waiting on a transplant (Source: the United Network for Organ Sharing [UNOS]). Approximately 4,000 new patients are added to an organ transplant waiting list each month (Source: the National Kidney Foundation). As a result, dialysis becomes the only option for many people suffering from advanced CKD and ESRD.

<table>
<thead>
<tr>
<th>Organ</th>
<th>Number of Transplants in 2008</th>
<th>Number of Patients on Waiting List (as of Nov. 2009)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>16,520</td>
<td>82,364</td>
</tr>
<tr>
<td>Kidney/Pancreas</td>
<td>837</td>
<td>2,220</td>
</tr>
<tr>
<td>Pancreas</td>
<td>436</td>
<td>1,488</td>
</tr>
<tr>
<td>Liver</td>
<td>6,319</td>
<td>15,915</td>
</tr>
<tr>
<td>Heart</td>
<td>2,163</td>
<td>2,884</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>27</td>
<td>83</td>
</tr>
<tr>
<td>Lung</td>
<td>1,478</td>
<td>1,863</td>
</tr>
<tr>
<td>Intestine</td>
<td>185</td>
<td>229</td>
</tr>
<tr>
<td>Total</td>
<td>27,965</td>
<td>107,046</td>
</tr>
</tbody>
</table>

*Source: the National Kidney Foundation.*
Hemodialysis

Dialysis is the process of cleansing blood of harmful wastes, salts, and fluid—a task normally performed by the kidneys. This treatment is typically initiated when there is 10% to 15% kidney function remaining, before a patient’s kidneys have completely shut down. There are two types of dialysis: peritoneal dialysis and hemodialysis. Peritoneal dialysis uses the patient’s own body tissues as a filter. In this technique, a plastic tube is inserted into the patient’s abdominal cavity where it delivers a special fluid into the cavity that washes around the intestinal walls. The intestines act as a filter between the fluid and the bloodstream.

The far more common approach is hemodialysis. Hemodialysis uses a machine outside of the body, connected to the patient’s vascular system, to filter the blood. With this treatment, patients’ blood is passed through a filter a few ounces at a time. Once the blood has been cleaned, it is returned to the body. While some individuals are taught how to perform dialysis at home, hemodialysis is a life-long therapy that usually requires visits to a hospital or dialysis center three times a week. Each visit may average three to five hours. CorMedix estimates that more than 90% of people in the U.S. requiring chronic dialysis receive hemodialysis.

There are a few methods for obtaining vascular access for hemodialysis, including using a central venous catheter (CVC). As illustrated in Figure 3, a CVC is a thin, flexible tube inserted into a large vein within the arm or chest. The CVC has two chambers to allow a dual flow of blood. It does not require needles. Alternative vascular access options include an arteriovenous fistula or graft. The fistula, a connection between two otherwise separate body parts, is surgically created by connecting an artery directly to a vein. This effect causes more blood to flow into the vein, which becomes larger and stronger. As a result, repeated needle insertions for hemodialysis treatments are easier. For people with small veins that cannot be turned into fistulas, a synthetic tube or graft can be implanted under the skin to connect the artery and vein. This graft serves as an artificial vein for needle placement. A graft may be ready for use as soon as two or three weeks after the surgery, whereas a fistula could take up to two years to develop. In some individuals, neither a graft nor a fistula is possible, thus a long-term CVC is used (Source: National Kidney and Urologic Diseases Information Clearinghouse 2008). As of 2002, approximately 25% of the hemodialysis patient population relied on a CVC (Source: Interscience Conference on Antimicrobial Agents and Chemotherapy 2002).

![Figure 3](image)

**TYPES OF VASCULAR ACCESS FOR HEMODIALYSIS**

<table>
<thead>
<tr>
<th>Central Venous Catheter (CVC)</th>
<th>Arteriovenous Fistula</th>
<th>Arteriovenous Graft</th>
</tr>
</thead>
</table>

Sources: U.S. Food and Drug Administration (FDA) and National Kidney and Urologic Diseases Information Clearinghouse.
Complications—Catheter-related Bloodstream Infections (CRBSI)

Because of its growing prevalence and its high socioeconomic burden, CKD is often considered to be a silent epidemic (Source: *Kidney International* 2009). It is characterized by secondary complications, such as bone disease and anemia, as well as a considerably increased risk for cardiovascular disease and ESRD. In addition, the vascular access methods required for hemodialysis—CVCs, arteriovenous fistulas, and arteriovenous grafts—are also associated with complications that may require further treatment or surgeries. The most common obstacles are infection and low blood flow due to blood clots forming within the vascular access.

CVCs are more susceptible to infection and clotting than the fistulas and grafts and, to CorMedix’s knowledge, there is not yet a marketed product in the U.S. that can address both of these concerns. Catheter-related bloodstream infection (CRBSI) from the chronic use of a CVC is a considerable source of morbidity and mortality in hemodialysis patients. The risk of CRBSI is proportionate to the duration of CVC use. Infection is estimated to occur in 35% of patients within three months of CVC use, and in 48% of patients within six months (Source: *American Journal of Kidney Diseases* February 2008). Within just the hemodialysis application of CVCs, CorMedix estimates that there are over 160,000 infections each year due to CRBSI and approximately 6,000 related deaths annually.

As well, CVCs are used in multiple other indications beyond hemodialysis. These devices are also used for patients receiving chemotherapy, chronic antibiotic therapy, total parenteral nutrition, and intensive care. CVCs deliver a variety of long-term medicinal treatments for pain, infections, cancer, malnutrition, and heart conditions. There are approximately 80,000 CRBSI annually in U.S. intensive care units, which lead to as many as 24,000 patient deaths each year. Furthermore, each CRBSI is associated with approximately 12 days of hospitalization, and the average cost to the healthcare system is $18,000 per episode of CRBSI (Source: *Journal of the American Medical Association* March 2009). Thus, CorMedix views the prevention of CRBSI and clotting in CVCs as an urgent, unmet medical need important to patients, dialysis providers, and nephrologists.

To enhance the safety and efficacy of the more than five million CVCs used in the U.S. every year, CorMedix is developing a catheter lock called Neutrolin® (detailed on pages 24-28) to prevent CRBSI and clotting from occurring between hemodialysis sessions. Initial studies with Neutrolin® have demonstrated that when this solution is placed into both chambers of a CVC at the end of each hemodialysis session, it may reduce infection by 90%. Consequently, Neutrolin® could decrease patients’ need for local and systemic antibiotics and may prolong catheter life. It has also been shown to overcome antibiotic-resistant microbes.

Contrast-induced Nephropathy (CIN)

**Contrast media** serve to increase the image contrast of anatomical structures that are not otherwise easily visualized. Radiographic contrast media are commonly used in cardiology, and are associated with the onset of contrast-induced kidney disease (contrast-induced nephropathy [CIN]). CIN is essentially acute kidney injury occurring within 48 hours of exposure to intravascular radiographic contrast material that cannot be attributed to other causes. It is the third leading cause of hospital-acquired renal failure and is associated with significant morbidity and mortality (Source: *Catheterization and Cardiovascular Interventions* 2007). CKD is the primary predisposing factor for CIN, although there are a variety of other risk factors as well (as listed in Table 9 [page 22]).

As described on pages 29-31, one of CorMedix’s lead initiatives is creating novel formulations of deferiprone, a generic pharmaceutical for iron chelation. The Company is developing deferiprone to potentially reduce the morbidity and mortality of CIN. In the future, CorMedix may also evaluate its deferiprone formulation as a method to slow the progression of CKD. The U.S. Food and Drug Administration (FDA) has approved Investigational New Drug (IND) applications for both of these uses.
CORMEDIX’S APPROACH: TREATING THE KIDNEY TO TREAT THE HEART

As illustrated in Figure 4, CorMedix’s cardiorenal focus straddles the current renal and cardiovascular markets. CorMedix believes that two of the key processes with a role in cardiorenal disease are oxidative stress, which harms tissue at the cellular level, and damage to the endothelium (or blood vessel lining). These processes are overviewed below.

**Oxidative Stress and Endothelial Dysfunction**

The Company’s therapeutic goals include preventing and reducing acute kidney injury and delaying or preventing the progression of CKD. CorMedix believes that excess labile (free) iron has a causative role in acute kidney injury and the progression of CKD. To this effect, there is a body of experimental evidence supporting the assumption that labile iron is increased in models of kidney disease (Source: Hemoglobin 2009). Moreover, iron chelators have been found to provide protection, validating the role of labile iron in these diseases. CorMedix believes that iron chelators may offer an innovative method of preventing and treating renal disorders. The Company’s deferiprone product candidate is intended to treat or decrease the risk of cardiorenal disease by reducing the oxidative stress caused by excess labile iron.

**Table 9**

<table>
<thead>
<tr>
<th>Modifiable Risk Factors</th>
<th>Non-modifiable Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Contrast volume</td>
<td>• Diabetes</td>
</tr>
<tr>
<td>• Hydration status</td>
<td>• CKD</td>
</tr>
<tr>
<td>• Concomitant nephrotoxic agents</td>
<td>• Shock/hypotension</td>
</tr>
<tr>
<td>• Recent contrast administrations</td>
<td>• Advanced age (&gt;75 years)</td>
</tr>
<tr>
<td></td>
<td>• Advanced congestive heart failure</td>
</tr>
</tbody>
</table>


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**Pre-procedural clinical risk factors for CIN**

**Figure 4**

CorMedix Inc.

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**CORMEDIX: TRANSFORMING MEDICINE AT THE CARDIORENAL CROSSROADS**

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**Oxidative Stress and Endothelial Dysfunction**

The Company’s therapeutic goals include preventing and reducing acute kidney injury and delaying or preventing the progression of CKD. CorMedix believes that excess labile (free) iron has a causative role in acute kidney injury and the progression of CKD. To this effect, there is a body of experimental evidence supporting the assumption that labile iron is increased in models of kidney disease (Source: Hemoglobin 2009). Moreover, iron chelators have been found to provide protection, validating the role of labile iron in these diseases. CorMedix believes that iron chelators may offer an innovative method of preventing and treating renal disorders. The Company’s deferiprone product candidate is intended to treat or decrease the risk of cardiorenal disease by reducing the oxidative stress caused by excess labile iron.
Oxidative stress is physiological stress on the body caused by free radicals and other reactive oxygen species (ROS) that were inadequately neutralized by the body's antioxidants. Biological free radicals, an independent chemical species possessing at least one unpaired electron, are highly reactive and unstable. They seek stability by removing an electron from a surrounding molecule. The attacked molecule, having lost an electron, then becomes a free radical itself. ROS entail free radicals as well as non-radical oxygen derivatives that facilitate the rise of free radicals, harm cellular macromolecules (such as deoxyribonucleic acid [DNA] and ribonucleic acid [RNA]), and participate in apoptosis (programmed cell death). Free radicals and ROS attack DNA, lipids, proteins, and other cell components. Consequently, they are believed to accelerate the progression of cardiovascular disease, cancer, and age-related diseases, including cataracts, arthritis, Alzheimer's disease, and diabetes.

Free radicals are produced by normal chemical reactions, oxygen metabolism, and inflammation. They are instrumental at helping white blood cells destroy bacteria and virus-infected cells, and have been linked to several normal cell signaling processes. In normal, healthy cells, excess free radicals are deactivated by an antioxidant defense system, which is a group of protective agents that regulate oxidative reactions. In addition to the well-known antioxidants, vitamins C and E, this defense system also uses a variety of enzymes to minimize and repair free radical-induced damage. Free radicals can also be introduced to the body by external factors, including exercise, radiation, environmental toxins, altered atmospheric conditions where too little or too much oxygen is entering the tissues, nitrous oxide, automobile exhaust, cigarette smoke, and alcohol consumption.

The antioxidant defense system typically works to either remove ROS (scavenger antioxidants) or hinder the formation of new ROS (preventative antioxidants). Essential antioxidants are supplied in two ways: (1) produced by the body (endogenous); and (2) consumed through a well-balanced diet (exogenous). However, many people do not eat the recommended daily servings of fruits and vegetables that are needed to obtain the nutrients and antioxidants required for a healthy diet. Scavenger antioxidants include small molecules, such as vitamin C or glutathione, and lipid soluble antioxidants (LSAs), such as vitamin E, carotene, and Coenzyme Q10. Consuming carotene allows the body to produce vitamin A, and Coenzyme Q10 works synergistically with vitamin E in the antioxidant cycle to protect the fatty part of the cell from free radical attack. Scavenger antioxidants also include large molecules that are synthesized by cells to detoxify other agents. In addition, there are many proteins found in plasma that function as natural preventative antioxidants by binding ROS.

When there are more free radicals and ROS than the body’s antioxidant defense system can neutralize, oxidative stress occurs. This stress on vital molecules triggers harmful inflammatory responses and cell death. Oxidative stress could have a role in the pathogenesis of CIN. While there are an array of possible underlying mechanisms of CIN, causes may include a direct toxic effect on renal tubular cells with damage caused by oxygen free radicals. ROS have also been implicated as a contributing factor, and there is evidence that renal free radical production is increased after contrast administration (Source: American Journal of Roentgenology 2004).

Likewise, oxidative stress and inflammation are known to have an integral role in the pathophysiology of many cardiovascular diseases, including atherosclerosis, diabetes, heart failure, and hypertension. Oxidative stress alters many functions of the endothelium, which may ultimately lead to the formation of atherosclerotic lesions in cardiovascular disease (Source: Journal of Molecular and Cellular Cardiology 2009). There are exogenous factors as well that contribute to the production of damaging free radicals, such as smoking and diabetes, which are also significant risk factors for heart disease.
CORMEDIX’S PRODUCT PIPELINE

To address the significant unmet needs of patients with cardiorenal disease, CorMedix is studying two novel technology platforms. One technology is intended to prevent the infection and clotting that may occur among hemodialysis patients due to the use of implanted central venous catheters (CVCs). The other platform aims to prevent or treat cardiorenal disease by reducing oxidative stress. CorMedix’s therapeutic approaches include small molecules, biologicals, devices, and diagnostics (tests). Under its two chief technology platforms, CorMedix is presently focused on advancing four product candidates, as summarized below.

- **CRMD003 or Neutrolin®** is a liquid catheter lock solution that functions as both an antimicrobial and an anticoagulant. It is a drug/device combination designed to keep hemodialysis CVCs free of infection and clotting. CorMedix intends to submit an Investigational Device Exemption (IDE) during 2010 to support a pivotal clinical trial for Neutrolin®.

- **CRMD001 or deferiprone**, CorMedix’s pharmaceutical compound to reduce oxidative stress, is a proprietary formulation of deferiprone, which has been used in its generic format in over 50 countries but is not yet marketed in the U.S. Deferiprone is an oral iron chelator that CorMedix is studying for its ability to bind the body’s toxic iron, potentially reducing the morbidity and mortality of contrast-induced nephropathy (CIN) as well as slowing the progression of chronic kidney disease (CKD). In June 2010, CorMedix commenced a Phase II biomarker proof-of-concept study in which CRMD001 is being evaluated for its ability to prevent CIN among high-risk CKD patients.

- **CRMD004** is a thixotropic gel formulation of a catheter lock that may provide additional benefits as a catheter lock and may extend the anticipated benefits of Neutrolin®. This gel, which becomes fluid under the pressure of being inserted into or withdrawn from a catheter, is intended to keep implanted CVCs free of infection and fully flowing.

- **CRMD002**, a diagnostic labile iron biomarker test, may support the use of deferiprone in CKD by identifying patients at risk for CKD, diagnosing CKD patients, and monitoring patients’ responses to therapy.

The section below and continued through page 28 details Neutrolin® and the thixotropic gel, and pages 29-31 describe the Company’s novel deferiprone formulations and diagnostic test.

**CRMD003 (Neutrolin®)**

CorMedix acquired exclusive worldwide rights to Neutrolin® from ND Partners LLC, which was one of the Company’s first licensing/partnership agreements. CorMedix believes that Neutrolin® is representative of its future activities as the Company strives to become a leading entity in cardiorenal therapy.

To the Company’s knowledge, there is no approved antimicrobial and anticoagulant catheter-locking solution for the prevention of catheter-related bloodstream infection (CRBSI) in the U.S. today. Neutrolin® has the potential to become an innovative catheter lock with a wide range of applicable markets.

Neutrolin®, illustrated in Figure 5 (page 25), is a catheter lock solution to address CRBSI and clotting in hemodialysis patients who have a chronic CVC. When applied to both ends of the CVC between hemodialysis sessions, Neutrolin® seals the catheter to keep it free of infection and to prevent clotting from occurring within the catheter (i.e., keeping the blood flowing freely). At the end of a hemodialysis session, approximately 2.5 mL of each end of the CVC is filled with the Neutrolin® solution. At the start of the next hemodialysis session, the Neutrolin® is extracted from the catheter and saline is flushed through the CVC. Then the patient can be reconnected to the dialysis machine.
Overall, Neutrolin® provides a broad-spectrum antimicrobial approach. Importantly, Neutrolin® is not an antibiotic, which decreases the likelihood of antibiotic-resistant infections occurring. The key features of Neutrolin®, as CorMedix views the product, are as follows:

- It is a broad-spectrum antimicrobial;
- It is not likely to produce cross-resistance, because it is not an antibiotic;
- It prevents buildup of biofilm (microscopic disease-causing bacteria);
- It contains anticoagulants to prevent clotting; and
- It has been shown to have low toxicity and be well tolerated.

Neutrolin® was previously under development at Biolink Corp., where preclinical testing demonstrated an acceptable efficacy and safety profile for the compound. Biolink submitted the original Investigational Device Exemption (IDE) for Neutrolin® in 2003, which was cleared by the FDA. Initial clinical studies were conducted that allowed Biolink to optimize the composition of Neutrolin®, however, Biolink subsequently filed for bankruptcy, which ended the candidate’s development. TauroPharm GmbH then launched Neutrolin® in Europe as “TauroLock” (taurodine and 4% citrate without heparin). At present, TauroLock (which holds a CE Mark) is used in Europe and the Middle East as a catheter lock solution in hemodialysis, in intensive care units, and for oncology/chemotherapy patients.

The composition of CorMedix’s Neutrolin® includes 1.35% taurodine (the antimicrobial and antifungal agent) and 4% citrate as well as 1,000 u/mL heparin (the anti-clotting components). Currently, heparin is considered a standard method of sealing CVCs between uses. However, while standard heparin catheter locks reduce the likelihood of a clot, they have not been shown to prevent infection in the same manner as combination antimicrobial locks (such as Neutrolin®). Figure 6 (page 26) illustrates this finding using data from seven randomized third-party clinical trials conducted over a five-year period. Through this multi-trial comparison, the frequency of catheter-related bacteremia (“CRB” in Figure 6) in patients receiving a standard heparin catheter lock was weighed against the frequency of infection in patients who were given a prophylactic antimicrobial catheter lock. Each study revealed a considerably lower rate (50% to 100%) of catheter-related bacteremia in patients randomized to an antimicrobial lock versus those receiving a conventional heparin lock (Source: American Journal of Kidney Diseases February 2008).
Similarly, initial studies with Neutrolin® have demonstrated that when it is placed into both limbs of a CVC at the end of each hemodialysis session, it eliminates biofilm and reduces infection by approximately 90%. As such, the candidate potentially reduces the need for local and systemic antibiotics. Table 10 summarizes several of the research studies that have helped provide proof of concept for Neutrolin®, noting that this is not an exhaustive list.

Table 10
CorMedix Inc.

NEUTROLIN® PROOF OF CONCEPT:
PUBLISHED CLINICAL TRIALS SUPPORT A >90% REDUCTION IN CRBSI

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of catheters (No. of patients)</th>
<th>Average duration (days)</th>
<th>CRBSI per 1,000 catheter days (Neutrolin® vs. control)</th>
<th>Control group</th>
<th>Neutrolin®: % of patients without infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betjes</td>
<td>76 (58)</td>
<td>158</td>
<td>0 vs. 2.1 (P=0.047)</td>
<td>heparin 5,000 u/mL</td>
<td>100</td>
</tr>
<tr>
<td>Sodemann et. al.</td>
<td>76 (76)</td>
<td>250</td>
<td>0.20</td>
<td>None</td>
<td>96</td>
</tr>
<tr>
<td>Poster: ASN 2001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allon</td>
<td>20/30</td>
<td>85</td>
<td>0.60 vs. 5.6 (P&lt;0.001)</td>
<td>heparin 5,000 u/mL</td>
<td>94</td>
</tr>
<tr>
<td>Taylor</td>
<td>Actual Use (pre and post)</td>
<td>N/A</td>
<td>0.60 vs. 5.2</td>
<td>heparin 5,000 u/mL</td>
<td>89</td>
</tr>
<tr>
<td>J Renal Care (2008) 34 (3) 116-120</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: CorMedix Inc.

Figure 6
A SUMMARY OF THE FREQUENCY OF CATHETER-RELATED BACTEREMIA WITH ANTIMICROBIAL LOCKS VERSUS HEPARIN LOCKS IN PUBLISHED RANDOMIZED CLINICAL TRIALS

**Biofilm and Antibiotic Resistance**

Biofilm is a collection of microscopic disease-causing bacteria called microbes that form on the surface of catheter lines, contact lenses, pacemakers, heart valve replacements, and artificial joints, among other surgical implants. Biofilm bacteria can be as much as 1,000 times more resistant to antibiotics than non-biofilm bacteria (Source: MedicineNet, Inc.). Once they have contaminated an implanted medical device (such as a catheter), these microbes can lead to life-threatening systemic infections, particularly as the affected patient is often already immunocompromised.

Neutrolin® may be active against common and antibiotic-resistant microbes, including strains of methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-resistant *Staphylococcus epidermidis* (MRSE), and vancomycin-resistant enterococcus (VRE). Each of these infections occur most frequently in patients at healthcare facilities (e.g., dialysis centers) due to the weakened immune systems of these individuals as well as the presence of a CVC or other medical device that remains inside these patients for an extended period of time (Source: U.S. Centers for Disease Control and Prevention [CDC]). Enterococci are among the most common antibiotic-resistant bacteria. During 2006 and 2007, enterococci caused roughly 1 out of every 8 infections in hospitals, with 30% of these classified as VRE (Source: CDC). Moreover, because many CRBSI are resistant to antibiotics, treatment often entails removing the contaminated catheter from the patient. Thus, by reducing the likelihood of these bacteria from forming, Neutrolin® may also be able to prolong catheter life. CorMedix believes that catheter use in hemodialysis could increase as a result of the reduced infection probabilities due to Neutrolin®.

**Development Status**

At present, CorMedix is in the process of finalizing and submitting an IDE application for Neutrolin® to the FDA. An IDE allows an investigational device to be used in a clinical study designed to collect safety and effectiveness data. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. In 2003, there was a former IDE on file for Neutrolin®, which was prior to CorMedix’s licensing of the candidate. In October 2008, the Company began meeting with the FDA to finalize a new IDE supplement. CorMedix anticipates submitting the revised IDE during 2010. In support of the filing, the Company is working on the submission of further metanalysis data that was obtained based on seven years of clinical experience in the EU, including published papers.

Once an IDE is granted and the subsequent clinical study is completed, CorMedix intends to submit a Premarket Approval (PMA) application to the FDA for Neutrolin®. The PMA is the FDA’s required process of scientific review to ensure the safety and effectiveness of certain medical devices, similar to filing a New Drug Application (NDA) for pharmaceutical products. CorMedix is working toward a potential market launch of Neutrolin® in 2013.

**Trial Design**

Neutrolin® is poised to undergo a pivotal trial following submission and anticipated approval of its IDE. The Company may only need to complete a single trial with approximately 400 patients for this candidate. To CorMedix’s knowledge, Neutrolin® has already demonstrated safety and efficacy, factors that the Company believes lowers the risk of this candidate’s clinical program.

The trial’s protocol is likely to entail a comparative study of Neutrolin® to the current standard of care, which is the heparin lock. The Company plans to recruit patients over a nine-month period and then follow these individuals for the ensuing six months. CorMedix expects this study to demonstrate the safety and effectiveness of Neutrolin® in preventing CRBSI and maintaining catheter patency in patients who are receiving hemodialysis therapy three times a week to treat ESRD.
Orphan Designation

Additionally, due to the significant unmet need surrounding CRBSI, CorMedix has applied for an orphan grant from the U.S. National Institutes of Health (NIH). The Neutrolin® application that was submitted was based upon a previously approved IDE for the product. The Company plans to resubmit for orphan designation following approval of the new IDE. Orphan registration is only eligible for products addressing niche diseases afflicting less than 200,000 people. Orphan products are associated with several benefits, including opportunities for further development funding. CorMedix submitted an orphan device grant request for Neutrolin® in February 2009.

Manufacturing

CorMedix has secured clinical trial material and manufacturing options for the finished product. The key aspect of establishing the production of Neutrolin® entailed finding a manufacturer to make the active pharmaceutical ingredient (API) for the taurolidine antimicrobial constituent. The Company identified a partner in New Jersey that has already manufactured a limited quantity and has plans to scale-up production via operations in India. CorMedix is also considering proposals from a separate manufacturer for the finished product.

Product Line Extensions

While CorMedix’s initial focus is on preventing CRBSI in hemodialysis catheters, Neutrolin® may also be applicable to a range of catheter-based procedures in the future. The Company expects that future indications for Neutrolin® could include preventing infection in catheters used for cancer chemotherapy, intravenous nutrition, and intravenous administration of fluids in an intensive care setting, among other applications.

CRMD004 (Thixotropic Gel)

CorMedix’s thixotropic gel formulation of a catheter lock may extend the anticipated benefits of the liquid Neutrolin® formulation described on the preceding pages. CRMD004 may represent an alternative to CRMD003 in the dialysis setting and could be associated with a longer patent life. The gel is designed to change from a semi-solid state to a free-flowing liquid state in response to the pressure of insertion into or withdrawal from a catheter. The Company believes that this candidate may provide additional benefits as a catheter lock and could help prevent CRBSI in many settings, including hemodialysis, cancer chemotherapy, and intravenous nutrition. The gel’s thixotropic properties may be able to prevent spillage from the catheter tip and end, in the event the luer lock becomes disengaged. Likewise, the gel’s solid state when in the catheter may negate the need for an anticoagulant within the formulation.

CorMedix considers the thixotropic gel to be a lifecycle management tool for Neutrolin®. This candidate is currently in preclinical studies. At this stage, CorMedix is conducting preclinical laboratory tests including the animal studies required before starting human pilot studies.
CorMedix is also advancing a cardiorenal treatment approach that uses novel formulations of the generic pharmaceutical deferiprone to reduce the tissue-damaging oxidative stress caused by labile (toxic) iron in the body. Similar to Neutrolin®, CorMedix believes that deferiprone is targeted toward indications where there is considerable unmet need.

The initial deferiprone indication is prevention of contrast-induced nephropathy (CIN), which is a common problem for CKD patients. As detailed on page 19, CKD patients have a high likelihood of developing cardiovascular disease. As such, these individuals are predisposed to laboratory tests for heart disease, such as coronary angiographies, which require radiographic contrast (a solution containing iodine that can be visualized on an X-ray) to be injected into the area being viewed. For example, in the coronary angiogram depicted in Figure 7, the resulting angiographic images allow physicians to view the extent and severity of coronary arterial blockages. However, in certain high-risk patients, the use of radiographic contrast can cause injury to the kidneys and can increase cardiovascular morbidity and mortality. The cardiovascular events associated with CIN include heart attacks and strokes. CIN is the third leading cause of hospital-acquired renal failure.

CorMedix believes that catalytic iron and its associated oxidative stress is a critical mechanism related to the pathogenesis of acute kidney injury in CIN. To this extent, removal (chelation) of labile iron has been found to be protective in experimental CIN as well as in multiple other models of acute kidney injury. Iron chelation has also shown to be protective in cardiac ischemia, improving outcomes after a coronary artery bypass graft.

The compound that CorMedix is using is deferiprone, an oral iron chelator. It is a generic pharmaceutical in its current formulation and is available as Ferriprox® from ApoPharma Inc. in 58 countries. However, it is not yet approved for use in the U.S. Ferriprox®, first approved by the European Medicines Agency (EMEA) in August 1999, is indicated for the treatment of iron overload in patients with thalassemia major when deferoxamine therapy is contraindicated or inadequate. Deferoxamine (Desferal® from Novartis AG) is a medication used to treat acute iron poisoning as well as chronic iron overload due to transfusion-dependent anemia. ApoPharma estimates that thousands of people with iron overload are being treated with Ferriprox® (deferiprone). Greater details of ApoPharma and Ferriprox® are provided on page 33.

CorMedix believes that deferiprone has several beneficial characteristics, including efficacy at reducing the heart disease associated with iron overload and being generally well tolerated. The compound essentially traps the body’s toxic and non-catalytic forms of iron. The drug binds excess iron at the molecular level and then excretes it out of the body. This iron is bound at the center of three deferiprone molecules. CorMedix believes that deferiprone is able to access toxic iron both within and outside of cells. Deferiprone has iron-scavenging characteristics that set it apart from other antioxidants. While traditional antioxidants remove oxidative radicals after they have formed, deferiprone is thought to function as an upstream inhibitor that is able to halt the production of ROS.

To CorMedix’s knowledge, it possesses specific formulations of immediate and extended-release deferiprone that are not available elsewhere. These novel compositions, which have been studied in a U.S. pharmacokinetic study among mild-to-moderate CKD patients, are designed to enable twice daily dosing rather than three times a day and to reduce nausea. CorMedix holds patent rights for deferiprone in the area of kidney diseases, with methods of use patents entailing the application of iron chelators in CKD patients. As a result, the Company expects to obtain five years of market exclusivity in the U.S. for deferiprone as a new chemical entity (NCE). With only approximately 165,000 individuals in this patient population, CorMedix is also pursuing orphan drug registration, which may lead to additional benefits.
Human Proof-of-Concept Studies

Prior to human clinical trials, preclinical studies demonstrated that iron can aggravate CKD by catalyzing free radical reactions that put oxidative stress on cardiorenal systems. This early research also indicated that patients with diabetic renal disease have abnormally high levels of catalytic iron (labile or toxic iron) in their urine. Subsequently, CorMedix’s licensor completed two proof-of-concept studies of deferiprone in humans. Through these studies, it found that deferiprone had the potential to become a new therapy for slowing the progression of CKD and its metabolic and cardiovascular complications.

Proof of concept was established in two types of kidney disease: diabetic nephropathy and glomerulonephritis. The Company presented these results in 2007 at the 40th Annual Meeting of the American Society of Nephrology (ASN). These studies are summarized below.

- The first study occurred at the Baroda Medical Center in India, where 38 diabetic nephropathy patients received a 50 mg/Kg oral dose of deferiprone daily. Throughout the nine-month study designed to test deferiprone’s safety and efficacy, patients’ mean albumin-to-creatinine ratios declined steadily and kidney function remained stable. Additionally, there were no significant safety issues reported.

- In the second trial, 14 patients with glomerulonephritis received a 50 mg/Kg dose of deferiprone daily. Throughout this six-month study, patients’ total urinary protein levels significantly decreased.

Development Status

The FDA has approved Investigational New Drug (IND) applications for the use of deferiprone in both the prevention of CIN and in the treatment of CKD. Table 11 summarizes some of CorMedix’s perceived benefits of preventing CIN, followed by an overview of the ongoing Phase II biomarker proof-of-concept trial, the upcoming Phase III trial, and a potential future indication in CKD.

Table 11
CorMedix Inc.

KEY ADVANTAGES OF TARGETING CIN PREVENTION

- High-risk orphan population ≈ 165,000
- Market penetration may be faster due to morbidity/mortality benefits
- CorMedix is unaware of any competitive pharmaceutical therapies either approved or near approval
- Low cost of sales and marketing, which is specialty care and guidelines driven
- Premium pricing may be possible due to reduction of hard clinical endpoints
- Opportunity for expansion beyond the initial patient (orphan) population into diagnostic cardiac and peripheral angiography, gadolinium toxicity, and other renal toxins (e.g., antibiotics, cytotoxics)

Source: CorMedix Inc.

CIN Prevention: Ongoing Phase II Proof-of-Concept Trial

For the acute CIN indication, CorMedix is performing a confirmatory biomarker study. Following the biomarker study, the Company intends to complete a pivotal Phase III study and aims to submit a New Drug Application (NDA) to support a market launch.

The first patient was enrolled into the Phase II proof-of-concept biomarker-driven trial for deferiprone in June 2010. The trial is anticipated to provide additional data as well as to reduce risk in the forthcoming Phase III trial. The double-blind, placebo-controlled Phase II trial design is recruiting approximately 60 high-risk CKD patients at two U.S. centers—Providence Hospital and Medical Center in Southfield, Michigan, and Northern Michigan Regional Hospital in Petoskey, Michigan. The Company aims to prevent CIN in these patients by administering deferiprone orally for eight days prior to a coronary angiography. The study is also evaluating the safety and tolerability of the candidate in short-term use.
Although the Phase II study uses biomarkers as the primary endpoint, it is also designed to evaluate clinical endpoints. The primary endpoint is a reduction in a panel of sensitive biomarkers of acute kidney injury, as elicited with CorMedix’s proprietary deferiprone formulation versus placebo. Secondary endpoints include clinical outcomes and persistent changes in kidney function. The protocol presently comprises eight days of treatment with deferiprone versus placebo. Biomarker, safety, and clinical endpoints are being assessed over 90 days. Clinical material for this trial is already manufactured and packaged.

An additional benefit of first conducting a proof-of-concept Phase II study is that this strategy enables cost efficiency. After receiving the data from the Phase II trial, CorMedix believes it will likely be positioned to seek a larger investment to fund Phase III. Following the biomarker study, the future Phase III trial is currently scheduled to enroll approximately 800 patients.

Upcoming Phase III Trial

CorMedix has already designed the next clinical study for its deferiprone candidate—a Phase III trial called DEFEND-AKI. To the Company’s knowledge, this study, which could enroll up to 800 patients, may be the largest pharmaceutical study conducted for the prevention of CIN. DEFEND-AKI’s protocol entails a randomized, double-blind, placebo-controlled, parallel-arm, multicenter study in a high-risk patient population characterized by moderate-to-severe CKD.

CorMedix intends to dose patients with one immediate-release deferiprone tablet and two extended-release tablets between one and three hours before scheduled angiographies. Dosing is then continued twice daily for a total of eight days. Patients are monitored for a further 90 days.

Slowing the Progression of CKD: Potential Future Indication

Based on the results of studies for the CIN indication, CorMedix could move forward with clinical research targeted at validating deferiprone as a therapy for slowing the progression of CKD. Development in this indication will likely be dependent on the following: (1) existing clinical data; (2) access to capital; (3) clinical and regulatory considerations; and (4) the Company’s assessment of its intellectual property estate for both the CIN and the CKD indications.

CRMD002 (Diagnostic Test)

Additionally, CorMedix is developing a readily available and reproducible diagnostic biomarker test for urinary labile iron. Biomarkers are substances that can be used as an indicator of a disease or a pathophysiological process. These substances can appear in body tissue, blood, or urine. Detecting a biomarker in higher-than-normal amounts in the body may signify the presence of the disease. For some indications, the expressed amount of a particular marker can also signal the disease’s stage (i.e., how far it has progressed) and the effects of treatment.

The Company believes that its biomarker test could be an important supportive tool for the commercialization of deferiprone. CorMedix holds intellectual property related to the use of a urine marker of labile iron in the diagnosis and treatment of kidney disease. Based on the toxicity of raised labile iron to cells and tissues, CorMedix believes that testing for toxic labile iron could become prevalent, similarly to cholesterol testing. As such, the Company views this assay as ultimately being performed in most large hospital and reference laboratories, with the potential for use as a point-of-care test in physicians’ offices.

While the timeline for full development of CRMD002 is resource dependent, CorMedix believes that this assay could be licensed to a global diagnostic company before the launch of deferiprone for CKD.
Competition

CorMedix targets markets where the Company perceives significant unmet medical need and where there are few available alternatives for patients. The following summation of products is representative of the type of competition that CorMedix may face as it seeks to commercialize its product candidates in the U.S. and globally, but is not meant to be an exhaustive listing of possible competitors. In addition to the entities overviewed below, the Company may compete against a range of off-label or investigational cardiorenal therapies as well as established products intended for cardiovascular or renal diseases. For example, **lovastatins**, such as Merck and Co., Inc.’s (MRK-NYSE) Mevacor®; and nitroglycerin products, such as Pfizer Inc.’s (PFE-NYSE) Nitrostat®, are widely used for cardiovascular diseases.

While antibiotic- or antimicrobial-coated catheters have been launched by some device companies for short-term prevention of catheter infection, CorMedix does not believe that these are effective for hemodialysis catheters, which are characterized by long-term use and high blood flow. To the Company’s knowledge, there is no approved, combined antimicrobial and anticoagulant catheter-locking solution for the prevention of CRBSI in the U.S. today. Likewise, in the CIN treatment market (CorMedix’s initial indication for its deferiprone formulation), the most common treatments include intravenous hydration and avoidance of nephrotoxic drugs (Source: *American Journal of Roentgenology* 2004). As deferiprone is an oral iron chelator, the deferiprone competition summarized on pages 33-34 consists of other available iron chelators, although these products are not specifically indicated for CIN.

**Neutrolin®: CorMedix’s Catheter Lock Solution**

*Great Lakes Pharmaceuticals, Inc.*

Great Lakes Pharmaceuticals aims to develop and commercialize products against infections associated with indwelling catheters. The closely held company is headquartered in Cleveland, Ohio. Its first product is an anticoagulant catheter lock solution called B-Lock™. Great Lakes believes that B-Lock™ can have broad spectrum activity against bacterial and fungal biofilms in indwelling catheters, particularly those associated with CRBSI. Great Lakes intended to initiate clinical studies of B-Lock™ during 2009. Great Lakes holds exclusive licenses to anti-biofilm technology from the University of Texas M.D. Anderson Cancer Center and Wake Forest University. In July 2009, the company received a Notice of Award from the NIH, National Heart, Lung, and Blood Institute (NHLBI) in support of the project “Development of B-Lock an anti-biofilm catheter lock product.” This award entailed a $2.6 million grant to support efforts to move B-Lock™ into human clinical trial testing for the prevention of infections related to CVCs.

*AngioDynamics, Inc.*

AngioDynamics (ANGO-NASDAQ) was founded in 1988. It provides medical devices used by interventional radiologists, nephrologists, and surgeons primarily for the minimally invasive treatment of cancer and peripheral vascular disease. Among its products, AngioDynamics’ portfolio includes vascular access products, angiographic products and accessories, dialysis products, and venous products. The company holds an exclusive license from Ash Access Technology, Inc. to manufacture and market the Centros® Chronic Dialysis Catheter. Centros® is a long-term CVC for hemodialysis with the intention of addressing key complications of today’s catheters, including frequent flow failures, recirculation, and high incidences of sheathing and clotting. The FDA granted 510(k) clearance for Centros® in June 2007.

*Ash Access Technology, Inc.*

Ash Access is a closely held specialty pharmaceutical and medical device company headquartered in Lafayette, Indiana. Founded in 2003, the company is focused on the care of patients requiring vascular access and infection control in the acute and chronic healthcare environments. Ash Access’ product portfolio targets CRBSI and poor blood flow related to the use of both acute and chronic catheters. Among its candidates, Ash Access is developing an antimicrobial/antithrombotic therapy called Zuragen® for the prevention and treatment of CRBSI as well as the eradication of biofilm. In *in vitro* studies, Zuragen® was shown to be effective against both gram positive and negative strains of bacteria.
including *S. aureus*, *S. epidermidis*, *P. aeruginosa*, and *E. coli*. Additional studies with biofilm also demonstrated Zuragen® Solution’s antibacterial activity. In June 2009, Ash Access announced that the FDA accepted the company’s PMA submission for filing and review. Ash Access is also pursuing the integration of Zuragen® technology with catheter designs to create a barrier for infection that may potentially last months instead of days.

**Gambro AB**

Gambro is a closely held medical technology company focused on in-center and self care hemodialysis, peritoneal dialysis, renal intensive care, and hepatic care. Founded in 1964, Gambro has over 8,000 employees. The company makes equipment for kidney dialysis, including dialyzers, dialysis machines, water purifiers, catheter locks, and other devices. Gambro’s Vascular Access unit, in particular, offers a range of products for accessing the blood during dialysis and other extracorporeal therapies, including catheters, fistula needles, and related accessories. Products are designed for both clinical and home use and are sold in over 100 countries. One of Gambro’s products is TauroSept®, a catheter lock solution for both at home and in-center dialysis. TauroSept® is believed to have broad antimicrobial activity effective in the prevention and treatment of catheter-associated infection. TauroSept® prevents biofilm development and, consequently, bacteria and fungi colonization, thus decreasing the risk of infection. It contains taurolidine and, both *in vitro* and clinically, has not been shown to induce any development of microbial resistance. Distributed by Gambro, TauroSept® is manufactured by Geistlich Pharma AG.

Additionally, in June 2010, Gambro announced the introduction of the EverFlow Dolphin Protect™ hemodialysis catheter, which integrates an antibacterial additive into the surface coating of the catheter to reduce the risk of catheter-related infections. EverFlow Dolphin Protect™ is CE marked and available for sale within the European Economic Area. Registration is ongoing in other markets.

**Deferiprone**

*ApoPharma Inc.*

ApoPharma, the closely held drug division of Apotex Inc., supplies a formulation of the iron chelator deferiprone branded as Ferriprox®, which was approved by the European Medicines Agency (EMEA) in August 1999. Altogether, Ferriprox® tablets are now available in 58 countries but have not been approved in North America. The product is indicated for the treatment of iron overload in patients with thalassemia major when deferoxamine therapy (Desferal® from Novartis, described below) is contraindicated or inadequate. ApoPharma estimates that thousands of individuals with iron overload are being treated with Ferriprox®. Both solid and liquid Ferriprox® are usually taken three times a day. In October 2008, ApoPharma announced final data from a multicenter, 100-patient study of liquid deferiprone. According to investigators, results demonstrated that Ferriprox® successfully reduced serum ferritin levels over the 24-week study period and was tolerated well with no unexpected adverse reactions. Additionally, clinical studies have shown that Ferriprox® is more effective than deferoxamine at removing excess cardiac iron and improving cardiac function, and that its use is associated with a lower incidence of iron-induced cardiac disease. ApoPharma’s parent company Apotex is a Canadian pharmaceutical company with over 6,800 employees. Founded in 1974, Apotex produces more than 260 generic pharmaceuticals that are exported to 115 countries.

**Novartis AG**

Novartis employs nearly 100,000 people worldwide who discover, develop, and market products that prevent and cure diseases, ease suffering, and enhance the quality of life. Novartis operates in four divisions: (1) Pharmaceuticals; (2) Vaccines and Diagnostics; (3) Sandoz, which creates generic pharmaceuticals to replace branded medicines after patent expiry; and (4) Consumer Health, which entails Over the Counter (OTC), Animal Health, and CIBA Vision. Novartis Oncology employs more than 4,500 people in over 50 countries. Among its marketed products, Novartis Oncology supplies Desferal® (deferoxamine), which is used to treat acute iron poisoning as well as chronic iron overload due to transfusion-dependent anemia. Desferal® is contraindicated in patients with severe renal disease, since the drug and the iron chelate are excreted primarily by the kidney, and its side effects may include cardiovascular events, such as tachycardia, hypotension, and shock, among other symptoms. Although
deferoxamine has been used clinically for over four decades, its effectiveness is limited by a demanding therapeutic regimen that leads to poor compliance (Source: *Therapeutics and Clinical Risk Management* 2007). Deferoxamine requires daily subcutaneous drug infusions or injections lasting 8 to 24 hours. In contrast, Novartis Oncology’s Exjade® (deferasirox), also an iron chelator, is administered as an oral tablet once a day. Exjade® has been shown to be as efficacious as deferoxamine at comparable therapeutic doses. It has a demonstrated long-term efficacy and safety in transfusion-dependent adult and pediatric patients followed for an average of 3.4 years. Exjade® is indicated in most countries for the treatment of chronic iron overload due to blood transfusions in patients two years and older. However, Exjade® has not been studied in patients with renal impairment, and the development of severe, occasionally fatal kidney problems is a known side effect of Exjade® therapy.
Milestones

Recent Milestones

Over the past several years, CorMedix has achieved the following notable corporate milestones.

- The Company dosed the first patient with CRMD001 (deferiprone) in a randomized, double-blind, placebo-controlled clinical trial during June 2010.

- In April 2010, the Company was issued a new U.S. patent for Neutrolin®, which expires in 2025 and relates to an improved composition for maintaining patency of indwelling catheters involved in central blood access.

- In March 2010, CorMedix completed an IPO for net proceeds of approximately $10.4 million and began trading on the NYSE Amex.

- The Company has licensed liquid and gel formulations of Neutrolin® (CRMD003 and CRMD004, respectively) pursuant to agreements with ND Partners LLC and Dr. Hans-Dietrich Polaschegg.

- Deferiprone was granted a Special Protocol Assessment (SPA) from the FDA for a single Phase III study as the basis of a New Drug Application (NDA) for reducing the kidney damage and associated morbidity and mortality of CIN.

- CorMedix’s licensor published early proof-of-concept studies for the use of deferiprone in slowing the progression of CKD.

- The Company entered into a development agreement with Afferix Ltd. for a diagnostic labile iron biomarker test (CRMD002).

Potential Milestones

In the near term, CorMedix is working toward achieving the following clinical milestones:

- Submit a finalized IDE application for Neutrolin® to the FDA;

- Initiate a clinical trial with approximately 400 patients for Neutrolin®;

- Continue pursuing an orphan grant for Neutrolin® from the NIH; and

- Complete the Phase II proof-of-concept biomarker-driven trial for deferiprone for preventing CIN.
Key Points to Consider

- CorMedix develops products for cardiorenal disease. The Company believes that much of the illness and death attributed to renal disease is cardiovascular in nature and may be preventable; thus, it is focused on addressing kidney dysfunction and associated cardiovascular and metabolic complications. This platform is known by CorMedix as "treating the kidney to treat the heart."
  - Cardiorenal disease is an increasing healthcare concern. Approximately six million people in the U.S. have simultaneous cardiovascular dysfunctions and chronic kidney disease (CKD). Factors contributing to the prevalence of cardiorenal disorders include obesity, high blood pressure, diabetes, and an aging population.

- CorMedix’s pipeline includes Neutrolin®, a catheter lock for the prevention of infection and clotting in patients with chronic central venous catheters (CVCs), and a proprietary formulation of deferiprone to prevent contrast-induced nephropathy (CIN) in high-risk CKD patients. CorMedix is also developing a thixotropic gel catheter lock and a diagnostic labile iron biomarker test.
  - Both Neutrolin® and deferiprone have demonstrated safety and efficacy and are supported by broad intellectual property. While neither product is yet approved for use in the U.S., taurodine (the active antimicrobial component in Neutrolin®) has been employed for nearly 10 years in Europe and deferiprone has a 15-year history. The FDA has previously approved an Investigational Device Exemption (IDE) for Neutrolin® and Investigational New Drug (IND) applications for deferiprone in both the prevention of CIN and in the treatment of CKD.

- CorMedix intends to submit a revised IDE for Neutrolin® during 2010. Initial studies with Neutrolin® have demonstrated that when it is placed into both limbs of a CVC at the end of each hemodialysis session, it eliminates biofilm and reduces infection by approximately 90%. The Company is also developing a lifecycle management tool for Neutrolin®—a thixotropic gel—that may provide additional benefits as a catheter lock and may extend the anticipated benefits of Neutrolin®.
  - More than five million CVCs are used in the U.S. annually for hemodialysis, chemotherapy, chronic antibiotic therapy, total parenteral nutrition, and intensive care, among other functions. However, CVCs are prone to infection and blood clots, which increases patients’ risk of illness and death, and limits the life of the catheter. There are over 80,000 CRBSI annually in U.S. intensive care units, which lead to as many as 24,000 patient deaths each year.

- Deferiprone entered a Phase II proof-of-concept study in June 2010. CorMedix believes that deferiprone has several advantages, including efficacy at reducing iron overload and being generally well tolerated. The Company holds patent rights for deferiprone in the area of kidney diseases, and possesses formulations of immediate and extended-release deferiprone that are not available elsewhere to its knowledge. These compositions are designed to reduce nausea and enable twice daily dosing rather than three times a day.
  - CIN is the third leading cause of hospital-acquired renal failure and is associated with significant morbidity and mortality. The main risk factor for CIN is CKD, which affects 26 million people in the U.S.

- Over the past two years, CorMedix has focused on enhancing its intellectual property and now believes that it holds a solid intellectual property position with key exclusivities. In addition, the Company believes that deferiprone may be classified as an orphan product by the FDA.

- The Company is led by an executive management team that blends science and commercial expertise, which CorMedix believes is necessary to bring its products to market. Management is supported by a Board of Directors comprising individuals skilled in investment, commercial, and clinical fields, as well as multiple Scientific Advisory Boards. The Company’s scientific advisors have considerable experience in cardiorenal disease and ferroscience.

- Following the completion of a $10.4 million (net proceeds) IPO in March 2010, CorMedix had cash and cash equivalents of $11.7 million at March 31, 2010, versus $1.5 million at December 31, 2009.
Historical Financial Results

Tables 12, 13, and 14 provide a summary of CorMedix’s key historical financial statements—its Statements of Operations, Balance Sheets, and Statements of Cash Flows.

Table 12
CorMedix Inc. (A Development Stage Company)
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

<table>
<thead>
<tr>
<th></th>
<th>For the three months ended March 31, 2010</th>
<th>For the three months ended March 31, 2009</th>
<th>Period from July 28, 2006 (inception) Through March 31, 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPERATING EXPENSES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>$3,096,661</td>
<td>$232,844</td>
<td>$15,641,110</td>
</tr>
<tr>
<td>General and administrative</td>
<td>$646,843</td>
<td>$405,329</td>
<td>$5,423,035</td>
</tr>
<tr>
<td>Total Operating Expenses</td>
<td>$3,743,504</td>
<td>$638,173</td>
<td>$21,064,145</td>
</tr>
<tr>
<td><strong>LOSS FROM OPERATIONS</strong></td>
<td>$(3,743,504)</td>
<td>$(638,173)</td>
<td>$(21,064,145)</td>
</tr>
<tr>
<td><strong>OTHER INCOME (EXPENSE)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest income</td>
<td>$28</td>
<td>$1,496</td>
<td>$88,891</td>
</tr>
<tr>
<td>Interest expense, including amortization and write-off of deferred financing costs and debt discounts</td>
<td>$(3,093,763)</td>
<td>$(513,724)</td>
<td>$(11,193,028)</td>
</tr>
<tr>
<td><strong>NET LOSS</strong></td>
<td>$(6,837,239)</td>
<td>$(1,150,401)</td>
<td>$(32,168,282)</td>
</tr>
<tr>
<td><strong>NET LOSS PER SHARE – BASIC AND DILUTED</strong></td>
<td>$(6.40)</td>
<td>$(1.37)</td>
<td></td>
</tr>
<tr>
<td><strong>WEIGHTED AVERAGE SHARES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outstanding – Basic and Diluted</td>
<td>1,067,937</td>
<td>842,149</td>
<td></td>
</tr>
</tbody>
</table>

Source: CorMedix Inc.
<table>
<thead>
<tr>
<th></th>
<th>March 31, 2010 (Unaudited)</th>
<th>December 31, 2009 (Note 1)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$11,724,713</td>
<td>$1,505,179</td>
</tr>
<tr>
<td>Prepaid research and development expenses</td>
<td>175,264</td>
<td>175,000</td>
</tr>
<tr>
<td>Other prepaid expenses and current assets</td>
<td>116,483</td>
<td>3,114</td>
</tr>
<tr>
<td>Total current assets</td>
<td>12,016,460</td>
<td>1,683,293</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>28,053</td>
<td>24,116</td>
</tr>
<tr>
<td>Deferred financing fees, net</td>
<td>—</td>
<td>506,510</td>
</tr>
<tr>
<td>Security deposits</td>
<td>25,075</td>
<td>11,733</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>$12,069,588</td>
<td>$2,225,652</td>
</tr>
<tr>
<td><strong>LIABILITIES AND STOCKHOLDERS’ EQUITY (DEFICIENCY)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>$1,045,746</td>
<td>$549,638</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>375,059</td>
<td>75,000</td>
</tr>
<tr>
<td>Senior Convertible Notes, net of discount</td>
<td>—</td>
<td>12,229,897</td>
</tr>
<tr>
<td>Interest payable – Senior Convertible Notes</td>
<td>—</td>
<td>2,393,132</td>
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<tr>
<td>Notes payable – related parties</td>
<td>—</td>
<td>535,428</td>
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<tr>
<td>Interest payable – related parties</td>
<td>—</td>
<td>97,456</td>
</tr>
<tr>
<td>Notes payable – Galenica, Ltd.</td>
<td>—</td>
<td>1,000,000</td>
</tr>
<tr>
<td>Interest payable – Galenica, Ltd.</td>
<td>—</td>
<td>54,000</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES</strong></td>
<td>1,420,805</td>
<td>16,934,551</td>
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<tr>
<td><strong>STOCKHOLDERS’ EQUITY (DEFICIENCY)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common Stock - $0.001 par value: 40,000,000 shares authorized, 11,408,288 shares issued and outstanding at March 31, 2010; 33,000,000 shares authorized, 787,010 shares issued and outstanding at December 31, 2009</td>
<td>11,408</td>
<td>787</td>
</tr>
<tr>
<td>Common Stock – Non-Voting Subordinated Class A, $0.001 par value: none authorized, issued, or outstanding at March 31, 2010; 5,000,000 shares authorized, 193,936 shares issued and outstanding at December 31, 2009</td>
<td>—</td>
<td>194</td>
</tr>
<tr>
<td>Deferred stock issuances</td>
<td>(27)</td>
<td>(27)</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>42,805,684</td>
<td>10,621,190</td>
</tr>
<tr>
<td>Deficit accumulated during the development stage</td>
<td>(32,168,282)</td>
<td>(25,331,043)</td>
</tr>
<tr>
<td><strong>TOTAL STOCKHOLDERS’ EQUITY (DEFICIENCY)</strong></td>
<td>10,648,783</td>
<td>(14,708,899)</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY (DEFICIENCY)</strong></td>
<td>$12,069,588</td>
<td>$2,225,652</td>
</tr>
</tbody>
</table>

* For greater information, please refer to Note 1 — Organization, Business, and Basis of Presentation on page 5 of the Company's Form 10-Q filed with the U.S. Securities and Exchange Commission on May 12, 2010.

Source: CorMedix Inc.
<table>
<thead>
<tr>
<th>Description</th>
<th>For the Three Months Ended March 31, 2010</th>
<th>For the Three Months Ended March 31, 2009</th>
<th>Period from July 28, 2006 (Inception) To March 31, 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CASH FLOWS FROM OPERATING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (6,837,239)</td>
<td>$ (1,150,401)</td>
<td>$ (32,168,282)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>122,817</td>
<td>20,426</td>
<td>588,212</td>
</tr>
<tr>
<td>Stock issued in connection with license agreements</td>
<td>2,587,576</td>
<td>—</td>
<td>6,983,370</td>
</tr>
<tr>
<td>Stock issued in connection with consulting agreement</td>
<td>130,091</td>
<td>—</td>
<td>158,262</td>
</tr>
<tr>
<td>Amortization of deferred financing costs</td>
<td>358,495</td>
<td>51,879</td>
<td>2,047,881</td>
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<tr>
<td>Amortization of debt discount</td>
<td>1,135,076</td>
<td>186,805</td>
<td>4,979,461</td>
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<tr>
<td>Non-cash charge for beneficial conversion feature</td>
<td>1,137,762</td>
<td>—</td>
<td>1,137,762</td>
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<tr>
<td>Non-cash interest expense</td>
<td>462,429</td>
<td>275,040</td>
<td>3,007,017</td>
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<tr>
<td>Expenses paid on behalf of the Company satisfied through the issuance of Notes</td>
<td>—</td>
<td>—</td>
<td>51,253</td>
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<tr>
<td>Depreciation</td>
<td>2,864</td>
<td>2,487</td>
<td>28,471</td>
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<tr>
<td>Changes in operating assets and liabilities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(113,633)</td>
<td>1,650</td>
<td>(291,747)</td>
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<tr>
<td>Security deposits</td>
<td>(13,342)</td>
<td>—</td>
<td>(25,075)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>496,108</td>
<td>70,925</td>
<td>1,045,746</td>
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<tr>
<td>Accrued expenses</td>
<td>300,059</td>
<td>—</td>
<td>375,059</td>
</tr>
<tr>
<td><strong>Net cash used in operating activities</strong></td>
<td>(230,937)</td>
<td>(541,189)</td>
<td>(12,082,610)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM INVESTING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchase of equipment</td>
<td>(6,799)</td>
<td>—</td>
<td>(56,522)</td>
</tr>
<tr>
<td><strong>Net cash used in investing activities</strong></td>
<td>(6,799)</td>
<td>—</td>
<td>(56,522)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM FINANCING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from Notes payable to related parties</td>
<td>—</td>
<td>—</td>
<td>2,465,749</td>
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<td>Proceeds from Senior Convertible Notes</td>
<td>—</td>
<td>—</td>
<td>13,364,973</td>
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<tr>
<td>Proceeds from Galenica, Ltd. Promissory Note</td>
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<td>—</td>
<td>1,000,000</td>
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<tr>
<td>Deferred financing costs</td>
<td>—</td>
<td>—</td>
<td>(1,447,400)</td>
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<tr>
<td>Repayment of amounts loaned under related-party Notes</td>
<td>—</td>
<td>—</td>
<td>(1,981,574)</td>
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<tr>
<td>Proceeds from sale of equity securities, net of issuance costs</td>
<td>10,457,270</td>
<td>—</td>
<td>10,457,270</td>
</tr>
<tr>
<td>Proceeds from receipt of stock subscriptions and issuances of Common Stock</td>
<td>—</td>
<td>—</td>
<td>4,827</td>
</tr>
<tr>
<td><strong>Net cash provided by financing activities</strong></td>
<td>10,457,270</td>
<td>—</td>
<td>23,863,845</td>
</tr>
<tr>
<td><strong>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</strong></td>
<td>10,219,534</td>
<td>(541,189)</td>
<td>11,724,713</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD</strong></td>
<td>1,505,179</td>
<td>1,380,012</td>
<td>—</td>
</tr>
<tr>
<td><strong>CASH AND CASH EQUIVALENTS – END OF PERIOD</strong></td>
<td>$ 11,724,713</td>
<td>$ 838,823</td>
<td>$ 11,724,713</td>
</tr>
<tr>
<td><strong>Supplemental Disclosure of Non-Cash Financing Activities:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conversion of Notes payable and accrued interest to Common Stock</td>
<td>$ 18,897,167</td>
<td>—</td>
<td>$ 18,897,167</td>
</tr>
<tr>
<td>Reclassification of deferred financing fees to additional paid-in capital</td>
<td>$ 148,014</td>
<td>—</td>
<td>$ 148,014</td>
</tr>
</tbody>
</table>

*Source: CorMedix Inc.*
Risks

Some information in this Executive Informational Overview® (EIO®) relates to future events or future business and financial performance. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in CorMedix's statements on Forms 424B4, 10-Q, and 8-K, as well as other forms filed from time to time. The content of this EIO® with respect to CorMedix has been compiled primarily from information available to the public released by the Company through news releases and U.S. Securities and Exchange Commission (SEC) filings. CorMedix is solely responsible for the accuracy of that information. Information about other companies has been prepared from publicly available documents and has not been independently verified by CorMedix. For more information about CorMedix, please refer to the Company’s website at www.cormedix.com.

One should carefully consider the risks and the information about CorMedix’s business described below. One should not interpret the order in which these considerations are presented as an indication of their relative importance. The risks and uncertainties described below are not the only ones the Company faces. Additional risks and uncertainties not presently known or those it currently considers immaterial may also have an adverse effect on its business. If any of the matters discussed in the accompanying risk factors were to occur, CorMedix’s business, financial condition, results of operations, cash flows, or prospects could be materially adversely affected.

RISKS RELATED TO CORMEDIX’S FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

CorMedix has a limited operating history and a history of escalating operating losses, and expects to incur significant additional operating losses.

The Company was established in July 2006 and has only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of the Company’s performance. CorMedix’s prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. As of March 31, 2010, the Company had an accumulated deficit of approximately $32.2 million. The Company expects to incur substantial additional operating expenses over the next several years as its research, development, preclinical testing, and clinical trial activities increase. The amount of future losses and when, if ever, it will achieve profitability are uncertain. CorMedix has no products that have generated any commercial revenue, does 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. The Company’s ability to generate revenue and achieve profitability will depend on the following, among other things: successful completion of product development; 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 activities. The Company might not succeed at these undertakings. If it is unsuccessful at some or all of these, its business, prospects, and results of operations may be materially adversely affected.

The Company is not currently profitable and may never become profitable.

CorMedix has a history of losses and expects to incur substantial losses and negative operating cash flow for the foreseeable future, and may never achieve or maintain profitability. Even if it succeeds in developing and commercializing one or more product candidates, CorMedix expects to incur substantial losses for the foreseeable future and may never become profitable. The Company also expects to continue to incur significant operating and capital expenditures and anticipates that its expenses will increase substantially in the foreseeable future as it continues to undertake development of product candidates, undertake clinical trials of product candidates, seek regulatory approvals for product candidates, implement additional internal systems and infrastructure, and hire additional personnel.

The Company also expects to experience negative cash flow for the foreseeable future as it funds operating losses and capital expenditures. As a result, CorMedix will need to generate significant revenues in order to achieve and maintain profitability. The Company may not be able to generate these revenues or achieve profitability in the future. A failure to achieve or maintain profitability would negatively impact the value of the Company’s securities.
The Company may need to finance its future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. Any additional funds that it obtains may not be on terms favorable to CorMedix or its stockholders and may require the Company to relinquish valuable rights.

To date, CorMedix has no approved product on the market and has generated no product revenues. Unless and until it receives approval from the FDA and other regulatory authorities for its product candidates, it cannot sell products and will not have product revenues. Therefore, for the foreseeable future, CorMedix will have to fund all of its operations and capital expenditures from the net proceeds of its March 2010 offering, cash on hand, licensing fees, and grants. For greater information on the offering, please refer to CorMedix’s Form 424B4 filed with the SEC on March 26, 2010.

The Company believes that the net proceeds from its offering and existing cash will likely be sufficient to fund its projected operating requirements through the first quarter 2012. However, CorMedix may need to raise additional funds more quickly if one or more of the Company’s assumptions prove to be incorrect or if it chooses to expand product development efforts more rapidly than presently anticipated. CorMedix may decide to raise additional funds even before needed if the conditions for raising capital are favorable.

The Company 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 CorMedix’s stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company’s operations. Raising additional funds through collaboration or licensing arrangements with third parties may require CorMedix to relinquish valuable rights to its technologies, future revenue streams, research programs, or product candidates, or to grant licenses on terms that may not be favorable to the Company or its stockholders.

CorMedix’s independent registered public accounting firm has identified material weaknesses in the Company’s financial reporting process.

CorMedix’s independent registered public accounting firm has identified material weaknesses in the Company’s financial reporting process with respect to lack of segregation of duties and lack of independent review over financial reporting. The Company’s independent registered public accounting firm also identified numerous errors in the accounting for non-routine, complex transactions during their audit of the Company’s financial statements. CorMedix’s failure to successfully implement its plans to remediate these material weaknesses could cause the Company to fail to meet reporting obligations, to produce timely and reliable financial information, and to effectively prevent fraud. Additionally, such failure could cause investors to lose confidence in the Company’s reported financial information, which could have a negative impact on financial condition and stock price.

RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF CORMEDIX’S PRODUCT CANDIDATES

CorMedix’s product candidates are still in development. The Company is a pharmaceutical company focused on the development of product candidates that are in various stages of development. Its products are currently at the following stages of development:

- **CRMD003 (CorMedix Neutrolin®)**—CorMedix intends to submit an Investigational Device Exemption (IDE) during 2010 to support a pivotal clinical trial;
- **CRMD004**—preclinical stage;
- **CRMD001**—CorMedix has begun a Phase II biomarker proof-of-concept study to support a Phase III trial for prevention of contrast-induced nephropathy (CIN); and
- **CRMD002**—preclinical stage.

The Company’s product development methods may not lead to commercially viable products for any of several reasons. For example, the Company’s product candidates may fail to be proven safe and effective in clinical trials, or CorMedix may have inadequate financial or other resources to pursue development efforts for its product candidates. The Company’s product candidates will require significant
additional development, clinical trials, regulatory clearances, and investment by the Company or its collaborators before they can be commercialized.

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

It is the Company’s 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 listed on page 46), CorMedix does not intend to consider the development of CRMD001 for the treatment of CKD until after data is generated with respect to the use of CRMD001 in the prevention of CIN. Moreover, even after that data is generated, the Company’s determination to develop CRMD001 for the treatment of CKD will depend on other relevant factors, including the Company’s access to capital, clinical and regulatory considerations regarding development of CRMD001 for the CKD indication, and the Company’s assessment of the then-current state of the intellectual property estate in CRMD001 with respect to both the CIN and the CKD indications. If CorMedix determines not to proceed with the development of CRMD001 for CKD, the size of the potential target population for CRMD001 will be reduced and the Company’s potential future revenues from CRMD001 may be adversely affected.

Successful development of the Company’s products is uncertain.

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; an inability to manufacture product candidates on a commercial scale independently or in collaboration with third parties; and a failure to achieve market acceptance.

Because of these risks, the Company’s 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, the Company’s business, financial condition, and results of operations may be materially harmed.

Clinical trials required for the Company’s product candidates are costly and time-consuming and their outcome is uncertain.

In order to obtain FDA approval to market a new drug or device product, CorMedix must demonstrate proof of safety and effectiveness in humans. To meet these requirements, the Company must conduct “adequate and well-controlled” clinical trials. Conducting clinical trials is a lengthy, time-consuming, and costly 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 CorMedix is directly conducting clinical trials may cause the Company to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including the following:

- an inability to manufacture sufficient quantities of qualified materials under the FDA’s current Good Manufacturing Practices (cGMP) requirements for use in clinical trials;
- slower than expected rates of patient recruitment;
- a 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 CorMedix obtains positive results from early clinical trials, it may not achieve the same success in later clinical trials.

The Company’s 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, the Company’s 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 the Company's products. The Company cannot ensure that safety issues will not arise with respect to its 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 the Company’s product candidates. Such a failure could cause CorMedix to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, the Company's clinical trials would delay the filing of New Drug Applications (NDAs) or Premarket Approval Applications with the FDA and, ultimately, the Company’s ability to commercialize product candidates and generate product revenues. Any change in, or termination of, the Company’s clinical trials could materially harm business, financial condition, and results of operations.

CorMedix does not have, and may never obtain, the regulatory approvals it needs to market its product candidates.

To date, CorMedix has not applied for nor received the regulatory approvals required for commercial sale of any of its products in the U.S. or in any foreign jurisdiction. None of the Company’s product candidates have been determined to be safe and effective, and CorMedix has not submitted an NDA or Premarket Approval Application to the FDA or an equivalent application to any foreign regulatory authority for any of its product candidates. It is possible that none of the Company’s 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 CorMedix or its partners develop, impose additional costs on the Company or its collaborators, diminish any competitive advantages that it or its partners may attain, and/or adversely affect the receipt of revenues or royalties.

Even if approved, the Company’s 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 the Company to enter into supply contracts, including government contracts. In addition, even if CorMedix complies 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 the Company’s products will depend on obtaining coverage and reimbursement for use of these products from third-party payors.

Sales of pharmaceutical products largely depend on the reimbursement of patients’ medical expenses by government healthcare programs and private health insurers. Without the financial support of the government or third-party payors, the market for the Company’s 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 U.S. healthcare system have included measures that would limit or eliminate payments for medical products and services or subject the pricing of medical treatment products to government control. Significant uncertainty exists as to the reimbursement status of
newly approved healthcare products. Third-party payors may not reimburse sales of the Company’s products or enable the Company’s collaborators to sell them at profitable prices.

Physicians and patients may not accept and use the Company’s products.

Even if the FDA approves one or more of the Company’s product candidates, physicians and patients may not accept and use it. Acceptance and use of the Company’s products will depend upon a number of factors including the following:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of the Company’s drug or device product;
- cost-effectiveness of the Company’s product relative to competing products;
- reimbursement availability for CorMedix’s product from government or other healthcare payors; and
- effectiveness of marketing and distribution efforts by CorMedix, its licensees, and distributors, if any.

Because CorMedix expects sales of its current product candidates, if approved, to generate substantially all of its product revenues for the foreseeable future, the failure of these products to find market acceptance would harm the Company’s business and could require it to seek additional financing.

RISKS RELATED TO CORMEDIX’S BUSINESS AND INDUSTRY

Competition and technological change may make the Company’s product candidates and technologies less attractive or obsolete.

The Company competes with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications CorMedix is pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than the Company does, obtaining FDA approval for products more rapidly, or developing products that are more effective than the Company’s product candidates. Research and development by others may render the Company’s technology or product candidates obsolete or non-competitive, or result in superior treatments or cures. The Company faces 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 CorMedix’s product commercialization efforts, which would result in a decrease in the revenue the Company would be able to derive from the sale of any products.

There can be no assurance that any of the Company’s product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if competitors’ products are approved before CorMedix’s, it could be more difficult for the Company to obtain approval from the FDA. Even if the Company’s products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept the Company’s 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 CorMedix from forecasting revenues or income with certainty or even confidence.

The Company faces the risk of product liability claims and may not be able to obtain insurance.

CorMedix’s business exposes it to the risk of product liability claims that are inherent in the development of drugs. If the use of one or more of the Company’s or its collaborators’ drugs harms people, CorMedix may be subject to costly and damaging product liability claims brought against it by clinical trial participants, consumers, healthcare providers, pharmaceutical companies, or others selling the Company’s products. Its inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products CorMedix develops, alone or with collaborators.
The Company currently does not carry clinical trial insurance or product liability insurance. The Company intends to obtain such insurance in the future. It cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage it holds may not be adequate to cover all liabilities it might incur. The Company intends to expand its insurance coverage to include the sale of commercial products if it obtains marketing approval for product candidates in development, but may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. If CorMedix is unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, it may be exposed to significant liabilities, which may materially and adversely affect the Company’s business and financial position. If CorMedix is sued for any injury allegedly caused by its or collaborators’ products and does not have sufficient insurance coverage, the Company’s liability could exceed total assets and its ability to pay the liability. A product liability claim or series of claims would decrease cash and could reduce the Company’s value or marketability.

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

CorMedix’s research, development, and manufacturing activities and/or those of the Company’s third-party contractors may involve the controlled use of hazardous materials and chemicals. Although the Company believes that its safety procedures for using, storing, handling, and disposing of these materials comply with federal, state, and local laws and regulations, it cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, CorMedix could be held liable for any resulting damages and any liability could materially adversely affect the Company’s 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 the Company to incur substantial compliance costs that could materially adversely affect its business, financial condition, and results of operations.

If CorMedix loses key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel, or experiences increases in compensation costs, the Company’s business may materially suffer.

The Company is highly dependent on the principal members of its management and scientific staff, specifically, John Houghton, chief executive officer (CEO); Brian Lenz, chief financial officer (CFO); and Dr. Mark Houser, chief medical officer (CMO). While CorMedix has employment agreements with such persons, employment agreements cannot ensure the Company’s retention of the employees covered by such agreements. Furthermore, CorMedix’s future success will also depend in part on its ability to identify, hire, and retain additional personnel. The Company experiences intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of its business. Moreover, the Company’s work force is located in the New York/New Jersey metropolitan area, where competition for personnel with the required scientific and technical skills is high and is likely to remain high. Because of this competition, the Company’s compensation costs may increase significantly. In addition, CorMedix has only limited ability to prevent former employees from competing with it.

If CorMedix is unable to hire additional qualified personnel, its ability to grow business may be harmed.

Over time, CorMedix 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. The Company competes for qualified individuals with numerous pharmaceutical companies, universities, and other research institutions. Competition for such individuals is intense, and CorMedix cannot be certain that the Company’s search for such personnel will be successful. Attracting and retaining such qualified personnel will be critical to the Company’s success.

The Company may not successfully manage growth.

CorMedix’s success will depend upon the expansion of operations and the effective management of growth, which will place a significant strain on management and administrative, operational, and financial resources. To manage this growth, CorMedix must expand facilities, augment operational, financial, and management systems, and hire and train additional qualified personnel. If the Company is unable to manage growth effectively, its business may be materially harmed.
RISKS RELATED TO CORMEDIX’S INTELLECTUAL PROPERTY

If CorMedix materially breaches or defaults under any of the Company’s license agreements, the licensor party to such agreement will have the right to terminate the license agreement, which termination may materially harm the Company’s business.

CorMedix’s commercial success will depend in part on the maintenance of its license agreements. Each license agreement provides the licensor with a right to terminate the license agreement for the Company’s material breach or default under the agreement. Particularly, the license agreement with Shiva Biomedical, LLC (the “Shiva Contribution Agreement”) provides for a right of termination for, among other things, the Company’s failure to perform the following: (1) initiate patient dosing in a proof-of-concept trial for a licensed product on or before June 30, 2010, and (2) initiate patient dosing in a pivotal trial on or before September 30, 2011. Additionally, the Company’s license agreement with Dr. Hans-Dietrich Polaschegg (the “Polaschegg License Agreement”) provides for a right of termination for, among other things, the Company’s 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 the following: (1) the date of the Polaschegg License Agreement; and (2) the priority date of any new patent. CorMedix’s intellectual property licensed under the Shiva Contribution Agreement serves as the basis for CRMD001 and CRMD002, and the Company’s intellectual property licensed under the Polaschegg License Agreement serves as a basis for CRMD004. Should the licensor party to any of the Company’s license agreements exercise such a termination right, CorMedix would lose its right to the intellectual property under the license agreement at issue, which loss may materially harm business.

If CorMedix and its licensors do not obtain protection for and successfully defend its respective intellectual property rights, competitors may be able to take advantage of the Company’s research and development efforts to develop competing products.

CorMedix’s commercial success will depend in part on obtaining further patent protection for its products and other technologies and successfully defending any patents that it currently has or will obtain against third-party challenges. The patents most material to the Company’s business are as follows:

- 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); and

- 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)—a family of patents related to the diagnosis and treatment of CKD and other kidney diseases and disorders (for CRMD001) (the “CKD patents”).

The Company is 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 CorMedix will be successful in protecting 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.

- Competitors, many of which have substantially greater resources than CorMedix and many of which have made significant investments in competing technologies, may seek, or may have already obtained, patents that will limit, interfere with, or eliminate the Company’s ability to make, use, and sell its potential products either in the U.S. or in international markets.

- There may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside of the U.S. for treatments that prove successful as a matter of public policy regarding worldwide health concerns.
Countries other than the U.S. may have less restrictive patent laws than those upheld by U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

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

The patent applications in the Company’s patent portfolio are exclusively licensed to CorMedix. To support its patent strategy, CorMedix has 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 the Company cannot provide assurances that a relevant patent office and/or relevant court will agree with its conclusions regarding patentability issues or with the Company’s conclusions regarding freedom to operate issues, which can involve subtle issues of claim interpretation and/or claim liability. Furthermore, CorMedix may not be aware of all patents, published applications, or published literature that may affect its business either by blocking the Company’s ability to commercialize product candidates, preventing the patentability of product candidates to the Company or its licensors, or covering the same or similar technologies that may invalidate the Company’s patents, limit the scope of future patent claims, or adversely affect ability to market the product candidates.

In addition, CorMedix also relies on trade secrets and proprietary know-how. Although the Company takes measures to protect this information by entering into confidentiality and inventions agreements with employees, scientific advisors, consultants, and collaborators, it cannot provide any assurances that these agreements will not be breached, that it will be protected from the harmful effects of disclosure if they are breached, or that its trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events occurs, or CorMedix otherwise loses protection for its 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 CorMedix’s business and prospects. There is a substantial risk that such protections will prove inadequate.

Intellectual property disputes could require CorMedix to spend time and money to address such disputes and could limit the Company’s 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. The Company may become subject to infringement claims or litigation arising out of patents and pending applications of the Company’s competitors, or additional proceedings initiated by third parties or the USPTO to reexamine the patentability of the Company’s licensed or owned patents. The defense and prosecution of intellectual property suits, USPTO 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 issued patents, to protect 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 USPTO proceedings to which CorMedix may become a party could subject the Company to significant liabilities, require it to obtain licenses from third parties, restrict or prevent the Company from selling products in certain markets, or invalidate or render unenforceable its 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 the Company’s paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

If CorMedix infringes the rights of third parties, it could be prevented from selling products and forced to pay damages and defend against litigation.

If the Company’s products, methods, processes, and other technologies infringe the proprietary rights of other parties, it could incur substantial costs and 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 the Company’s 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 the Company wins or loses, and which could result in a substantial diversion of financial and management resources.

RISKS RELATED TO CORMEDIX’S DEPENDENCE ON THIRD PARTIES

If the Company is not able to develop collaborative marketing relationships with licensees or partners or create an effective sales, marketing, and distribution capability, it may be unable to market products successfully.

CorMedix’s business strategy may rely on outlicensing product candidates to or collaborating with larger firms that have experience in marketing and selling pharmaceutical products. There can be no assurance that the Company will be able to successfully establish marketing, sales, or distribution relationships, that such relationships, if established, will be successful, or that it will be successful in gaining market acceptance for its products. To the extent that CorMedix enters into any marketing, sales, or distribution arrangements with third parties, its product revenues will be lower than if it marketed and sold the products directly, and any revenues it receives will depend upon the efforts of such third parties. If CorMedix is unable to establish such third-party sales and marketing relationships, or choose not to do so, the Company will have to establish its own in-house capabilities. The Company currently has no sales, marketing, or distribution infrastructure. To market any of its products directly, CorMedix 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 the Company’s costs, possibly requiring substantial additional capital. In addition, there is intense competition for proficient sales and marketing personnel, and the Company may not be able to attract individuals who have the qualifications necessary to market, sell, and distribute its products. There can be no assurance that the Company will be able to establish internal marketing, sales, or distribution capabilities. If CorMedix is unable to, or chooses not to establish these capabilities, or if the capabilities established are not sufficient to meet needs, the Company will be required to establish collaborative marketing, sales, or distribution relationships with third parties.

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

Completion of the Company’s clinical trials and commercialization of its product candidates require access to, or development of, facilities to manufacture a sufficient supply of product candidates. All of the manufacturing processes currently are, and CorMedix expects them to continue to be, outsourced to third parties. If, for any reason, the Company becomes unable to rely on current sources for the manufacture of product candidates, either for clinical trials or, at some future date, for commercial quantities, then it would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for preclinical, clinical, and commercial purposes. The Company may not be successful in identifying such additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that are identified. 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. The Company 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. If CorMedix is unable to secure and maintain third-party manufacturing capacity, the development and sales of its products and its financial performance may be materially affected.

Before CorMedix can begin to commercially manufacture product candidates, it must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with cGMP and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP
and non-U.S. regulatory requirements will require that the Company expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. The Company, or its 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 the Company’s products. If CorMedix fails to comply with these requirements, it would be subject to possible regulatory action and may be limited in the jurisdictions in which it is permitted to sell products. As a result, the Company’s 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 the Company’s products.

CorMedix’s operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on its entering into collaborations with corporations, academic institutions, licensors, licensees, and other parties. The Company’s current strategy assumes that it will successfully establish these collaborations or similar relationships. However, there can be no assurance that CorMedix will be successful establishing such collaborations. Some of the Company’s 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 the Company’s control and may not be within the Company’s power to influence. There can be no assurance that any collaborator will perform its obligations to the Company’s satisfaction or at all, that CorMedix will derive any revenue or profits from such collaborations, or that any collaborator will not compete with CorMedix. If any collaboration is not pursued, the Company may require substantially greater capital to undertake development and marketing of 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 CorMedix relies that has not been independently verified could turn out to be false, misleading, or incomplete.

The Company relies on third-party vendors, scientists, and collaborators to provide significant data and other information related to its projects, clinical trials, and business. If such third parties provide inaccurate, misleading, or incomplete data, the Company’s business, prospects, and results of operations could be materially adversely affected.

RISKS RELATED TO THE COMPANY’S INITIAL PUBLIC OFFERING (IPO) AND OWNERSHIP OF CORMEDIX’S SECURITIES

The Company is currently controlled by executive officers, directors, and principal stockholders, and its executive officers, directors, and principal stockholders will have significant influence regarding all matters submitted to stockholders for approval.

As of March 24, 2010, the Company’s directors, executive officers, and 5% or greater stockholders beneficially owned approximately 65.1% of the Company’s voting capital stock. Subsequent to the completion of the IPO, the Company’s directors, executive officers, and 5% or greater stockholders will, in the aggregate, beneficially own shares representing 4.0% of the Company’s voting capital stock, assuming such persons do not purchase any Units in the offering. As a result, if these stockholders were to choose to act together, they would be able to exercise significant influence with respect to all matters submitted to the Company’s stockholders for approval, as well as the Company’s management and affairs. For example, these persons, if they choose to act together, will exercise significant influence with respect to the election of directors and approval of any merger, consolidation, sale of all or substantially all of the Company’s assets or other business combination or reorganization. This concentration of voting power could delay or prevent an acquisition of CorMedix on terms that other stockholders may desire. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders, and might affect the prevailing market price for the Company’s securities.
There are certain interlocking relationships among the Company and certain affiliates of Paramount BioCapital, Inc., which may present potential conflicts of interest.

Lindsay A. Rosenwald, M.D. is the chairman, CEO, and sole stockholder of Paramount BioCapital, Inc. As of March 24, 2010, Dr. Rosenwald beneficially owned approximately 2.9% of the Company’s voting capital stock. In addition, as of March 24, 2010, certain trusts established for the benefit of Dr. Rosenwald and his family beneficially owned approximately 2.1% of the Company’s voting capital stock. Certain other employees of Paramount BioCapital, Inc. or its affiliates are also current stockholders and/or directors of CorMedix. Paramount Biosciences, LLC (PBS), of which Dr. Rosenwald is the sole member, and certain trusts established for the benefit of Dr. Rosenwald’s children also have loaned the Company amounts from time to time pursuant to the PBS Note and Family Trusts Note. On July 28, 2006, CorMedix issued a 5% Promissory Note payable to PBS, an affiliate of a significant stockholder of the Company. This Note and all accrued interest was scheduled to mature on June 15, 2009, or earlier if certain events occurred. The maturity date of this Note was extended until July 31, 2010. 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 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, which consist of 60,998 shares of Common Stock and 30,499 Warrants with an exercise price of $3.4375. On August 11, 2006, CorMedix issued a 5% Promissory Note payable to an entity related to the sole member of PBS. This Note and all accrued interest was to mature on August 11, 2009, or earlier if certain events occur. The maturity date of this Note was extended until July 31, 2010. On March 30, 2010, the principal and accrued interest amount under this Note was $452,007, which converted into 69,539 Units, which consist of 139,078 shares of Common Stock and Warrants to purchase 69,539 shares of Common Stock at an exercise price of $3.4375 in conjunction with the IPO.

Generally, Delaware corporate law, under which CorMedix is governed, requires that any transactions between the Company and any of its affiliates be on terms that, when taken as a whole, are substantially as favorable to CorMedix as those then reasonably obtainable from a person who is not an affiliate in an arms-length transaction. The Company believes that the terms of the agreements it has entered into with its affiliates satisfy the requirements of Delaware law, but in the event that one or more parties challenges the fairness of such terms, the Company could have to expend substantial resources in resolving the challenge and can make no guarantees as to the result. Furthermore, none of the Company’s affiliates, PBS, or Dr. Rosenwald is obligated pursuant to any agreement or understanding with CorMedix to make any additional products or technologies available to it, nor can there be any assurance, and the Company does not expect and purchasers of the Units should not expect, that any biomedical or pharmaceutical product or technology identified by such affiliates, PBS, or Dr. Rosenwald in the future will be made available to the Company. In addition, certain of the current officers and directors or certain of any officers or directors hereafter appointed may from time to time serve as officers or directors of other pharmaceutical or biotechnology companies. There can be no assurance that such other companies will not have interests in conflict with the Company’s own.

Provisions in the Company’s corporate charter documents and under Delaware law could make an acquisition of CorMedix, which may be beneficial to the Company’s stockholders, more difficult.

Provisions in the Company’s 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 the Company, even if such a change in control would be beneficial to the Company’s stockholders. These provisions include prohibiting the Company’s stockholders from fixing the number of the Company’s directors and establishing advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to the Company’s Board of Directors.

Section 203 of the DGCL prohibits a person who owns in excess of 15% of the Company’s outstanding voting stock from merging or combining with it for a period of three years after the date of the transaction in which the person acquired in excess of 15% of the outstanding voting stock, unless the merger or combination is approved in a prescribed manner. CorMedix has not opted out of the restrictions under Section 203.
An active trading market for the Company’s Common Stock and other securities may not develop.

The Company recently conducted its IPO of equity securities and prior to that, there has been no public market for its Common Stock or other securities. An active trading market for the Company’s Common Stock and other securities may never develop or be sustained. If an active market for the Company’s Common Stock and other securities does not develop, it may be difficult to sell securities without depressing the market price for such securities.

If the prices of the Company’s securities are volatile, purchasers of the securities could incur substantial losses.

The prices of the Company’s 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 paid in the IPO. The market prices of the Company’s securities may be influenced by many factors, including but not limited to the following:

- results of clinical trials of the Company’s product candidates or those of the Company’s competitors;
- the Company’s entry into or the loss of a significant collaboration;
- regulatory or legal developments in the U.S. and other countries, including changes in the healthcare payment systems;
- variations in the Company’s financial results or those of companies that are perceived to be similar;
- 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 the Company’s securities by CorMedix or its stockholders; and
- any other factors described in this Risk Factors section.

For these reasons and others, investors should consider an investment in the Company’s securities as risky and invest only if they can withstand a significant loss and wide fluctuations in the value of the investment.

CorMedix has broad discretion in its use of the net proceeds from the IPO.

Management will have broad discretion in the application of the net proceeds. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on business, cause the price of the Company’s securities to decline, and delay the development of product candidates. Pending the application of these funds, the Company intends to use the proceeds from the IPO as follows: (1) approximately $5.3 million for CRMD003 development; (2) approximately $1 million for CRMD001 development for the CIN indication; (3) approximately $100,000 for CRMD004 development; (4) approximately $100,000 for CRMD002 development; and (5) the balance to fund working capital and other general corporate purposes, which may include the acquisition or licensing of complementary technologies, products, or businesses. Because of the number and variability of factors that will determine the Company’s use of the proceeds, the ultimate use may vary substantially from the intended use.
A significant number of the Company's shares of Common Stock became eligible for sale upon the completion of the IPO and a significant number of additional shares may become eligible for sale at a later date. Their sale could depress the market price of the Company's Common Stock.

On March 24, 2010, the Company issued 1,925,000 Units in the IPO, which consisted of two shares of Common Stock and a Warrant to purchase one share of Common Stock. On May 13, 2010, the 1,925,000 Units issued in the IPO separated into 3,850,000 shares of Common Stock. Additionally, there are 7,564,627 shares, which are composed of shares issued to founders, licensors, and Noteholders that converted debt issued in previous private financing rounds, that are locked-up for 180 days after March 24, 2010, subject to saleable Rules 144 and 701. The Company also issued a Warrant to purchase 1,925,000 shares at an exercise price of $3.4375 and 2,406 Units to the underwriters 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 as part of the IPO.

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

To the extent that CorMedix raises additional capital by issuing equity securities, its stockholders may experience substantial dilution. The Company may sell Common Stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner it determines from time to time. If it sells Common Stock, convertible securities, or other equity securities in more than one transaction, investors may be further diluted by subsequent sales, which may also result in material dilution to the Company's existing stockholders, and new investors could gain rights superior to existing stockholders.

Pursuant to the Company's Amended and Restated 2006 Stock Incentive Plan, the Company's 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 the Company's officers, directors, and employees. As of March 31, 2010, Options to purchase 1,605,378 shares of Common Stock issued under the Amended and Restated 2006 Stock Incentive Plan at a weighted average exercise price of $3.20 per share, were outstanding. Stockholders will experience dilution in the event that additional shares of Common Stock are issued under the Amended and Restated 2006 Stock Incentive Plan, or Options previously issued or to be issued under the Amended and Restated 2006 Stock Incentive Plan are exercised. For greater information, please refer to the Company's Form 10-Q filed with the SEC on May 12, 2010.

If the Company's existing security holders exercise their registration rights, they may substantially reduce the market price of the Company's Common Stock. The existence of these rights may make it more difficult for CorMedix to effect future offerings.

Following the completion of the IPO, holders of 2,341,057 Units and holders of 1,748,371 shares of Common Stock became entitled to certain "demand" and "piggyback" registration rights. Additionally, a Warrant to purchase 2,406 Units issued to the underwriters as partial compensation for their services as underwriters will provide for certain "demand" and "piggyback" registration rights at the Company's expense with respect to the underlying shares of Common Stock during the five-year period commencing six months after the effective date.

If these holders exercise their registration rights with respect to all of their securities, then there would be up to an additional 6,430,485 shares of Common Stock eligible for trading in the public market. The presence of this additional number of shares of Common Stock eligible for trading in the public market may substantially reduce the market price of the Company's Common Stock. In addition, the existence of these holders' piggyback registration rights may make it more difficult for CorMedix to effect future public offerings and may reduce the amount of capital it is able to raise for its own account in these offerings.
The Company will incur significant increased costs as a result of operating as a public company, and management will be required to devote substantial time to new compliance initiatives.

As a public company, CorMedix will incur significant legal, accounting, and other expenses that it did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and NYSE Amex, have imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. CorMedix's management and other personnel will need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations will increase the Company's legal and financial compliance costs and will make some activities more time consuming and costly. The Company expects these rules and regulations to make it more difficult and more costly for it to obtain director and officer liability insurance and it may be required to incur substantial costs to maintain the same or similar coverage.

The Sarbanes-Oxley Act of 2002 requires, among other things, that CorMedix maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, the Company will be required to perform system and process evaluation and testing of internal control over financial reporting to allow management and possibly the independent registered public accounting firm to report, commencing in the Company's annual report on Form 10-K for the year ending December 31, 2011, on the effectiveness of internal control over financial reporting. To date, the independent registered public accounting firm has identified a number of deficiencies in the Company’s internal controls over financial reporting that it deemed to be material weaknesses. Compliance with Section 404 will require that CorMedix incur substantial costs and expend significant management efforts. The Company currently does not have an internal accounting group, and will need to hire additional accounting and financial staff. Moreover, if it is not able to comply with the requirements of Section 404 in a timely manner or if it is not able to remediate the material weaknesses identified by the independent registered public accounting firm, the market price of its stock could decline and it could be subject to sanctions or investigations by NYSE Amex, the SEC, or other regulatory authorities, which would require additional financial and management resources.

If securities or industry analysts do not publish research or reports or if they publish unfavorable research about the Company, the price of CorMedix’s Common Stock and other securities and their trading volume could decline.

The trading market for the Company’s Common Stock and other securities will depend in part on the research and reports that securities or industry analysts publish about CorMedix or its business. In the event CorMedix obtains securities or industry analyst coverage, if one or more of the analysts who covers the Company downgrades its securities, the price of the securities would likely decline. If one or more of these analysts ceases to cover the Company or fails to publish regular reports, interest in the purchase of the Company’s securities could decrease, which could cause the price of its Common Stock and other securities and their trading volume to decline.

CorMedix has never paid dividends and does not expect to pay dividends for the foreseeable future.

CorMedix has never paid dividends on the Company’s Capital Stock and does not anticipate paying any dividends for the foreseeable future.
**Recent Events**

**06/29/2010**—CorMedix Inc. announced that it was added to the broad-market Russell Microcap® Index when Russell Investments reconstituted its set of U.S. and global equity indexes on June 25, 2010. Russell indexes are used by investment managers and institutional investors for index funds and as benchmarks for both passive and active investment strategies.

**06/25/2010**—Announced dosing of the first patient with CRMD001 (a proprietary formulation of deferiprone) in a randomized, double-blind, placebo-controlled clinical trial. Greater details of the study are presented on pages 30-31.


Net loss for the first quarter 2010 was $6.8 million, or ($6.40) per diluted share, versus a net loss of $1.2 million, or ($1.37) per diluted share, for the first quarter 2009. The increase in net loss was primarily attributable to an increase of $2.9 million in research and development expense in the first quarter 2010 as a result of anti-dilution stock issuances to licensors in connection with the conversion of all outstanding convertible debt upon the closing of the initial public offering (IPO) and an increase of $2.6 million in interest expense during the quarter due to charges related to the amortization and write-off of deferred financing costs and debt discounts and beneficial conversion charges in connection with the debt conversion.

**05/07/2010**—Announced that the units issued in CorMedix’s recent IPO separate on May 13, 2010, instead of the scheduled separation date of May 23, 2010, following the determination by Maxim Group LLC, the representative of the underwriters of CorMedix’s IPO, that the earlier separation date is acceptable. Each unit consists of two shares of CorMedix’s Common Stock and a Warrant to purchase one share of Common Stock. Upon the commencement of trading on May 13, 2010, each unit automatically separated into its underlying two shares of Common Stock and one Warrant and the Common Stock and Warrants began trading separately on NYSE Amex under the symbols “CRMD” and “CRMD.WS,” respectively.

**04/20/2010**—Announced that the U.S. Patent and Trademark Office (USPTO) issued a patent for the use of Neutrolin® for preventing infection and clotting in hemodialysis catheters. The invention further relates to an improved composition for maintaining patency of indwelling catheters involved in central blood access. U.S. Patent No. 7,696,182 was issued to ND Partners, LLC, and expires in 2025. CorMedix holds an exclusive worldwide license with ND Partners to develop Neutrolin® for the prevention of catheter-related bloodstream infection (CRBSI).

**04/08/2010**—CorMedix visited the NYSE to celebrate the Company’s listing on March 25, 2010. In honor of the occasion, Mr. John C. Houghton, president and chief executive officer (CEO), rang the closing bell.

**03/25/2010**—Announced the pricing of its IPO of 1,925,000 units at $6.50 per unit (before underwriting discounts and commissions).
Anemia—A condition in which the number of red blood cells or the hemoglobin in the red blood cells is below normal. As a result, a person’s blood is too low in red blood cells to carry oxygen to their tissues, causing a number of symptoms, which may include weakness, pale skin, a fast heartbeat, shortness of breath, chest pain, dizziness, cognitive problems, numbness or coldness in the extremities, and headaches.

Angiography—An imaging procedure used to evaluate blood vessels.

Arrhythmias—An abnormal rate of muscle contractions in the heart.

Biomarker—A biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment.

Cardiac Ischemia—Not enough blood and oxygen flowing into the heart.

Cardiorenal—Of, relating to, or involving the heart and the kidney.

Carotene—An orange-yellow pigment usually found in vegetables. A precursor of vitamin A.

CE Mark—A European standard for medical devices, a CE Mark indicates that a device meets the requirements of the Medical Device Directive and appropriate Quality System standards.

Central Venous Catheters (CVCs)—Catheters (tubes) that are passed through a vein to the thoracic (chest) portion of the vena cava (the large vein returning blood to the heart) or the right atrium of the heart.

Chelator—A substance that binds particular ions, removing them from solution.

Chronic Kidney Disease (CKD)—A condition that occurs when the kidneys cannot do their job of cleaning blood of toxins and waste products.

Citrate—A compound of citric acid and a base. In the body, it is involved in blood coagulation (clotting) and the synthesis of fatty acids.

Coenzyme Q₁₀—A compound needed for the proper functioning of an enzyme; a protein that speeds up the rate at which chemical reactions take place in the body. Coenzyme Q₁₀ is used to produce energy to fuel cell growth and maintenance.

Contrast Media—Any internally administered substance that has a different opacity from soft tissue on radiography or computed tomography. This includes barium used to opacify parts of the gastrointestinal tract and water-soluble iodinated compounds used to opacify blood vessels or the genitourinary tract. It may also refer to air occurring naturally or introduced into the body and paramagnetic substances used in magnetic resonance imaging (MRI).

Contrast-induced Nephropathy (CIN)—Kidney damage caused by certain X-ray dyes.

Coronary Angiography—Used to identify the exact location and severity of coronary artery disease (CAD). During coronary angiography, a small catheter is inserted through the skin into an artery in the groin or the arm. Guided with the assistance of a special x-ray viewing instrument, the catheter is then advanced to the opening of the coronary arteries. A small amount of radiographic contrast is injected into each coronary artery. The images that are produced are called the angiogram. Angiographic images accurately reveal the extent and severity of all coronary arterial blockages.

Coronary Artery Bypass Graft—A form of bypass surgery that can create new routes around narrowed and blocked coronary arteries, permitting increased blood flow to deliver oxygen and nutrients to the heart muscle.
**Deferoxamine**—Iron-chelating agent used therapeutically to treat acute iron intoxication or chronic iron overload in transfusion-dependent patients.

**Diabetic Nephropathy**—The kidney disease associated with long-standing diabetes. It typically affects the network of tiny blood vessels (the microvasculature) in the glomerulus, a key structure in the kidney composed of capillary blood vessels. The glomerulus is critically necessary for the filtration of blood. Features of diabetic nephropathy include nephrotic syndrome with excessive filtration of protein into the urine (proteinuria), high blood pressure (hypertension), and progressively impaired kidney function. When it is severe, diabetic nephropathy leads to kidney failure, end-stage renal disease (ESRD), and the need for chronic dialysis or a kidney transplant.

**Endothelial**—Relating to the endothelium, which is the smooth inner lining of some body structures, including the heart (endocardium) and blood vessels.

**Erythropoietin (EPO)**—A glycoprotein secreted by the kidneys that stimulates the production of red blood cells.

**Ferritin**—An iron-containing protein complex found principally in the intestinal mucosa, spleen, and liver that functions as the primary form of iron storage in the body.

**Gadolinium**—A malleable, ductile metallic rare earth element used as a contrast medium for magnetic resonance imaging (MRI) and as a radioisotope in bone mineral analysis; atomic number 6.

**Glomerulonephritis**—A type of kidney disease in which the part of the kidneys that helps filter waste and fluids from the blood is damaged.

**Glutathione**—A tri-peptide of the amino acids glycine, cystine, and glutamic acid occurring widely in plant and animal tissues and forming reduced and oxidized forms important in biological oxidation-reduction reactions.

**Hemodialysis**—Dialysis of the blood to remove toxic substances or metabolic wastes from the bloodstream; used in the case of kidney failure.

**Heparin**—An anticoagulant medication. Heparin is useful in preventing thromboembolic complications (clots that travel from their site of origin through the bloodstream to clog another vessel). Heparin is also used in the early treatment of blood clots in the lungs (pulmonary embolisms).

**Hyperlipidemia**—High lipid (fat) levels in the blood.

**Investigational Device Exemption (IDE)**—Allows an investigational device to be used in a clinical study designed to collect safety and effectiveness data. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

**Investigational New Drug (IND)**—A drug that has not been approved for general use by the FDA but that is under investigation in clinical trials regarding its safety and efficacy. An IND must be approved by the FDA before clinical testing can begin.

**Left Ventricular Hypertrophy**—Thickening of the heart’s lower left chamber due to some disease that is blocking the blood outflow from the heart. It is often caused by high blood pressure, valvular disease, or coronary artery disease.

**Lovastatins**—One of the most often prescribed classes of medicines for patients with cardiovascular disease who need lower cholesterol levels are statins. Today’s main statin products include Lipitor®, Mevacor®, Zocor®, Pravachol®, Lescol® XL, and Crestor®. Statins function by slowing cholesterol production and increasing the liver’s ability to clear LDL from the blood. However, this class of medications is associated with several side effects, including neuropathy, depression, muscle weakness, and a possible increase in hemorrhagic stroke.
**Metabolic**—Relating to metabolism, the whole range of biochemical processes that occur within any living organism. Metabolism consists of anabolism (the buildup of substances) and catabolism (the breakdown of substances).

**Metanalysis**—A common technique in medical research whereby all data from all available studies of a subject are combined. The technique is used by researchers to obtain a maximum amount of statistical information (the most “power” possible), at times without considering data quality.

**Myocardial Microangiopathy**—Angiopathy means disease of the blood vessels (arteries, veins, and capillaries). There are two types of angiopathy: macroangiopathy and microangiopathy. With macroangiopathy, fat and blood clots build up in the large blood vessels, stick to the vessel walls, and block the flow of blood. With microangiopathy, the walls of very small blood vessels (capillaries) become so thick and weak that they bleed, leak protein, and slow the flow of blood. Myocardial microangiopathy occurs within the myocardium, which is the middle muscular layer of the heart wall.

**Nephrogenic Systemic Fibrosis**—A severe delayed fibrotic reaction of the body tissues to some gadolinium-based contrast media.

**Orphan Drug**—A designation of the FDA to indicate a therapy developed to treat a rare disease that affects fewer than 200,000 people or a common disease that has been ignored because it is less prominent in the U.S. than in developing nations.

**Oxidative Stress**—An increase in reactive oxygen species (ROS) and/or a decrease in the body’s antioxidant defense mechanisms.

**Parenteral**—Delivered by piercing mucous membranes or the skin barrier via needlesticks, human bites, cuts, and abrasions.

**Tachycardia**—Abnormally rapid heartbeat (over 100 beats per minute).

**Taurolidine**—An antibacterial and anti-endotoxic compound that is also being studied as a treatment for cancer. It belongs to the family of drugs called anti-infectives.

**Thalassemia Major**—A complex contingent of genetic disorders, all of which involve underproduction of hemoglobin.

**Thixotropic Gel**—A formulation that is viscous under normal conditions but is able to flow under conditions where pressure is applied.

**Vascular Access**—The ability to enter the vascular system; the ease with which the vascular system can be entered for administering therapy or obtaining blood for testing.
Intentionally Blank.
Legal Notes and Disclosures: This report has been prepared by CorMedix Inc. ("CorMedix" or "the Company") with the assistance of Crystal Research Associates, LLC ("CRA") based upon information provided by the Company. CRA has not independently verified such information. In addition, CRA has been compensated by the Company in cash of forty thousand dollars and five thousand shares for its services in creating this report, for updates, and for printing costs.

Some of the information in this report relates to future events or future business and financial performance. Such statements can be only predictions and the actual events or results may differ from those discussed due to, among other things, the risks described in CorMedix’s reports on Forms 424B4, 10-Q, 8-K, and other forms filed from time to time. The content of this report with respect to CorMedix has been compiled primarily from information available to the public released by the Company through news releases and SEC filings. CorMedix is solely responsible for the accuracy of that information. Information as to other companies has been prepared from publicly available information and has not been independently verified by CorMedix or CRA. Certain summaries of scientific activities and outcomes have been condensed to aid the reader in gaining a general understanding. For more complete information about CorMedix, the reader is directed to the Company’s website at www.cormedix.com. This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. Additional information about CorMedix and its public filings, as well as copies of this report, can be obtained in either a paper or electronic format by calling (908) 517-9500.