

# at a glance™



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**Recent Events:** CorMedix's lead product candidate, targeted to launch in Europe in 1H 2012, has shown in early clinical studies to prevent a leading cause of premature death and hospitalization among patients undergoing kidney dialysis; a Phase III pivotal trial for U.S. approval is expected to begin during 2H 2011, pending FDA approval; an approved SPA with FDA for a Phase III trial of the company's second development candidate is planned to start 1H 2012 pending review of Phase II results which are expected in 2H 2011. With a strong pipeline, CorMedix believes that its current market cap underscores an unusual investment opportunity. Both products have the benefit of significant market experience outside of the U.S. and defined FDA regulatory pathways, potentially reducing development risk.

## HIGHLIGHTS

- CorMedix has two thematically similar in-development products, both designed to prevent procedure-associated deaths and morbidity; that can be directly traced to or related to the performance of a medical procedure.

- The company's lead product candidate, Neutrolin® (*new-tro-lin*), if approved, is expected to be the first-ever U.S. approved product to reduce the rising number of premature deaths among kidney dialysis patients: through prevention of lethal bloodstream infections commonly contracted by dialysis patients. In this country 6,000 patients a year, an average of 16 each day, die from these infections. In Europe, the number of deaths is similar.

- The company plans to launch Neutrolin in Europe in 1H 2012 and to start a U.S. Pivotal Phase III registration trial 2H 2011 pending FDA approval.

- The company has several proprietary product candidates in clinical development that address large market opportunities, including its most advanced product candidates, Neutrolin and deferiprone.

- CorMedix's second late-stage product candidate, Deferiprone (*da-fera-prone*), is designed to prevent Contrast-Induced Nephropathy (CIN), a potentially fatal complication to the kidneys caused by the contrast dye used to visualize coronary vessels during angiograms and other X-ray procedures.

- CorMedix has received a SPA (Special Protocol Assessment) with FDA for a Phase III trial.

- CorMedix has just successfully completed patient enrollment in its Phase II proof of concept trial for deferiprone, an iron binding chemical

### CorMedix Inc. (AMEX: CRMD)

Recent Price:	\$1.45
Shares Outstanding:	11.4 million
Approx. MktCap:	\$16.5 million
Fiscal Year Ends:	Dec. 31

Published: July 2011

widely used for other indications. Data is expected to be reported during the 2H this year. Pending review of the Phase II results, the company plans to start a Phase III trial during 1H 2012.

- CorMedix raised \$10.5 million through an Initial Public Offering in March 2010. Management projects it has sufficient funding for its current clinical programs and operating requirements into 1Q 2012.

## NEUTROLIN

Neutrolin is proposed to prevent Catheter-Related Bloodstream Infections (CRBIs), a frequent procedure-associated complication among patients with chronic kidney disease who receive hemodialysis treatments utilizing a central venous catheter (CVC). The catheters are surgically implanted through the patient's chest into the jugular vein and heart in order to facilitate the rapid exchange of blood between the patient and the dialysis machine allowing for the filtering of blood which occurs during dialysis.

Typical clinical practice is to fill the inside of the catheter lumen, or tube, with heparin at the end of each hemodialysis session to prevent blood from clotting and clogging the line. Currently nothing is routinely added to prevent the formation of biofilm and the consequent build

up of bacteria and fungi on the lining of the catheter that can result in serious infections in the patient's bloodstream.

As a result, each chronic CVC dialysis patient (there are approximately 80,000 in the U.S.) is expected to typically experience an average of one to two potentially fatal bloodstream infections a year, for a total of 160,000 episodes annually; 1 in 13 patients or 6,000 are expected to die, putting the average daily death toll from these infections at 16. Treating the 160,000 episodes costs the U.S. healthcare system approximately \$1 billion annually.

The company is seeking approval for European marketing under a CE Mark in the first half of 2012. It plans to start a pivotal Phase III trial in the U.S. in the 2H 2011 pending FDA approval. The 15-month (9-month recruitment, 6 month treatment and follow-up) multi-center, double-blind, active-control, randomized study is expected to enroll approximately 400 patients. The company anticipates submitting the product for FDA approval as a medical device in early 2013. A resulting FDA approval would allow the launch of Neutrolin in the U.S. in late 2013.

Neutrolin combines a broad-spectrum antimicrobial (taurolidine) with two anticoagulants (heparin and citrate) to produce a novel combination solution which not only prevents the formation of toxic biofilm and consequent build up of bacteria and fungi in the catheter, but also prevents the catheter from clotting. The product is used as a "catheter lock" through

## Proposed Development Timelines

1H 2011:	Completed submission for European approval of Neutrolin
2H 2011:	Report data from Phase II of Deferiprone
2H 2011:	Start pivotal Phase III trial of Neutrolin
2H 2011:	Commence planning for pivotal Phase III of Deferiprone
1H 2012:	European approval/launch of Neutrolin
2H 2013:	Submit Neutrolin for FDA approval
2H 2013:	U.S. approval/launch of Neutrolin

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### Neutrolin In The Market

There are an estimated 12.5 million chronic CVC-based dialysis sessions annually in the U.S. Since heparin alone as the current standard of care "catheter lock" offers no protection against bloodstream infections, adoption of Neutrolin as the new standard of care would seem likely. The European market is slightly larger than the U.S. with an estimated 97,000 patients undergoing more than 14 million dialysis sessions annually using the CVC technique. A dialysis patient typically undergoes three treatments a week, each lasting approximately four hours.

The company believes that a growing focus on preventing hospital-acquired infections, as well as trends towards capitation rather than service-based payments for medical providers, is expected to lead to rapid acceptance of Neutrolin. The company also believes that introduction of an effective technique for the prevention of these procedure-associated infections is expected to lead to a rise in the percentage of patients who receive dialysis treatments through CVC (currently 25 percent) as opposed to surgically-created AV fistulas, which can be painful, unsightly and potentially unstable over time.

In addition to its use in dialysis, the company believes Neutrolin could also be effective in preventing bloodstream infections from other CVC-based treatments, including cancer chemotherapy, long term antibiotic therapy, total parenteral nutrition and other hospital-based intensive care treatments. In total, there are an estimated five million CVCs implanted in the US annually.

CorMedix holds six issued patents which provide protection for Neutrolin through 2019-2025.

injection into the catheter lumen following each dialysis treatment.

Neutrolin has been demonstrated to reduce infections by 90 percent or more in three earlier controlled studies. In one study, the product reduced the number of infection events per 1,000 days of dialysis treatments from 5.5 to 0.5 for the same group of patients. Following cessation of the Neutrolin treatments, the number of infections per 1,000 dialysis days rose back to 5.0.

Since it utilizes an antimicrobial rather than an antibiotic to prevent the formation of biofilm and build up of bacteria and fungi, there is far less likelihood of the

development of resistance to Neutrolin compared to antibiotics. Neutrolin's antimicrobial ingredient, taurolidine, also has an established safety history in humans, having been used in more than 14,000 patients for other conditions.

Each infection requires an extensive and costly course of treatment typically including hospitalization, removal of the existing catheter, antibiotic therapy and subsequent surgical re-implantation of a new catheter – all at a total cost to the U.S. healthcare system estimated at close to \$1 billion yearly.

### DEFERIPRONE

Deferiprone is CorMedix's other late stage pharmaceutical product candidate. It is being developed to prevent Contrast-Induced Nephropathy (CIN), a potentially fatal complication to the kidneys caused by iodinated contrast agents used in coronary angiograms and other X-ray procedures to image blood vessels.

There are approximately 4.6 million coronary and peripheral angiograms conducted annually in the U.S. Among this group, the initial target population for the deferiprone label for prevention of CIN is expected to be approximately 250,000 patients that are at high risk for developing CIN after coronary angiography only. Without deferiprone treatment, approximately 1/3 of these are expected to have significant associated morbidity and mortality. As many as a quarter of these

patients may die. Many experts agree that a large portion of these deaths are directly attributable to CIN. But because many of these patients suffer multiple maladies, their official cause of death is often recorded as something other than CIN.

There is accumulating evidence that iron plays an important role in the development of CIN as well as in the progression of chronic kidney disease. The company believes that Deferiprone, which binds or "chelates" iron, importantly "catalytic" iron, reducing oxidative stress and cellular injury, is expected to be an effective treatment for prevention of CIN. The product has a history of safe usage in more than 50 countries outside the U.S. for treatment of thousands of patients with other conditions. CorMedix has in-licensed method of use and formulation patents for deferiprone and is prosecuting a patent for this specific condition.

CorMedix has received an SPA with FDA for a Phase III trial; and has just successfully completed patient enrollment in its Phase II proof of concept trial for an eight-day oral treatment with deferiprone. It completed an interim analysis of safety and efficacy data in March 2011 and anticipates announcing final data and results for the trial during the second half of 2011.

The company plans to start a Phase III trial during the 1H 2012 pending review of the Phase II results.

There are no current or near-term pharmaceutical therapies for CIN.

### SUMMARY POINTS

- **CorMedix plans to commercialize its first product, Neutrolin, in Europe in 1H 2012, while conducting a Pivotal Phase III FDA registration trial planned for 2H 2011 in the U.S. pending FDA approval.**
- **Neutrolin may substantially reduce the occurrence of catheter-related bloodstream infections among kidney dialysis patients, which currently results in as many as 6,000 premature deaths a year in the U.S. and an equal or greater number in Europe. Currently, there is no approved product in the U.S. to prevent these infections.**
- **Neutrolin has been shown to reduce procedure-associated bloodstream infections in CVC dialysis patients by more than 90 percent.**
- **The company's second lead candidate, Deferiprone, is intended to prevent Contrast-Induced Nephropathy (CIN), a potentially fatal complication to the kidneys caused by angiograms and other X-ray procedures utilizing iodinated contrast dye. There are 150,000 cases of CIN annually in the U.S.; half of these patients die. There are no current or near-term pharmaceutical therapies for this condition.**
- **CorMedix has an approved SPA with FDA for a Phase III trial, and has recently completed patient enrollment of its Phase II trial of Deferiprone with expected data during the 2H 2011. The company plans to start a Phase III trial during the 1H 2012 pending review of the Phase II results.**

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