Zacks Small-Cap Research

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Nile Therapeutics, Inc. (NLTX-OTC)

NLTX: Expecting A Deal For Phase 2 In The Next Few Months…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/26/2010
Current Price (01/20/12)	$0.50
Target Price	**$2.00**

UPDATE

The phase 1 trial with Medtronic is complete. The data is being analyzed and talks continue for the phase 2 program. We expect that Medtronic will exercise its exclusive right to partner for the phase 2 program before the exclusivity period expires (mid-February 2012). The data and market potential with cenderitide are too intriguing to let go.

We view Nile Therapeutics as a high risk / high reward speculative play, where at $0.50 the stock is trading like a call option. With two potential indications and chances to partner cenderitide, the current market capitalization vastly under-values the potential in our view. We reiterate our 'Outperform' rating and $2 target.

SUMMARY DATA

52-Week High	**$0.88**
52-Week Low	**$0.48**
One-Year Return (%)	**-8.62**
Beta	**1.70**
Average Daily Volume (sh)	**15,293**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**23**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	0 A	0 A	0 A	0 A	0 A
2011	0 A	0.3 A	0.8 A	0.5 E	1.7 E
2012					2.5 E
2013					5.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.07 A	-$0.05 A	-$0.05 A	-$0.02 A	-$0.19 A
2011	-$0.03 A	-$0.03 A	-$0.03 A	-$0.04 E	-$0.13 E
2012					-$0.12 E
2013					-$0.05 E

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WHAT'S NEW

Phase 1 Complete

On November 16, 2011, Nile Therapeutics announced top-line data from its recently completed phase 1 clinical trial evaluating the pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability of subcutaneous bolus and subcutaneous infusion of cenderitide in patients with chronic heart failure. The trial was designed to understand the doses required to achieve pre-determined steady-state plasma levels of cenderitide when delivered through a subcutaneous infusion pump. The pump used in the trial was Medtronic's MiniMed Paradigm pump, most commonly used for delivering a continuous infusion of insulin.

The target cenderitide plasma levels in the trial were based on PK/PD data from previous phase 2 clinical trials in which cenderitide was delivered through continuous intravenous infusion. The phase 1 study enrolled a total of 58 patients and employed three parts:

Part A – A total of 12 patients received two subcutaneous bolus injections of cenderitide.
Part B – A total of 34 patients received a 24-hour continuous subcutaneous infusion of either of two fixed doses of cenderitide or placebo.
Part C – A total of 12 patients received a 24-hour continuous subcutaneous infusion of either a weight-based dose of cenderitide, or placebo.

The top line results from the phase 1 trial show that the primary end-point was met. Cenderitide achieved target steady-state PK/PD levels consistent with the previous phase 2 data when delivered through Medtronic's MiniMed Paradigm subcutaneous pump. Additionally, target bioavailability and stead-state PK levels were achieved when delivered through subcutaneous infusion. The drug was well-tolerated when delivered through a 24 hour subcutaneous infusion with no injection site irritation or adverse reaction. Finally, weight-based dosing reduced PK variability, as compared to a fixed dosing regimen.

…Waiting For Medtronic…

We expect full data coming in March 2012 at the American College of Cardiology (ACC) meeting. However, it is clear the trial was a success. Nile and Medtronic feel as though they understand the target dose range for continuous subcutaneous delivery of cenderitide when dosed continuously in the out-patient setting during the post-acute period. The next step for cenderitide would be a phase 2 trial in 2012 seeking to test the hypothesis that cenderitide can help reduce hospital re-admission in the post-acute period following ADHF.

In the press release on November 16, 2011, Medtronic mentions moving into this study. However, the collaboration between Nile and Medtronic (signed in February 2011) was for a phase 1 study only. Medtronic has 90 days to review the phase 1 data and make a decision on moving into phase 2. We think it is clear that they are interested in continuing to develop cenderitide. Nile and Medtronic are now negotiating on a longer-term licensing / collaboration. If a deal is not reached by the middle of February 2012, Nile can seek alternative partners.

From Niles's standpoint, we think it is wise for them to seek alternative partners. A deal is never done until it's signed. That being said, Medtronic probably feels pretty comfortable with their position. Nile is trading at only $0.50 today and will require significant cash to move cenderitide into phase 2 alone. Our best guess is that a deal with Medtronic eventually gets done, but it may not be until March 2012. We expect that Medtronic will pick up the bulk of the funding for the cenderitide phase 2 trial and pay Nile an upfront payment for the rights to the drug. If this next phase 2 trial is successful, we would then expect that Nile becomes an acquisition target by Medtronic.

…Next Step, Phase 2…

Once a deal is secured, we expect that the phase 2 program will begin quickly thereafter. The trial will most likely be a randomized, placebo-controlled, dose-ranging study seeking to evaluate the safety of continuous subcutaneous infusion of cenderitide in post-acute heart failure patients with systolic dysfunction. The primary endpoint of the study will be safety and tolerability compared to placebo, with key secondary endpoints in CV rehospitalization during the 120 day dosing window, renal function, left ventricular systolic volume, a 6 minute walk test, and started pharmacokinetic / pharmacodynamic parameters.

We expect that the phase 2 trial will employ a two-part approach. The first part of the trial will seek to enroll 96 patients testing 3 active doses of cenderitide (350 pg/ml, 600pg/ml, and 900pg/ml) vs. placebo. The infusion will past for 90 days, with follow-up at day 90 and day 120. Safety will be assessed by changes in blood pressure, left ventricle systolic function, and renal function (creatinine and cystatin-C levels). Patients will receive an echocardiogram at start and completion of the trial. The second part of the trial, we expect will seek to enroll another 200+ patients, with a narrowed dose down to one active group (with one of the above 3 selected). Again, safety will be the primary endpoint, with management looking to assess exploratory efficacy for the design of the phase 3 trial. We expect that part one of the phase 2 (phase 2a) will complete mid-2013 and part two (phase 2b) will complete around mid-2014. If all goes well, the phase 3 trials should start late 2014.

Nile Financial Situation

We forecast that Nile exited 2011 with just over $1 million in cash and investment. Burn should be pretty low for the first quarter 2012, and with a deal likely in February or March, investors shouldn't be overly concerned right now that Nile will run out of cash. We think a partner, most likely Medtronic, funds the bulk of the phase 2 trial. Nile will likely receive an upfront payment for the licensing deal, but then have to fund some of the phase 2 costs. Still, we do not see meaningful financing risk for Nile in the next month or two.

INVESTMENT THESIS

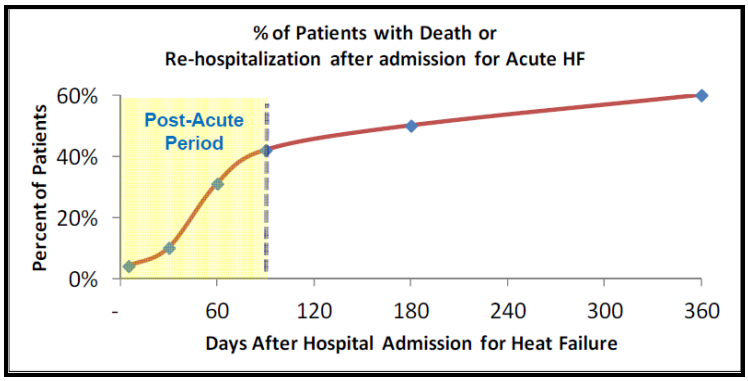
New Post-Acute Indication Takes Center Stage

We like the opportunity here for investors. Nile's stock is dirt cheap, trading with a market value of only $20 million. And, for a $0.50 stock, the risk is far less than one would assume. We see several reasons to own the stock.

There are an estimated 5 million Americans living with chronic heart failure (low cardiac output). Every year, approximately one-quarter (1.2 million) of these patients will suffer an acute exacerbation in which cardiac output decreases precipitously. The body's response to this rapid drop in cardiac output is often to retain fluid. This can manifest in the periphery (peripheral edema) or in the lungs (pulmonary edema). Standard of care once the patient reaches the hospital is to administer rescue medications such as intravenous furosemide (Lasix) and nitroglycerine. The furosemide is used to reduce the swelling and fluid retention by jump-starting the kidneys. Nitroglycerine is a powerful vasodilator used to relax blood vessels and easy pressure on the heart.

While these drugs are typically effective in reducing symptoms of the acute attack, they do little to improve long-term outcomes for patients with acute decompensated heart failure (ADHF), including death or rehospitalization, after discharge from the hospital. This "post-acute" period of approximately 90 days is the dangerous window between the attack and stabilization where patients are vulnerable to additional episodes of acute exacerbation.

Patient non-compliance with prescribed medication is among the chief reasons for the nearly 40% death or re-hospitalization rate during this "post-acute" phase. Once patients are discharged from the hospital they stop taking furosemide and nitroglycerine and return to their prescribed chronic medications, including beta-blockers, ACE inhibitors, ARB inhibitors, or cardiac-assist devices.



…Along Comes Natrecor…

In August 2001, a small biotechnology company, Scios Inc., received approval for what, at the time, was considered to be a major breakthrough for the treatment of ADHF in Natrecor (nesiritide). Nesiritide is the recombinant form of the 32 amino acid human B-type natriuretic peptide (BNP), which is normally produced by the ventricular myocardium. Nesiritide works to facilitate cardiovascular fluid homeostasis through counter-regulation of the renin-angiotensin-aldoesterone system, stimulating cyclic guanosine monophosphate, leading to smooth muscle cell relaxation. The product was believed to provide all of the vasodilating characteristics of nitroglycerine, with the diuretic and natriuretic properties of furosemide, while also reducing cardiac filling pressure. This was virtually a homerun in terms of treating patients with ADHF, as long as the risk of hypotension (low blood pressure) could be effectively managed. Scios was later acquired by Johnson & Johnson, in 2003 for $2.4 billion in cash. At the time the deal valued Scios at over 50x Natrecor's revenue.

Natrecor sales were annualizing over $400 million in 2004 and were on schedule to be the billion-dollar blockbuster J&J had anticipated. Unfortunately, in 2005, a meta-analysis of patient outcomes on Natrecor painted a very different profile than the drugs proposed mechanism. Use of Natrecor was identified with increased mortality and increased renal dysfunction compared to the standard of care. Natrecor was thought to increase GFR by causing dilation of the afferent renal arterioles and constriction of the efferent renal arterioles. BNP stimulation also leads to relaxation of renal mesangial cells, increasing the surface area for filtration, thus further increasing GFR. Unfortunately, there were significant indirect effects that actually lead to a decrease in GFR (worsening in renal function) in the real world setting. BNP, a rather potent vasodilator, lowers systemic blood pressure (SBP), decreasing renal blood flow and hence decreasing GFR. In addition, BNP inhibits angiotensin II production. Angiotensin II normally causes constriction of the efferent renal arterioles (increasing GFR). Inhibition of angiotensin II results in a decreased GFR.

In June 2005, the U.S. FDA and J&J issued a "Dear Doctor" letter reminding physicians that, "Nesiritide should be strictly limited to patients presenting to the hospital with acutely decompensated heart failure who have dyspnea at rest." The warning also urged physicians to consider the possible risks of the drug, and the availability of alternate therapies to relieve the symptoms of congestive heart failure. The warning finally noted that nesiritide should not be used for intermittent outpatient infusion, for scheduled repetitive use, to improve renal function, or to enhance diuresis. This was a significant blow to the sales prospect of the drug. Some even lobbied for the drugs withdrawal from the market. Sales plummeted.

Despite the "Dear Doctor" letter and meta-analysis, J&J was convinced Natrecor was good drug. In 2005 J&J initiated a massive cardiac outcome program, called ASCEND-HF, to prove that Natrecor was safe and effective. ASCEND-HF (Acute Study of Clinical Effectiveness of Nesiritide in Decompensated Heart Failure) was an enormous trial looking at the clinical effectiveness of nesiritide in decompensated heart failure. The program enrolled 7,141 patients at 398 clinical sites in 30 countries around the world, and cost an estimated $200 million to complete.

Unfortunately for J&J, and ADHF patient, results from ASCEND-HF were less than stellar. The data show that Natrecor is indeed safe to use in these patients, but has little effect on outcomes. The co-primary endpoint of the trial was 30-day all-cause mortality or heart failure rehospitalization.

ASCEND-HF	Natrecor	Placebo
30-Day Death	3.6%	4.0%
HF Rehospitalization	6.0%	6.1%
Cumulative Endpoint	**9.4%**	**10.1%**
(p=0.31) / Hazard Ratio 0.93 (95% CI: 0.8, 1.08)		

Secondary endpoints also failed to impress, including a lack of statistical significance in improvement in dyspnea (shortness of breath) at 6 and 24 hours:

ASCEND-HF	Natrecor	Placebo
Well Being at 6-hours	41.4%	40.3%
Well Being at 24-hours	65.7%	63.7%
Days alive and outside hospital	20.9 days	20.7 days
CV death or CV rehospitalization	10.9%	11.8%

Although safety concerns of renal dysfunction and mortality were quashed, hypotension was markedly higher for patients on Natrecor:

ASCEND-HF	Natrecor	Placebo
Any Hypotension	26.6%	15.3%
Asymptomatic Hypotension	21.4%	12.4%
Symptomatic Hypotension	7.1%	4.0%

The rise and fall of Natrecor (nesiritide) sent physicians back almost a decade in treating ADHF. Natrecor was headed towards blockbuster sales before the "Dear Doctor" letter ended its run. Nitroglycerin and furosemide returned as the standards of care despite significant limitations. Negative outcomes remain high, and the market for an effective product is still wide open.

…Nesiritide vs. Cenderitide…

Nesiritide is the recombinant form of the 32 amino acid human B-type natriuretic peptide (B-NP), which is normally produced by the ventricular myocardium. Nesiritide works to facilitate cardiovascular fluid homeostasis through counter-regulation of the renin-angiotensin-aldoesterone system, stimulating cyclic guanosine monophosphate, leading to smooth muscle cell relaxation. The product was believed to provide all of the vasodilating characteristics of nitroglycerine, with the diuretic and natriuretic properties of furosemide, while also reducing cardiac filling pressure. This was virtually a homerun in terms of treating patients with HF, as long as the risk of hypotension (low blood pressure) could be effectively managed.

Natrecor was thought to improved renal function by causing dilation of the afferent renal arterioles and constriction of the efferent renal arterioles. B-NP stimulation also leads to relaxation of renal mesangial cells, increasing the surface area for filtration, thus increasing glomerular filtration rate (GFR). Unfortunately, there were significant indirect effects that actually lead to a decrease in GFR (worsening in renal function) in the real world setting.

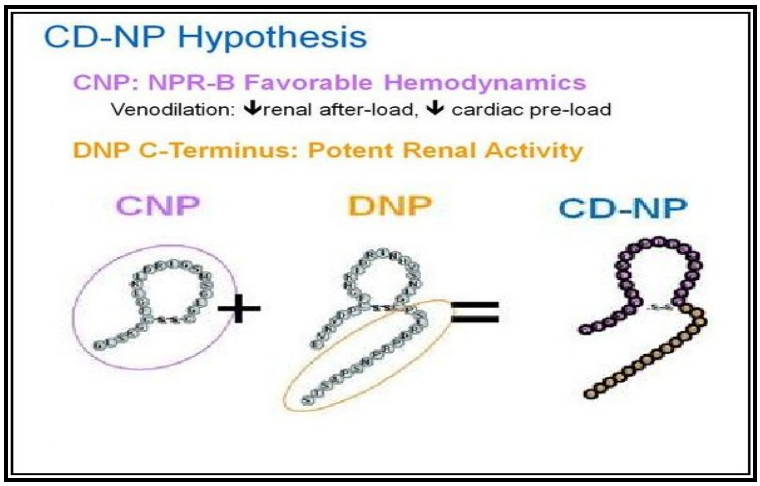
B-NP, a rather potent vasodilator, lowers systemic blood pressure, decreasing renal blood flow and hence decreasing GFR. In addition, B-NP inhibits angiotensin II production. Angiotensin II normally causes constriction of the efferent renal arterioles (increasing GFR). Inhibition of angiotensin II results in a decreased GFR.

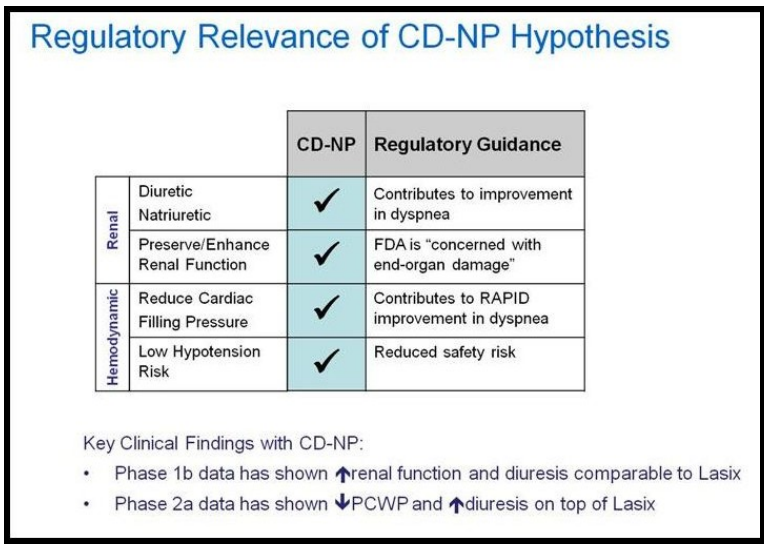
Cenderitide was rationally designed by scientists at the Mayo Clinic's cardio-renal research labs to overcome the issues that negatively impacted nesiritide. The candidate was designed to preserve the favorable effects of current therapies while eliminating or attenuating the hypotensive response, and enhancing or preserving renal function. Natriuretic peptides are naturally occurring proteins produced in the heart and blood vessels that cause natriuresis (the removal of sodium and water from the blood).

There are four naturally produced natriuretic peptides: atria "A-type" natriuretic peptide (ANP), brain "B-type" natriuretic peptide (BNP), cell "C-type" natriuretic peptide, (CNP), and dendroaspis "D-type" natriuretic peptide (DNP). These peptides possess potent natriuretic, diuretic, and vasodilating activities and are implicated in body fluid homeostasis and blood pressure control. Unlike ANP, BNP and DNP, CNP does not have direct natriuretic activity. This is because CNP is a selective agonist for the B-type natriuretic receptor (NPR_B) whereas ANP, BNP and DNP are selective for NPR_A. ANP, BNP and DNP have potent arteriodilation effects, whereas CNP has venodilation effects. ANP and BNP have direct renal effects offset by reduced renal perfusion. DNP, on the other hand is potent direct renal activator. CNP has no known renal effects.

Niles' CD-NP is a combination of two natriuretic peptides, CNP and DNP. The scientists at the Mayo Clinic developed the drug combining the n-terminus of the CNP molecule, preserving the favorable venodilating and hemodynamic properties of the molecule, with the c-terminus of the DNP molecule, preserving the potent direct renal activity. Preclinical data demonstrates the drug has both natriuretic and diuretic properties. Animal studies yielded very encouraging data with respect to improvement in GFR (improvement in renal function) and less risk of hypotension as compared to BNP. Preclinical data on the mechanism of action was published in the Journal of the American College of Cardiology (ACC), Vol. 52, No. 1, 2008.

…Rationally Designed…





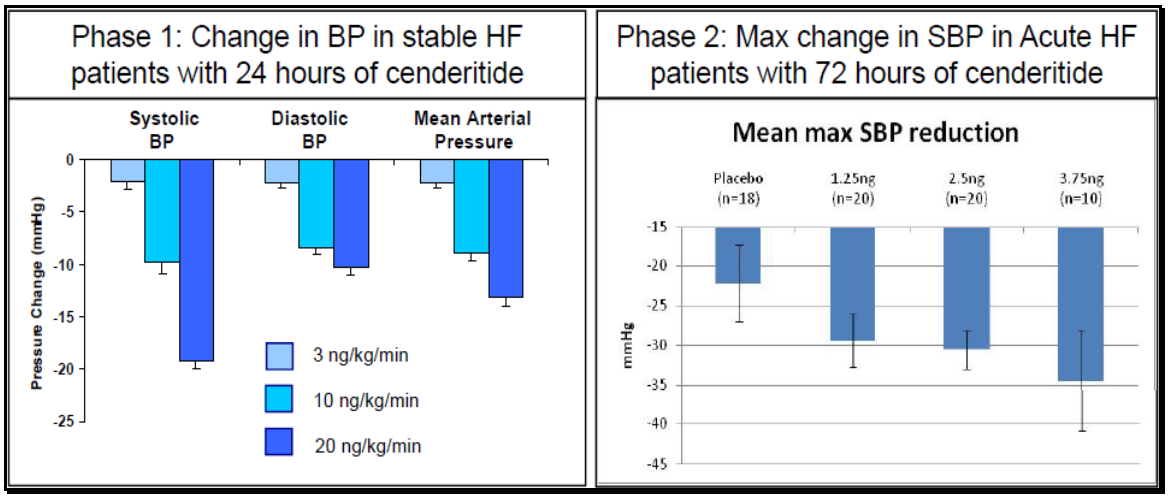
Natrecor and the ASCEND-HF program failed because B-NP has a negative effect on renal function. Prevalence and severity of renal dysfunction in patients with HF, along with mortality rate, demonstrates the relationship between worsening kidney function and heart failure. An effective HF drug must have preserve or enhance renal function. We believe the favorable hemodynamic effects of C-NP and the potent renal activity of D-NP combined to create the ideal treatment for ADHF.

Clinical Profile	Ideal Drug	Lasix	Nitro	Inotropes	Natrecor
Diuretic & Natriuretic	✓	✓	-	-	-
Preserve / Enhance Renal Function	✓	✗	-	✗	✗
Reduce Cardiac Filling Pressure	✓	✓	✓	✓	✓
Low Risk of Hypotension	✓	✓	✗	✓	-

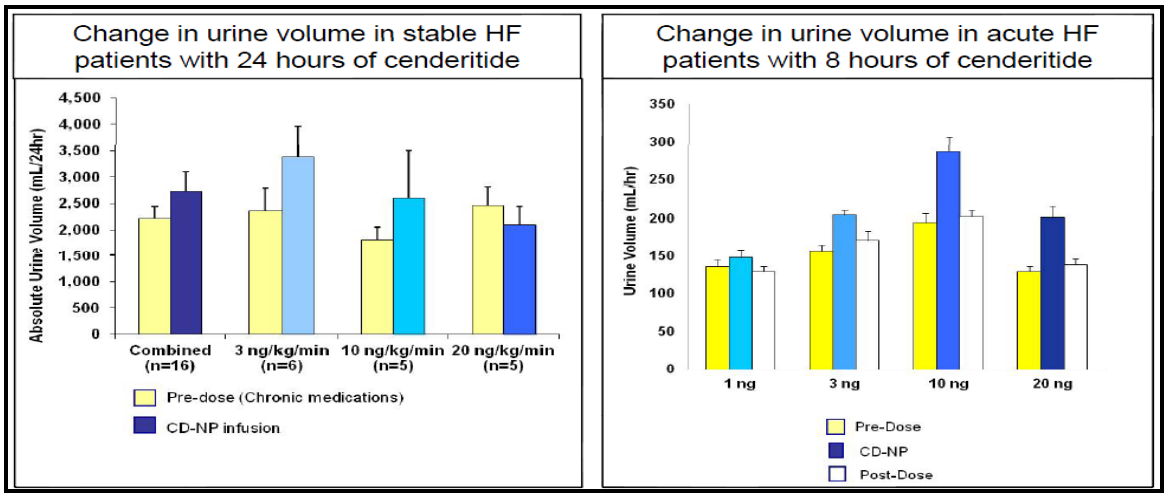
….Efficacy Confirmed In Previous Trials…

In November 2010, Nile presented encouraging data from a 77 patient phase 2a program with cenderitide in patients with ADHF and mild to moderate renal insufficiency. Patients received study drug for up to 72 hours and were followed for 30 days. The primary objective of the study was to assess the safety and tolerability of cenderitide in an ADHF population with renal insufficiency. Secondary endpoints included several assessments of drug activity.

Results demonstrated that multiple doses were characterized as well tolerated, with promising signs of favorable drug activity in this acute population. Specifically, cenderitide infusion at 1.25, 2.5 and 3.75 ng/kg/min appeared to be well tolerated. A dose-dependent effect on blood pressure was observed, with minimal or mild blood pressure reduction at 1.25 and 2.5 ng/kg/min, and moderate blood pressure reduction at 3.75 ng/kg/min. Dose escalation was limited by significant blood pressure reduction at 5 ng/kg/min.



Cenderitide has also demonstrated consistent signals of improved diuresis. Below are two charts from the previous clinical work with the drug showing increases in urine volume following dosing with cenderitide (CD-NP).

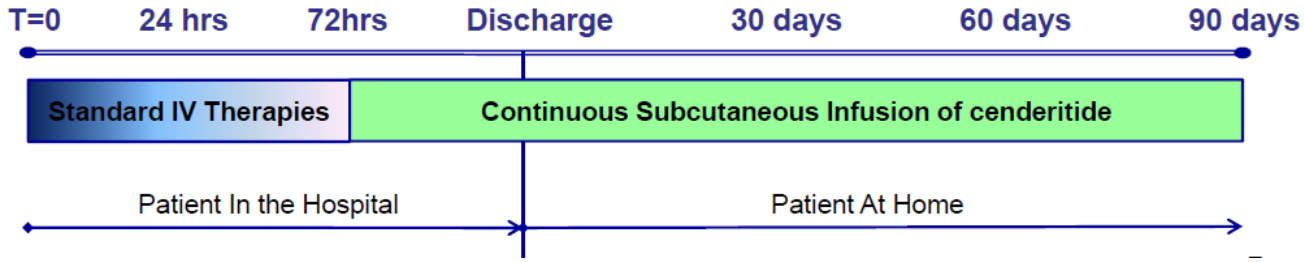


We think the data from the phase 2a study, which was presented at the 60th annual American College of Cardiology (ACC) meeting in April 2011, clearly show the drug has utility and warrants further clinical testing.

…What is "Post-Acute" Heart Failure…

Nile and Medtronic are looking at the potential to administer cenderitide continuously for 90-day using Medtronic's MiniMed Paradigm pump currently used for continuous infusion of insulin. The pump utilizes MiniMed's minimally invasive, subcutaneous micro-needle technology. If Nile can capture only 10% of the 1.2 million post-acute HF patients, at a cost of $5,000 per treatment, sales would be $600 million. We think the opportunity exists to charge even more for this therapy given the high burden and unmet medical need. The potential to use cenderitide in a post-acute indication is very exciting in our view. There are currently no approved heart failure drugs targeting cardio-renal improvement in an outpatient setting.





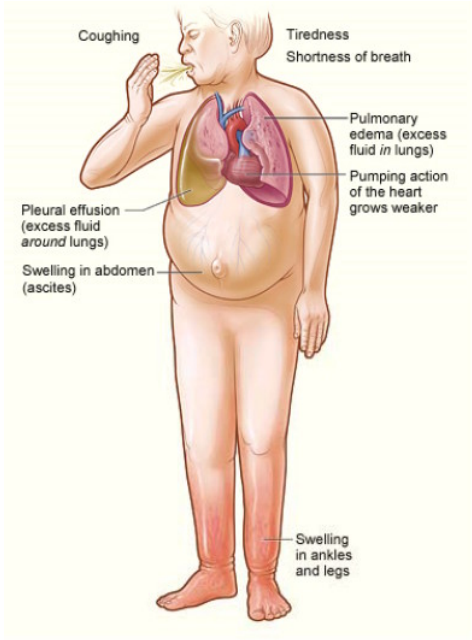
…A Potential Blockbuster Indication…

We believe this new "post-acute" indication could be a blockbuster opportunity for cenderitide. In the U.S., approximately 5 million people (~2% of the population) suffer from heart failure (HF). The incidence is even higher for patients above the age of 65, where approximately 6% to 10% of the population is at risk. There are an estimated 650,000 new cases diagnosed annually. Treatment of heart failure generates annual costs of approximately $35 billion, of which approximately $3 billion is spent on drugs and $19 billion is spent in the acute hospital setting.

…FDA Grants Fast Track Designation…

We also note that the U.S. FDA has taken a keen interest in cenderitide and been working with Nile on its early-stage development.

On March 31, 2011, the U.S. FDA granted Nile "Fast Track" designation for cenderitide for reducing cardiovascular mortality and cardiovascular re-hospitalization in the post-acute period in patients with acute decompensated heart failure.



- Fast Track is a designation that the FDA reserves for products that demonstrate the potential to address unmet medical needs for serious or life-threatening conditions. The Fast Track process is designed to facilitate the development and expedite the review of these products. In addition, sponsors of drugs that receive Fast Track designation can file a new drug application (NDA) on a rolling basis as data become available and have the possibility to be considered for Priority Review, which could reduce the time it takes the FDA to review the NDA from ten to six months.

RECOMMENDATION

Taking a Stab at Partnership Terms

There are four deals we are using as a basis for predicting what a potential partnership between Nile Therapeutics and a larger or specialty pharmaceutical company on cenderitide could look like:

- J&J acquires Scios for $2.4 billion in February 2003. J&J paid a very hefty premium for Scios and Natrecor back in 2003. At the time of the deal close, Natrecor had trailing twelve-month sales of only $50 million. However, the trajectory was straight up, and J&J had hopes that Natrecor was going to be a blockbuster. We note that J&J has not given up on Natrecor however. The company is current conducting a massive, 10,000 patient outcome study over a four year period with Natrecor called ASCEND-HF (Acute Study of Clinical Effectiveness of Nesiritide in Decompensated Heart Failure). ASCEND-HF is a testing lower doses of Natrecor with the goal to show reduced mortality. It began in September 2006 and is expected to offer data in November 2010 at the American Heart Association (AHA) meeting in Chicago.

- Merck acquires NovaCardia for $350 million in July 2007: Valuing Merck's purchase of NovaCardia is a little difficult because the company was privately-held at the time of the deal. NovaCardia's lead product candidate, rolofylline (MK-7418), was an adenosine A1 receptor antagonist in phase 3 clinical trials in patients with acute congestive heart failure (CHF). KW-3902 was believed to block adenosine-mediated constriction of blood flow to the kidneys and inhibit reabsorption of salt and water by the kidney, thereby increasing urine volume and maintaining renal function in patients with CHF. Merck believed they would be first to market with a vasodilator that demonstrated that helps preserve renal function. Unfortunately for Merck, the drug failed its phase 3 program (PROTECT-1 and PROTECT-2) and future development is on hold.

- Novartis acquires Corthera for $120 million in December 2009: Novartis scooped up Corthera, and its phase 3 candidate, relaxin, for the potential treatment of acute decompensated heart failure (ADHF) in late 2009. Relaxin, a naturally occurring hormone, is a potent vasodilator, which has shown in previous clinical trials to increase cardiac output after a 48-hour infusion post hospitalization for ADHF. The $120 million seems like a steal for Novartis until you factor in the potential $500 million in future milestones the company could still owe to Corthera shareholders upon successful commercialization of the drug.

- Amgen licenses CK-1827452 from Cytokinetics for up to $675 million in May 2009: CK-1827452 is a novel cardiac myosin activator that has been the subject of a clinical trials program comprised of multiple Phase 1 and Phase 2a trials. In December 2006, Amgen paid Cytokinetics $75 million through a $42 million technology access fee and a $33 million equity investment to commence the development plan for CK-1827452. In May 2009, Amgen exercised an option, paying Cytokinetics $50 million, to take over development. Amgen and Cytokinetics plan a phase 2b program for later in 2011. Cytokinetics can earn an additional $525 million in future development and commercialization milestones from Amgen.

It is clear that a post phase 2 candidate in this space is worth in the area of $350+ million. However, given the failures of the Merck deal, and what happened with Natrecor at J&J, we are not surprised at all to see Novartis acquire Corthera with a heavily back-end loaded milestone format. Amgen did the same thing with Cytokinetics. The first $75 million upfront was staggered between a technology fee and equity investment. The initial deal was done when CK-1827452 was only in phase 1 trials. Amgen came back three years later with another $600 million to secure the compound after phase 2a. Over the past year we seeing more pharma-biotech deals taking this upfront + future cash format. If management at Nile is looking to sell the entire company, we expect a similar type deal.

The question is when Nile looks to sell or partner? Obviously the farther along the development timeline management can take cenderitide, the more money they will command on the open market. This is what is particularly exciting about the phase 1 deal for the post-acute indication with Medtronic. Nile gets the potential to test its drug in a new, blockbuster, indication and Medtronic is paying for the study costs.

Positive phase 2 data with the acute or post-acute trial puts the value of the candidate at $90 to 100 million in our view. Not bad considering the current market capitalization is only $20 million. This is how we arrive at our $2 price target. We view Nile Therapeutics as a high risk / high reward speculative play, where at $0.50 the stock is trading like a call option.

PROJECTED FINANCIALS

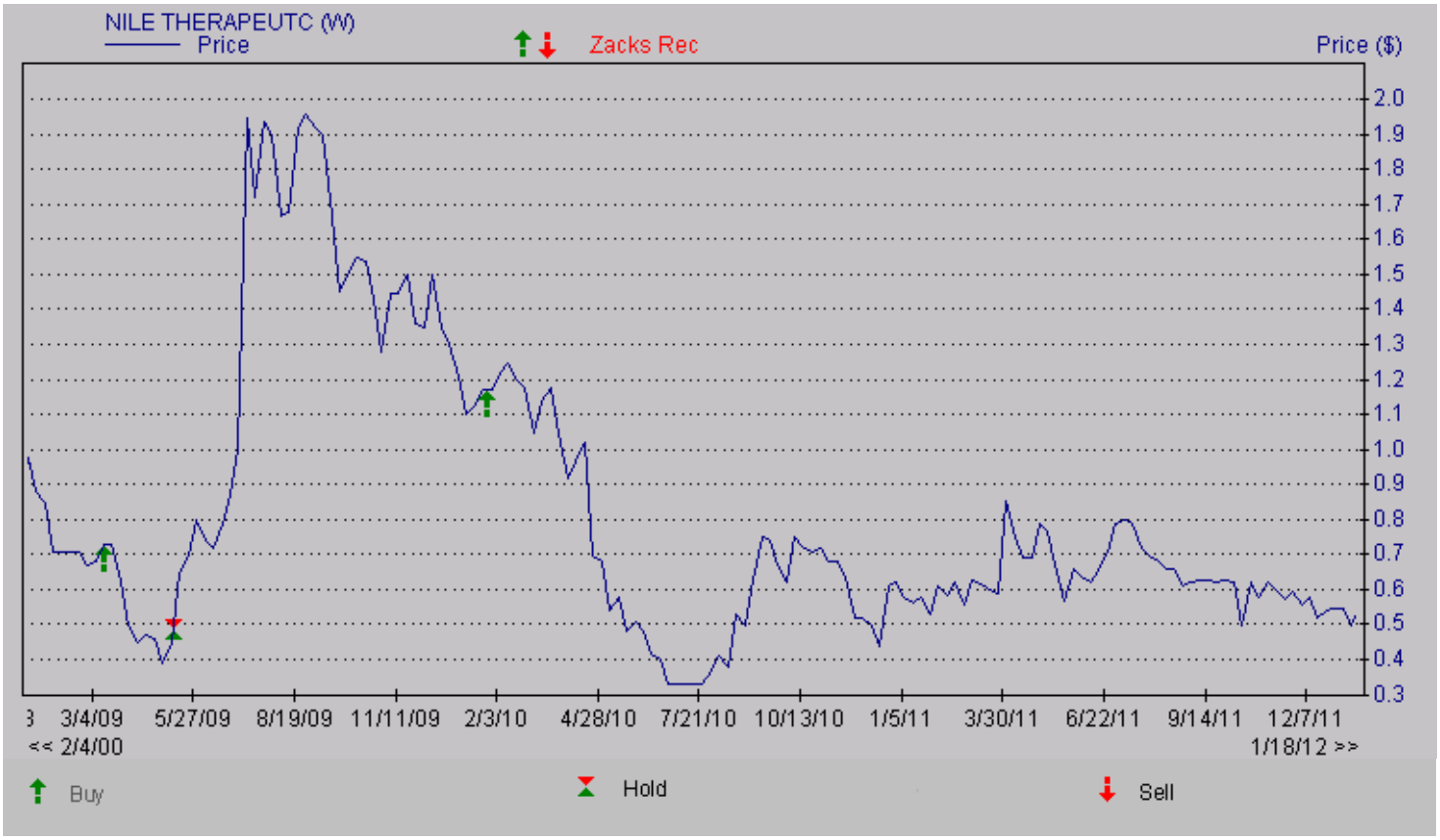
Nile Therapeutics, Inc.
Income Statement

	2009 A	2010 A	Q1 A	Q2 A	Q3 A	Q4 E	2011 E	2012 E	2013 E	2014 E
cenderitide (U.S. Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-
cenderitide (Row Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-
cenderitide (Royalties)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Grants, Licenses & Milestones	**$0**	**$0**	**$0**	**$0.3**	**$0.8**	**$0.5**	**$1.7**	**$2.5**	**$5.0**	**$5.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0.3**	**$0.8**	**$0.5**	**$1.7**	**$2.5**	**$5.0**	**$5.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
R&D	$4.5	$4.1	$0.6	$0.7	$1.5	$1.5	$4.3	$5.0	$5.0	$5.0
% R&D	-	-	-	-	-	-	-	-	-	-
SG&A	$3.4	$2.2	$0.6	$0.5	$0.5	$0.6	$2.2	$2.5	$2.5	$2.7
% SG&A	-	-	-	-	-	-	-	-	-	-
Operating Income	($7.9)	($6.3)	($1.2)	($0.9)	($1.2)	($1.6)	($4.8)	($5.0)	($2.5)	($2.7)
Operating Margin	*0%*	*0%*	-	-	-	-	*0%*	*0%*	*0%*	*0%*
Interest & Other Income	($0.1)	$0.3	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($7.9)	($6.0)	($1.2)	($0.9)	($1.1)	($1.6)	($4.8)	($4.9)	($2.4)	($2.6)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($7.9)	($6.0)	($1.2)	($0.9)	($1.1)	($1.6)	($4.8)	($4.9)	($2.4)	($2.6)
Net Margin	*0%*	*0%*	-	-	-	-	*0%*	*0%*	*0%*	*0%*
Reported EPS	**($0.31)**	**($0.19)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.04)**	**($0.13)**	**($0.12)**	**($0.05)**	**($0.05)**
YOY Growth	-	*-39.8%*	-	-	-	-	*-31.8%*	*-10.0%*	*-53.7%*	*-2.5%*
FAS-123R Expense	$2.2	$1.1	$0.3	$0.2	$0.2	$0.2	$0.9	$1.0	$1.5	$2.0
EPS Impact of FAS-123R	*($0.09)*	*($0.03)*	*($0.01)*	*($0.00)*	*($0.01)*	*($0.00)*	*($0.02)*	*($0.02)*	*($0.03)*	*($0.04)*
Weighted Ave. Shares Out	25.5	32.1	34.7	35.1	39.7	41.0	37.6	42.5	45.0	50.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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