Zacks Small-Cap Research

August 15, 2011
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# Nile Therapeutics, Inc. (NLTX-OTC)

***NLTX: Remaining Optimistic On Nile…***

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 01/26/2010 |
| Current Price (08/15/11) | $0.66 |
| **Target Price** | **$2.00** |

## UPDATE

Nile Therapeutics is developing cenderitide for the treatment of acute decompensated heart failure (ADHF). Management has presented positive data from a phase 2a program demonstrating safety and tolerability in an acute population, as well as clear signs of efficacy and biological activity. The company is currently seeking a partner for a larger-scale phase 2b program. Nile is also looking at the potential to treat patients post-acute with cenderitide on an out-patient basis using a subcutaneous micro-needle infusion pump. Medtronic is currently conducting a phase 1 pk/pd study in this population. We view Nile Therapeutics as a high risk / high reward speculative play, where at $0.66 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** | **$0.38** |
| **One-Year Return (%)** | **73.59** |
| **Beta** | **1.87** |
| **Average Daily Volume (sh)** | **22,483** |
| **Shares Outstanding (mil)** | **35** |
| **Market Capitalization ($mil)** | **$23** |
| **Short Interest Ratio (days)** | **0.25** |
| **Institutional Ownership (%)** | **13** |
| **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** |
| **Zacks Rank** | **2** |

| | |
|---|---|
| **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 | 0.2 E | 0.3 E | 0.8 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 E | -$0.02 E | -$0.11 E |
| 2012 | | | | | -$0.07 E |
| 2013 | | | | | -$0.02 E |

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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## WHAT'S NEW

**Second Quarter Financials**

On August 15, 2011, Nile Therapeutics reported financial results for the second quarter 2011. Total revenues in the quarter were $0.3 million, and consisted of reimbursement of expenses for the ongoing phase 1 trial with cenderitide from partner Medtronic. Operating expenses totaled $1.2 million in the quarter, in-line with expectations. Net loss for the quarter was $0.9 million, or $0.03 per share. This was also in-line with expectations.

Nile exited the second quarter with $3.3 million in cash. We forecast that this is enough cash to fund operations into the second quarter 2012. As a reminder, on June 23, 2011, Nile raised $2.5 million in proceeds through a private placement of 5.0 million shares of common stock and five-year warrants to purchase an additional 2.5 million shares of common stock. Data from the phase 1 study should be available by the end of the year. Medtronic would then have three months to review the data and make a decision to partner for phase 2. If the data is positive, we would be surprised to see Medtronic pass up on the opportunity to scoop-up Nile at such a discounted price.

**Phase 1 "Part-B" Rolling Ahead**

All patients in the low dose cohort of Part B have been enrolled. As a reminder, in Part B of the trial, patients receive a 24-hour continuous infusion of either cenderitide or placebo, delivered through Medtronic's subcutaneous (MiniMed Paradigm) pump technology. We are expecting around 30 patients in Part B of the trial. We expect enrollment in the higher dose cohort will complete in October 2012, with top-line data later in the fourth quarter 2011. We expect full data coming in March 2012 at the American College of Cardiology (ACC) meeting.

We remind investors that Part A of the study evaluated the pharmacokinetics of administering cenderitide through two subcutaneous bolus injections. The goal was to show bioavailability and safety at a level that provided a strong therapeutic window at an effective cost. Based on comments from Medtronic's VP of Clinical Research, Hsiao Lieu, MD, we believe Part A clearly obtained its goal.

The primary purpose of the trial is to understand the doses required to achieve pre-determined plasma levels of cenderitide delivered through a subcutaneous infusion pump and the pharmacodynamic activity at these doses. Costs of the phase 1 trial are being reimbursed by Medtronic (we estimate around $2 million). As a result, Nile has agreed to not partner cenderitide with any other company while the trial is ongoing. This exclusivity period expires three months after the delivery of the phase 1 data to Medtronic, or in May 2012. We think based on the current enrollment pace, the three month post data delivery expiration will come long before May 2012.

The next step for cenderitide would be a phase 2b trial in 2012. Following release of the phase 1 data later this year, we expect that Nile and Medtronic will begin negotiating on a longer-term licensing / collaboration for the phase 2b trial. We would not be surprised to see an outright acquisition of Nile by Medtronic if the stock price remains this low, assuming the phase 1 data shows encouraging results. We believe Nile is vastly under-valued at today's price.

## INVESTMENT THESIS

**New Post-Acute Indication Takes Center Stage**

On February 28, 2011, Nile Therapeutics announced it will begin development of cenderitide (formerly CD-NP) in a new indication, seeking to treat patients with acutely decompensated heart failure (ADHF) on an outpatient basis for up to 90 days after discharge from the hospital. As a reminder, Nile previously studied cenderitide in a phase 2a trial in acute ADHF on an in-hospital basis.

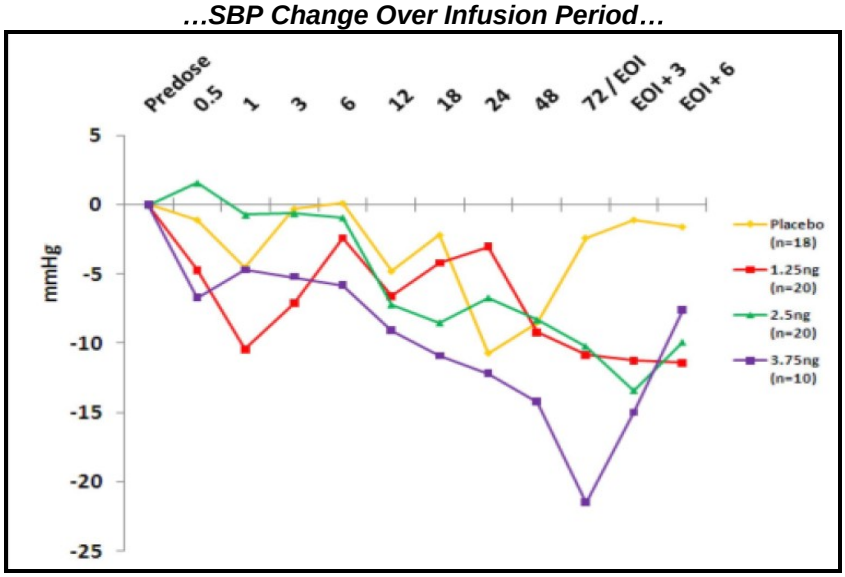
We like the opportunity here for investors. Nile's stock is dirt cheap, trading with a market value of only $26 million. And, for a $0.66 stock, the risk is far less than one would assume. We see several reasons to own the stock.

***….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.

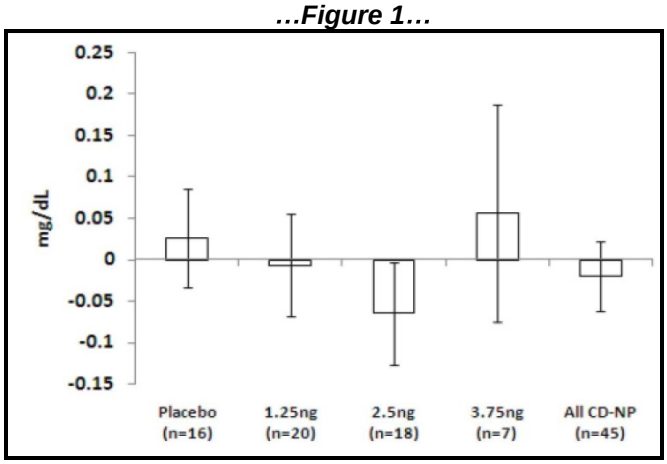
Results demonstrated that multiple doses were characterized as well tolerated, with promising signs of favorable drug activity in this acute population. Specifically, cenderitide infusion at 1.25, 2.5 and 3.75 ng/kg/min appeared to be well tolerated. A dose-dependent effect on blood pressure was observed,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

***…SBP Change Over Infusion Period…***

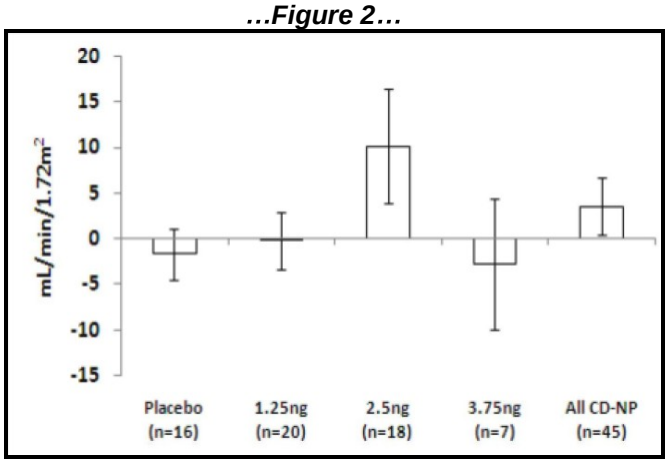



Secondary analyses demonstrated favorable effects of cenderitide on renal function, particularly at the 1.25 and 2.5 ng/kg/min doses. There was a trend for improved renal function at lower doses (1.25 and 2.5 ng/kg/min) by the end of infusion relative to placebo (Figure 1). In the 3.75 ng cohort, serum creatinine increased from baseline presumably because the blood pressure lowering effect of this dose off set any direct renal enhancing actions of cenderitide. Mean eGFR showed the greatest improvement at the 2.5 ng cohort (Figure 2).There was no change at the 1.25 ng dose.

***…Figure 1…***




***…Figure 2…***




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. We are particularly excited about moving the drug from the “acute” to “post-acute” setting because of the larger patient population and lack of available effective treatment options.

As noted above, Part A of the ongoing phase 1 with Medtronic was designed to study the pharmacokinetics and bioavailability of a bolus injection of cenderitide. We believe moving into Part B of the trial clearly demonstrates the type of pharmacokinetics and bioavailability Nile and Medtronic were looking for (i.e. a wide therapeutic window with a reasonable manufacturing cost).

***…A Potential Blockbuster Indication…***

We believe this new "post-acute" indication could be a blockbuster opportunity for cenderitide. In the U.S., approximately 5.5 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.

HF patients frequently suffer acute episodes of decompensated heart failure (ADHF) which require hospitalization. Each year, HF is responsible for over 1.2 million hospitalizations. For Americans over the age of 65, ADHF is the most frequent cause of hospital admission, and the incidence has doubled in the past 15 years. The average length of hospital stay is 4.3 days. Subsequent to a discharge for ADHF, the average time to re-admission is 3 months and mortality is high. In fact, 50% of patients discharged with a primary or secondary code of ADHF will require re-hospitalization during the following 9 months. Mortality at 1-year is over 10%.

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.



***…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 and Medtronic 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.

***…Cash Not A Concern, For Now…***

Management will be the first to admit, they do not have the funds to take cenderitide to the market. Funding a phase 2b and phase 3 trial with cenderitide could cost over $100 million. We point to J&J's recent ASCEND-HF trial looking at the clinical effectiveness of Natrecor (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. J&J initiated the program in 2005, and just presented the data in March 2011.

What Nile needs to fund, however, is its overhead operations for the next 3 months while the phase 1 trial is ongoing. Then the company needs an additional 6 months of cash to negotiate with Medtronic or a new partner for phase 2. We believe Nile has sufficient cash to get this done.

***…A Deal Likely…***

Partnering remains the end-game for Nile. As noted above, the company has enough cash to make it through the third quarter 2012. Based on when we expect the data from phase 1, Nile will have the first quarter 2012 to negotiate with Medtronic, and then the second quarter 2012 to negotiate with new partners if Medtronic is not interested. Based on comments from Medtronic management, we believe Medtronic is already in the initial planning stage for the phase 2b trial. We do not expect Medtronic to let their exclusivity period expire without a deal. We expect a full licensing agreement sometime during the first half of 2012.

## INVESTMENT OVERVIEW

**Not All Heart Drugs Are Created Equally**

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. In our view, the market for an effective product is wide open. The objectives are simple, increase cardiac output while offloading fluid and preserving renal function.

But it is now becoming clear that the failure of Natrecor (nesiritide) is impacting the potential out-licensing of cenderitide. Nile's hopes for a deal with cenderitide seems to have been hurt by the recent "less-than-stellar" ASCEND data out of J&J on Natrecor. Investors and potential partners are grouping the two products together, assuming that if Natrecor failed, cenderitide will follow the same path. For a little background info on ASCEND:

- 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. J&J initiated the program in 2005, shortly after physicians began having concerns over the safety of Natrecor in acutely decompensated population.

Results from ASCEND-HF demonstrated 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% |

***…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.

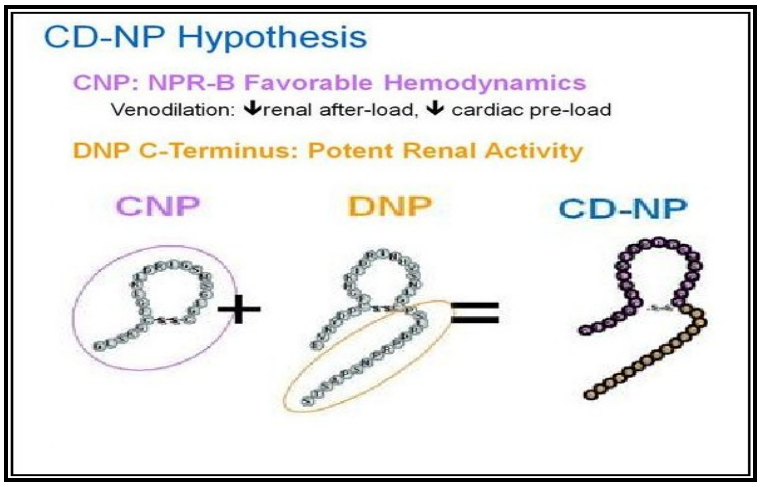
B-NP, a rather potent vasodilator, lowers systemic blood pressure, decreasing renal blood flow and hence decreasing GFR. In addition, B-NP inhibits angiotensin II production. Angiotensin II normally causes constriction of the efferent renal arterioles (increasing GFR). Inhibition of angiotensin II results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

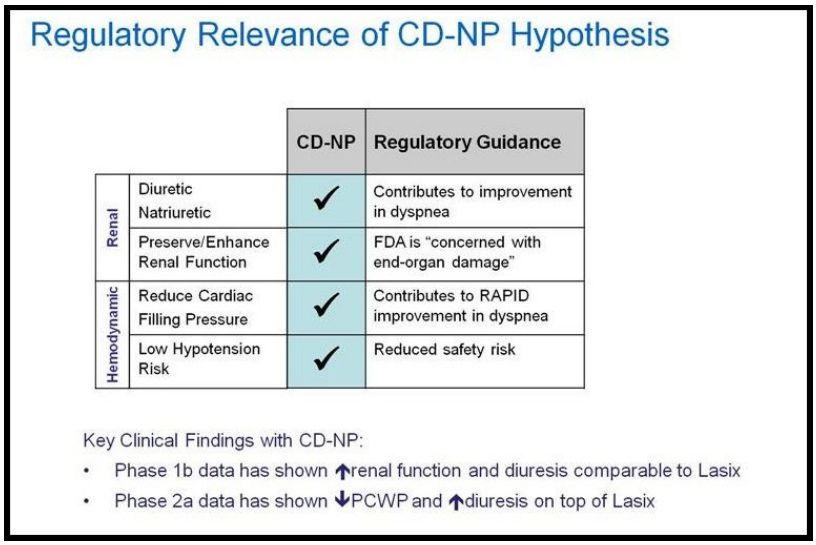
Cenderitide was rationally designed by scientists at the Mayo Clinic's cardio-renal research labs to overcome the issues that negatively impacted nesiritide. The candidate was designed to preserve the favorable effects of current therapies while eliminating or attenuating the hypotensive response, and 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* | ✓ | ✓ | ✗ | ✓ | - |

## 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 2b 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 $26 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 $0.66 the stock is trading like a call option.

## PROJECTED FINANCIALS

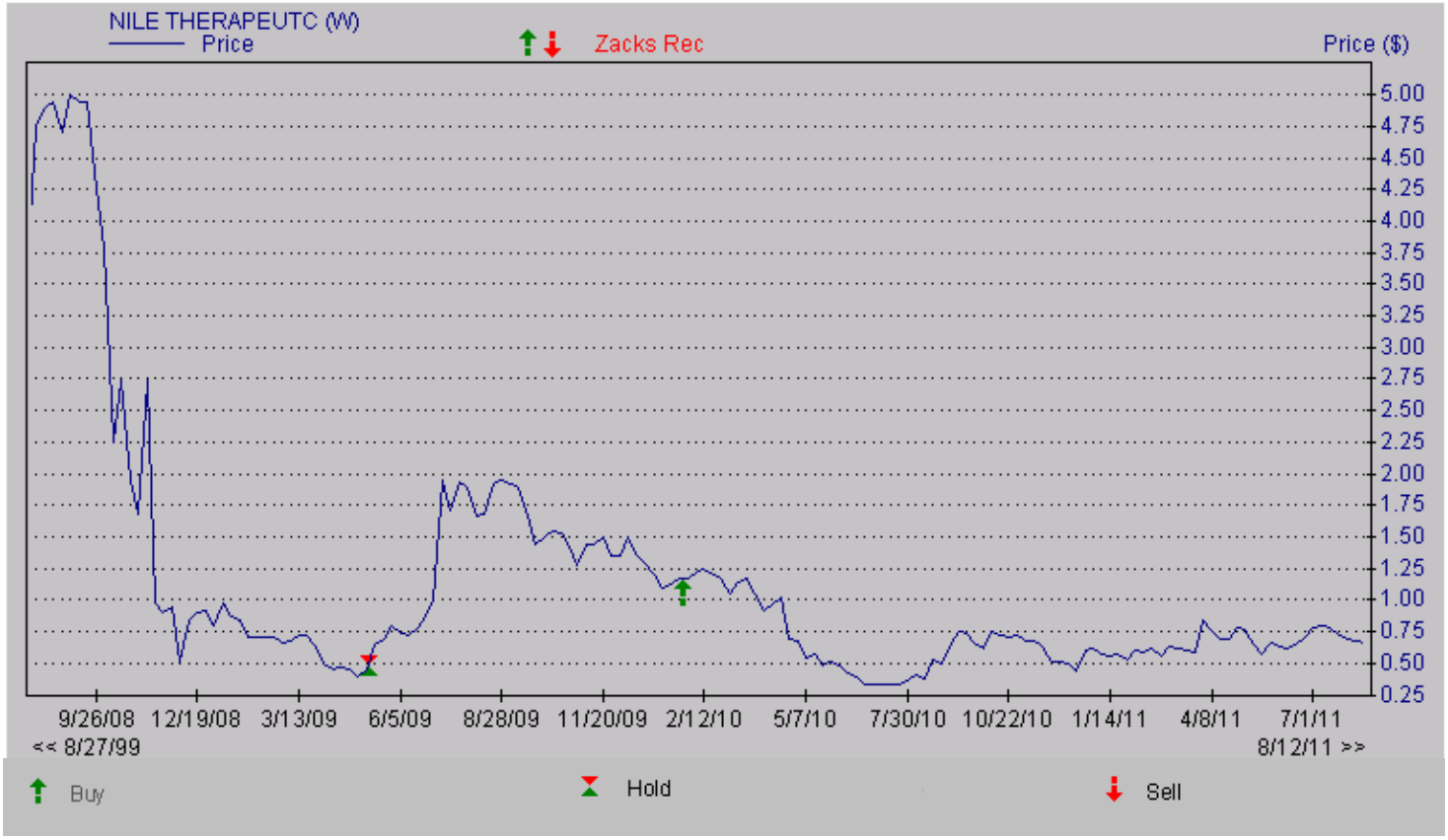
**Nile Therapeutics, Inc.**
Income Statement

| | 2009 A | 2010 A | Q1 A | Q2 A | Q3 E | 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** | **$0.2** | **$0.3** | **$0.8** | **$2.5** | **$5.0** | **$5.0** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$0** | **$0** | **$0** | **$0.3** | **$0.2** | **$0.3** | **$0.8** | **$2.5** | **$5.0** | **$5.0** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - |
| R&D | $4.5 | $4.1 | $0.6 | $0.7 | $0.7 | $0.6 | $2.6 | $3.0 | $3.5 | $4.0 |
| *% R&D* | - | - | - | - | - | - | - | - | - | - |
| SG&A | $3.4 | $2.2 | $0.6 | $0.5 | $0.6 | $0.6 | $2.3 | $2.5 | $2.5 | $2.7 |
| *% SG&A* | - | - | - | - | - | - | - | - | - | - |
| Operating Income | ($7.9) | ($6.3) | ($1.2) | ($0.9) | ($1.1) | ($0.9) | ($4.1) | ($3.0) | ($1.0) | ($1.7) |
| *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) | ($0.9) | ($4.1) | ($2.9) | ($0.9) | ($1.6) |
| 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) | ($0.9) | ($4.1) | ($2.9) | ($0.9) | ($1.6) |
| *Net Margin* | *0%* | *0%* | - | - | - | - | *0%* | *0%* | *0%* | *0%* |
| **Reported EPS** | **($0.31)** | **($0.19)** | **($0.03)** | **($0.03)** | **($0.03)** | **($0.02)** | **($0.11)** | **($0.07)** | **($0.02)** | **($0.04)** |
| *YOY Growth* | - | *-39.8%* | - | - | - | - | *-42.4%* | *-36.8%* | *-69.3%* | *73.7%* |
| FAS-123R Expense | $2.2 | $1.1 | $0.3 | $0.2 | $0.1 | $0.2 | $0.7 | $1.0 | $1.5 | $2.0 |
| *EPS Impact of FAS-123R* | *($0.09)* | *($0.03)* | *($0.01)* | *($0.00)* | *($0.00)* | *($0.00)* | *($0.02)* | *($0.02)* | *($0.03)* | *($0.05)* |
| Weighted Ave. Shares Out | 25.5 | 32.1 | 34.7 | 35.1 | 40.0 | 41.0 | 37.7 | 42.5 | 43.0 | 44.0 |

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

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## HISTORICAL ZACKS RECOMMENDATIONS




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