Zacks Small-Cap Research

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Nile Therapeutics, Inc. (NLTX-OTC)

NLTX: Financing Buys Nile Time To Keep Negotiating…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/26/2010
Current Price (04/03/12)	$0.34
Target Price	**$2.00**

UPDATE

Earlier this week, Nile entered into a private placement to raise an estimated $1.34 million in cash. We believe this financing buys the company an additional 6+ months to continue negotiations with Medtronic and other partners for the advancement of cenderitide into a phase 2 trial for the treatment of post-acute heart failure.

We view Nile Therapeutics as a high risk / high reward speculative play where at $0.34 the stock is trading like a call option. We believe the current market capitalization vastly under-values the potential in our view. We reiterate our 'Outperform' rating and $2 target. We caution investors that the name is high risk, and that future dilutive financings are a possibility if a deal does not get done by this summer.

SUMMARY DATA

52-Week High	**$0.88**
52-Week Low	**$0.34**
One-Year Return (%)	**-61.34**
Beta	**1.68**
Average Daily Volume (sh)	**84,238**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$14**
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 2012 Estimate	**N/A**
P/E using 2013 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)
2011	0 A	0.3 A	0.8 A	0.2 A	1.4 A
2012	0.1 E	0 E	0 E	0 E	0.1 E
2013					0.0 E
2014					0.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.03 A	-$0.03 A	-$0.03 A	-$0.04 A	-$0.13 A
2012	-$0.02 E	-$0.02 E	-$0.03 E	-$0.05 E	-$0.12 E
2013					-$0.16 E
2014					-$0.15 E

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WHAT'S NEW

On March 26, 2012, Dr. Hsiao D. Lieu, MD, FACC, Nile Therapeutics' (NLTX) Vice President of Clinical Research, presented the results from the company's phase 1 safety and pharmacokinetic / pharmacodynamic (PK/PD) clinical trial with cenderitide at the 61th annual Scientific Session of the American College of Cardiology (ACC) meeting held in Chicago, IL. The poster presentation (board #628) was titled, "Initial Experience with Subcutaneous Infusion of Cenderitide in Patients with Chronic Heart Failure."

The design of the study was a multicenter, dose escalating evaluation of the PK and PD responses to various subcutaneous doses of cenderitide boluses and infusion regimens in patients with chronic heart failure. The phase 1 study enrolled a total of 58 patients (45 on cenderitide + 13 placebo) and employed three parts:

	Description	Dose	Number
Part A	Subcutaneous bolus, 1 mL, dose escalation design	Cohort 1: Day 1 : 12 µg Day 2: 24 µg Cohort 2: Day 1: 100 µg, Day 2: 200 µg Cohort 3: Day 1 150 µg, Day 2: 200 µg	Cohort 1: N=2 Cohort 2: N=2 Cohort 3: N=8
Part B	Subcutaneous 24-hr infusion. In the dose confirmation cohorts, subjects were randomized 2:1 to cenderitide: placebo	Lead-in cohort A: 18 µg/hr Lead-in cohort B: 36 µg/hr Dose-confirmation cohort 1: 18 µg /hr Dose-confirmation cohort 2: 24 µg /hr	Cohort A: N=2 Cohort B: N=2 Cohort 1: N=10 Placebo 1: N=5 Cohort 2: N=10 Placebo 2: N=5
Part C	Subcutaneous 24-hr infusion with dosing adjusted by weight (µg/kg/hr): Planned dosing range 15 – 30 with 1.25 ug/kg/hr increments for each additional 5 kg, starting at 70 Kg. Subjects randomized 3:1 to cenderitide: placebo	Cenderitide: Actual dosed range 15 to 30 µg /kg/hr	Cenderitide: N=9 Placebo: N=3

Patients were infused using Medtronic's MiniMed Paradigm pump, currently indicated for continuous infusion of insulin. The pump utilizes MiniMed's minimally invasive, subcutaneous micro-needle technology. The goal of the phase 1 study was two-fold. From Medtronic's point of view, they wanted to test the feasibility of using the MiniMed Paradigm for indications outside of continuous insulin therapy. From Nile's point of view, the company wanted to achieve steady-state target plasma PK levels, reduce weight-based variability in dosing, and demonstrate a dose-dependent reduction in mean maximum systolic blood pressure (SBP).



...The Results...

The data show the trial was a success, from both Medtronic's and Nile's standpoint. We see nothing that prohibits movement into a phase 2 program.

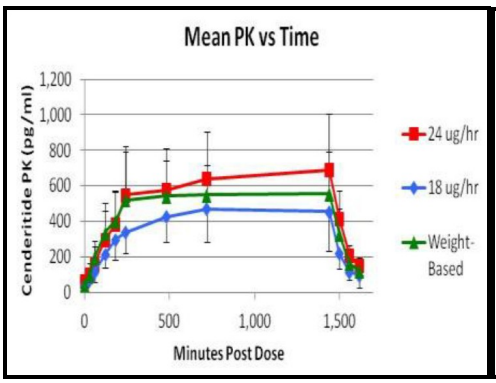


Figure 1

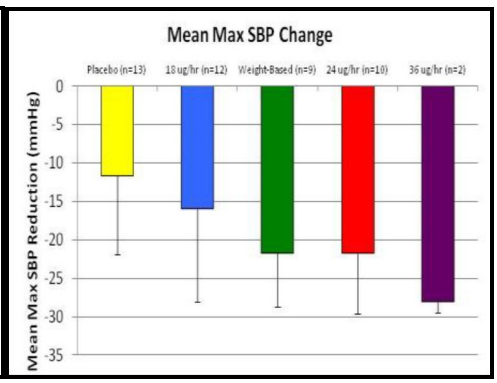


Figure 2

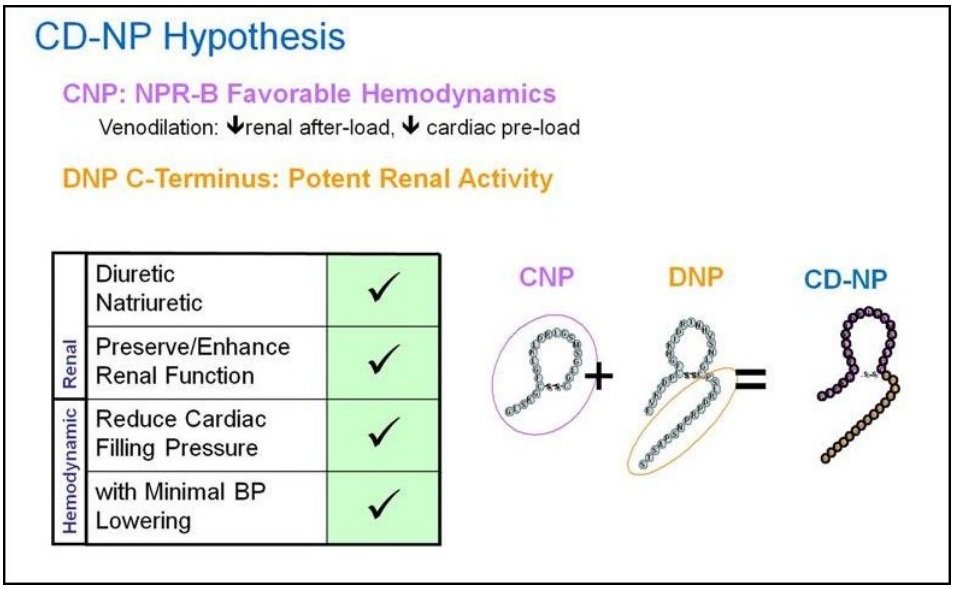
Figure-1 shows the achieved steady-state plasma levels with 18 ug/hr, 24 ug/hr, and weight-based doses. Based on preclinical and previous phase 2 data in acute heart failure patients, management at Nile targeted a cenderitide plasma concentration of 600 pg/ml. We believe the 24 ug/hr or the weight-based dose will be what Nile moves into the next proof-of-concept program.

Figure-2 shows the dose-dependent reduction in systolic blood pressure (SBP). Nile was targeting a reduction in blood pressure between 5 and 10 points beyond the placebo. Based on the results depicted in Figure-2, 18 ug/hr, 24 ug/hr, and weight-based dose all were within the target range. The dose of 36 ug/hr reduced SBP outside the target safety range.

The phase 1 trial was not adequately powered to test efficacy endpoints such as glomerular filtration rate (GFR), creatinine, cystatin-C, or urine output. We note that previous phase 2 data with cenderitide was presented at the 60th annual Scientific Session of the American College of Cardiology (ACC). The poster presentation (board #256) demonstrates encouraging proof-of-concept in 77 patients with acute decompensated heart failure (ADHF), including dose-dependent reductions in mean eGFR and serum creatinine. This trial showed trends in the all-important improvement / preservation of renal function and reductions in blood pressure designed by to make cenderitide a blockbuster drug.

...Little Background Info...

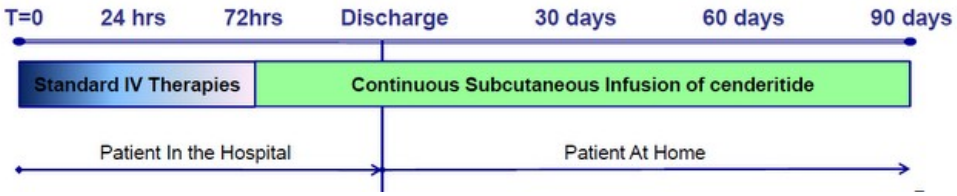
Cenderitide is Nile's novel chimeric natriuretic peptide. Natriuretic peptides are naturally occurring proteins produced in the heart and blood vessels that cause natriuresis (the removal of sodium and water from the blood). Cenderitide was rationally designed by scientists at the Mayo Clinic's cardio-renal research labs to confer both arterial and venodilation activity. Cenderitide is a combination of two natriuretic peptides, CNP and DNP. The drug combines the n-terminus of the CNP molecule, preserving the favorable venodilating and hemodynamic properties, 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.

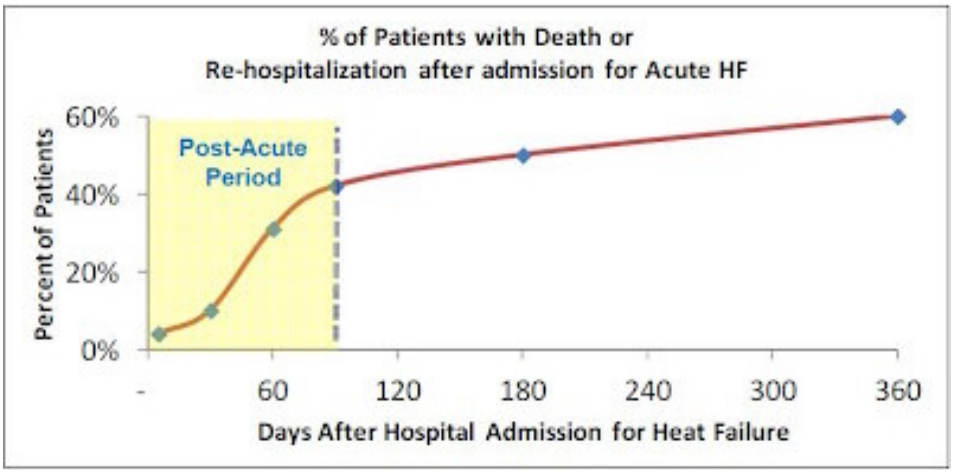
…A Potential Blockbuster Indication…

We believe the post-acute heart failure 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.



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 (ADHF).

There is nothing on the market for this post-acute indication. During the acute (in-hospital) phase, patients receive standard-of-care, which includes various vasodilators (nitroglycerin), diuretics (furosemide), and inotropes (dobutamine or levosimedan). Chronic heart failure patients are typically on beta blockers, ACE inhibitors, ARB inhibitors, and may even have an implantable cardio-rhythm device. However, the 30-90 day window after hospital discharge is where the risk of re-hospitalization and death are highest. The graph below shows the post-acute risk period that Nile is focusing its development on with cenderitide.



...Financing Buys Time...

Nile exited 2011 with $1.0 million in cash. We forecast operating burn for the first quarter 2012 was approximately $0.7 million, meaning cash on hand as of today is around $0.3 million. That left management with only 6 to 8 weeks of cash. Therefore, we are not surprised to see the private placement announced on March 30, 2012 to raise $1.34 million in net proceeds. Nile issued 3.6 million shares of common stock at $0.40 per share, along with 2.7 million warrants at $0.50 per share to investors that participated in the deal.

We note that Nile's Executive Chairman, Richard B. Brewer, President and CEO, Joshua A. Karam, CFO, Daron Evans, and VP of Clinical Development, Hsiao Lieu, MD, all participated in the deal, ponying up $110,000 of their own money.

We believe this $1.34 million buys Nile another 6 to 8 months to negotiate a deal on cenderitide. We remind investors, Medtronic was only on board for only the phase 1 trial. Medtronic wanted to test the feasibility of their MiniMed Paradigm pump for uses outside of insulin delivery. Did they get what they were looking for? We think so. Are they interested in cenderitide from a commercialization standpoint? Perhaps.

Remember, Medtronic is a medical device company, not a pharmaceutical company, but they clearly have an interest in the acute and post-acute heart failure market. The company makes cardiology products for atrial fibrillation, coronary artery disease, heart and pulmonary valve disease, stroke, sudden cardiac arrest, and tachycardia. Combining cenderitide with their pump to offer a complete product to cardiologists for post-acute heart failure is certainly an attractive option for Medtronic. However, we question just how much Medtronic, not known to "up-send" for pharmaceutical products, would offer Nile. Chances are Medtronic has made Nile an offer to date, and Nile turned it down. Hence, today's private placement.

A deal with another medical device / pharmaceutical company certainly makes sense. We remind investors that J&J paid $2.4 billion for Scios and Natrecor (nesiritide) in 2002. This was before the Dear Healthcare Provider letter in 2005 that derailed Natrecor's meteoric rise. Natrecor, a B-type natriuretic peptide (BNP) was a $400 million drug and soaring in 2004.

We know that Nile is speaking to other potential partners besides Medtronic. The $1.34 million raise today tells us that Nile needed a "bridge financing" to keep negotiations going. That's clearly not enough to fund the entire phase 2 trial - in an estimated 360 patients - alone. That would have required more like $20 million. The small private placement was designed to buy Nile more time. In the end, this small dilution today should pay off if management can get a better deal a few months from now.

Conclusion

We currently rate shares of Nile Therapeutics 'Outperform' with a $2 price target. We'd love to see a deal with Medtronic or another big device / pharma name in the coming months. We would use this significant sell off as an opportunity to acquire the shares / average down. We see the downside risk to $0.25. If management cannot get a deal done by June / July 2012, we expect the company to enter into another, significantly larger, financing designed to move cenderitide into phase 2 alone. This raise – estimated at $10 million – would be massively dilutive to current shareholders.

Our DCF Model

Nile Therapeutics	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	
U.S. Adult Population	232	235	237	239	242	244	247	249	252	254	257	
Percent with CHF	*2%*	*2%*	*2%*	*2%*	*2%*	*2%*	*2%*	*2%*	*2%*	*2%*	*2%*	
Patients with Chronic HF	5.1	5.2	5.2	5.3	5.3	5.4	5.4	5.5	5.5	5.6	5.6	
Acute Exacerbations	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	*25%*	
Systolic Dysfunction	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	
At-Risk Post-ADHF	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	
Estimated Market Share	*0%*	*0%*	*0%*	*0%*	*0.1%*	*1.5%*	*3.0%*	*5.0%*	*7.0%*	*8.5%*	*10.0%*	
Price per Treatment	*$0*	*$0*	*$0*	*$0*	*$6,500*	*$6,500*	*$6,760*	*$7,030*	*$7,241*	*$7,386*	*$7,534*	
Cenderitide U.S. Sales	**$0**	**$0**	**$0**	**$0**	**$4.3**	**$65.5**	**$137.5**	**$240.8**	**$350.6**	**$438.6**	**$531.6**	
YoY Growth	-	-	-	-	-	*1415%*	*110%*	*75%*	*46%*	*25%*	*21%*	
Cenderitide EU Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$32.7**	**$82.5**	**$156.5**	**$245.5**	**$307.0**	**$372.1**	
YoY Growth	-	-	-	-	-	-	*152%*	*90%*	*57%*	*25%*	*21%*	
Royalties (15-25%)	**$0**	**$0**	**$0**	**$0**	**$0.6**	**$14.7**	**$38.5**	**$79.5**	**$119.2**	**$167.8**	**$203.4**	*x-2026*
Licensing & Collaborative	**$10.0**	**$0**	**$10.0**	**$0**	**$25.0**	**$0**	**$10.0**	**$10.0**	**$15.0**	**$20.0**	**$25.0**	
Revenues (in Millions)	**$10.0**	**$0.0**	**$10.0**	**$0.0**	**$25.6**	**$14.7**	**$48.5**	**$89.5**	**$134.2**	**$187.8**	**$228.4**	
CoGS	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	
R&D	*$5.0*	*$10.0*	*$10.0*	*$10.0*	*$5.0*	*$4.0*	*$4.0*	*$4.0*	*$4.0*	*$4.0*	*$4.0*	
SG&A	*$2.5*	*$2.5*	*$2.7*	*$2.8*	*$2.9*	*$3.0*	*$3.1*	*$3.2*	*$3.3*	*$3.4*	*$3.5*	
Other Expenses	*$0.6*	*$0.0*	*$0.6*	*$0.0*	*$1.5*	*$0.9*	*$2.9*	*$5.4*	*$8.1*	*$11.3*	*$13.7*	
EBITDA	$1.9	($12.5)	($3.3)	($12.8)	$16.2	$6.8	$38.5	$76.9	$118.9	$169.1	$207.1	
Depreciation and amortization	*$0.1*	*$0.1*	*$0.1*	*$0.1*	*$0.1*	*$0.5*	*$1.0*	*$1.5*	*$2.0*	*$2.0*	*$2.0*	
EBIT	**$1.9**	**($12.6)**	**($3.4)**	**($12.9)**	**$16.2**	**$6.3**	**$37.5**	**$75.4**	**$116.9**	**$167.1**	**$205.1**	
EBITDA margin	-	-	-	-	*63.0%*	*43.1%*	*77.3%*	*84.3%*	*87.1%*	*89.0%*	*89.8%*	
Cash Taxes	$0	$0	$0	$0	($0.8)	($1.3)	($11.2)	($22.6)	($35.1)	($50.1)	($61.5)	
Tax Rate	*0%*	*0%*	*0%*	*0%*	*5.0%*	*20.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	
Balance Sheet												
Capital Expenditures	$0.0	$1.0	$2.0	$2.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	
Working Capital	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	
Non-Cash Adjustments	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	
Capital demployed	**($1.0)**	**$0.0**	**$1.0**	**$1.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	
Net Margin	*18.5%*	*#DIV/0!*	*-33.5%*	*#DIV/0!*	*59.9%*	*34.5%*	*54.1%*	*59.0%*	*60.9%*	*62.3%*	*62.9%*	
Discounted Cash Flow												
Net Income	$1.9	($12.6)	($3.4)	($12.9)	$15.4	$5.1	$26.2	$52.8	$81.8	$117.0	$143.6	
Depreciation and amortization	$0.1	$0.1	$0.1	$0.1	$0.1	$0.5	$1.0	$1.5	$2.0	$2.0	$2.0	
Net Cash Changes	$1.0	$0.0	($1.0)	($1.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	
Post-Tax Operating Cash Flow	**$2.9**	**($12.5)**	**($4.3)**	**($13.8)**	**$15.4**	**$5.6**	**$27.2**	**$54.3**	**$83.8**	**$119.0**	**$145.6**	
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	
Free Cash Flow	**$2.9**	**($12.5)**	**($4.3)**	**($13.8)**	**$15.4**	**$5.6**	**$27.2**	**$54.3**	**$83.8**	**$119.0**	**$145.6**	

Assumptions	
Beta:	2.2
Equity Risk Premium:	7.0%
Risk Free Rate:	2.5%
Firm Risk Premium:	200%
Discount Rate:	**23.5%**

Valuation	
10-Year Model:	$50.3
Terminal Growth:	2%
Terminal Value:	$67.8
Net Cash - LT Debt:	$1.6
Firm Value:	**$119.7**

Price Target	
Basic Outstanding:	42.7
Warrants / Options:	17.0
Dilution:	0.0
Fully Diluted:	59.7
Target Price:	**$2.01**

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

PROJECTED FINANCIALS

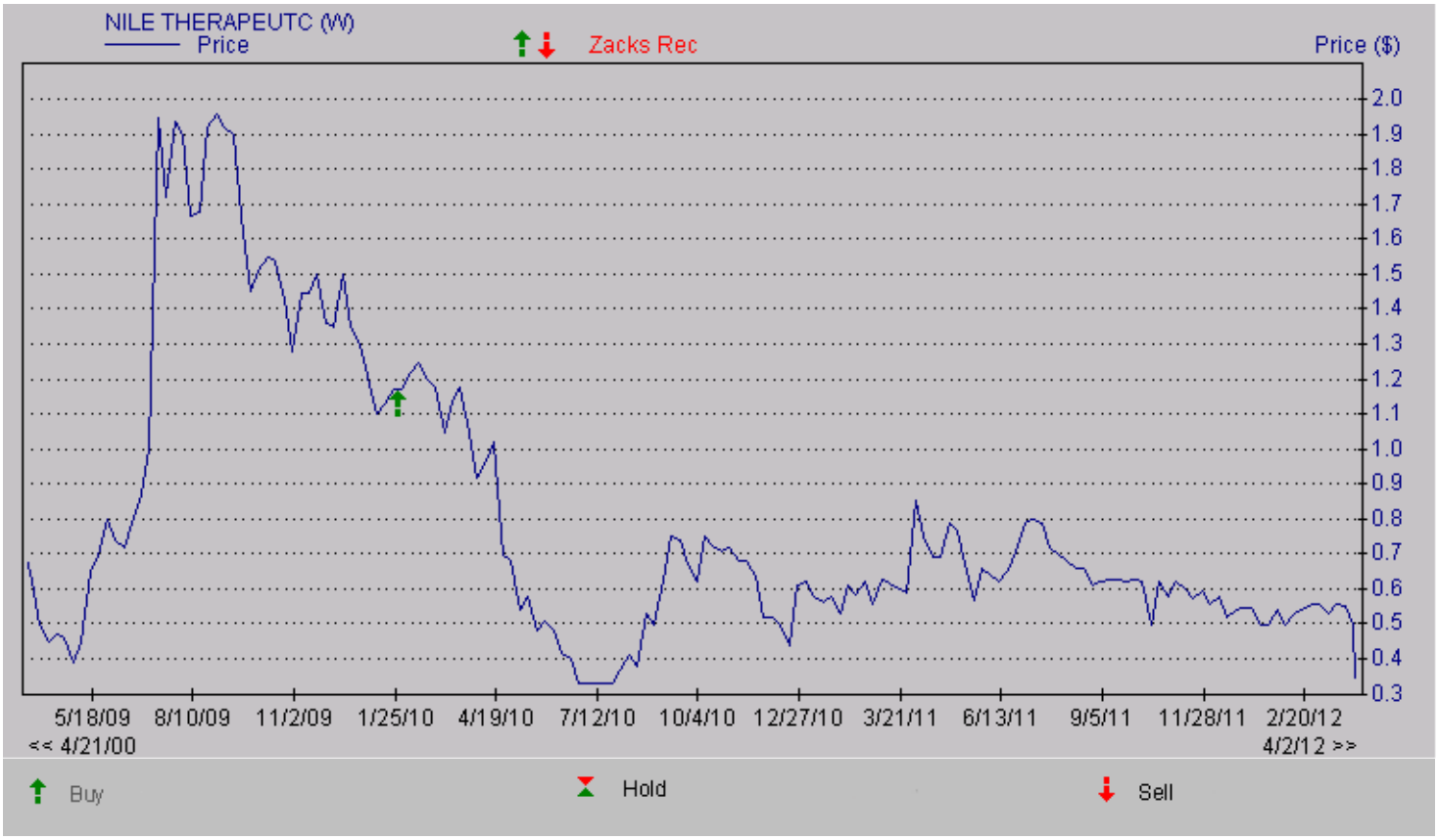
Nile Therapeutics, Inc.
Income Statement

	2010 A	2011 A	Q1 E	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E
cenderitide (U.S. Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
cenderitide (Row Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
cenderitide (Royalties)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Grants, Licenses & Milestones	**$0**	**$1.4**	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$1.4**	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-	-
R&D	$4.1	$4.1	$0.5	$0.5	$1.0	$1.5	$3.5	$5.0	$5.0
% R&D	-	-	-	-	-	-	-	-	-
SG&A	$2.2	$2.1	$0.5	$0.5	$0.5	$0.5	$2.0	$2.2	$2.5
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($6.3)	($4.9)	($0.9)	($1.0)	($1.5)	($2.0)	($5.4)	($7.2)	($7.5)
Operating Margin	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Interest & Other Income	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
Pre-Tax Income	($6.0)	($4.9)	($0.9)	($1.0)	($1.5)	($2.0)	($5.4)	($7.1)	($7.4)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($6.0)	($4.9)	($0.9)	($1.0)	($1.5)	($2.0)	($5.4)	($7.1)	($7.4)
Net Margin	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Reported EPS	**($0.19)**	**($0.13)**	**($0.02)**	**($0.02)**	**($0.03)**	**($0.05)**	**($0.12)**	**($0.16)**	**($0.15)**
YOY Growth	*-39.8%*	*-30.3%*	*-40.1%*	*-9.4%*	*18.3%*	*8.9%*	*-5.9%*	*28.2%*	*-6.2%*
FAS-123R Expense	$1.1	$0.8	$0.2	$0.1	$0.1	$0.2	$0.6	$1.0	$1.5
EPS Impact of FAS-123R	*($0.03)*	*($0.02)*	*($0.00)*	*($0.00)*	*($0.00)*	*($0.00)*	*($0.01)*	*($0.02)*	*($0.03)*
Weighted Ave. Shares Out	32.1	37.3	43.5	44.0	44.0	44.0	43.9	45.0	50.0

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

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HISTORICAL ZACKS RECOMMENDATIONS



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