Zacks Small-Cap Research

May 2, 2012
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: Investment In Neurocrine Just Makes Sense At this Level…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (05/02/12)	$7.37
Target Price	**$12.00**

UPDATE

We remain optimistic on Neurocrine Bio and believe the company is on track with key pipeline products elagolix and NBI-98854. We have previously written that the collaboration with Abbott Labs for endometriosis and uterine fibroid drug elagolix was a “homerun” deal for the company. We think NBI-98854 for tardive dyskinesia and other related disorders could be a meaningful driver of shareholder value over the next few quarters.

At the end of the first quarter 2012, Neurocrine held nearly $190 million in cash and investments. With a strong pipeline, plenty of cash, and great collaboration partners in Abbott and Boehringer Ingelheim, we think Neurocrine makes sense for a long-term investment in biotech.

SUMMARY DATA

52-Week High	**$9.79**
52-Week Low	**$5.50**
One-Year Return (%)	**-5.87**
Beta	**0.29**
Average Daily Volume (sh)	**426,486**
Shares Outstanding (mil)	**66**
Market Capitalization ($mil)	**$478**
Short Interest Ratio (days)	**2.63**
Institutional Ownership (%)	**60**
Insider Ownership (%)	**1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**36.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**13.9**
P/E using 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**

Risk Level	**Below Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	12.5 A	12.2 A	41.6 A	11.1 A	77.4 A
2012	11.3 A	12.5 E	8.5 E	9.0 E	41.3 E
2013					40.0 E
2014					40.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	$0.05 A	$0.04 A	$0.56 A	$0.02 A	$0.67 A
2012	-$0.01 A	-$0.01 E	-$0.09 E	-$0.10 E	-$0.16 E
2013					-$0.15 E
2014					$0.06 E

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WHAT'S NEW

Recent Financial Results

On May 2, 2012, Neurocrine Bio reported financial results for the first quarter 2012. The company reported total revenues in the quarter of $11.3 million, in-line with our expectations. Revenues in the quarter consisted of $2.0 million in sponsored R&D and reimbursement from Abbott Labs and Boehringer Ingelheim (BI), and $9.2 million in amortization of upfront payments from Abbott, BI, and Dainippon Sumitomo Pharma (DSP).

For the first quarter 2012, Neurocrine reported net loss of $0.9 million, or $0.01 per share. This was slightly greater than our estimate on higher SG&A than we modeled. R&D was also slightly higher than expected. Management noted a $0.7M expense for external testing and scientific consulting during the quarter. Operating costs in the quarter also included $0.7 million in share-based compensation. Nevertheless, results were still generally in line with the company's previously reported financial guidance.

The company's balance sheet on March 31, 2012 reflected total assets of $210.1 million, including cash and short-term investments of $181.1 million. We remind investors that in January 2012, Neurocrine raised approximately $82.9 million in cash through an underwritten public offering of 10.925 million shares of common stock at $8.10 per share. We find the existing cash balance sufficient to fund operations for the foreseeable future. The additional cash should allow management to accelerate the clinical development for its VMAT-2 program, which recently successfully completed a phase 2a program, as well as bring new candidates into the clinic later in 2012.

…Financial Guidance…

For the full year 2012, management expects revenues to be between $40 and $45 million, about $34 million of which will be amortization of previous upfront payments. Operating expenses should total between $55 and $60 million. For 2012, management is expecting a net loss of approximately $9 to $14 million. Based on roughly 66.5 million shares outstanding, we forecast EPS in 2012 will be between ($0.21) and ($0.09). Management expects to exit 2012, barring no additional financial transactions or out-licensing activity, with approximately $170 million in cash, investments and receivables. We note this number could change if the company out-licenses the rights to Urocortin-2 following the phase 2 data expected shortly.

INVESTMENT OVERVIEW

Elagolix Development Continues At Abbott

In Uterine Fibroids

On September 13, 2011, Abbott Labs announced it had commenced a phase 2 clinical trial to evaluate elagolix in an exploratory trial for the treatment of uterine fibroids. The trial is expected to enroll up to 325 women with heavy uterine bleeding associated with uterine fibroids at clinical sites around the U.S. for a total of 3 months. We expect the trial to take about twelve months to complete, meaning we should see data late in the fourth quarter 2012. The primary endpoint will be quantified blood loss assessed by alkaline hematin. The initiation of the trial triggered a $10 million milestone payment from Abbott to Neurocrine Bio. We think this is an important step forward for Abbott and Neurocrine because development of elagolix outside the U.S., specifically in Europe, will probably focus on the uterine fibroids indication.

In Endometriosis

On October 4, 2011, Neurocrine announced that it has achieved a second major milestone from Abbott Labs on elagolix. Neurocrine and Abbott held a pre-phase 3 meeting with the U.S. FDA in September 2011, the results of which triggered a $20 million payment from Abbott to Neurocrine. Abbott recently made it known that they were pursuing a special protocol assessment (SPA) for the phase 3 program in endometriosis. Abbott received feedback on the SPA from the U.S. FDA in February 2012. According to management, the FDA had constructive input on the SPA in-line with Abbotts plans. Abbott plans to begin the phase 3 program in the second quarter 2012. We are encouraged by the fact that Abbott is pursuing an SPA. It improves the likelihood of approval if the phase 3 trials succeed.

We expect the phase 3 elagolix program in endometriosis to begin in the next month or so. We expect that this pivotal program will include two large-scale (n~750) patient programs with co-primary Dysmenorrhea and Non-Menstrual Pelvic Pain endpoints, testing 150mg elagolix QD after six months of controlled treatment. Efficacy will be assessed by a responder analysis for statistical evaluation. We expect that secondary endpoints will include Dyspareunia and Patient Global Impression of Change (PGIC). Following the six month controlled portion of the trial, patients will be eligible to enroll in a six month extension study where Abbott will look for signs of persistent efficacy. Patients will be followed for a total of 24 months, after which Abbott will conduct a DXA scan to assess changes in bone mineral density.

We are confident in the design of the phase 3 trials, and the efficacy and safety previously seen with elagolix. In total, Neurocrine has presented data from 12 phase 1 programs and 6 phase 2 programs (2 phase 2a and 4 phase 2b) on roughly 1,000 patients. Results from the phase 2b (n=137) Daisy PETAL (Study-901) program first released in May 2010 provide the best proof-of-concept data for the planned phase 3. Results were statistically significant in all primary and secondary endpoints.

The planned phase 3 program will seek to enroll patients with more severe disease and employ a two-cycle run-in period both designed to mitigate the placebo response. We note the 33% placebo response on both primary endpoints in the Daisy PETAL program was rather high, but elagolix at 63% for both was statistically significant at a p-value less than 0.01. All Abbott needs to do is replicated these results in the two phase 3 trials and then show no clinically meaningful changes in bone mineral density and we think approval is likely.

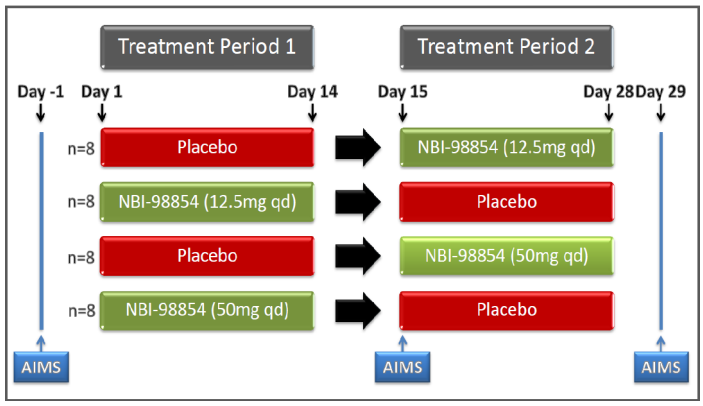
Encouraging Signals In Phase 2a For VMAT2

On March 26, 2012, Neurocrine Bio announced results from the company's phase 2a program with NBI-98854, a VMAT2 inhibitor for the treatment of tardive dyskinesia (TD). We believe the results were overall a positive for the company, despite what management referred to as "inconsistent and incorrect application of the efficacy assessment protocol" at one of the eight sites used during the trial. When this site was removed (post-hoc), analysis of the primary and secondary endpoints showed encouraging results, we believe strong enough to warrant movement into a larger-scale phase 2b study.

…The Design…

The trial was a double-blind, placebo-controlled, design in which patients were randomized to receive either 12.5mg or 50mg of NBI-98854 or placebo for 14 days, then crossed-over to the placebo or active 12.5mg or 50mg arm for another 14 days.

The primary efficacy endpoint in the trial was the change in Abnormal Involuntary Movement Scale (AIMS) from active to placebo groups. AIMS assessments were taken at baseline (Day-1), after the first period (Day-15) and after the second period (Day-29). The trial was powered to detect a 3 point change in AIMS from active to placebo group.



Secondary endpoints included the Clinical Global Impression of Tardive Dyskinesia (CGI-TD) and the Patient Global Impression of Change (PGIC) questionnaire. Management also measured adverse events, Brief Psychiatric Rating Scale (BPRS), Columbia Suicide Severity Rating Scale (CSSRS), Calgary Depression Scale for Schizophrenia (CDSS), Barnes Akathisia Rating Scale (BARS), and the Simpson-Angus Scale (SAS).

…Inconsistencies Found At One Site Lead To Post-Hoc Analysis…

Following analysis of the unblinded data, management found inconsistent application of the AIMS efficacy assessment at one of the eight clinical sites. Management noted that the issues were not a result of randomization or dosing errors, but rather incorrect application of the AIMS assessment that lead to discrepancies between the clinical scores and the video record of the analysis. Application of the AIMS assessment at the other seven sites was found to be consistent with the video record.

Neurocrine performed two analyses of the primary AIMS endpoint, one that included all eight sites and one post-hoc analysis that included only the seven sites in which the AIMS assessment was performed correctly. We present the results below on the primary AIMS endpoint for the active vs. placebo periods.

AIMS – All 8 Sites			
Baseline = 14.7	**Placebo**	**12.5mg**	**50mg**
…LS Mean	9.9	9.1	8.8
…Difference		-0.7	-1.1
…p-value		0.59	0.42

AIMS – 7 Site Post-Hoc			
Baseline = 14.9	**Placebo**	**12.5mg**	**50mg**
…LS Mean	10.3	9.9	6.1
…Difference		-0.4	-4.2
…p-value		0.68	0.002

Analysis of the primary endpoint was also assessed on a change in baseline. The data below shows the post-hoc analysis including both crossover periods. The data show a significant reduction from baseline in subjects randomized to the 50mg dose, which we believe is clinically meaningful for patients with Tardive Dyskinesia.

Change From Baseline			
	Placebo	**12.5mg**	**50mg**
…Change	-4.7	-4.9	-9.2
…Difference		-0.2	-4.5
…p-value		0.79	0.0004

Responder analysis of the secondary efficacy endpoints conducted post-hoc showed strong trends in favor of both the 12.5mg and 50mg doses.

Responder Rates By Treatment			
	Placebo	**12.5mg**	**50mg**
CGI-TD …"much or very much improved"	46%	67%	80%
PGIC …much or very much improved"	38%	62%	80%

…Good Safety Profile…

Data from the trial showed that NBI-98854 was generally safe and well tolerated. The most common adverse event was headache. Treatment-emergent adverse events were limited, a surprise to management given the severity of the underlying schizophrenia and the rigorous trial protocol (patients had to come into the study center for several hours, once per day for 29 days). There were no serious adverse events during the active portion of the trial. One patient in the 50mg group discontinued due to akathisia (restless leg). One patient with a history of emphysema experienced an acute exacerbation of COPD after the trial completed. However, investigators deemed the episode not related to NBI-98854.

Safety & Tolerability			
	Placebo	**12.5mg**	**50mg**
Treatment-Emergent Adverse Events	17%	24%	32%
Serious Adverse Events (Days 1-29)	-	-	-
Serious Adverse Events (Day 29+)	-	-	1
Discontinuations (Days 1-29)	-	-	1

We note there was no drug-drug interactions seen during the study, a very encouraging sign considering patients were on a mix of typical and atypical antipsychotic drugs. Analysis showed no gender, smoking, or body weight impact on the results. Patients were assessed for depression, suicidal ideation, and parkinsonism, with no affect found attributed to NBI-98854. A total of 37 patients were randomized for treatment, and 32 were included in the ITT database. 31 patients completed the study.

…Up Next, Phase 2b…

Despite the inconsistencies found at one of the eight clinical sites, we believe the trial was a success. We remind investors that the ultimate goal of a phase 2a program is to confirm proof-of-concept, safety, and help design the protocol for a larger-scale phase 2b trial designed to truly assess efficacy. We believe Neurocrine clearly accomplished this goal.

Management is now planning a phase 2b trial that will assess NBI-98854 in patients with moderate-to-severe schizophrenia and tardive dyskinesia. The trial will seek to enroll approximately 120 patients in a placebo-controlled, double-blind, parallel group, multiple dose format. Management plans to test 25mg and 50mg NBI-98854 over a 12 week treatment period, with six weeks of placebo-controlled dosing followed by six-weeks of active treatment. The trial will incorporate a new capsule formulation of NBI-98854.

We expect that the AIMS assessment in the phase 2b program will be altered slightly to separate the clinician and the reader, with added certification training and monitoring. Management also mentioned the potential for an independent AIMS reader at the clinical site, or having a central reader assess all the videotaped patients. Although, we do not see management doing down the route of one centralized reader. We expect this trial to start during the middle of 2012 and potentially offer top-line data by the end of the year.

…Background on VMAT2 & TD…

VMAT-2 is a protein concentrated in the human brain that is primarily responsible for re-packaging and transporting monoamines (dopamine, norepinephrine, serotonin, and histamine) among nerve cells. Neurocrine's molecule, NBI-98854, is a novel, highly-selective VMAT2 inhibitor that modulates presynaptic dopamine release during nerve communication, while at the same time having minimal impact on the other monoamines thereby reducing the likelihood of "off target" side effects. NBI-98854 is designed to provide low, sustained, plasma and brain concentrations of the active drug to minimize side effects associated with excessive dopamine depletion.

We see TD as a meaningful market opportunity for Neurocrine. There are an estimated 500,000 TD patients in the U.S. with no real treatment options. In January 2012, the U.S. FDA granted "Fast Track" designation to NBI-98854 for neuroleptic-induced tardive dyskinesia. NBI-98854 is patent protected until May 2029. In addition, NBI-98854 may well be useful in other disorders, such as Huntington's chorea, schizophrenia, Tourette's syndrome, and Tardive Dystonia. We expect that management will move into a second indication, most likely schizophrenia, during the second half of the year. The above planned phase 2b trials in schizophrenia patients with TD should give us an early look at the potential for the drug in this indication. We are particularly excited about the VMAT-2 program at Neurocrine. It represents significant upside and diversification from elagolix. We note that management plans to retain the U.S. rights to VMAT-2 all the way to commercialization.

Looking to Monetize Urocortin-2

Management expects data very soon from the Christchurch Cardioendocrine Research Group (CCRG). This program has been going on for some time now. Previous data with Urocortin-2 has demonstrated the candidate to be generally well tolerated with hemodynamic effects on systolic and diastolic blood pressure, heart rate, cardiac work and, most importantly, cardiac output. The pilot study at CCRG, called Unicorn, enrolled 50 patients. CCRG funded the study and Neurocrine supplied the drug. The trial has completed and CCRG is analyzing the data. We expect results to be presented in the next month. If positive, we expect for management to look to out-licenses Urocortin-2 later in 2012.

IND's Later In 2012

In June 2010, Neurocrine Bio announced a worldwide collaboration with Boehringer Ingelheim to research and develop small molecule GPR119 agonists for the treatment of Type-2 diabetes and other indications, with BI responsible for the global development and commercialization. BI is currently conducting preclinical studies looking at candidate selection for an IND. We anticipate an IND in 2012.

Management also noted that it has several neuroscience compounds in the discovery stage. We are expecting to see the first IND on one of these novel compounds perhaps during the second half of 2012.

Neurocrine Looks Well Positioned for the Future

We continue to very positive on Neurocrine Bio. The basis for our optimism is our belief that the collaboration deal with Abbott Labs for elagolix was a 'Homerun'. Neurocrine received $75 million upfront and has the potential to earn an additional $530 million in future milestones, of which CEO Kevin Gorman noted the "vast majority" are for development. This gives us confidence that Neurocrine will recognize a significant portion of these milestones prior to potential FDA approval in 2014 or 2015. In fact, Neurocrine received $30 million in milestones in the fourth quarter 2011 on the initiations of the phase 2 uterine fibroid and planned phase 3 endometriosis trials.

Abbott is the pioneer and market leader in GnRH antagonists with Lupron (leuprolide) for the treatment of hormone-responsive cancers such as prostate cancer or breast cancer. The drug is also used by Ob/Gyns for the treatment of endometriosis and uterine fibroids. Abbott has a strong appreciation for the GnRH mechanism and the company is clearly committed to see elagolix a success with Lupron expected to lose patent protection in 2015. Abbott's Lupron sales in 2009 were $800 million ($540 million U.S.). We believe that Abbott will look to replace Lupron in the Ob/Gyn market with elagolix thanks to superior efficacy and tolerability, as well as patent protection.

Since that time, the company has signed a second deal with Boehringer Ingelheim and successfully completed phase 2a studies on VMAT-2. This has allowed us to maintain our target price to $12 per share.

The collaboration with BI focuses on the research and development of G-protein coupled receptor (GPCR) small molecules for the treatment of Type-2 diabetes. The activation of GPR119 receptors located in the digestive system stimulates incretins, resulting in increased insulin production, while activation of GPR119 receptors located on pancreatic islet beta cells also stimulates insulin secretion. As part of terms of the collaboration, Neurocrine received another $10 million upfront milestone payment for research funding, and is eligible to receive up to $225 million in future milestone payments based on the achievement of development, regulatory and commercial goals. Again, CEO Kevin Gorman noted that a "substantial amount" can be achieved in clinical development.

The company's balance sheet reflected total assets of $210.1 million, including cash and short-term investments of $181.1 million. We remind investors that in January 2012, Neurocrine raised approximately $82.9 million in cash through an underwritten public offering of 10.925 million shares of common stock at $8.10 per share.

The company should see its lead product candidate, elagolix, enter phase 3 trials during the summer 2012 under a special protocol assessment (SPA) at Abbott Labs. Our market research shows elagolix as a $1.5 billion drug in the U.S., potentially $2-3 billion worldwide. Meanwhile, phase 2 programs with Uro-2 and VMAT-2 are also moving forward with little cost to the company. We believe Neurocrine is in an outstanding position to build shareholder value over the next several years based on these factors. We recommend accumulating the stock at today's price, up to our $12 target.

PROJECTED FINANCIALS

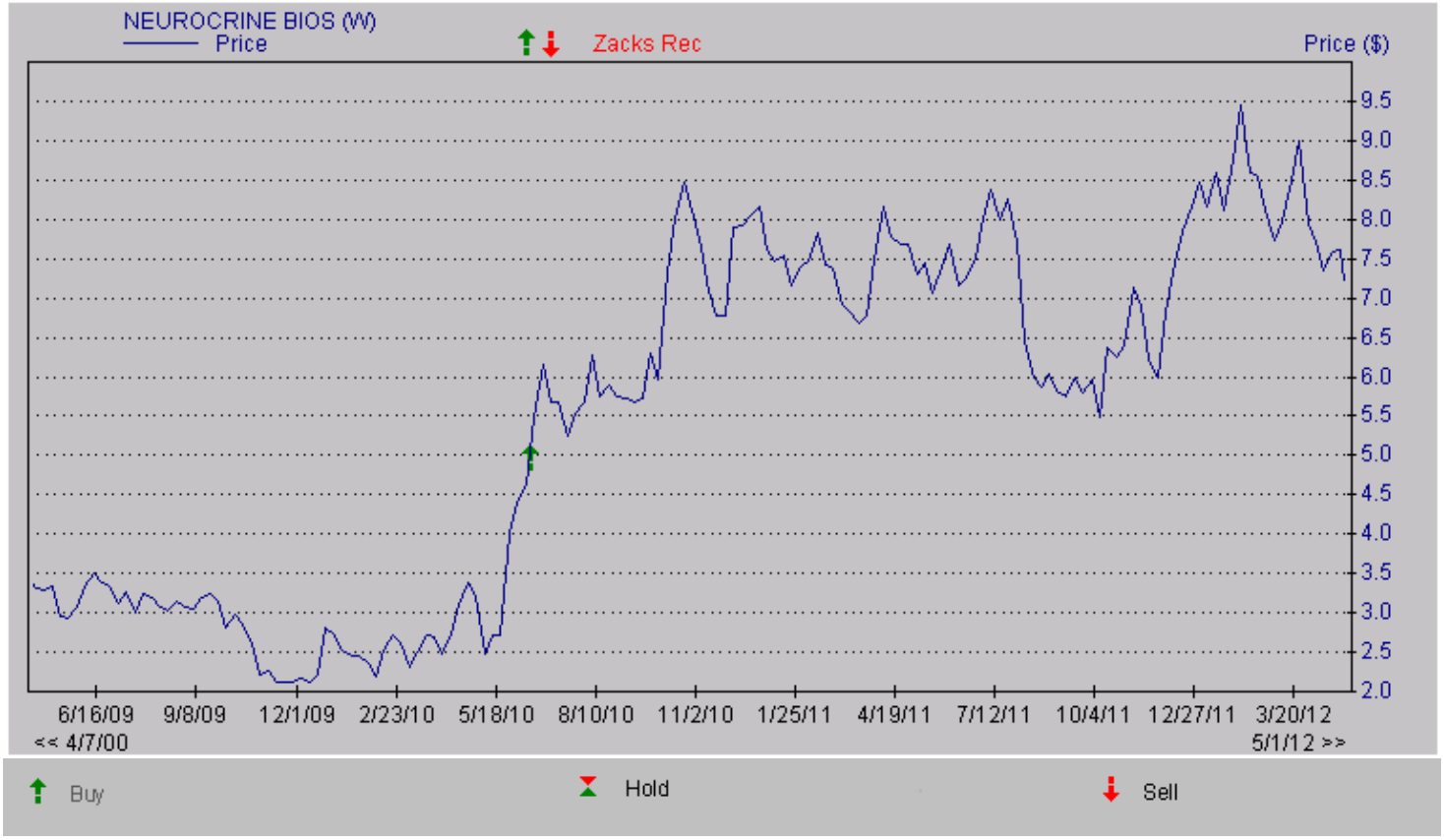
Neurocrine Biosciences Inc.
Income Statement

	2010 A	2011 A	Q1A	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
R&D / Milestones & Fees	**$33.5**	**$77.4**	**$11.3**	**$12.5**	**$8.5**	**$9.0**	**$41.3**	**$40.0**	**$40.0**	**$40.0**
YOY Growth	*1034.5%*	*131.1%*	*-10.0%*	*2.8%*	*-79.6%*	*-19.0%*	*-46.7%*	*-3.1%*	*0.0%*	*0.0%*
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$6.3**	**$15.9**
YOY Growth	-	-	-	-	-	-	-	-	-	-
VMAT-2	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$33.5**	**$77.4**	**$11.3**	**$12.5**	**$8.5**	**$9.0**	**$41.3**	**$40.0**	**$46.3**	**$55.9**
YOY Growth	*1034.5%*	*131.1%*	*-10.0%*	*2.8%*	*-79.6%*	*-19.0%*	*-46.7%*	*-3.1%*	*15.7%*	*20.7%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0.0
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*0.0%*	*0.0%*	*0.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$16.1	$12.4	$3.7	$3.3	$3.4	$3.5	$13.9	$14.0	$14.5	$15.0
% SG&A	*48.0%*	*16.0%*	*32.6%*	*26.4%*	*40.0%*	*38.9%*	*33.6%*	*35.0%*	*31.3%*	*26.8%*
R&D	$31.2	$31.0	$9.4	$9.5	$11.0	$12.0	$41.9	$40.0	$30.0	$30.0
% R&D	*93.0%*	*40.0%*	*83.3%*	*76.0%*	*129.4%*	*133.3%*	*101.5%*	*100.0%*	*64.8%*	*53.7%*
Operating Income	($13.7)	$34.1	($1.8)	($0.3)	($5.9)	($6.5)	($14.5)	($14.0)	$1.8	$10.9
Operating Margin	-	*44.0%*	-	-	-	-	*-35.1%*	*-35.0%*	*3.9%*	*19.5%*
Interest / Other Income	$5.8	$3.6	$0.9	$0.9	$0.9	$0.9	$3.6	$3.5	$3.0	$2.5
Pre-Tax Income	($8.0)	$37.6	($0.9)	$0.6	($5.0)	($5.6)	($10.9)	($10.5)	$4.8	$13.4
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0.7	$4.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5.0%*	*15.0%*	*30.0%*
Net Income	($8.0)	$37.6	($0.9)	$0.6	($5.0)	($5.6)	($10.9)	($10.5)	$4.1	$9.4
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	-	*48.5%*	-	-	-	-	*-26.4%*	*-26.3%*	*8.8%*	*16.8%*
Reported EPS	**($0.15)**	**$0.67**	**($0.01)**	**$0.01**	**($0.07)**	**($0.08)**	**($0.16)**	**($0.15)**	**$0.06**	**$0.13**
YOY Growth	-	-	-				*-124.6%*	*-6.4%*	*-137.9%*	*122.2%*
Stock Options	*$3.1*	*$2.9*	*$0.7*	*$0.6*	*$0.8*	*$1.0*	*$3.1*	*$3.5*	*$4.0*	*$5.0*
EPS Impact of FAS-123R	*$0.06*	*$0.05*	*$0.01*	*$0.01*	*$0.01*	*$0.01*	*$0.05*	*$0.05*	*$0.06*	*$0.07*
Shares Outstanding	52.8	56.3	63.4	67.4	67.5	67.6	66.5	68.5	70.0	72.5

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

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