Zacks Small-Cap Research

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Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: Update Following Meeting With Management…

UPDATE

Earlier in the week we sat down with management at Neurocrine Biosciences to receive an update on the status of elagolix at Abbott Labs and the pipeline.

We expect Abbott to initiate the phase 3 program with elagolix in endometriosis shortly. The delay from previous guidance was a result of Abbott pursuing an SPA. The phase 2 uterine fibroid program is enrolling. Neurocrine expects data from Urocortin-2 and VMAT-2 later in the first quarter 2012. We expect that if positive, management will seek to out-license Uro-2. The next steps for VMAT-2 would be a larger phase 2b program in tardive dyskinesia.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (01/13/12)	$8.48
Target Price	**$12.00**

SUMMARY DATA

52-Week High	**$8.66**
52-Week Low	**$5.50**
One-Year Return (%)	**13.35**
Beta	**0.35**
Average Daily Volume (sh)	**246,002**
Shares Outstanding (mil)	**55**
Market Capitalization ($mil)	**$479**
Short Interest Ratio (days)	**9.67**
Institutional Ownership (%)	**76**
Insider Ownership (%)	**2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-36.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**127.8**
P/E using 2011 Estimate	**9.8**
P/E using 2012 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)
2010	0.8 A	4.6 A	14.4 A	13.7 A	33.5 A
2011	12.5 A	12.2 A	41.6 A	12.0 E	78.7 E
2012	5.0 E	6.0 E	6.0 E	7.0 E	24.0 E
2013					30.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.18 A	-$0.09 A	$0.06 A	$0.04 A	-$0.15 A
2011	$0.05 A	$0.04 A	$0.56 A	$0.01 E	$0.66 E
2012	-$0.09 E	-$0.07 E	-$0.08 E	-$0.08 E	-$0.32 E
2013					-$0.18 E

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Elagolix Development Rolling Forward

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 300 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. will probably focus on uterine fibroids.

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. Despite the delay in starting the trial while talks continue with the U.S. FDA, we are encouraged by the fact that Abbott is pursuing the 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.

Data at Week 8	Baseline	Elagolix	Placebo
Change in Baseline (ITT population) of…			
Dysmenorrhea (mean, 0-3)	2.1 / 2.1	-1.13	-0.37
Non-Menstrual Pelvic Pain (mean, 0-3)	1.4 / 1.3	-0.47	-0.19
Dyspareunia (pain, 0-3)	1.6 / 1.3	-0.61	-0.23
All p<0.01			

Data at Week 8	Elagolix	Placebo
Responder Analysis (>30%)…		
Dysmenorrhea	63% [1]	33%
Non-Menstrual Pelvic Pain	63% [1]	33%
Dyspareunia	58% [2]	34%
1 = p<0.01 2 = p<0.05		

Data at Week 8	Elagolix	Placebo
Secondary Efficacy Endpoints (ITT population) on…		
Patient Global Impression of Change (PGIC) "much" or "very much improved"	60%	30%
Endometriosis Health Profile 5 (EHP-5) Related-Pain Assessment, 0-100	-28 pts	-13 pts
Composite Pelvic Signs & Symptoms Scale (CPSSS) Reduction from Baseline (9.5), 0-15)	-4.45 pts	-2.19 pts
All p<0.001		

We are also encouraged by the fact that during the phase 2b Daisy PETAL program, the elagolix demonstrated excellent safety and tolerability. Discontinuation due to adverse events (AEs) was low at 4.4% for elagolix vs. 1.4% for the placebo during the first eight weeks of the program. The discontinuation rate increased to only 5.1% at week 24. The most common adverse event reported more often with elagolix than with placebo was nausea (~10% of the subjects). This was consistent with what we saw in previous clinical studies. Importantly, there were no elagolix treatment-related serious adverse events (SAEs).

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.

VMAT-2 Data Soon

In September 2011, Neurocrine initiated a phase 2 clinical trial with NBI-98854 studying the drug in patients with Tardive dyskinesia (TD). The design of this phase 2 study is a randomized, double-blind, placebo controlled, cross-over trial, using a within-subject comparison for safety and efficacy evaluation. This 32 patient study will assess once-daily NBI-98854 (12.5mg and 50mg) over a two week dosing period. The primary endpoint of the study will be a comparison of placebo vs. active scores using the Abnormal Involuntary Movement Scale (AIMS).

We expect data from this trial in March 2012. If successful, we anticipate Neurocrine moving into a larger-scale (n=150, 3-month dosing) phase 2b program during the first half of 2012. We expect that management will look to narrow the dose and study the drug for longer duration in this program. Depending on when this trial can get underway, we may see data either late 2012 or early 2013. 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. We remind investors that in June 2011, Neurocrine received correspondence from the U.S. Patent and Trademark Office (USPTO) that the agency had issued a Notice of Allowance for the composition of matter patent on NBI-98854. The initial patent term extends to 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 are particularly excited about the VMAT-2 program at Neurocrine. It represents significant upside and diversification from elagolix. 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.

Looking to Monetize Urocortin-2

Management expects data in February 2012 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. If positive, we expect for management to look to out-licenses Urocortin-2 later in 2012.

First IND With Boehringer Ingelheim 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.

RECOMMENDATION

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 2013 or 2014. In fact, Neurocrine just received another $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 on September 30, 2011 reflected total assets of $149.0 million, including cash, restricted cash, investments and receivables of roughly $140.2 million. Management guided to cash at the end of 2011 in excess of $130 million. We believe this is sufficient cash to fund operations, including the in-house development of the VMAT-2 trials and the remaining preclinical work on elagolix for the foreseeable future. We expect total cash burn in 2012 of around $35 to $40 million, meaning cash should still be north of $90 million at year end 2012.

The company should see its lead product candidate, elagolix, enter phase 3 trials during the first quarter of 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. We have posted our DCF model in the back.

PROJECTED FINANCIALS

Neurocrine Biosciences Inc.
Income Statement

	2010 A	2011 E	Q1 E	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
R&D / Milestones & Fees	**$33.5**	**$78.3**	**$12.0**	**$12.0**	**$7.0**	**$7.0**	**$38.0**	**$40.0**	**$40.0**	**$40.0**
YOY Growth	*1034.5%*	*133.7%*	*-4.1%*	*-1.3%*	*-83.2%*	*-41.7%*	*-51.5%*	*5.3%*	*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**	**$78.3**	**$12.0**	**$12.0**	**$7.0**	**$7.0**	**$38.0**	**$40.0**	**$46.3**	**$55.9**
YOY Growth	*1034.5%*	*133.7%*	*-4.1%*	*-1.3%*	*-83.2%*	*-41.7%*	*-51.5%*	*5.3%*	*15.7%*	*20.7%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0.0
Gross Margin	*100.0%*	*100.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$16.1	$13.2	$3.2	$3.4	$3.4	$3.4	$13.4	$14.5	$15.0	$16.0
% SG&A	*48.0%*	*16.8%*	*26.7%*	*28.3%*	*48.6%*	*48.6%*	*35.3%*	*36.3%*	*32.4%*	*28.6%*
R&D	$31.2	$31.9	$8.0	$7.5	$8.0	$9.0	$32.5	$30.0	$30.0	$30.0
% R&D	*93.0%*	*40.8%*	*66.7%*	*62.5%*	*114.3%*	*128.6%*	*85.5%*	*75.0%*	*64.8%*	*53.7%*
Operating Income	($13.7)	$33.2	$0.8	$1.1	($4.4)	($5.4)	($7.9)	($4.5)	$1.3	$9.9
Operating Margin	-	*42.4%*	-	-	-	-	*-20.8%*	*-11.3%*	*2.8%*	*17.7%*
Interest / Other Income	$5.8	$3.7	$0.9	$0.9	$0.9	$0.9	$3.6	$3.5	$3.0	$2.5
Pre-Tax Income	($8.0)	$36.8	$1.7	$2.0	($3.5)	($4.5)	($4.3)	($1.0)	$4.3	$12.4
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0.6	$3.7
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5.0%*	*15.0%*	*30.0%*
Net Income	($8.0)	$36.8	$1.7	$2.0	($3.5)	($4.5)	($4.3)	($1.0)	$3.6	$8.7
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	-	*47.0%*	-	-	-	-	*-11.3%*	*-2.5%*	*7.9%*	*15.5%*
Reported EPS	**($0.15)**	**$0.65**	**$0.03**	**$0.04**	**($0.06)**	**($0.08)**	**($0.08)**	**($0.02)**	**$0.06**	**$0.13**
YOY Growth	-	-					*-111.5%*	*-77.9%*	*-449.9%*	*128.6%*
Stock Options	*$3.1*	*$2.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$3.0*	*$3.5*	*$4.0*	*$4.5*
EPS Impact of FAS-123R	*$0.06*	*$0.04*	*$0.01*	*$0.01*	*$0.01*	*$0.01*	*$0.05*	*$0.06*	*$0.06*	*$0.07*
Shares Outstanding	52.8	56.4	56.6	56.8	57.0	57.5	57.0	60.0	62.5	65.0

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

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Neurocrine Biosciences Inc.
DCF Model

Neurocrine Biosciences (NBIX)	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Royalties on Elagolix	$0	$0	$0	$6	$16	$48	$103	$142	$190	$227	$254	$278
YoY Growth	-	-	-	-	*153%*	*203%*	*114%*	*38%*	*34%*	*19%*	*12%*	*10%*
Royalties on NBI-98854	$0	$0	$0	$0	$0	$6	$13	$22	$33	$45	$58	$60
YoY Growth	-	-	-	-	-	-	*124%*	*66%*	*46%*	*37%*	*31%*	*4%*
Royalties on GSK-5616679	$0	$0	$0	$0	$0	$0	$0	$3	$7	$11	$17	$21
YoY Growth	-	-	-	-	-	-	-	-	*119%*	*64%*	*45%*	*29%*
Pipeline	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Licensing & Collaborative	$79	$24	$30	$36	$30	$45	$40	$30	$25	$25	$35	$30
Revenues (in Millions)	$79	$24	$30	$42	$46	$99	$156	$198	$255	$308	$364	$390
CoGS	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*
R&D	*$32*	*$33*	*$30*	*$30*	*$30*	*$30*	*$30*	*$30*	*$35*	*$35*	*$40*	*$45*
SG&A	*$13*	*$13*	*$15*	*$15*	*$16*	*$18*	*$20*	*$22*	*$25*	*$30*	*$35*	*$40*
Other Expenses	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*
EBITDA	$34	($22)	($14)	($3)	($0)	$51	$106	$146	$195	$243	$289	$305
Depreciation and amortization	*$3*	*$3*	*$3*	*$3*	*$3*	*$3*	*$3*	*$3*	*$3*	*$3*	*$3*	*$3*
EBIT	$31	($25)	($17)	($6)	($3)	$48	$103	$143	$192	$240	$286	$302
EBITDA margin	-	-	*-56.6%*	*-13.5%*	*-6.8%*	*48.5%*	*66.1%*	*72.2%*	*75.3%*	*77.9%*	*78.6%*	*77.4%*
Cash Taxes	$0	$0	$0	$0	$0	($12.0)	($31)	($42.8)	($57.6)	($71.9)	($85.7)	($90.6)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*25%*	*30%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*
Balance Sheet												
Capital Expenditures	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1
Working Capital	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)
Non-Cash Adjustments	($2)	($2)	($2)	($2)	($2)	($2)	($2)	($2)	($2)	($2)	($2)	($2)
Capital Adjustments	**($2)**	**($2)**	**($2)**	**($2)**	**($2)**	**($2)**	**($2)**	**($2)**	**($2)**	**($2)**	**($2)**	**($2)**
Net Margin	*39.1%*	*-101.0%*	*-56.6%*	*-13.5%*	*-6.8%*	*36.4%*	*46.3%*	*50.5%*	*52.7%*	*54.5%*	*55.0%*	*54.2%*
Discounted Cash Flow												
Net Income	$31	($25)	($17)	($6)	($3)	$36	$72	$100	$134	$168	$200	$211
Depreciation and amortization	$3	$3	$3	$3	$3	$3	$3	$3	$3	$3	$3	$3
Net Cash Changes	$2	$2	$2	$2	$2	$2	$2	$2	$2	$2	$2	$2
Post-Tax Operating Cash Flow	**$36**	**($20)**	**($12)**	**($1)**	**$2**	**$41**	**$77**	**$105**	**$139**	**$173**	**$205**	**$216**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**$36**	**($20)**	**($12)**	**($1)**	**$2**	**$41**	**$77**	**$105**	**$139**	**$173**	**$205**	**$216**

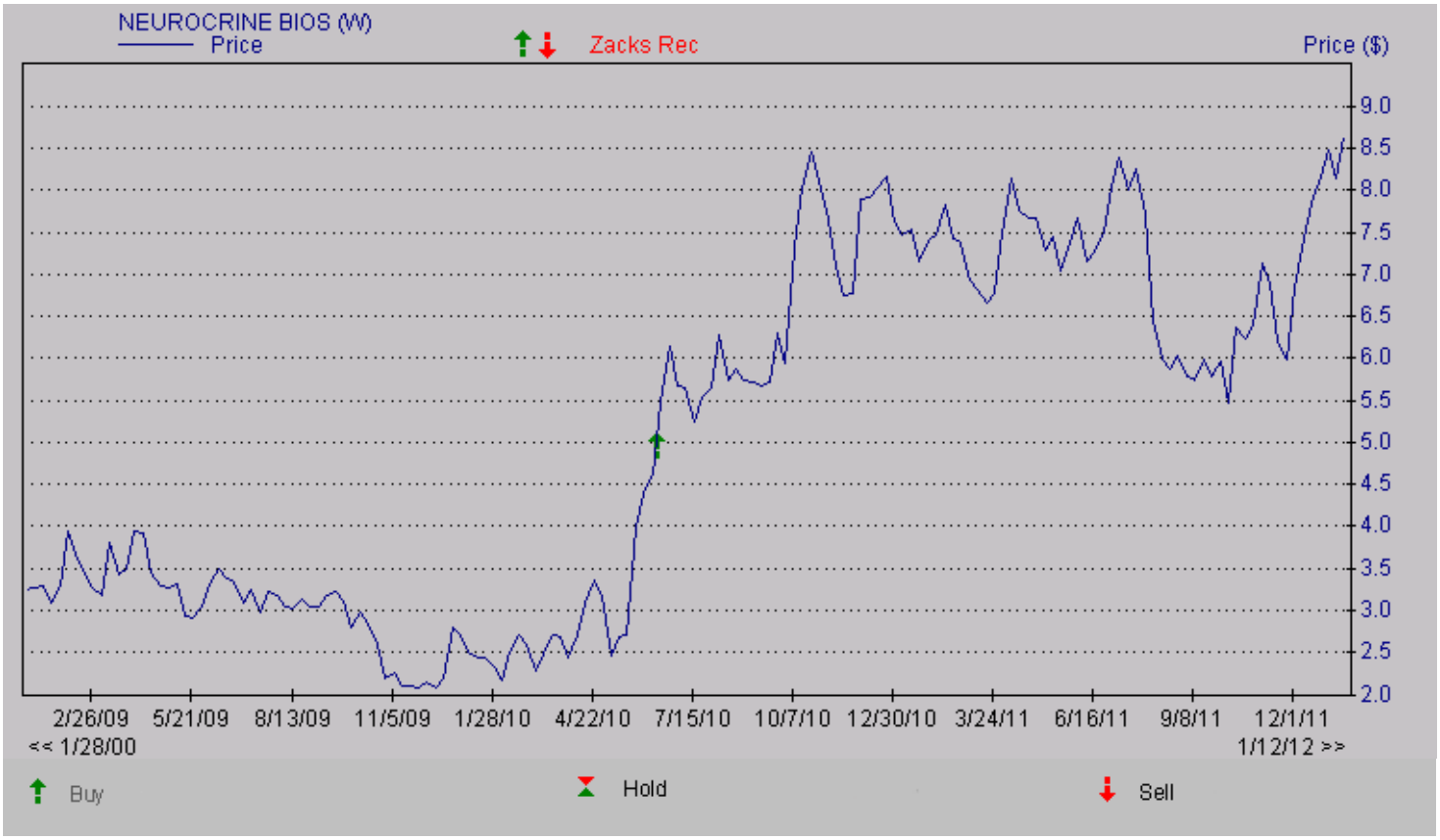
Assumptions	
Beta:	1.3
Equity Risk Premium:	8%
Risk Free Rate:	3%
Firm Risk Premium:	45%
Discount Rate:	**15%**

Valuation	
10-Year Model:	$268
Terminal Growth:	2%
Terminal Value:	$391
Net Cash - LT Debt:	$105
Firm Value:	**$764**

Price Target	
Basic Outstanding:	56.4
Warrants / Options:	8.6
Dilution:	0
Fully Diluted:	61.1
Target Price:	**$12.50**

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

HISTORICAL ZACKS RECOMMENDATIONS



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