Zacks Small-Cap Research

May 3, 2013
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Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: Pipeline Keeps Rolling Ahead…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (05/03/13)	$11.23
Target Price	**$14.00**

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 AbbVie 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.

Neurocrine currently holds nearly $180 million in cash and investments. With a strong pipeline, plenty of cash, and great collaboration partners in AbbVie and Boehringer Ingelheim, we think Neurocrine makes sense for a long-term investment in biotech.

SUMMARY DATA

52-Week High	**$12.65**
52-Week Low	**$6.45**
One-Year Return (%)	**55.94**
Beta	**0.58**
Average Daily Volume (sh)	**485,186**
Shares Outstanding (mil)	**67**
Market Capitalization ($mil)	**$725**
Short Interest Ratio (days)	**6.30**
Institutional Ownership (%)	**85**
Insider Ownership (%)	**5**
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 2013 Estimate	**N/A**
P/E using 2014 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)
2012	11.3 A	10.6 A	9.4 A	21.9 A	53.1 A
2013	0.7 A	0.8 E	0.8 E	0.8 E	3.0 E
2014					5.0 E
2015					50.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.01 A	-$0.01 A	-$0.05 A	$0.14 A	$0.08 A
2013	-$0.18 A	-$0.19 E	-$0.19 E	-$0.18 E	-$0.75 E
2014					-$0.50 E
2015					-$0.02 E

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WHAT'S NEW

Recent Financial Results

On May 3, 2013, Neurocrine Bio reported financial results for the first quarter 2013. The company reported total revenues in the quarter of $0.73 million, essentially in-line with our expectation at $0.75 million. Management noted on their update call that AbbVie paid the final installment of the collaboration payment on elagolix in the fourth quarter 2012. Management expects no sizable milestone payments from AbbVie on elagolix in 2013. Similarly, there are no milestone payments from Boehringer Ingelheim expected in 2013. As such, revenues for 2013 are expected to be only modest, at around $3.0 million for the entire year. We expect milestones to resume in 2014 on elagolix given the expected phase 3 endometriosis data expected in the first quarter 2014. For the first quarter 2013, Neurocrine reported net loss of $12.1 million, or $0.18 per share. This was smack-on with our estimate.

…Financial Guidance…

The company's balance sheet on March 31, 2012 reflected total assets of $183.9 million, including cash and short-term investments of $158.2 million and current assets of $160.4 million. We note the company has another $21.7 million in long-term investments and restricted cash. Financial guidance for 2013 remains the same as provided back in February 2013. Management expects a net cash burn from operations of approximately $50 to $55 million in 2013. Revenue is expected to approximate $3.0 million which consists solely of the amortization of up-front license fees. Expenses for 2013 should approximate $55 to $60 million. Net loss for 2013 is expected to be $50 to $55 million, or $0.75 to $0.83 loss per share based on 66.7 million basic shares outstanding. The company expects to end 2013 with in excess of $130 million in cash, investments and receivables.

Elagolix Development Continues At AbbVie

…In Endometriosis…

In June 2012, Abbott Labs (now AbbVie) initiated a phase 3 trial with elagolix to evaluate the safety and efficacy in female patients with endometriosis. The phase 3 trial, called Violet Petal (ClinicalTrial.gov identifier: NCT01620528) is a 24-week, multinational, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of elagolix in 875 women, age 18 to 49, with moderate-to-severe endometriosis-associated pain. It is being conducted at approximately 160 sites in the United States, Puerto Rico and Canada. As of May 2013, AbbVie reports being pleased with the patient recruitment and enrollment to date. Almost all sites are online and Neurocrine management continues to believe that top-line data will be available in the first quarter 2014.

The primary endpoint will be a dual-endpoint in reduction in dysmenorrhea and non-menstrual pelvic pain (NMPP) for women on two doses of elagolix (150 mg and a yet unannounced higher dose) vs. placebo in a 1-1-2 randomization over 6 months. We have heard some rumblings around the endpoints from investors, some noting that a subjective pain endpoint will be difficult to hit and others commenting that dysmenorrhea does not adequately signal efficacy due to the disruption of ovarian stimulation. However, we note the protocol for the trial has been well vetted by Neurocrine, AbbVie, and the U.S. FDA. AbbVie stopped short of seeking a Special Protocol Assessment (SPA) with the FDA, but Neurocrine management tells us all aspects of an SPA agreement are in place for Violet Petal. Plus, efficacy will be assessed by a responder analysis for statistical evaluation. The inclusion of a higher dose of elagolix, perhaps 250mg or 300mg (150mg BID) is intriguing. It allows for a potential full label with dose titration and prescribing options post approval.

Arms	Assigned Interventions
Experimental: Elagolix Dose 1 Elagolix Dose 1	Drug: Elagolix Elagolix Dose 1 for 6 month treatment period Other Name: ABT-620, elagolix sodium
Experimental: Elagolix Dose 2 Elagolix Dose 2	Drug: Elagolix Elagolix Dose 2 for 6 month treatment period Other Name: ABT-620, elagolix sodium
Placebo Comparator: Placebo Placebo	Other: Placebo Placebo for 6 Month Treatment Period

An electronic diary will be dispensed to participants in the trial and training provided to record endometriosis-associated pain, uterine bleeding, and analgesic medication use for endometriosis-associated pain on a daily basis. Pregnancy testing will be performed monthly throughout the study. Subjects will be required to use non-hormonal dual contraception during the study, and will be counseled on appropriate and effective forms of birth control to promote pregnancy prevention.

Responder analysis from the phase 2b trial showed an 85% response rate with 150mg elagolix. We believe AbbVie is looking for greater than 90% response rate in the phase 3 trial through the inclusion of a higher dose. Secondary endpoints include Dyspareunia and Patient Global Impression of Change (PGIC), as well as analgesic use. Following the 6 month controlled portion of the trial, patients will enroll in a 6 month open-label extension study where AbbVie will look for signs of persistent efficacy. For the safety analysis, patients will be followed for an additional 12 months, after which AbbVie will conduct a DXA scan to assess changes in bone mineral density.

AbbVie plans to conduct a second confirmatory phase 3 trial mirroring the Violet Petal trial expected to start in 2013. We expect that this program will include sites outside North America, with an emphasis on Western Europe. Full analysis from the second trial is expected in 2016, along with the New Drug Application (NDA) planned for 2016.

…In Uterine Fibroids…

On September 13, 2011, Abbott Labs announced it had commenced a phase 2a clinical trial to evaluate elagolix in an exploratory trial for the treatment of uterine fibroids (ClinicalTrial.gov identifier: NCT01441635). The trial is expected to enroll women with heavy uterine bleeding associated with uterine fibroids at clinical sites around the U.S. for a total of 3 months. The doses for the trial have not been disclosed, but Neurocrine describes them as a broad range with previous work done in phase 1 trial. ClinicalTrial.gov notes four doses in the trial. AbbVie is analyzing the data from each dosing cohort looking signs of safety and efficacy. We expect to begin to see data over the summer of 2013. The primary endpoint will be quantified blood loss assessed by alkaline hematin.

However, based on the data that AbbVie is seeing, the company has made a decision to progress into a phase 2b before the phase 2a study completed. We believe the fact that AbbVie is seeing the kind of safety and efficacy signals necessary to make this jump into phase 2b before the phase 2a completes is clearly a good sign for Neurocrine investors.

On March 27, 2013, this phase 2b study commenced. The phase 2b uterine fibroids study (ClinicalTrials.gov identifier: NCT01688037) is a randomized, parallel, double-blind, placebo-controlled clinical trial evaluating elagolix in women with heavy uterine bleeding associated with uterine fibroids. This study will evaluate 280 subjects over a six-month placebo-controlled dosing period. The primary efficacy endpoint of the study is an assessment of the change in menstrual blood loss utilizing the alkaline hematin method comparing baseline to month six.

Additional secondary efficacy endpoints will be evaluated including assessing the change in fibroid volume and hemoglobin. Bone mineral density will be assessed via DXA scan at baseline, the conclusion of dosing, and six months post-dosing. We expect this study to complete and offer top-line data around mid-2014. If all goes well, AbbVie could be in phase 3 for UF by the end of 2014.

NBI-98854 Moving Forward

…Phase 2b – KINECT-1 Enrolling…

Management is currently screening patients for a phase 2b trial, called KINECT-1, which will assess NBI-98854 in patients with confirmed moderate-to-severe tardive dyskinesia (TD) and schizophrenia or schizo-affective disorder. Neurocrine invested significantly in the training and certification of AIMS readers for KINECT-1 (ClinicalTrial.gov identifier: NCT01688037). The company is also employing a group of independent readers to assess entry criteria prior to enrollment. For example, patients are video-taped during the screening process and the videos are sent to an independent reader to confirm moderate-to-severe TD. Neurocrine's Chief Medical Officer, Chris O'Brien, is also viewing the video tapes to QC the enrollment process.

As of May 2013, the company reported being very pleased with how this process is proceeding. The company has screened around 180 patients at 40 clinical sites to date, enrolling 90 patients (of the target 120) at around 30 sites. Management noted on the most recent call that the majority of patients fail screening because they either do not have moderate-to-severe disease or have some other type of movement disorder besides TD associated with schizophrenia or schizo-affective disorder. Other reasons for screen failure include patients with a history of drug use / abuse, patients with liver abnormalities, including HCV, or those with potential other consequential drug-drug related interactions. Management noted on the call that the blinded baseline AIMS score of the 90 patients enrolled so far was around 15 (with a standard deviation of around 4). We are pleased to see the design and enrollment criteria holding up.

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 and each patient will be on a fixed dose of the drug during the 12 week treatment period. We remind investors that the 50mg dose was the dose that showed efficacy in the phase 2a study.

We expect enrollment of the 120th patient in the next few months. Management noted that data should be available approximately ten weeks after the last patient has been randomized. We expect this trial to offer data early in the third quarter 2013.

...KINECT-2 Also On Track…

Neurocrine is currently conducting a second phase 2b study with NBI-98854, to be called KINECT-2 (ClinicalTrial.gov identifier: NCT01733121). This trial will seek to enroll up to 90 patients at 30 sites with moderate-to-severe TD, only in patients with bipolar disorder, mood disorder, or metoclopramide-induced TD, and potentially some patients with schizophrenia or schizoaffective disorder that did not qualify for KINECT-1. Management believes that the pathophysiology of TD is similar in each patient, but wants to generate appropriate safety data in each potential patient population before proceeding into a phase 3 program. We note that KINECT-2 will be a dose-titration program where patients will start off on 25 mg and escalate up to 75 mg if tolerable. This is in contrast to the fixed dose KINECT-1 program.

Patient screening for KINECT-2 began in December 2012. As of May 2013, 45 patients have been screened with 26 enrolled. We note the 26 have been enrolled at only 13 of the target 30 sites, so we expect the enrollment pace to accelerate in the next month or two. The target enrollment is 90 patients. Similar to KINECT-1, we expect top-line data from this program roughly ten weeks after the announcement that full enrollment has been met.

In total the phase 2b KINECT program will enroll 210 patients with moderate-to-severe TD and various underlying conditions, testing doses ranging from 25 mg to 75 mg. Understanding this full range of dosing options in various patient populations should help management design a highly effective phase 3 trial for the drug. Neurocrine's goal is to schedule an end of phase 2 meeting with the U.S. FDA in late 2013.

Management plans to go back and look at the excluded populations from KINECT (i.e. patients with liver abnormalities, HCV, or history of drug abuse) before starting a phase 3 study that might include these patients. We note there remains some preclinical and phase 1 work that needs to be completed as well before the initiation of a phase 3 trial in 2014. This includes the six and nine month toxicology and carcinogenicity work, as well as a thorough QTc prolongation and hepatic impairment analysis. In previous phase 1 work with NBI-98854 patients were required to wear a Holter monitor to detect potential cardiovascular affects and the safety profile looked clean.

…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 Tourette's, in 2014. Tourette's is a disease that primarily affects adolescents starting at the age of six. Before this trial can begin, management must complete some additional toxicology work and an adolescent bridging study. However, we note that so far, in the KINECT studies, NBI-98854 has offered a pretty clean safety and tolerability profile. Management noted on the first quarter 2013 conference call that discontinuation rates for KINECT-1 and KINECT-2 are tracking well below what would normally be expected in a moderate-to-severe TD patient population. This is clearly a good sign in terms of both NBI-98854 safety and tolerability, along with efficacy.

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 North American rights to NBI-98854 all the way to commercialization, but may seek a rest of world (ROW) partnership for the initiation of phase 3 in 2014.

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, now AbbVie, 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 2017. To date, roughly $70 million has been received.

The company has also signed a second deal with Boehringer Ingelheim and successfully completed phase 2a studies on internal candidate, NBI-98854, VMAT-2 inhibitor for tardive dyskinesia. 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 March 31, 2012 reflected total assets of $183.9 million, including cash and short-term investments of $158.2 million and current assets of $160.4 million. We note the company has another $21.7 million in long-term investments and restricted cash. The company expects to end 2013 with in excess of $130 million in cash, investments and receivables. Our market research shows elagolix as a $1.5 billion drug worldwide. Meanwhile, two phase 2b trials on VMAT-2 inhibitor, NBI-98854, called KINECT-1 and KINECT-2, are underway with data expected from both studies in the third quarter 2013.

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 $14 target.

PROJECTED FINANCIALS

Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2011 A	2012 A	Q1 A	Q2 E	Q3 E	Q4 E	2013 E	2014 E	2015 E	2016 E
R&D / Milestones & Fees	**$77.4**	**$53.1**	**$0.7**	**$0.8**	**$0.8**	**$0.8**	**$3.0**	**$5.0**	**$50.0**	**$50.0**
YOY Growth	*131.1%*	*-31.4%*	*-93.5%*	*-92.9%*	*-92.0%*	*-96.6%*	*-94.4%*	*67.8%*	*900.0%*	*0.0%*
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
VMAT-2	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$77.4**	**$53.1**	**$0.7**	**$0.8**	**$0.8**	**$0.8**	**$3.0**	**$5.0**	**$50.0**	**$50.0**
YOY Growth	*131.1%*	*-31.4%*	*-93.5%*	*-92.9%*	*-92.0%*	*-96.6%*	*-94.4%*	*67.8%*	*900.0%*	*0.0%*
CoGS / Royalties	$0	$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	$12.4	$14.5	$3.4	$3.3	$3.5	$3.6	$13.8	$14.5	$15.0	$15.5
% SG&A	*16.0%*	*27.3%*	*464.7%*	*440.0%*	*466.7%*	*480.0%*	*462.8%*	*290.0%*	*30.0%*	*31.0%*
R&D	$31.0	$37.2	$10.3	$11.0	$11.5	$10.5	$43.3	$35.0	$40.0	$40.0
% R&D	*40.0%*	*69.9%*	*1412.7%*	*1466.7%*	*1533.3%*	*1400.0%*	*1453.5%*	*700.0%*	*80.0%*	*80.0%*
Operating Income	$34.1	$1.4	($13.0)	($13.6)	($14.3)	($13.4)	($54.1)	($44.5)	($5.0)	($5.5)
Operating Margin	*44.0%*	*2.7%*	-	-	-	-	*-1816.3%*	*-890.0%*	*-10.0%*	*-11.0%*
Interest / Other Income	$3.6	$3.6	$0.9	$1.0	$1.0	$1.0	$3.9	$3.5	$2.5	$2.5
Pre-Tax Income	$37.6	$5.0	($12.1)	($12.6)	($13.3)	($12.4)	($50.2)	($41.0)	($2.5)	($3.0)
Taxes	$0	$0	$0	$0	$0	$0	$0	$6.2	$0.8	$0.9
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5%*	*15.0%*	*30.0%*	*30.0%*
Net Income	$37.6	$5.0	($12.1)	($12.6)	($13.3)	($12.4)	($50.2)	($34.9)	($1.8)	($2.1)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	*48.5%*	*9.5%*	-	-	-	-	*-1685.4%*	*-697.0%*	*-3.5%*	*-4.2%*
Reported EPS	**$0.67**	**$0.08**	**($0.18)**	**($0.19)**	**($0.20)**	**($0.18)**	**($0.75)**	**($0.50)**	**($0.02)**	**($0.03)**
YOY Growth	-	*-88.5%*					*-1082.2%*	*-33.8%*	*-95.2%*	*16.0%*
Shares Outstanding	56.3	65.6	66.6	66.7	66.8	67.0	66.8	70.0	72.5	75.0

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

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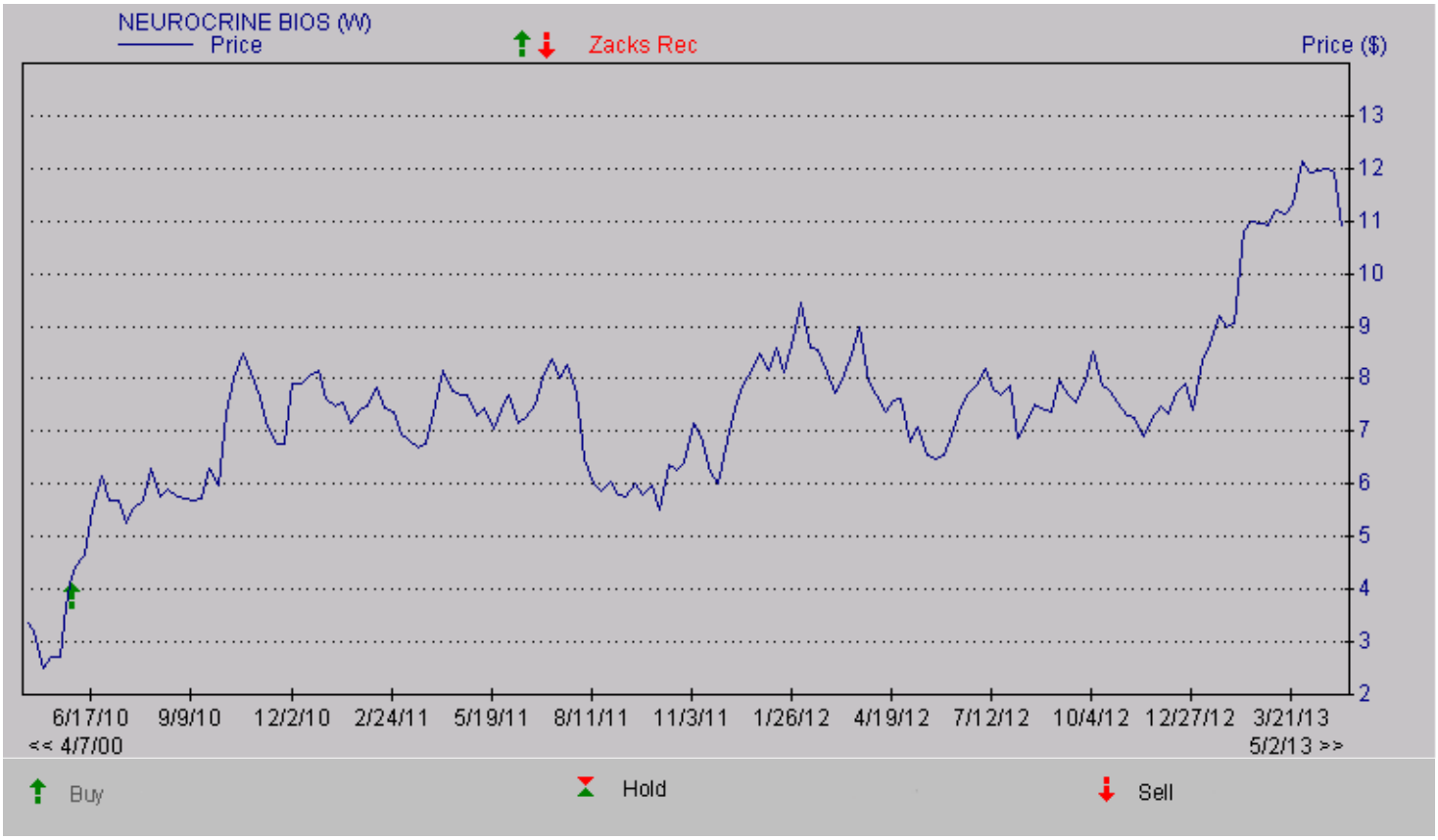
HISTORICAL ZACKS RECOMMENDATIONS



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