Zacks Small-Cap Research

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Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: Everything proceeding as planned for Neurocrine Biosciences…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (05/01/14)	$14.02
Target Price	**$19.00**

UPDATE

On April 30, 2014, Neurocrine Bio reported financial results for the first quarter of 2014. Results were essentially right-on with our expectations. The company ended the quarter with approximately $272 million in cash, cash equivalents, investments, and receivables. For 2014, management continues to expect net cash burn of approximately $43 million to $47 million.

We remain optimistic on the future of Neurocrine Bio. We believe elagolix and NBI-98854 both offer significant upside for investors over the next few years. We value the shares at $19.

SUMMARY DATA

52-Week High	**$19.65**
52-Week Low	**$8.68**
One-Year Return (%)	**27.45**
Beta	**-0.24**
Average Daily Volume (sh)	**753,476**
Shares Outstanding (mil)	**75**
Market Capitalization ($mil)	**$1,056**
Short Interest Ratio (days)	**4.04**
Institutional Ownership (%)	**70**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	0.7 A	0.7 A	0.7 A	0.7 A	2.9 A
2014	0 A	0 E	0 E	0 E	0.0 E
2015					25.0 E
2016					50.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.18 A	-$0.18 A	-$0.17 A	-$0.16 A	-$0.69 A
2014	-$0.17 A	-$0.18 E	-$0.20 E	-$0.22 E	-$0.77 E
2015					-$0.28 E
2016					-$0.02 E

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WHAT'S NEW

First Quarter Financials

On April 30, 2014, Neurocrine Bio reported financial results for the first quarter of 2014. The company reported no revenues for the quarter, as was expected. Research and development expenses were $8.6 million, a decrease from $10.3 million during the same period in 2013. This decrease was due to lower external clinical development expenses related to the development of NBI-98854, which completed Phase 2 development during 2013 and is currently being prepared for Phase 3 development. G&A expenses were $4.2 million, an increase from $3.4 million for the first quarter a year ago. The increase was due mostly to higher share-based compensation expense. The company reported a net loss of $11.8 million ($0.17 per share) for the quarter, roughly in line with our expectation.

…Financial Guidance…

The company's balance sheet at the end of the first quarter 2014 reflected cash, cash equivalents, investments and receivables of $272.3 million, compared with a balance at December 31, 2013 of $146.8 million. During the quarter, the company completed a public offering of eight million shares of common stock that resulted in net proceeds of approximately $133 million. For 2014, management continues to expect a net cash burn of approximately $43 million to $47 million. Net loss for 2014 is expected to be $56 million to $61 million, or $0.75 to $0.81 loss per share based on approximately 75 million basic shares outstanding. The company expects to end 2014 with approximately $230 million in cash, investments and receivables.

Recent Meeting With Management

We sat down with management at Neurocrine Bio in January 2014. They had particularly large smiles on their faces considering the stock had just doubled the week before on the top-line results from the KINECT-2 study (discussed below). Hat's off to management because they did a lot of work after the failure of KINECT-1 to re-design the KINECT-2 trial. Management knew the drug worked, it was a question of designing the proper trial and using the correct assessment and endpoints to show it that was a challenge. After all, there are no approved therapies for tardive dyskinesia (TD), so Neurocrine is pioneering the pathway for all intents and purposes.

But the thing that hit home the most with us was the before and after videos of TD patients CMO Chris O'Brien had on his iPad. We viewed five total videos of patients from KINECT-2, before and after treatment, and all we can say is – Wow, NBI-98854 really works. After the KINECT-2 conference call, we wondered whether or not Neurocrine had the right dose and if the company was truly ready to progress into Phase 3 without exploring more doses in another Phase 2b study. But the videos were a slam-dunk case of efficacy in our view. Patients that had significant dyskinesia of the hands, legs, mouth, and tongue all showed dramatic improvements after six weeks on drug. Unfortunately, Neurocrine cannot make these videos public – probably due to some HIPAA privacy issue – but if you get a chance to sit down with management in the next few months we think the videos really drive home how NBI-98854 is going to be a big drug for Neurocrine.

Management will continue to analyze the data from KINECT-2 over the next few months to further qualify and fully understand the patient population and design characteristics for the planned Phase 3 program. Neurocrine is also working both in-house and with outside consultants to analyze drug exposure and the pooled PK and PD data as it relates to changes in AIMS score seen in both KINECT-1 and KINECT-2. We remind investors that the company has also been doing early-stage toxicology work, namely a hepatic impairment special population study and drug-drug interaction studies to further build up the clinical and pre-clinical data package to bring in front of the U.S. FDA for an "End of Phase 2" meeting. The goal is to submit that package to the FDA in the second quarter of this year and hopefully sit down for a face-to-face meeting roughly 60 days after. One good thing to mention – the FDA does get to see those impressive video clips we mentioned above.

At the End of Phase 2 meeting Neurocrine will present a design protocol for the planned Phase 3 trials. Once the FDA gives their final blessing on the trial design, Neurocrine can begin to work with the institutional review boards to start the trial. We expect this to take place in the third quarter 2014. The company has already begun the process of identifying and qualifying additional clinical trial sites for the Phase 3 program. Management's belief is that the Phase 3 program will include two relatively modest sized (150-200 subjects) 12-week pivotal trials, with each having their own 12 month open-label safety extension study. We expect Neurocrine will also conduct, in parallel, a separate additional ~100 subject 12 month open label safety trial. We model the U.S. NDA filing in 2016.

Management noted on the most recently conference call that they are in partnering discussions with NBI-98854 for Ex-U.S. rights, but that the company is squarely focused on initiating the U.S. Phase 3 program in 2014 as a priority. We expect Neurocrine to commercialize NBI-98854 in the U.S. themselves, and partners for Phase 3 and commercialization in Europe in 2015. We believe a drug like NBI-98854 could capture as much as $50 million upfront and potentially $500 million in backend milestones, plus royalties on sales.

Beyond TD, Neurocrine is still working on completing the pre-clinical juvenile toxicology studies, along with some additional work, so they can file a new investigation new drug (IND) application to the U.S. FDA for Tourette's syndrome during the second half of 2014. Following U.S. IND approval, Neurocrine is expected to move quickly into a Phase 2 study for pediatric Tourette's syndrome by the end of 2014.

All-in, we think Phase 3 should cost Neurocrine around $40-50 million and the company should be in position to file for approval around the middle of 2016. Coincidently, that is also when AbbVie expects to be in position to file for approval of elagolix in endometriosis.

INVESTMENT OVERVIEW

KINECT-2 Hits

On January 6, 2014, Neurocrine Biosciences, Inc. (NBIX) announced results from the Phase 2b KINECT-2 study with small molecule VMAT2 inhibitor, NBI-98854, showed statistically significant and clinically meaningful reduction in tardive dyskinesia symptoms. The news is a pleasant surprise to Neurocrine investors after the mixed results of the KINECT-1 study in September 2013. The key differences between these two trials include dose titration and underlying disorder. Below we provide a quick background on the drug, a summary of the data from KINECT-2, a rehash of the KINECT-1 data, post some thoughts on what the future holds with respect to Phase 3.

Quick Background On Tardive Dyskinesia and NBI-98854

Tardive dyskinesia (TD) is a neurological disorder caused by the long-term use of psychiatric drugs (neuroleptics) used in the treatment of schizophrenia. The symptoms of tardive dyskinesia include involuntary and abnormal movements of the jaw, lips, and tongue, including grimacing, sticking out the tongue, and sucking or fish-like movements of the mouth. In some cases, other parts of the body may be affected by rapid, jerking motions (chorea) or slow writhing movements (athetosis). These symptoms cause considerable distress to patients due to the resulting social stigma, and may contribute to poor outcomes such as psychiatric hospitalization by discouraging compliance with treatment. Other medical complications of tardive dyskinesia include difficulty eating, difficulty breathing, and dental problems.

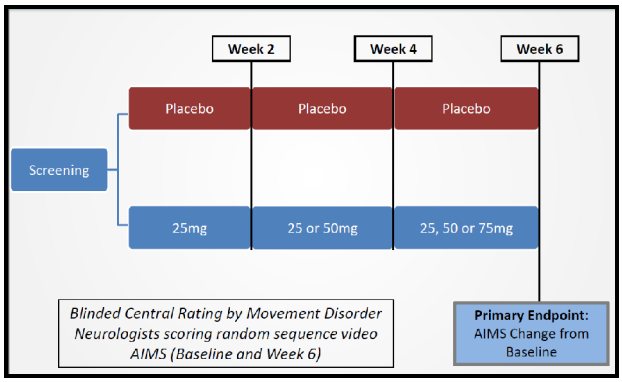
Tetrabenazine is probably the most common therapeutic option available for patients with tardive dyskinesia. The drug is believed to exert its therapeutic effect in tardive dyskinesia by inhibiting the activity of VMAT2, a transporter that serves to package dopamine into vesicles for release into the synapse. This reduces synaptic dopamine levels, thus relieving overstimulation of hypersensitive dopamine receptors. Investors may be familiar with data supporting the clinical efficacy of tetrabenazine, which includes nearly a dozen clinical trials and case studies to date.

Unfortunately, despite clinically meaningful efficacy, use of tetrabenazine is limited due to a high frequency of serious adverse events, including suicide, suicidal ideation/restlessness, and breast cancer. Other common dose limiting adverse events include sedation, akathisia, parkinsonism, and depressed mood. In fact, the tetrabenazine label includes a black box warning for depression and increased risk of suicidiality. Being an orphan drug, tetrabenazine carries a steep price at approximately $50,000 per year.

It is thought that much of the adverse events and poor tolerability of tetrabenazine is a result of high variability of metabolism among patients and unwanted activity at dopamine receptors. Tetrabenazine is sold as a complex mixture of four closely related compounds (isomers) and is metabolized in the liver to produce a related set of four isomers. One of these (Active Metabolite A) is a more potent VMAT2 inhibitor than the others and lacks activity at dopamine receptors. The other three are less potent VMAT2 inhibitors, two of which exhibit potent affinity for dopamine receptors. Neurocrine's NBI-98854 is a novel compound that is rapidly and completely converted into Metabolite A of tetrabenazine upon oral administration.

KINECT-2 Background & Data

KINECT-2 was a randomized, double-blind, placebo-controlled Phase 2b study that enrolled 102 subjects at 29 sites all in the U.S. Within the 102 subjects, 58% had schizophrenia and 38% had mood disorders. Neurocrine screen over 200 patients to enroll the target 102-patient population. Management noted that approximately half of patients screened did not qualify because of abnormal labs, non-TD movement disorder, TD of only mild severity or unstable medical condition (similar to prior KINECT study). To the right we present a schematic on the trial design and dose titration schedule.



KINECT-2 looks to have employed a very successful titration schedule given the statistically significant and clinically meaningful data. According to management, 84% of the patients up-titrated from the 25mg to the 50mg dose at week 2, followed by 76% up-titrating to 75mg at week 4. At the end of the trial, 70% (31 of 44) of the patient population were on the 75mg dose, 20% (9 of 44) were on 50mg, and 10% (5 of 44) remained on 25mg.

The primary endpoint of the study was change in Abnormal Involuntary Movement Scale (AIMS) from baseline at week 6. Management also provided a responder analysis, which included any subject showing a 50% reduction or greater in AIMS at week 6. Secondary endpoints included a clinician's global impression of change (CGI-TD). Neurocrine analyzed the data from KINECT-2 on an Intent-to-treat (ITT) and Per Protocol (PP) basis. The ITT population includes any subject with at least one dose of blinded study drug (active or placebo) and one post-treatment AIMS assessment at week 6 (n=89). The PP population excluded any subject randomized to NBI-98854 without quantifiable level of active metabolite at the evaluation time point (n= 78). Below we present the top-line data from the trial:

		Week 6		
		Placebo	NBI-98854	p-value
AIMS Change from Baseline				
	Baseline AIMS	7.9	8.0	-
	LS Mean AIMS ANCOVA (ITT)	-0.2	-2.6	<0.001
	LS Mean AIMS ANCOVA (PP)	-0.3	-3.3	<0.001
	Responder Rate (ITT)*	18%	49%	0.002
	Responder Rate (PP)*	18%	59%	<0.001

** a responder is defined as 50% or greater reduction in AIMS*

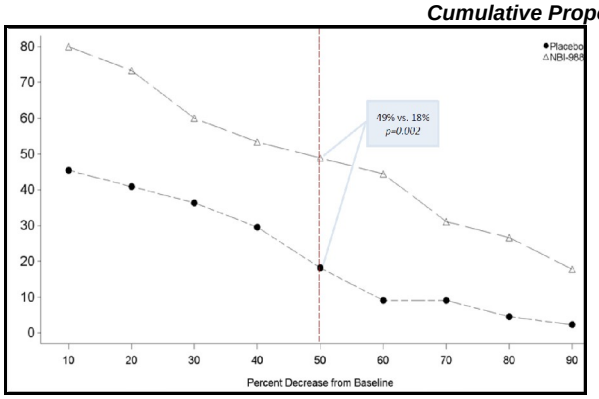
		Week 6		
CGI-TD		Placebo	NBI-98854	p-value
	LS Mean Score (ITT)	3.1	2.2	<0.001
	LS Mean Score (PP)	3.1	2.2	<0.001
	Responder Rate (ITT)*	16%	67%	<0.001
	Responder Rate (PP)*	16%	68%	<0.001

**a responder is defined as "much improved" or "very much improved" (a "2" or "1", respectively) on the CGI-TD. A "4" on the CGI-TD indicates "no change"*

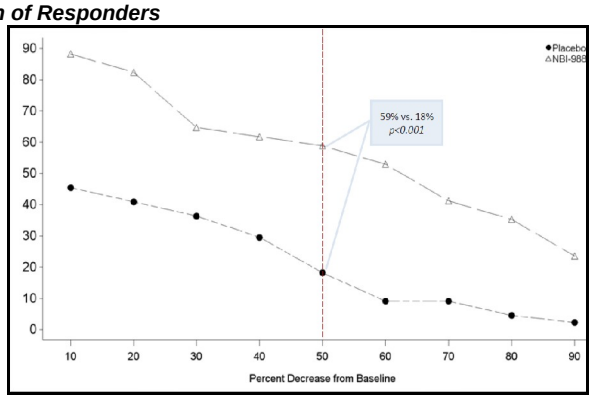
The results are highly statistically significant. This was a dramatic turnaround from the KINECT-1 study (discussed below) where 50mg of drug failed to separate from placebo at week 6. Additional digging to the data shows a trial that was well controlled and well randomized (note the near identical baseline scores of 7.9±4.5 for the placebo vs. 8.0±3.5 for the drug group. Other baseline measures such as age, mean age at time of diagnosis, and score as assessed by the Brief Psychiatric Rating Scale (BPRS) were very similar (both 30.1).

Below we present graphical representations of the profound and consistent separation between NBI-98854 and the placebo on measures of responder analysis:

Cumulative Proportion of Responders



ITT



PP

The safety and tolerability assessment showed that NBI-98854 is a clean drug. That will be very important to the marketing message for Neurocrine when positioning the drug vs. tetrabenazine. During the six-week treatment period the frequency of treatment-emergent adverse events was 33% for placebo and 43% for NBI-98854. There were no drug related serious adverse events. The most common treatment emergent adverse events were fatigue in five subjects (9.8%) randomized to NBI-98854 vs. two subjects (4.1%) in the placebo group, and headache reported by four subjects (7.8%) on NBI-98854 vs. two subjects (4.1%) on placebo. Discontinuation rates were similar in both the NBI-98854 and placebo treatment groups with five per study arm (none of which were study drug related). We note none of the 10 patients that discontinued during the study were included in the final ITT or PP assessment for the primary outcome. This is the only area where we can nit-pick a little about the results. All patients should be included in the final assessment, not just completers. Nevertheless, given the similar and high (~89%) completion rate for both the drug and placebo in both KINECT-1 and KINECT-2, this does not seem an area of major concern going forward.

Observations On NBI-98854 So Far

The outcome of KINECT-2 is quite a positive surprise for Neurocrine investors. Back in July 2013, we predicted that KINECT-1 would be a success in an article for Seeking-Alpha. Our background work on NBI-98854 gave us confidence in the mechanism of action. Turns out we were a little premature in our call given the lack of understanding on the optimal dose. However, the more we analyzed the outcome of KINECT-1, the more we realized the hiccup was a signal vs. noise issue, and we stayed positive on the story. Patience paid off on the release of the KINECT-2 data. Some observations from the two trials are noted below:

- ⇨ Neurocrine seems very happy with the idea of using a centralized rater for the Phase 3 studies. This seems the only logical route forward given the subjectivity of the rating scale. The U.S. FDA has clearly been amendable to these types of centralized assessments in the past.
- ⇨ The baseline AIMS rating for patients in the KINECT-1 study was significantly higher than in the KINECT-2 study (12.3±5.1 vs. 8.0±4.0). Management noted that the actual patient populations were similar on disease severity but that the difference in baseline varied based on what type of doctor was providing the initial assessment (movement disorder doctors vs. psychiatrists). Management may have the KINECT-1 raters go back and score the results from KINECT-2 (and vice versa) to provide additional data prior to the design of the Phase 3 studies.
- ⇨ The company has not had a chance to analyze the data from KINECT-2 based on schizophrenics vs. bipolar disorder patients or outcome by dose (25mg vs. 50mg, vs. 75mg) but intends to do so and present the result to investors when available. The initial assessment suggests that bipolar patients may have had a more powerful response to the drug than schizophrenics.
- ⇨ Throughout the course of both KINECT-1 and KINECT-2, approximately a dozen patients were excluded from the ITT and PP analysis because they never received drug. Management suggested that these were addicts looking for free drug or to be paid for enrollment.
- ⇨ There was good over-lap in enrollment at the highest enrolling sites for both KINECT-1 and KINECT-2.
- ⇨ At this point, management believes that using the new modified AIMS and having an experienced movement disorder doctor, triple-blind to the data, performing the centralized review, are the primary reasons for the improvement in outcome from KINECT-1 to KINECT-2. The company is putting less weight on dose level, and seems content to study 75mg in Phase 3. It remains to be seen whether or not the company will use a dose-titration schedule similar to KINECT-2 in the Phase 3 studies.

Conclusion: Valuation & Recommendation

Besides NBI-98854, Neurocrine obviously still has elagolix pushing forward at AbbVie (ABBV), and early-stage collaborations with Boehringer Ingelheim around the research and development of G-protein coupled receptor (GPCR) small molecules for the treatment of Type-2 diabetes. Phase 2 data on elagolix were just recently published electronically ahead of print in the Journal of Endometriosis and Pelvic Pain Disorders.

We remind investors that AbbVie is currently conducting the Violet Petal Study, a Phase 3 study of elagolix for endometriosis. The study 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. Approximately 160 sites in the United States, Puerto Rico and Canada are conducting this study. The study recently completed recruiting and screening of subjects and final patient randomization is anticipated later this month.

AbbVie has also initiated the second Phase 3 study of elagolix for endometriosis. This study is similar in design to the Violet Petal Study and will assess 788 women, age 18 to 49, with moderate to severe endometriosis-associated pain at more than 200 sites globally. AbbVie has stated recently that they expect data from the first Phase 3 during the second half of 2014. AbbVie is also currently conducting a Phase 2b study of elagolix in uterine fibroids. This study is assessing uterine blood loss in 520 women with heavy uterine bleeding due to uterine fibroids.

We believe elagolix is worth $10 per share based on the rate at which the two ongoing phase 3 studies at AbbVie enroll and report data, and the timelines for the uterine fibroids phase 3 study.

We see Tardive Dyskinesia as a meaningful market opportunity for Neurocrine. There are an estimated 500,000 TD patients in the U.S. with no real treatment options besides tetrabenazine. 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, Tourette's syndrome, and Tardive Dystonia. We expect that management will move into a second indication, most likely Tourette's during the second half of the year.

With a conservative 10% market penetration into the 500,000 U.S. patient population and a price tag of $10,000 per year, NBI-98854 is a $500 million drug. Expanding outside the U.S. in TD or expanding the label indication to things like Tourette's or Huntington's disease could easily double or triple this peak sales estimate. Our best guess at the timing for a new drug application (NDA) is mid-2016. This would suggest a U.S. FDA action date around the middle of 2017. We think Neurocrine could achieve peak sales for the drug by 2022.

Assuming the company choses to market the drug themselves, the NBI-98854 is worth $465 million in value (using 4.0x sales and a 20% discount rate to present day). This equates to $7 per share. Management has noted being in partnership discussions with potential interested parties on NBI-98854. A deal for the drug could provide significant upfront cash, backend milestones and royalties on sales. However, at this time we chose to model that Neurocrine will maintain complete ownership in the asset to commercialization. Along with a little over $2 in cash we see Neurocrine worth roughly $19 per share today.

PROJECTED FINANCIALS

Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2012 A	2013 A	Q1 A	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
R&D / Milestones & Fees	**$53.1**	**$2.9**	**$0**	**$0**	**$0**	**$0**	**$0**	**$25.0**	**$50.0**
YOY Growth	*-31.4%*	*-94.6%*	-	-	-	-	-	-	*100.0%*
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
VMAT-2	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$53.1**	**$2.9**	**$0**	**$0**	**$0**	**$0**	**$0**	**$25.0**	**$50.0**
YOY Growth	*-31.4%*	*-94.6%*	-	-	-	-	-	-	*100.0%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0
Gross Margin	*100.0%*	*100.0%*	-	-	-	-	-	*100.0%*	*100.0%*
SG&A	$14.5	$13.4	$4.2	$4.2	$4.2	$4.2	$16.8	$16.5	$17.5
% SG&A	*27.3%*	*463.1%*	-	-	-	-	-	*66.0%*	*35.0%*
R&D	$37.2	$39.2	$8.6	$10.0	$12.0	$14.0	$44.6	$40.0	$40.0
% R&D	*69.9%*	*1357.6%*	-	-	-	-	-	*160.0%*	*80.0%*
Operating Income	$1.4	($49.7)	($12.7)	($14.2)	($16.2)	($18.2)	($61.3)	($31.5)	($7.5)
Operating Margin	*2.7%*	*-1720.7%*	-	-	-	-	-	*-126.0%*	*-15.0%*
Interest / Other Income	$3.6	$3.6	$0.9	$0.9	$0.9	$0.9	$3.6	$4.0	$5.0
Pre-Tax Income	$5.0	($46.1)	($11.8)	($13.3)	($15.3)	($17.3)	($57.7)	($27.5)	($2.5)
Taxes	$0	$0	$0	$0	$0	$0	$0	$8.3	$0.8
Tax Rate	*0%*	*5%*	*0%*	*0%*	*0%*	*0%*	*15%*	*30.0%*	*30.0%*
Net Income	$5.0	($46.1)	($11.8)	($13.3)	($15.3)	($17.3)	($57.7)	($19.3)	($1.8)
YOY Growth	-	-	-	-	-	-	-	-	-
Net Margin	*9.5%*	*-1597.4%*	-	-	-	-	*#DIV/0!*	*-77.0%*	*-3.5%*
Reported EPS	**$0.08**	**($0.69)**	**($0.17)**	**($0.18)**	**($0.20)**	**($0.22)**	**($0.77)**	**($0.23)**	**($0.02)**
YOY Growth	*-88.5%*	*-995.4%*					*12.2%*	*-70.6%*	*-91.4%*
Shares Outstanding	65.6	67.3	70.3	73.0	77.0	80.0	75.1	85.0	90.0

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

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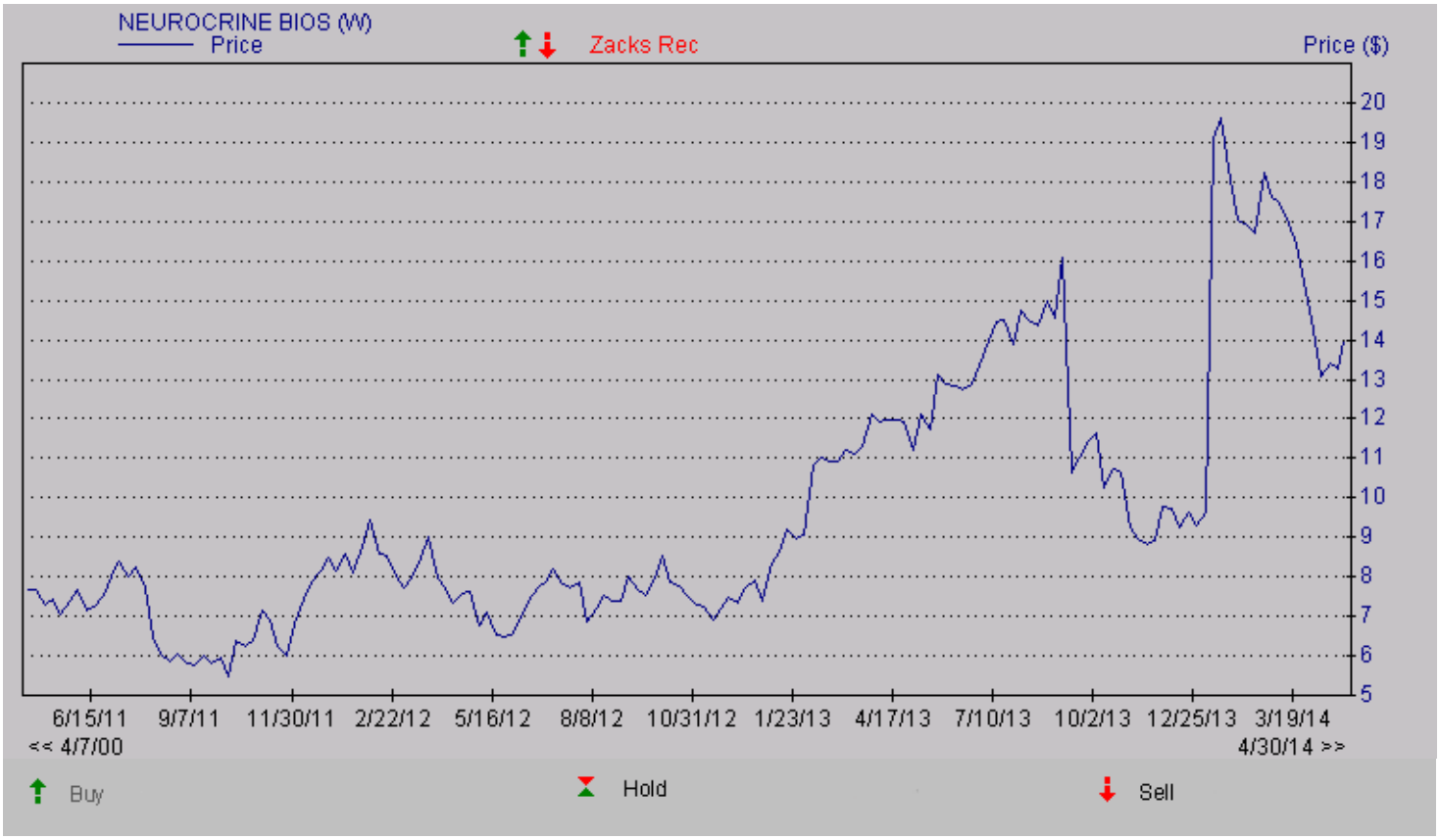
HISTORICAL ZACKS RECOMMENDATIONS



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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.9%, Hold/Neutral- 75.3%, Sell/Underperform – 6.8%. Data is as of midnight on the business day immediately prior to this publication.