Zacks Small-Cap Research

January 6, 2014
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Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: KINECT-2 Hits, Shares Soar!

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (01/06/13)	$15.45
Target Price	**$18.00**

UPDATE

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 KINECT-3, outline timelines for moving NBI-98854 forward, and conclude with a valuation for the shares based on this new data.

SUMMARY DATA

52-Week High	
52-Week Low	
One-Year Return (%)	
Beta	
Average Daily Volume (sh)	
Shares Outstanding (mil)	
Market Capitalization ($mil)	
Short Interest Ratio (days)	
Institutional Ownership (%)	
Insider Ownership (%)	
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	0.7 A	0.7 A	0.8 E	2.9 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	-$0.18 A	-$0.17 A	-$0.17 E	-$0.69 E
2014					-$0.52 E
2015					-$0.02 E

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WHAT'S NEW

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 KINECT-3, outline timelines for moving NBI-98854 forward, and conclude with a valuation for the shares based on this new data.

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.

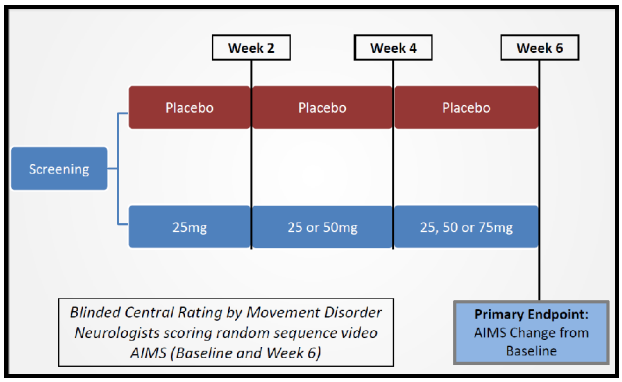
Tetrabenazine is probably the most common therapeutic option available for patients with tardive dyskinesia. The drug is believed to exert its therapeutic effect in tardive dyskinesia by inhibiting the activity of VMAT2, a transporter that serves to package dopamine into vesicles for release into the 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*

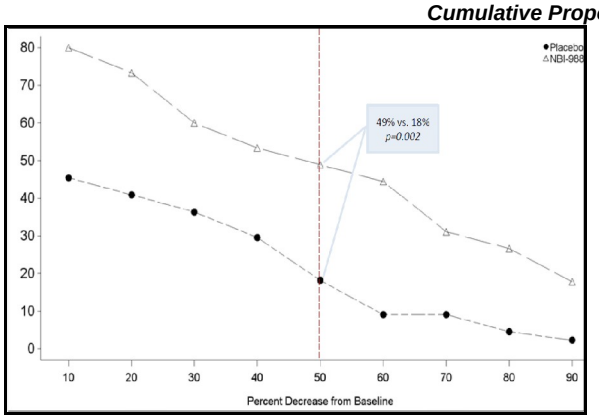
		Week 6		
CGI-TD		Placebo	NBI-98854	p-value
	LS Mean Score (ITT)	3.1	2.2	<0.001
	LS Mean Score (PP)	3.1	2.2	<0.001
	Responder Rate (ITT)*	16%	67%	<0.001
	Responder Rate (PP)*	16%	68%	<0.001

**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"*

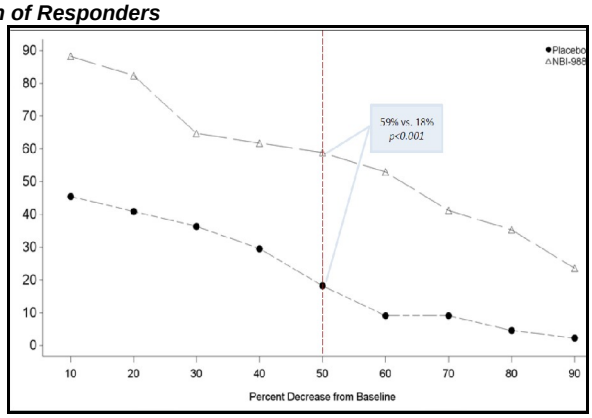
The results are highly statistically significant. This was a dramatic turnaround from the KINECT-1 study (discussed below) where 50mg of drug failed to separate from placebo at week 6. Additional digging to the data shows a trial that was well controlled and well randomized (note the near identical baseline 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



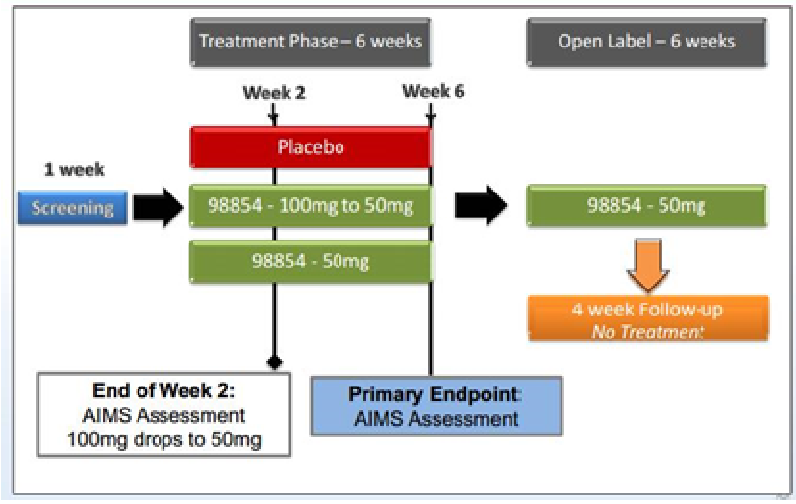
PP

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.

Brief Reminder of the KINECT-1 Results

The design of the KINECT-1 study is described in the figure below. Subjects with moderate-to-severe neuroleptic-induced tardive dyskinesia and a diagnosis of schizophrenia or schizoaffective disorder were randomized to one of two treatment arms: Arm 1) 50 mg of NBI-98854 daily for 6 weeks, or Arm 2) 100 mg of NBI-98854 daily for 2 weeks followed by 50 mg daily for 4 weeks. The primary endpoint of the trial was similar to KINECT-2 discussed above. The study randomized 109 subjects (Placebo: 54; 50 mg: 27; 100 mg: 26) at 33 sites around the U.S.



Neither arm of the trial achieved its primary endpoint of providing a statistically significant improvement in the AIMS score at Week 6. However, examination of the week 2 data showed that subjects in Arm 2, receiving 100 mg of NBI-98854, exhibited a nominally statistically significant improvement from baseline in the AIMS when evaluated by a central reviewer. Scores assigned by on-site reviewers were not significantly improved.

		Week 6		
		PBO	50mg	p-value
AIMS Change from Baseline (on-site assessment)				
	LS Mean AIMS ANCOVA (ITT)	-2.5	-3.3	ns
	LS Mean AIMS ANCOVA (PP)	-2.4	-3.0	ns
	Responder Rate (ITT)*	11%	24%	ns
	Responder Rate (PP)*	10%	21%	ns
AIMS Change from Baseline (video assessment)				
	LS Mean AIMS ANCOVA (ITT)	-2.2	-3.5	ns
	LS Mean AIMS ANCOVA (PP)	-1.9	-3.3	ns
	Responder Rate (ITT)*	21%	29%	ns
	Responder Rate (PP)*	18%	28%	ns

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

		Week 2				
		PBO	50mg	p-value	100mg	p-value
AIMS Change from Baseline (on-site assessment)						
	LS Mean AIMS ANCOVA (ITT)	-1.2	-2.1	ns	-2.1	ns
	LS Mean AIMS ANCOVA (PP)	-1.3	-2.4	ns	-2.5	ns
	Responder Rate (ITT)*	7%	7%	ns	12%	ns
	Responder Rate (PP)*	7%	8%	ns	14%	ns
AIMS Change from Baseline (video assessment)						
	LS Mean AIMS ANCOVA (ITT)	-2.7	-3.9	ns	-4.8	0.034
	LS Mean AIMS ANCOVA (PP)	-2.7	-3.9	ns	-5.5	0.008
	Responder Rate (ITT)*	23%	30%	ns	40%	ns
	Responder Rate (PP)*	23%	31%	ns	48%	0.034

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

Results of the KINECT-1 trial suggest patients were under-dosed, having responded nicely to the 100mg load-in dose during the first two weeks, but then failing to maintain separation from placebo during the next four weeks while on 50mg. In secondary assessments of efficacy based on a responder rate and CGI-TD, treating clinicians determined that 36% of the subjects taking 100 mg of NBI-98854 were "much improved" or "very much improved" at week 2 compared to only 8% of the placebo subjects (p=0.002). Below is a snap-shot of the CGI-TD data:

		Week 2				
CGI-TD		PBO	50mg	p-value	100mg	p-value
	LS Mean Score	3.6	3.2	ns	3.0	0.007
	Responder Rate*	8%	15%	ns	36%	0.002

*a responder is defined as "much improved" or "very much improved"

		Week 6		
CGI-TD		PBO	50mg	p-value
	LS Mean Score	3.2	3.3	ns
	Responder Rate*	22%	23%	ns

*a responder is defined as "much improved" or "very much improved"

Overall, the data from the KINECT-1 study is compatible with the hypothesis that higher doses would provide better efficacy and still be well-tolerated. This seems to be validated by the top-line data from KINECT-2. Safety assessments from KINECT-1 show the frequency of treatment-emergent adverse events was 37% for placebo and 26% for NBI-98854 during the six week trial.

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.

Next-Up: FDA Meeting and Phase 3

Neurocrine will no doubt spend the next several months analyzing the data from all Phase 2 trials with NBI-98854. This will include deeper analysis of the recent KINECT-2 trial and a re-analysis of KINECT-1 using the KINECT-2 centralized raters. The company's goal is to sit down with the U.S. FDA around the middle of the year for an "End of Phase 2" meeting. Results from KINECT-2 are highly statistically significant. Management noted on the conference call that approximately 50% response on the 50% or greater reduction in AIMS and CGI-TD is highly clinically meaningful and among the best data generated to date in TD. Accordingly, we believe Neurocrine will have no problem convincing the agency to allow them to move into pivotal registration trials.

We believe that the Phase 3 study will exclusively use a centralized reviewer on the modified AIMS. At this point, we are unsure if the outcome will be at week 6 or week 12. We are also unsure if management will employ a dose-titration schedule similar to KINECT-2. In our view, the KINECT-2 worked beautifully, so introducing change to the protocol would create risk. That being said, Neurocrine will follow the FDA's guidance on this issue and we would not be surprised to see them pursue a special protocol assessment (SPA). We believe that the agency will require Neurocrine to conduct two Phase 3 trials in TD. We expect Neurocrine to run these trials staggered, similar to KINECT-1 and KINECT-2.

We remind investors that the company is also conducting preclinical studies to support the advancement of NBI-98854 into clinical trials for individuals suffering from Tourette's syndrome. Upon successful completion of these preclinical studies, management anticipates entering phase 1 and phase 2 clinical studies in 2014.

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 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.

The company's balance sheet on September 30, 2013 reflected total assets of $166.0 million, including cash and short-term investments of $156.9 million and current assets of $159.2 million. We note the company has another $5.0 million in long-term investments and restricted cash. We believe the company exited 2013 with over $145 million on the books. We think operating burn for 2014 will be around $30-40 million, meaning the company should still have north of $100 million on the books at the end of 2014. That being said, we would not be surprised to see Neurocrine take advantage of this recent pop in the stock and secure an additional $75 to $100 million in cash during the first half of 2014.

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. Adding in approximately $2 per share in cash and we see Neurocrine worth roughly $19 per share today.

PROJECTED FINANCIALS

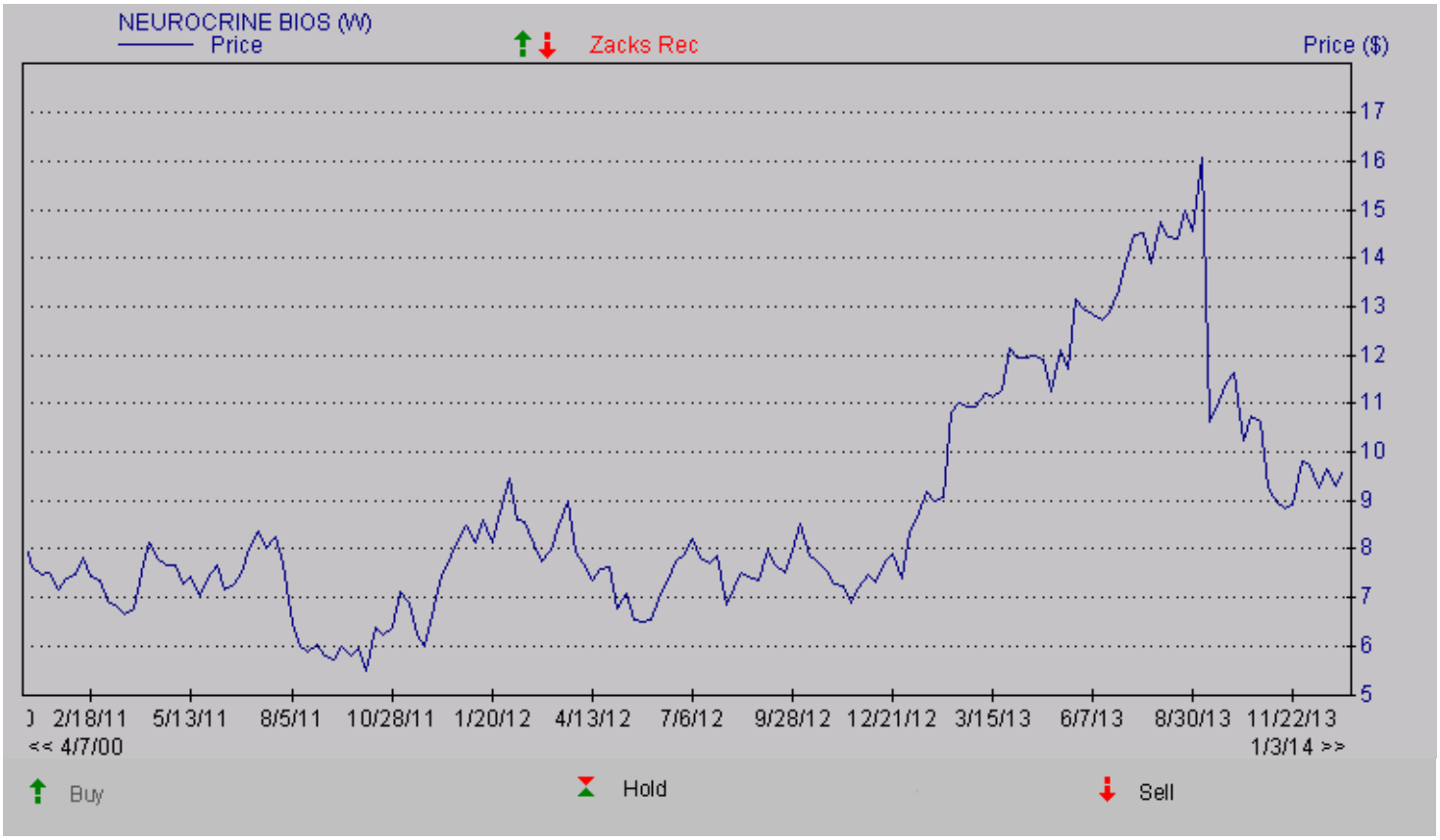
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2011 A	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E	2016 E
R&D / Milestones & Fees	**$77.4**	**$53.1**	**$0.7**	**$0.7**	**$0.7**	**$0.8**	**$2.9**	**$5.0**	**$50.0**	**$50.0**
YOY Growth	*131.1%*	*-31.4%*	*-93.5%*	*-93.4%*	*-92.2%*	*-96.6%*	*-94.5%*	*71.9%*	*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**	**$0.7**	**$0.7**	**$0.8**	**$2.9**	**$5.0**	**$50.0**	**$50.0**
YOY Growth	*131.1%*	*-31.4%*	*-93.5%*	*-93.4%*	*-92.2%*	*-96.6%*	*-94.5%*	*71.9%*	*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	$3.4	$3.2	$3.4	$13.4	$14.5	$15.0	$15.5
% SG&A	*16.0%*	*27.3%*	*464.7%*	*485.7%*	*445.1%*	*453.3%*	*461.9%*	*290.0%*	*30.0%*	*31.0%*
R&D	$31.0	$37.2	$10.3	$10.5	$9.5	$9.5	$39.8	$35.0	$40.0	$40.0
% R&D	*40.0%*	*69.9%*	*1412.7%*	*1500.0%*	*1301.8%*	*1266.7%*	*1368.3%*	*700.0%*	*80.0%*	*80.0%*
Operating Income	$34.1	$1.4	($13.0)	($13.2)	($12.0)	($12.2)	($50.3)	($44.5)	($5.0)	($5.5)
Operating Margin	*44.0%*	*2.7%*	-	-	-	-	*-1730.2%*	*-890.0%*	*-10.0%*	*-11.0%*
Interest / Other Income	$3.6	$3.6	$0.9	$0.9	$0.9	$1.0	$3.7	$3.5	$2.5	$2.5
Pre-Tax Income	$37.6	$5.0	($12.1)	($12.3)	($11.1)	($11.2)	($46.7)	($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)	($12.3)	($11.1)	($11.2)	($46.7)	($34.9)	($1.8)	($2.1)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	*48.5%*	*9.5%*	-	-	-	-	*-1603.9%*	*-697.0%*	*-3.5%*	*-4.2%*
Reported EPS	**$0.67**	**$0.08**	**($0.18)**	**($0.18)**	**($0.17)**	**($0.17)**	**($0.69)**	**($0.52)**	**($0.02)**	**($0.03)**
YOY Growth	-	*-88.5%*					*-1005.3%*	*-25.6%*	*-95.3%*	*16.0%*
Shares Outstanding	56.3	65.6	66.6	66.9	67.199	67.0	67.3	67.6	72.5	75.0

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

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HISTORICAL ZACKS RECOMMENDATIONS



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