Zacks Small-Cap Research

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Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: Ready to begin Phase 3 trial of NBI-98854 for the treatment of tardive dyskinesia…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (08/08/14)	$13.33
Target Price	**$18.00**

UPDATE

On August 6, 2014, Neurocrine Bio reported financial results for the second quarter of 2014. Results were essentially right-on with our expectations. The company ended the quarter with approximately $195 million in cash, cash equivalents, and investments. For 2014, management continues to expect net cash burn of approximately $43 million to $47 million.

The company is getting set to initiate a Phase 3 trial of NBI-98854 for the treatment of tardive dyskinesia. This trial is expected to take 18 months, with management still guiding for an NDA filing in mid 2016. 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 $18.

SUMMARY DATA

52-Week High	**$19.65**
52-Week Low	**$8.68**
One-Year Return (%)	**-2.73**
Beta	**-0.20**
Average Daily Volume (sh)	**542,894**
Shares Outstanding (mil)	**76**
Market Capitalization ($mil)	**$1,026**
Short Interest Ratio (days)	**11.44**
Institutional Ownership (%)	**92**
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 A	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 A	-$0.20 E	-$0.22 E	-$0.76 E
2015					-$0.23 E
2016					-$0.02 E

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WHAT'S NEW

Second Quarter Financials

On August 7, 2014, Neurocrine Bio reported financial results for the second quarter of 2014. The company reported no revenues for the quarter, as was expected. Research and development expenses were $10.2 million, a decrease from $10.5 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 second quarter a year ago. The increase was due mostly to higher share-based compensation expense. The company reported a net loss of $13.4 million ($0.18 per share) for the quarter, roughly in line with our expectation.

…Financial Guidance…

The company's balance sheet at the end of the second quarter 2014 reflected cash, cash equivalents, investments and receivables of $194.7 million, compared with a balance at December 31, 2013 of $146.8 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.

Update on NBI-98854

During the second quarter conference call management provided an update on the development of NBI-98854 (valbenazine), a compound being evaluated for the treatment of tardive dyskinesia (TD). For more background on valbenazine and TD we invite investors to review our previous update on Neurocrine.

The company recently completed and "end of Phase 2" meeting with the FDA to get guidance on the Phase 3 development plan for NBI-98854 as well as to determine what data will be necessary for an NDA filing for NBI-98854. One important takeaway from the meeting is that the company will need to perform a single, placebo controlled pivotal Phase 3 trial for TD (Kinect-3) that is expected to enroll 240 patients in total. The primary endpoint for the Phase 3 trial is change from baseline in the Abnormal Involuntary Movement Score (AIMS) as measured by blinded central raters, just as was done in Kinect-2.

The FDA provided guidance on the patient population for the Phase 3 trial by indicating it should be just as in the Kinect-2 study with the exception of excluding patients with TD due to metoclopramide exposure. This is a minor point as there were only a few of these patients in the Phase 2 trial and this patient population has decreased since the FDA's issuance of "Black Box" warnings in regards to metoclopramide and risk of developing TD.

The final doses chosen for the Phase 3 trial were 40 and 80 mg once daily. Management provided some further insight into the selection of 40 and 80 mg as the two doses being tested in the Phase 3 trial during the second quarter conference call. The company has had extensive experience dosing patients between 4.5 mg and 100 mg per day for at least two weeks with the most robust efficacy seen in the 50 to 75 mg range. The company spent a great deal of time going over exposure response data, which showed that as you go up on exposure there is no incremental benefit. In other words, if a patient is going to be a responder then as soon as they hit their required exposure they will respond with no additional benefit seen from increasing the dose. In addition, the company found that exposures over 80 mg did not provide any additional benefit.

One further point about dosing concerns the FDA's interest in seeing data regarding a minimal and maximal effective dose. At 25 mg the results seen with NBI-98854 are comparable to placebo. At 50 mg there are a good number of responders, but not the maximum number. Once the dose reaches 75-80 mg the effect is essentially maxed out. Thus, the company has extensive data showing an adequate dose response curve having data from all ends of the efficacy spectrum. Finally, with respect to the Phase 3 trial, management noted that NBI-98854 does not need to show efficacy at both doses; meaning if the 40 mg dose were to fail the company could still move ahead and file with the 80 mg data if that shows a statistically significant response.

To build upon the extensive safety database already compiled in regards to NBI-98554, the company will continue patients randomized to the 40 or 80 mg doses in the Phase 3 for a full year on the drug. Patients randomized to receive placebo will be randomized to either 40 or 80 mg for the remainder of the active portion of the trial. In

parallel, the company will be running an open-label safety trial with 100-150 subjects taking either 40 or 80 mg of NBI-98854, with that trial expected to commence in the first quarter of 2015. Alongside the pivotal trial the company will perform additional Phase 1 work that includes a QT study, a study involving patients with renal impairment, and another drug interaction study.

Thus far the company has qualified close to 80 clinical sites in North America and all contracts and IRB documents are getting put into place such that patient screening can begin in September with randomization occurring in October 2014. Management believes that the total duration of the Phase 3 program including both recruitment and treatment will be 18 months. This would put an NDA filing sometime in mid 2016, which is in line with previous guidance from the company. The open label safety trial should begin in the first quarter of 2015, but that trial will not delay the filing of the NDA as they will simply have a cutoff date, and all data from patients with one year of safety data at that time will be included in the NDA filing.

Conclusion: Valuation & Recommendation

We were pleased to hear about the successful “end of Phase 2” meeting that the company conducted with the FDA and the plan for a single pivotal Phase 3 study for NBI-98854 in TD. The details for the Phase 3 study were what we had expected, and we believe the similarities between Kinect-2 and the Phase 3 trial should increase the likelihood of success.

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. Management indicated during the second quarter conference call that an IND for Tourette’s syndrome will be filed within the next couple of days.

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. We continue to believe an NDA will be filed in 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.

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.

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. During the second quarter conference call management indicated that the last patient visit is scheduled for November 2014. After that it will be up to AbbVie to perform the data analysis with a reporting of top-line data in the December/January timeframe, although AbbVie will ultimately decide when results are released.

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 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 $9 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. Along with a little over $2 in cash we see Neurocrine worth roughly $18 per share today.

PROJECTED FINANCIALS

Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2012 A	2013 A	Q1 A	Q2 A	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	$10.2	$12.0	$14.0	$44.7	$40.0	$40.0
% R&D	*69.9%*	*1357.6%*	-	-	-	-	-	*160.0%*	*80.0%*
Operating Income	$1.4	($49.7)	($12.7)	($14.4)	($16.2)	($18.2)	($61.5)	($31.5)	($7.5)
Operating Margin	*2.7%*	*-1720.7%*	-	-	-	-	-	*-126.0%*	*-15.0%*
Interest / Other Income	$3.6	$3.6	$0.9	$1.0	$0.9	$0.9	$3.7	$4.0	$5.0
Pre-Tax Income	$5.0	($46.1)	($11.8)	($13.4)	($15.3)	($17.3)	($57.8)	($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)	($13.4)	($15.3)	($17.3)	($57.8)	($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)**	**($0.76)**	**($0.23)**	**($0.02)**
YOY Growth	*-88.5%*	*-995.4%*					*11.3%*	*-70.3%*	*-91.4%*
Shares Outstanding	65.6	67.3	70.3	75.9	77.0	80.0	75.8	85.0	90.0

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

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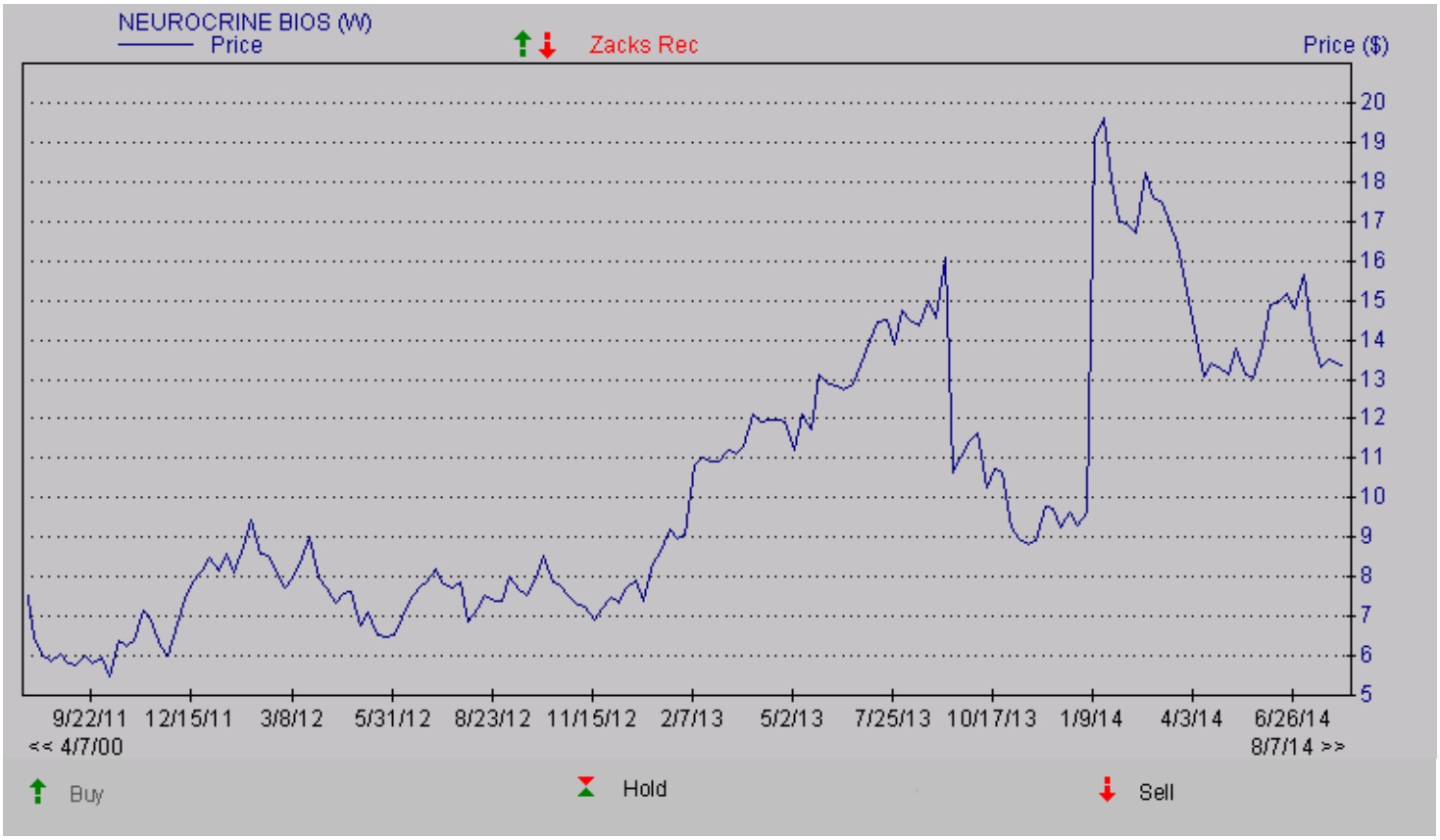

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