Zacks Small-Cap Research

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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Neurocrine Biosciences, Inc. (NBIX-NASDAQ)

NBIX: T-Forward Study Underway; T-Force Results in December 2015…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (10/30/15)	$49.97
Target Price	**$75.00**

UPDATE

On October 29, 2015, Neurocrine Biosciences, Inc. announced financial results for the third quarter of 2015. As expected, the company reported no revenues for the quarter. Neurocrine reported a net loss of $34.4 million, or $0.40 per share, which was driven by $24.4 million in R&D and $11.5 million in G&A expenses, offset by $1.4 million in other income.

Earlier in the month, Neurocrine announced positive results from the Phase 3 Kinect-3 trial of NBI-98854 in tardive dyskinesia. The company then announced the initiation of the T-Forward study of NBI-98854 in adults with Tourette syndrome, and we expect topline results from the T-Force study of NBI-98854 in children with Tourette syndrome to be reported in December 2015.

SUMMARY DATA

52-Week High	**$54.93**
52-Week Low	**$17.43**
One-Year Return (%)	**170.99**
Beta	**0.28**
Average Daily Volume (sh)	**1,620,462**
Shares Outstanding (mil)	**86**
Market Capitalization ($mil)	**$4,291**
Short Interest Ratio (days)	**6.77**
Institutional Ownership (%)	**96**
Insider Ownership (%)	**4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/M**
P/E using 2015 Estimate	**N/A**
P/E using 2016 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)
2014	0 A	0 A	0 A	0 A	0 A
2015	19.8 A	0 A	0 A	0 E	19.8 E
2016					25.0 E
2017					174.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.17 A	-$0.18 A	-$0.21 A	-$0.26 A	-$0.81 A
2015	-$0.01 A	-$0.28 A	-$0.40 A	-$0.34 E	-$1.05 E
2016					-$1.21 E
2017					-$0.19 E

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WHAT'S NEW

Financial Results

On October 29, 2015, Neurocrine Biosciences, Inc. (NBIX) announced financial results for the third quarter of 2015. The company did not report any revenue during the quarter. Operating expenses totaled $35.8 million and consisted of $24.4 million in R&D and $11.5 million in G&A expenses. This compares with $12.2 million in R&D and $4.6 million for the same time period of 2014. The increase in R&D expense was driven by $5 million in higher external development expenses and $6.6 million of higher personnel expenses. Share-based compensation expense increased by approximately $5 million, of which $4 million was related to performance restricted stock units (PRSUs) awarded in association with the positive results announced from the Kinect 3 trial. The increase in G&A expenses was mostly driven by $6.2 million in share-based compensation, with $4.3 million of that associated with PRSUs awarded in association with the positive results announced from the Kinect 3 trial.

Net loss for the quarter was $34.4 million, or $0.40 per share, compared with a net loss of $15.9 million, or $0.21 per share, for the third quarter of 2015. The company exited the third quarter of 2015 with approximately $478.8 million in cash and investments. We continue to believe that the company will end 2015 with more than $450 million in cash and investments on total cash burn of approximately $85 million for the year.

NBI-98854 Update

In early October 2015, Neurocrine announced positive results from the Phase 3 Kinect-3 clinical trial of NBI-98854 in tardive dyskinesia (NCT02274558). The Kinect-3 study is a randomized, parallel group, double blind, placebo controlled Phase 3 clinical trial testing NBI-98854 in moderate to severe tardive dyskinesia patients with underlying schizophrenia, schizoaffective disorder, or mood disorder. A total of 234 patients were randomized to receive placebo, 40 mg of NBI-98854, or 80 mg of NBI-98854 once daily for six weeks. The results showed a highly significant change from baseline in the Abnormal Involuntary Movement Scale (AIMS) at Week 6 ($p<0.0001$).

When the data was presented, the company did not provide many details about the results since the plan is to present the full data set at upcoming scientific conferences in 2016. During the third quarter conference call, management again emphasized that any details from the results of the Kinect-3 trial would be shared later in 2016, with possible conferences for presentation including the American Academy of Neurology 2016 annual meeting (April 15-21 in Vancouver, BC) or the International Parkinson's and Movement Disorders Society International Congress (June 19-23 in Berlin, Germany).

The topline data that was released for Kinect-3 shows that the trial was very successful, as shown in the following table.

		Week 6			
		40mg qd	p-value*	80mg qd	p-value*
AIMS Difference from Placebo					
	Least-Squares Mean (ITT population)	-1.8	0.0021	-3.1	<0.0001
	Least-Squares Mean (PP population)	-2.1	0.0009	-3.6	<0.0001
CGI-TD Difference from Placebo					
	Least-Squares Mean (ITT population)	-0.3	0.0742	-0.3	0.0560
	Least-Squares Mean (PP population)	-0.4	0.0097	-0.4	0.0122

Source: Neurocrine Biosciences, Inc.

The primary endpoint of the study was the change from baseline in the Abnormal Involuntary Movement Scale (AIMS) at Week 6 as determined by centrally blinded video raters. Secondary endpoints in the study included the Clinical Global Impression of Change (CGI-TD). The AIMS rating at Week 6 was reduced 3.1 points more than

placebo, which was a highly significant result (p<0.0001). For comparisons sake, in the Kinect-2 study the results showed the AIMS rating at Week 6 was reduced by 2.4 points more than placebo in the intent to treat (ITT) population and 3.0 points more than placebo in the per protocol (PP) population. 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, while the PP population excluded any subject randomized to NBI-98854 with levels of drug below the limit of quantitation (i.e., the subject had not ingested the drug). Data not released at this time includes what the reduction in AIMS rating was for placebo treated patients and what the baseline AIMS rating for each group was. However, since the results shown above are the difference from placebo, it is clear that the results in regards to AIMS rating from the Kinect-3 study were superior to the results seen in the Kinect-2 study. The CGI-TD results were not statistically significant for the ITT population, however since that was a secondary endpoint we do not believe this will hinder the approval of the drug.

Teva Pharmaceuticals is developing SD-809, which is a deuterium-modified version of tetrabenazine. In June 2015, Teva announced positive top-line results for SD-809 in the treatment of TD. The primary endpoint of that trial was also the change in AIMS from baseline, however that trial examined results after 12 weeks of treatment. Results showed that patients taking SD-809 had a reduction in AIMS of 3.0 points compared to 1.6 points for those taking placebo, representing a placebo-adjusted reduction of 1.4 points. While impossible to make direct comparisons between results from different clinical trials, the Kinect-3 results showing a placebo-adjusted reduction of 3.1 points look quite good in comparison to the results reported by Teva.

Importantly, the frequency of adverse events in the Kinect-3 trial was similar among all treatment groups and treatment emergent adverse effects were consistent with those of prior studies. Participants in the trial were also assessed for akathisia and parkinsonism and minimal symptoms were present at baseline and there was no worsening during the six-week treatment period. Lastly, clinical hematology, chemistry, and ECG monitoring indicated no emergent safety signals.

The Kinect-3 study, along with the previous efficacy studies of NBI-98854, is designed to complete the clinical efficacy evaluation of the drug in TD. The company is now turning its attention to completing the one-year open-label safety studies in TD patients with all data to be included in the company's New Drug Application (NDA), which we anticipate being filed in 2016.

Data from T-FORCE Expected in December 2015

In addition to TD, Neurocrine is also developing NBI-98854 as a treatment for Tourette syndrome (TS). The company is currently conducting a Phase 1b trial of NBI-988554 in both children and adolescents with TS (NCT02256475). The T-FORCE study is an open-label, multiple ascending dose, two-week study of 36 subjects with TS. The study participants are receiving once-daily dosing of NBI-98854 during a two-week treatment period to assess both the safety and tolerability of NBI-98854 in Tourette patients followed by seven days off-drug. The study is taking place at approximately 10 centers in the U.S.

The study is divided into two dosing groups: children (ages 6-11) and adolescents (ages 12-18). Each group is divided into three dosing cohorts of six patients each. Following the initial two weeks of dosing with the first adolescent cohort, an independent review of both safety and pharmacokinetic results will occur prior to escalating the dose level for the second cohort of adolescents. Concurrently, when the second group of adolescents is dosed the first group of children will be administered NBI-98854. Continued dose escalations for both children and adolescents will be contingent upon the pharmacokinetic and safety data from the previous cohort in each age group. Lastly, each patient's Tourette symptoms will be evaluated weekly using the Yale Global Tic Severity Scale (YGTSS), the Premonitory Urge for Tics Scale, and the Clinical Global Impression in Tourette syndrome Scale. The YGTSS was designed for use in studies in TS patients to evaluate the number, frequency, intensity, complexity, and interference of motor and phonic symptoms (Leckman *et al*., 1989). It has proven to be a reliable and valid instrument for assessing TS (Storch *et al*., 2005). The questionnaire is divided into three parts: one part identifies symptoms of motor phonic tics, one part covers obsessive compulsive disorder symptoms, and the last part concerns environmental effects of symptoms. We remind investors that the T-FORCE study is not powered to show efficacy in treating TS, but is rather a pharmacokinetic and pharmacodynamics focused study. Data from the T-FORCE study should be available in December of 2015.

On October 20, 2015, the company announced the initiation of the Phase 2 T-FORWARD study of NBI-98854 in adults with TS (NCT02581865). The T-FORWARD study is a randomized, double blind, placebo controlled, multi dose, parallel group study of up to 90 adults with TS. Study participants will receive once-daily dosing of NBI-98854 during an eight-week treatment period to assess the safety, tolerability, and efficacy in adults with TS. The primary

endpoint of the study is the change in baseline of placebo vs. active scores utilizing the YGTSS at the end of Week 8. We anticipate topline results from the T-FORWARD study later in 2016.

Conclusion and Recommendation

The treatment of TD is a very meaningful market opportunity for Neurocrine. There are an estimated 500,000 TD patients in the U.S. with no real treatment options besides tetrabenazine. For valuation purposes, we assume U.S. approval of NBI-98854 in TD will target roughly 150,000 of the total patients in the U.S. that are moderate-to-severe in disease state. During the third quarter conference call, management gave a wide range for potential pricing of NBI-98854 of $20,000 to $60,0000 per year, thus we have adjusted our model slightly to reflect a yearly cost of $20,000 (up from our previous $15,000 per year). If Neurocrine can capture 33% market share, which we believe is reasonable given the superior characteristics of NBI-98854 vs. generic tetrabenazine, then peak sales estimates are approximately $1.6 billion in this indication in the U.S. alone. We remind investors that NBI-98854 has received breakthrough designation from the U.S. FDA for the treatment of TD. Neurocrine is also pursuing development of NBI-98854 in TS. Phase 1b data are expected in December of 2015, with results from the T-FORWARD study of adults with TS later in 2016. We believe the opportunity for NBI-98854 in TS is another billion-dollar opportunity.

In addition to NBI-98854, Neurocrine is partnered with AbbVie for the development of elagolix as a treatment for endometriosis and uterine fibroids (UF). AbbVie recently announced that it was moving elagolix into a Phase 3 program for the treatment of UF. The Phase 3 program for UF is scheduled to begin in the first quarter of 2016 and will include two replicate, pivotal, six-month efficacy and safety studies followed by a six-month safety and efficacy extension study. Earlier in 2015, AbbVie reported positive data from the first Phase 3 elagolix trial in endometriosis along with data from the six-month extension trial showing results consistent with previously reported efficacy and safety findings. Data from the second Phase 3 elagolix trial in endometriosis is expected in the first quarter of 2016, and we believe AbbVie will file an NDA for elagolix in late 2016. Thus, Neurocrine could have two NDAs (one for elagolix, one for NBI-98854) on file with the FDA by the end of 2016!

With the recent positive results reported from the Kinect-3 study, the good news continues to accumulate for Neurocrine and as such we continue to be very positive about the future of the company. Additional near term catalysts include the Phase 1b clinical data from the T-FORCE trial for NBI-98854 in TS in the December of 2015 and the data from the second Phase 3 elagolix trial in endometriosis in the first quarter of 2016. The recent weakness in the stock price brought about by an overall negative sentiment towards the biotechnology sector has presented a nice buying opportunity in shares of Neurocrine. We are raising our price target to $75 due to the slight adjustment to our model, and we are maintaining a ‘Buy’ rating.

PROJECTED FINANCIALS

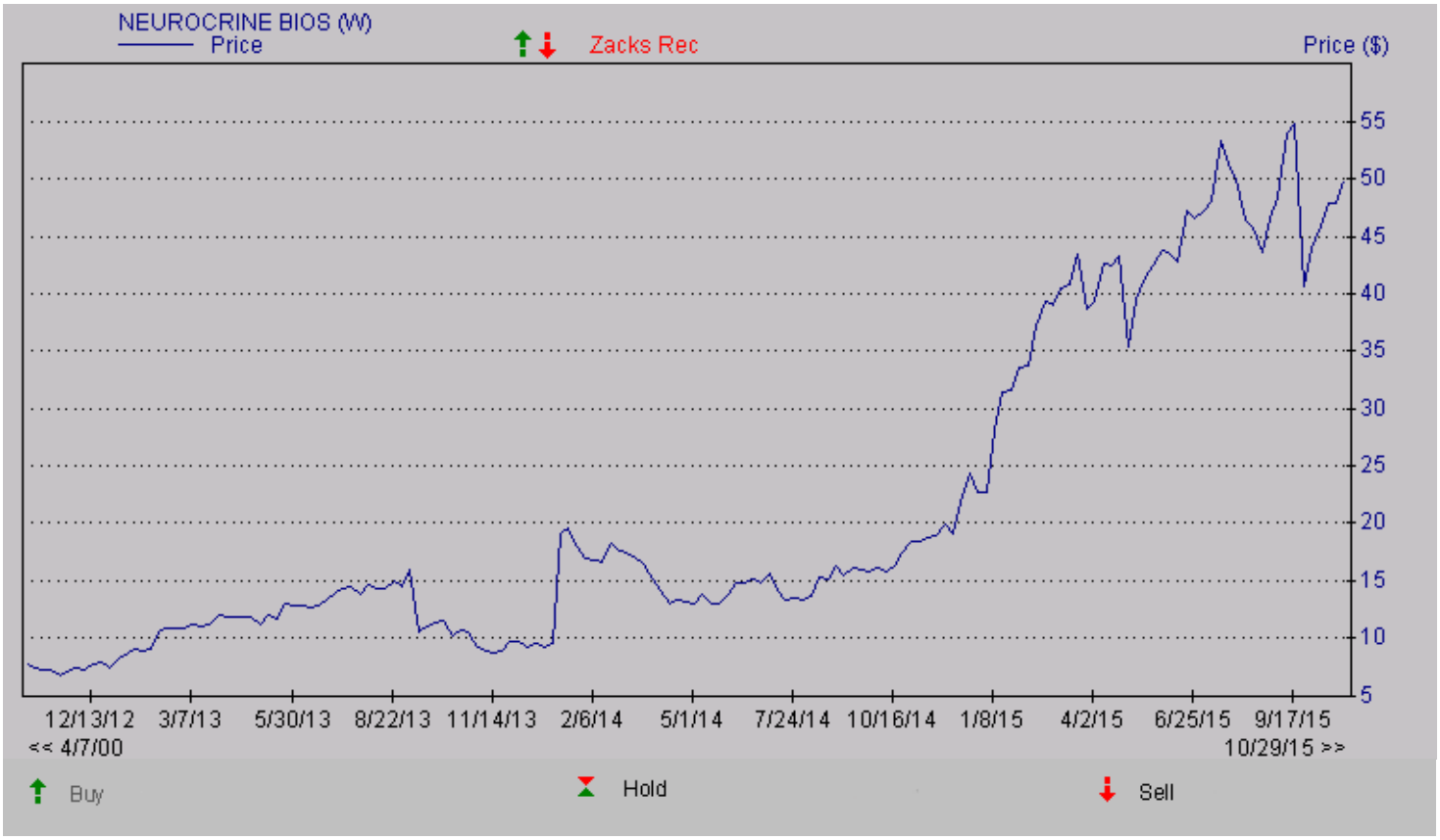
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 E
R&D / Milestones & Fees	**$0**	**$19.8**	**$0**	**$0**	**$0**	**$19.8**	**$25.0**	**$50.0**
YOY Growth	-	-	-	-	-	-	-	-
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$21**
YOY Growth	-	-	-	-	-	-	-	-
NBI-77860 (CRF1)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
NBI-98854 (VMAT2)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$103**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$19.8**	**$0**	**$0**	**$0**	**$19.8**	**$25.0**	**$174.0**
YOY Growth	-	-	-	-	-	-	-	*596.0%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$0	$15
Gross Margin	-	-	-	-	-	-	-	-
SG&A	$18.0	$5.5	$6.6	$11.5	$7.0	$30.5	$50.0	$90.0
R&D	$46.4	$16.6	$18.7	$24.4	$23.5	$83.2	$85.0	$90.0
Operating Income	($64.4)	($2.3)	($25.3)	($35.8)	($30.5)	($94.0)	($110.0)	($21.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest / Other Income	$3.9	$1.1	$1.3	$1.4	$1.4	$5.2	$4.0	$4.2
Pre-Tax Income	($60.5)	($1.2)	($24.0)	($34.4)	($29.1)	($88.7)	($106.0)	($17.3)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*15%*	*0%*	*0%*	*0%*	*0%*	*30%*	*30.0%*	*30.0%*
Net Income	($60.5)	($1.2)	($24.0)	($34.4)	($29.1)	($88.7)	($106.0)	($17.3)
YOY Growth	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.81)**	**($0.01)**	**($0.28)**	**($0.40)**	**($0.34)**	**($1.05)**	**($1.21)**	**($0.19)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	74.6	80.3	85.5	85.9	86.2	84.5	87.5	90.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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The current distribution is as follows: Buy/Outperform- 26.5%, Hold/Neutral- 51.6%, Sell/Underperform – 18.5%. Data is as of midnight on the business day immediately prior to this publication.