Zacks Small-Cap Research

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Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: Gearing up for multiple data readouts in 2015…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (11/04/14)	$17.85
Target Price	**$21.00**

UPDATE

On November 3, 2014, Neurocrine Bio reported financial results for the third quarter of 2014. Results were essentially right-on with our expectations. The company ended the quarter with approximately $179.7 million in cash, cash equivalents, and investments.

Next year is poised to be very 'data-rich', with multiple data readouts from numerous clinical trials, including Phase 3 data for elagolix in the treatment of endometriosis and NBI-98854 in treating tardive dyskinesia. We believe both products offer significant upside for investors over the next few years. We value the shares at $21.

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 A	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	-$0.21 A	-$0.22 E	-$0.77 E
2015					-$0.23 E
2016					-$0.02 E

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WHAT'S NEW

Third Quarter Financial Review

On November 3, 2014, Neurocrine Biosciences, Inc. (NBIX) reported financial results for the third quarter of 2014. The company did not have any revenues for the quarter, as expected. Neurocrine reported a net loss of $15.9 million, or $0.21 per share in the quarter, roughly in-line with our model. This compares with a net loss of $11.1 million, or $0.17 per share, for the same time period in 2013. The net loss was composed of $12.2 million in research and development expenses, compared to $9.5 million for the same period in 2013, and $4.7 million in general and administrative expenses, which was an increase from $3.2 million in the third quarter of 2013.

The company's balance sheet at the end of the third quarter 2014 reflected cash, cash equivalents, investments and receivables of $179.7 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.

Neurocrine is gearing up for an active 2015

Neurocrine is going to have a very 'data-rich' 2015 in the form of multiple data readouts from the many clinical trials being performed by the company and its partner, AbbVie Pharmaceuticals (ABBV). Below we present an update for each of the clinical programs along with when data is expected to be reported for each of them in the coming year.

…Kinect 3 Study is Underway…

On October 20, 2014, Neurocrine announced the initiation of a Phase 3 clinical trial called Kinect 3 (NCT02274558) of NBI-98854 for the treatment of tardive dyskinesia (TD). The study is a randomized, parallel-group, double-blind, placebo-controlled trial of approximately 240 patients with moderate to severe tardive dyskinesia and an underlying diagnosis of mood disorder, schizophrenia, or schizoaffective disorder. The trial will consist of a six week treatment period of 80 mg and 40 mg NBI-98854 dosed once daily against placebo. This will then be followed by a 46-week long-term safety assessment where all study subjects will be randomized in a blinded fashion to either 80 mg or 40 mg NBI-98854.

The primary endpoint for the Kinect 3 trial is change from baseline in the Abnormal Involuntary Movement Score (AIMS) as measured by blinded central raters, just as was done in Neurocrine's previous and successful Kinect 2 study (see our analysis of Kinect 2 here). 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 tardive dyskinesia. In parallel to the Kinect 3 study, 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.

During the third quarter conference call management indicated that the investigator meeting for the Kinect 3 study had recently occurred, with more than 200 personnel from 70 investigator sites taking part in the meeting. In addition, they indicated that the screening process is underway with the goal of getting all 70 trial sites up and running by the end of the year. Topline efficacy results from Kinect 3 are expected in the second half of 2015.

…FDA Awards Breakthrough Therapy Designation…

On October 30, 2014, Neurocrine announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for NBI-98854 in tardive dyskinesia. The breakthrough therapy designation is granted for a drug that is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on clinically significant endpoints over available therapies. The FDA had previously granted Fast Track status to NBI-98854 for tardive dyskinesia. Breakthrough therapy designation is quite similar to the Fast Track designation in that both programs are designed to expedite the development and review of drugs, which includes the following:

- ✓ Increased number of meetings with the FDA throughout the development of the drug,
- ✓ Maintaining an interactive dialogue with the FDA regarding drug development to ensure the sponsor is obtaining the proper nonclinical and clinical data necessary for approval expeditiously,
- ✓ Working with the FDA to ensure the clinical trials are being run as efficiently as possible,
- ✓ Rolling review and priority review.

NBI-98854 was granted breakthrough therapy designation based in part on the results of the Phase 2b studies of the drug in patients with tardive dyskinesia. Interestingly, breakthrough therapy has typically been designated for compounds in hematology and oncology with few compounds attaining the designation thus far in the neurology and psychiatry areas. Thus, by granting breakthrough designation to NBI-98854, the FDA has indicated it views tardive dyskinesia as a serious condition and one worthy of the agency's increased time and attention. Management indicated that the next interaction with the FDA in regards to the breakthrough designation would be a 'Type-B' meeting in 2015.

…Phase 1 Tourette Syndrome Initiates…

On October 2, 2014, Neurocrine announced the initiation of a Phase 1b clinical trial called T-FORCE (NCT02256475) of NBI-98854 in both children and adolescents with Tourette syndrome. The T-FORCE study is an open-label, multiple ascending dose, two-week study of 36 subjects with Tourette syndrome. The study participants will receive 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 will take place at approximately 10 centers in the U.S.

The study will be divided into two dosing groups: children (ages 6-11) and adolescents (ages 12-18). Each group will then be 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, the Premonitory Urge for Tics Scale, and the Clinical Global Impression in Tourette syndrome Scale. However, management indicated during the third quarter conference call that this study is not powered to show efficacy in treating Tourette syndrome, but is rather a pharmacokinetic and pharmacodynamics focused study. Data from the T-FORCE study should be available in the second half of 2015.

…Elagolix Violet Petal Top-Line Data Expected In January 2015…

The first set of data that Neurocrine is expecting in 2015 will be from the Violet Petal study (NCT01620528), 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 third 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 top-line data expected in January 2015.

AbbVie is also concurrently conducting a second Phase 3 study of elagolix for endometriosis, the Solstice study (NCT01931670). 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.

Since the Solstice study is still recruiting patients, the data that will be available from the Violet Petal study is likely to be quite limited. This is because AbbVie does not want to bias the ongoing study by releasing too much information, thus the only data that is likely to be presented in January from the Violet Petal study is a p-value for the dual-endpoints of a reduction in dysmenorrhea and non-menstrual pelvic pain after six months of treatment compared to placebo.

…Phase 2b uterine fibroids study…

In addition to studying the use of elagolix in treating endometriosis, AbbVie is also performing a Phase 2b randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of elagolix in treating heavy menstrual bleeding due to uterine fibroids (NCT01817530). The study is expected to enroll 520 women between the ages of 18 and 51. 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. Data from this study is expected to be reported by the end of 2015.

Conclusion: Valuation and Recommendation

AbbVie is expected to announce Phase 3 results from the Violet Petal study in early January 2015, and this could set the stage for a breakout year for Neurocrine Bio. The second half of the year should bring results from both the Phase 2b uterine fibroids study along with topline data from the Phase 3 study of NBI-98854 in tardive dyskinesia. In addition, data from the Phase 1b study of NBI-98854 in Tourette syndrome will be reported in the second half of 2015 as well.

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. For valuation purposes, we assume U.S. approval of NBI-98854 in tardive dyskinesia will target roughly 150,000 of the approximate 200-500,000 total TD patients in the U.S. that are moderate-to-severe in disease state. We assume Neurocrine will charge pricing comparable to atypical antipsychotics, or around $10,000 per year. If Neurocrine can capture 30% market share, which we believe is reasonable given the superior characteristics of NBI-98854 vs. generic tetrabenazine, then peak sales estimates are approximately $500 million in this indication in the U.S. alone (see our analysis of NBI-98854 vs. the competition here).

Based on obtaining breakthrough designation, we have reduced the discount rate we apply to 15% as we believe this de-risks the asset somewhat. Assuming peak sales for NBI-98854 in 2022, then we believe it is worth approximately $465 million in value. Adding an additional $300 million in value for sales outside the U.S. and add-on indications such as Tourette syndrome gives us a value of approximately $765 million, or $10 per share.

We believe elagolix is worth $9 per share based on the rate at which the two ongoing Phase 3 studies at AbbVie are enrolling and reporting data, and the timelines for the uterine fibroids Phase 3 study (see our analysis of the elagolix market opportunity here). Along with a little over $2 in cash, we see Neurocrine worth approximately $21 per share today, and we are maintaining a 'Buy' rating heading into 2015.

PROJECTED FINANCIALS

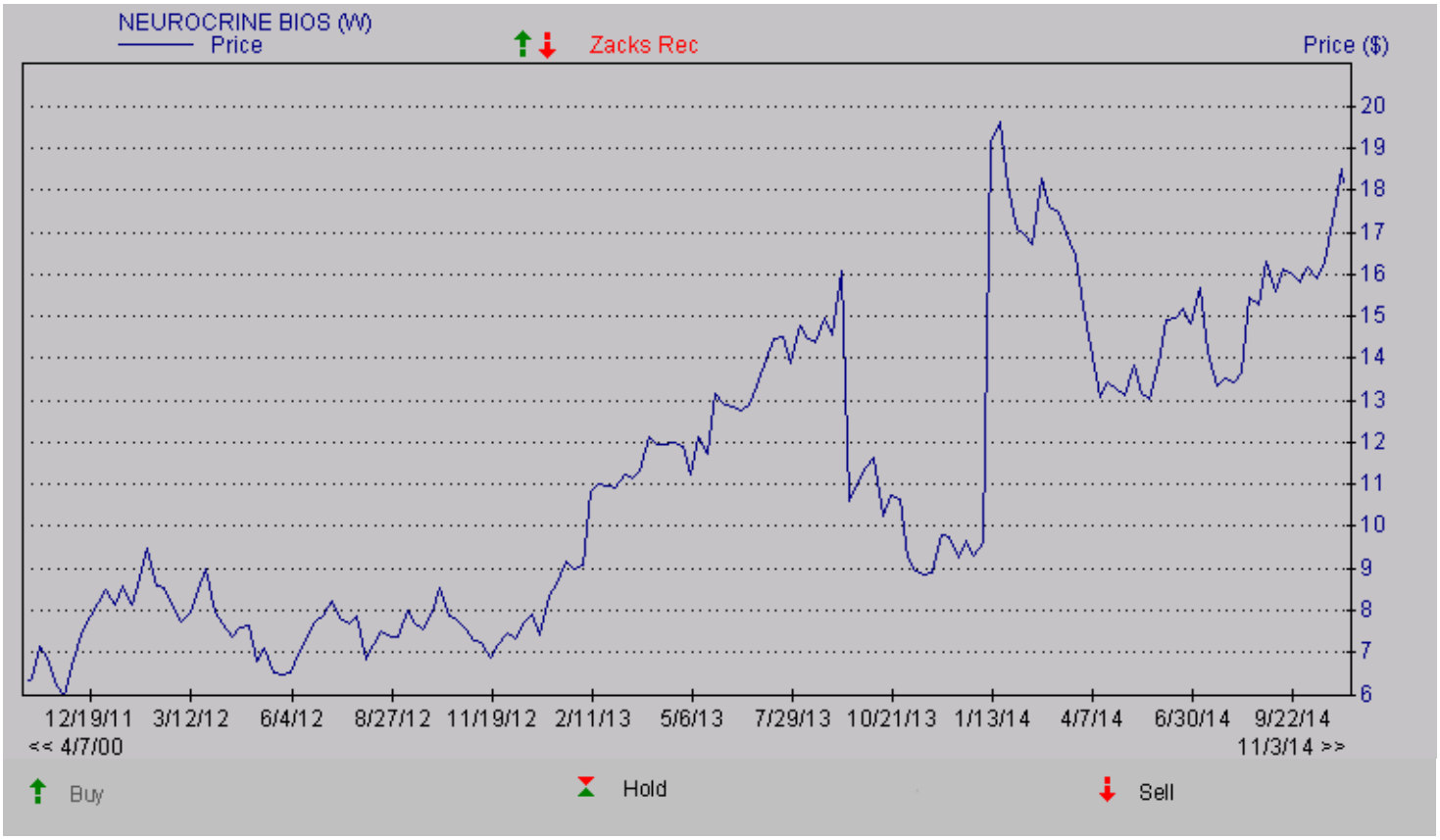
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2012 A	2013 A	Q1 A	Q2 A	Q3 A	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	-	-	-	-	-	-	-	-	-
NBI-98854	**$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	$4.7	$4.2	$17.2	$16.5	$17.5
% SG&A	*27.3%*	*463.1%*	-	-	-	-	-	*66.0%*	*35.0%*
R&D	$37.2	$39.2	$8.6	$10.2	$12.2	$14.0	$44.9	$40.0	$40.0
% R&D	*69.9%*	*1357.6%*	-	-	-	-	-	*160.0%*	*80.0%*
Operating Income	$1.4	($49.7)	($12.7)	($14.4)	($16.9)	($18.2)	($62.1)	($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	$1.0	$0.9	$3.7	$4.0	$5.0
Pre-Tax Income	$5.0	($46.1)	($11.8)	($13.4)	($15.9)	($17.3)	($58.4)	($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)	($15.9)	($17.3)	($58.4)	($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)**	**($0.21)**	**($0.22)**	**($0.77)**	**($0.23)**	**($0.02)**
YOY Growth	*-88.5%*	*-995.4%*					*12.8%*	*-70.7%*	*-91.4%*
Shares Outstanding	65.6	67.3	70.3	75.9	75.9	80.0	75.5	85.0	90.0

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

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