Zacks Small-Cap Research

July 26, 2013
Jason Napodano, CFA
John Tucker, PhD
312-265-9421 / jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: We Expect NBI-98854 Data In Early September To Be Positive…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (07/26/13)	$14.02
Target Price	**$18.00**

UPDATE

We remain optimistic on Neurocrine Bio and believe the company is on track with key pipeline products elagolix and NBI-98854. Data from the Phase 2b Kinect and Kinect-2 trials of NBI-98854 for tardive dyskinesia are expected in September and in the fourth quarter of 2013 respectively. We expect positive results from these trials and for NBI-98854 to contribute meaningfully to driving future revenues.

Neurocrine currently holds approximately $171 million in cash and investments. With a strong pipeline, plenty of cash, and great collaboration partners in AbbVie and Boehringer Ingelheim, we think Neurocrine makes sense for a long-term investment in biotech. Based on the company's continuing clinical progress we are raising our price target to $18.00.

SUMMARY DATA

52-Week High	**$14.79**
52-Week Low	**$6.87**
One-Year Return (%)	**82.77**
Beta	**0.53**
Average Daily Volume (sh)	**523,449**
Shares Outstanding (mil)	**67**
Market Capitalization ($mil)	**$934**
Short Interest Ratio (days)	**4.96**
Institutional Ownership (%)	**78**
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 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	0.8 E	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	-$0.18 E	-$0.18 E	-$0.73 E
2014					-$0.50 E
2015					-$0.02 E

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Recent Financial Results

On July 25, 2013, Neurocrine Bio reported financial results for the second quarter 2013. The company reported total revenues in the quarter of $0.73 million, essentially in-line with our expectation at $0.75 million and down from revenues of $10.6 million for the second quarter of 2013. The entire reduction in revenue from 2012 to 2013 is due to the completion of the sponsored research and development segments of the company's license agreements with both AbbVie and Boehringer Ingelheim during 2012, as scheduled. For the second quarter 2013, R&D expenses increased to $10.5 million, compared to $8.8 million for the same period in 2012, with the increase being due to development costs associated with the NBI-98854 phase 2b development program. The company's net loss for the second quarter was $12.24 million, in reasonable agreement with our expectation of $12.6 million.

…Financial Guidance…

The company's balance sheet on June 30, 2013 reflected total assets of $174.8 million, including cash and investments of $166.5 million. Financial guidance for 2013 remains the same as provided at the beginning of the year. Management expects a net cash burn from operations of approximately $50 to $55 million in 2013. Revenue is expected to approximate $2.9 million which consists solely of the amortization of up-front license fees. Expenses for 2013 should approximate $55 to $60 million. Net loss for 2013 is expected to be $50 to $55 million, or $0.75 to $0.83 loss per share based on 66.8 million basic shares outstanding.

NBI-98854 Moving Forward

…Phase 2b – KINECT to Report Top-Line Data in September…

Management reported the completion of enrollment for the Kinect study of NBI-98854 for the treatment of tardive dyskinesia in patients with schizophrenia or schizoaffective disorder earlier this month. Enrollment required screening approximately 240 patients, with the high screen fail rate reflecting the rigor of the subject selection process. Management expressed satisfaction with the conduct of the study, the training and certification of the raters, the patient and rating oversight process, and the videotaping and external review of the scoring of the AIMS trial endpoint. The median baseline AIMS score of the enrolled subjects is about 14.8, closely reflecting the severity of tardive dyskinesia that the company was targeting for this trial and providing good dynamic range for assessing the efficacy of NBI-98854.

The dropout rate to date has been about 15%, vs. up to 20% planned for in the trial design. There is no clear signal suggesting that discontinuations to date reflect any safety concern; some of the patients have experienced ongoing problems with their underlying schizophrenia, others have moved out of town and away from the trial site, and some have been discontinued for protocol violations due to illicit drug use or non-compliance. Although the trial remains blinded, management is pleased by the results of analysis of chemistry, hematology, urinalysis and other lab scores for the overall treatment population to date.

Management stated that top-line results from the blinded, 6 week portion of the trial should be available approximately 10 weeks from the completion of randomization, which occurred in the first week of July. By our calculation, the most likely timeframe for this release would then be in the two week period following September 9.

KINECT-2 Enrollment Proceeding, Top-Line Data Expected in the Fourth Quarter

The Kinect-2 trial is examining a dose-titration regimen of NBI-98854 for the treatment of tardive dyskinesia in patients with schizophrenia, schizoaffective disorder, mood disorders, or gastrointestinal disorders. Management reported that enrollment of this trial is approximately 50% complete, and that trial sites formerly involved in the Kinect trial were being transferred over to the Kinect-2 trial as they became available to further speed recruitment. Early discontinuations are lower in this trial compared to the Kinect study, around 5%. Management suggested that this lower dropout rate likely reflected the characteristics of the underlying treatment populations of the two trials, as well as the shorter duration of the Kinect-2 relative to the Kinect trial.

Top-line results from Kinect-2 are expected in the fourth quarter of 2013.

Other NBI-98854 Development and Pre-Commerical Activities

The company is in the process of initiating two Phase 1 studies of NBI-98854 assessing drug-drug interactions as well as the impact of hepatic impairment on NBI-98854 pharmacokinetics. Both of these studies will be complete prior to the initiation of Phase 3 trials and will support the planned NDA filing. The company plans to request an End of Phase 2 meeting with the FDA for NBI-98854 in tardive dyskinesia during the fourth quarter of 2013. The company has not yet determined whether to pursue a SPA (Special Protocol Assessment). Management stated that it was likely that a decision would come after the end of Phase 2 meeting, but some guidance could come earlier depending on the course of interactions with the FDA.

Ongoing market analysis includes analysis of a large insurance database (115 million covered lives) to determine the underlying diagnoses and characteristics of the US tardive dyskinesia patient population. The results of this analysis will be useful as input for the design of the Phase 3 trials, including the incorporation of secondary and tertiary endpoints that address payer concerns.

Additionally, the Company has initiated 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, the Company anticipates entering Phase I and Phase II clinical studies in 2014.

…Background on VMAT2 & TD…

VMAT-2 is a protein concentrated in the human brain that is primarily responsible for re-packaging and transporting monoamines (dopamine, norepinephrine, serotonin, and histamine) among nerve cells. Neurocrine's molecule, NBI-98854, is a novel, highly-selective VMAT2 inhibitor that modulates presynaptic dopamine release during nerve communication, while at the same time having minimal impact on the other monoamines thereby reducing the likelihood of "off target" side effects. NBI-98854 is designed to provide low, sustained, plasma and brain concentrations of the active drug to minimize side effects associated with excessive dopamine depletion.

We see TD as a meaningful market opportunity for Neurocrine. There are an estimated 500,000 TD patients in the U.S. with no real treatment options. 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, schizophrenia, Tourette's syndrome, and Tardive Dystonia. We expect that management will move into a second indication, most likely Tourette's, in 2014. Tourette's is a disease that primarily affects adolescents starting at the age of six. Before this trial can begin, management must complete some additional toxicology work and an adolescent bridging study. However, we note that so far, in the KINECT studies, NBI-98854 has offered a pretty clean safety and tolerability profile. Management noted on the first quarter 2013 conference call that discontinuation rates for KINECT-1 and KINECT-2 are tracking well below what would normally be expected in a moderate-to-severe TD patient population. This is clearly a good sign in terms of both NBI-98854 safety and tolerability, along with efficacy.

We are particularly excited about the VMAT-2 program at Neurocrine. It represents significant upside and diversification from elagolix. We note that management plans to retain the North American rights to NBI-98854 all the way to commercialization, but may seek a rest of world (ROW) partnership for the initiation of phase 3 in 2014.

Elagolix Development Continues At AbbVie

The initial Phase 3 study of elagolix for endometriosis, the Violet Petal Study, is ongoing at AbbVie. 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. On the earnings call, Neurocrine management noted that the study is on track with expectations for the completion of randomization this fall and top-line data availability in the first quarter of 2014.

The results of the Phase IIb Daisy Petal Study of elagolix in endometriosis were published electronically ahead of print in the Journal of Endometriosis and Pelvic Pain Disorders.

AbbVie is also currently conducting a Phase 2b study of elagolix in uterine fibroids. This study is assessing uterine blood loss in 280 women with heavy uterine bleeding due to uterine fibroids. These Phase 2b activities were described by management as "on track", but no additional details were available.

RECOMMENDATION

Raising our Price Target to $18

We continue to very positive on Neurocrine Bio. The basis for our optimism is our belief that the collaboration deal with Abbott Labs, now AbbVie, for elagolix was a 'Homerun'. Neurocrine received $75 million upfront and has the potential to earn an additional $530 million in future milestones, of which CEO Kevin Gorman noted the "vast majority" are for development. This gives us confidence that Neurocrine will recognize a significant portion of these milestones prior to potential FDA approval in 2017. To date, roughly $70 million has been received.

The company has also signed a second deal with Boehringer Ingelheim and successfully completed phase 2a studies on internal candidate, NBI-98854, VMAT-2 inhibitor for tardive dyskinesia. The collaboration with BI focuses on the research and development of G-protein coupled receptor (GPCR) small molecules for the treatment of Type-2 diabetes. The activation of GPR119 receptors located in the digestive system stimulates incretins, resulting in increased insulin production, while activation of GPR119 receptors located on pancreatic islet beta cells also stimulates insulin secretion. As part of terms of the collaboration, Neurocrine received another $10 million upfront milestone payment for research funding, and is eligible to receive up to $225 million in future milestone payments based on the achievement of development, regulatory and commercial goals. Again, CEO Kevin Gorman noted that a "substantial amount" can be achieved in clinical development.

The company's balance sheet on June 30, 2013 reflected total assets of $174.8 million, including cash and short-term investments of $153.7 million and current assets of $155.9 million. We note the company has another $17.1 million in long-term investments and restricted cash. The company expects to end 2013 with in excess of $130 million in cash, investments and receivables. Our market research shows elagolix as a $1.5 billion drug worldwide. Meanwhile, two phase 2b trials on VMAT-2 inhibitor, NBI-98854, called KINECT-1 and KINECT-2, are underway with data from the former expected in September and data from the latter expected in the fourth quarter of 2013.

We believe Neurocrine is in an outstanding position to build shareholder value over the next several years based on these factors. We recommend accumulating the stock at today's price, up to our $18 target.

PROJECTED FINANCIALS

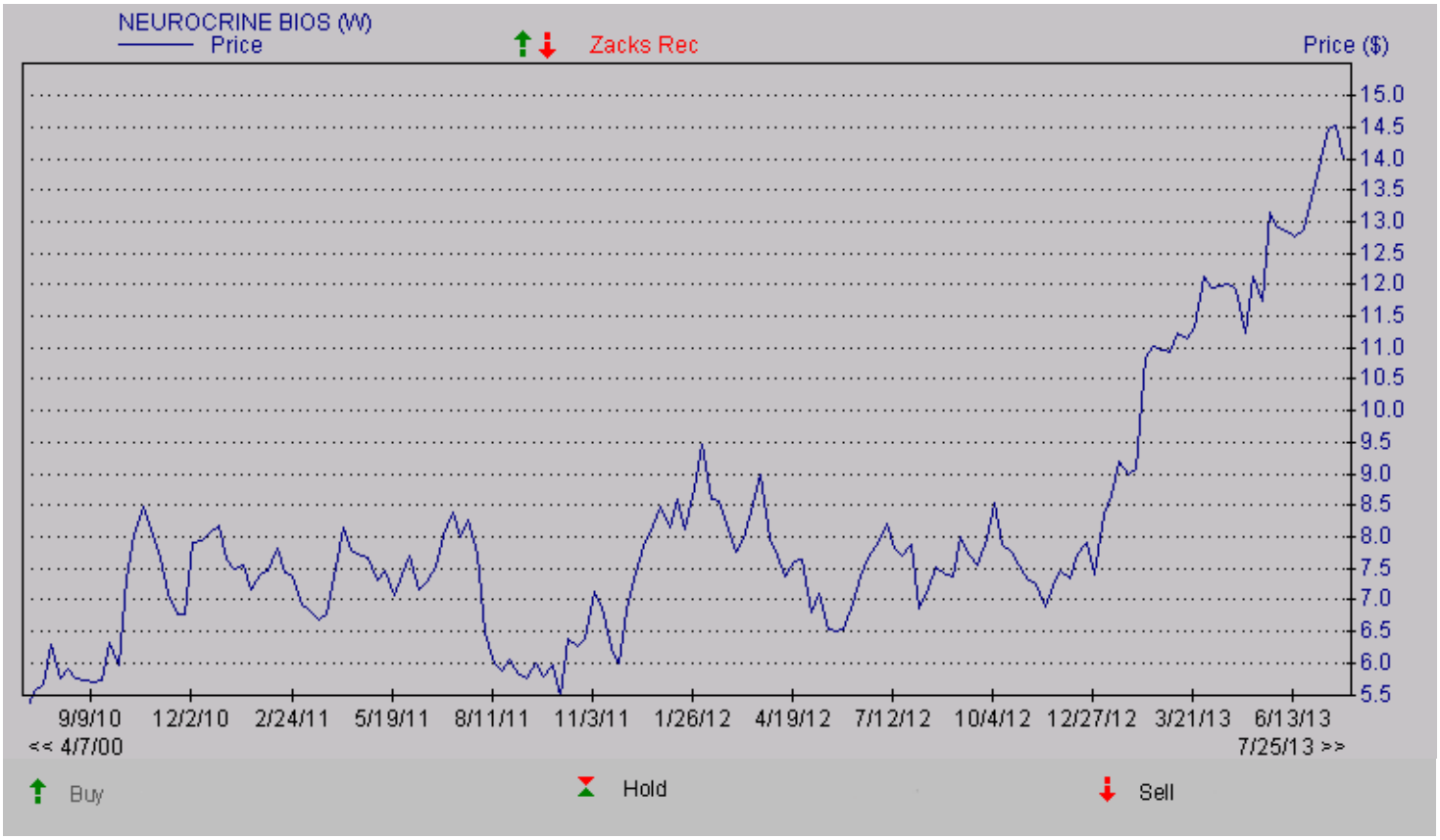
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2011 A	2012 A	Q1 A	Q2 A	Q3 E	Q4 E	2013 E	2014 E	2015 E	2016 E
R&D / Milestones & Fees	**$77.4**	**$53.1**	**$0.7**	**$0.7**	**$0.8**	**$0.8**	**$2.9**	**$5.0**	**$50.0**	**$50.0**
YOY Growth	*131.1%*	*-31.4%*	*-93.5%*	*-93.4%*	*-92.0%*	*-96.6%*	*-94.5%*	*70.6%*	*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**	**$0.8**	**$0.8**	**$2.9**	**$5.0**	**$50.0**	**$50.0**
YOY Growth	*131.1%*	*-31.4%*	*-93.5%*	*-93.4%*	*-92.0%*	*-96.6%*	*-94.5%*	*70.6%*	*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	$3.5	$3.6	$13.9	$14.5	$15.0	$15.5
% SG&A	*16.0%*	*27.3%*	*464.7%*	*485.7%*	*466.7%*	*480.0%*	*474.1%*	*290.0%*	*30.0%*	*31.0%*
R&D	$31.0	$37.2	$10.3	$10.5	$10.5	$10.5	$41.8	$35.0	$40.0	$40.0
% R&D	*40.0%*	*69.9%*	*1412.7%*	*1500.0%*	*1400.0%*	*1400.0%*	*1427.1%*	*700.0%*	*80.0%*	*80.0%*
Operating Income	$34.1	$1.4	($13.0)	($13.2)	($13.3)	($13.4)	($52.8)	($44.5)	($5.0)	($5.5)
Operating Margin	*44.0%*	*2.7%*	-	-	-	-	*-1801.2%*	*-890.0%*	*-10.0%*	*-11.0%*
Interest / Other Income	$3.6	$3.6	$0.9	$0.9	$1.0	$1.0	$3.8	$3.5	$2.5	$2.5
Pre-Tax Income	$37.6	$5.0	($12.1)	($12.3)	($12.3)	($12.4)	($49.0)	($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)	($12.3)	($12.4)	($49.0)	($34.9)	($1.8)	($2.1)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	*48.5%*	*9.5%*	-	-	-	-	*-1671.5%*	*-697.0%*	*-3.5%*	*-4.2%*
Reported EPS	**$0.67**	**$0.08**	**($0.18)**	**($0.18)**	**($0.18)**	**($0.18)**	**($0.73)**	**($0.50)**	**($0.02)**	**($0.03)**
YOY Growth	-	*-88.5%*					*-1057.0%*	*-32.1%*	*-95.2%*	*16.0%*
Shares Outstanding	56.3	65.6	66.6	66.9	66.8	67.0	66.8	70.0	72.5	75.0

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

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



© Copyright 2013, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Investment Research ("ZIR"), Zacks & Company (ZCO") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned.

ZCO and Zacks SCR are separate legal entities. ZCO is U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the Financial Industry Regulatory Authority and the Securities Investor Protection Corp. This report is for your information only and is not an offer to sell, or a solicitation of an offer to buy, the securities or instruments through ZCO.

Zacks SCR uses the following rating system for the securities it covers. 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 of Zacks Ratings is as follows on the 1019 companies covered: Buy/Outperform- 14.2%, Hold/Neutral- 78.6%, Sell/Underperform – 6.3%. Data is as of midnight on the business day immediately prior to this publication.