Zacks Small-Cap Research

January 19, 2017
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: Phase 2 Study of INGREZZA™ in Adults with Tourette Syndrome Fails to Hit Primary Endpoint…

Based on our probability adjusted DCF model that takes into account potential future revenues from valbenazine in TD and TS along with elagolix in endometriosis and UF, NBIX is valued at $75/share. This model utilizes a 11% discount rate and is highly contingent upon continued clinical success of both valbenazine and elagolix. It will be adjusted accordingly based upon future clinical results.

Current Price (01/19/17)	$42.04
Valuation	**$75.00**

OUTLOOK

On January 17, 2017, Neurocrine Biosciences, Inc. (NBIX) announced results from the Phase 2 study of INGREZZA™ in Adults with Tourette Syndrome. The study did not achieve the primary endpoint, which was the change from baseline in the Yale Global Tic Severity Scale (YGTSS) at Week 8 (*P*=0.18). Very few details regarding the results from the study were disclosed, as the company does not want to risk assessment bias in the ongoing Phase 2 study of INGREZZA™ in pediatric Tourette syndrome patients, the results of which are expected in the second quarter of 2017. Since the company never intended to initiate a Phase 3 program in adult TS, and we don't believe these results can be used as a read-through for the Phase 2 study in pediatric TS patients due to the differences in TS in adult and pediatric populations, there is no material change to our valuation.

SUMMARY DATA

52-Week High	**$54.77**
52-Week Low	**$32.19**
One-Year Return (%)	**-15.36**
Beta	**0.57**
Average Daily Volume (sh)	**1,260,434**
Shares Outstanding (mil)	**87**
Market Capitalization ($mil)	**$3,652**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**98**
Insider Ownership (%)	**5**
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)
2015	19.8 A	0 A	0 A	0 A	19.8 A
2016	15.0 A	0 A	0 A	0 E	15.0 E
2017					84.0 E
2018					420.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.01 A	-$0.28 A	-$0.40 A	-$0.34 A	-$1.05 A
2016	-$0.22 A	-$0.46 A	-$0.43 A	-$0.49 E	-$1.59 E
2017					-$1.51 E
2018					$1.48 E

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

On January 17, 2017, Neurocrine Biosciences, Inc. (NBIX) announced results from the Phase 2 T-Forward study of INGREZZA™ (valbenazine) in adults with Tourette syndrome. The study did not achieve the pre-specified primary endpoint, which was the change from baseline in the Yale Global Tic Severity Scale (YGTSS) at Week 8 (*P*=0.18). However, the study did show a statistically significant improvement in overall symptoms of Tourette syndrome by the Clinical Global Impression of Change (*P*=0.015). Due to the fact that a number of the same investigators from the T-Forward study are also taking part in the T-Force GREEN study of INGREZZA™ in children and adolescents with Tourette syndrome, the company did not release many details of the results in order to avoid potentially introducing assessor bias into the T-Force GREEN study. However, the company did indicate that a number of positive insights were gained into conducting a clinical trial with TS patients along with appropriate inclusion/exclusion criteria.

Tourette Syndrome

Tourette syndrome (TS) is a childhood neuropsychiatric disorder that is characterized by repetitive movements and unwanted sounds that are not easily controlled. TS is a genetically inherited condition that is passed on through families, however the precise abnormality responsible for the condition has not yet been elucidated. Diagnostic criteria for TS include multiple motor and vocal tics that occur many times a day nearly every day for one year, an age of onset of less than 18, and symptoms that are not due to any direct effects from substances or other conditions. Previously, diagnosis was also contingent on the condition causing marked distress or impairment in social, occupational, or other important areas of function. However, since a number of patients have a mild form of TS that does not interfere with their daily lives, this criterion was removed so that patients with TS would not be stigmatized.

The tics associated with TS are diverse and sometimes bizarre. They are divided into motor or vocal and can be simple or complex. Simple motor tics involve a single muscle or group of muscles, while complex motor tics are movements that involve multiple muscle groups and may appear semi-purposeful. Simple vocal tics are basic vocalizations or sounds while complex vocal tics involve words and/or complex phrases. Copralalia is a complex phonic tic characterized by the shouting of socially inappropriate language. While copralalia is often associated with TS, it occurs in fewer than half of TS patients, although it can be one of the most distressing symptoms of the condition.

TS symptoms can be evaluated by a number of different clinical measurements, including the Yale Global Tic Severity Scale (YGTSS) and the Premonitory Urge for Tics Scale (PUTS).

- YGTSS: This is a 10-item clinician-rating instrument that provides an evaluation of the number, frequency, intensity, complexity, and interference of motor and phonic tics. The items are scored on two subscales, one for motor and one for phonic, and are rated on a 6-point scale (Leckman *et al*., 1989).

- PUTS: Older children and adolescents often report tics to be preceded by an unpleasant sensation known as "premonitory urge", examples of which include a burning feeling in the eye before an eye blink, tension in the neck that is relieved by stretching the neck or jerking of the head, and nasal stuffiness before a sniff. PUTS is a means to quantify these urges, and data shows that the scale is internally consistent and correlates with overall tic severity in children older than 10 years of age (Woods *et al*., 2005).

Physicians typically take a multifaceted approach to treating TS using medication to control severe or frequent tics, behavioral modifications, and patient education. Medications given to suppress tics include dopamine receptor antagonists (pimozide, fluphenazine), alpha-2-adrenergic agonists (clonidine), benzodiazepines, dopamine depletors (tetrabenazine), and dopamine agonists (ropininirole). The only two medicines currently approved by the FDA for treating tics are haloperidol (Haldol®) and pimozide (Orap®).

T-FORWARD Study

On October 20, 2015, the company announced the initiation of the Phase 2 T-FORWARD study of INGREZZA™ in adults with TS (NCT02581865). The T-FORWARD study was a randomized, double blind, placebo controlled, multi dose, parallel group study of over 90 adults with TS. Study participants received once-daily dosing of INGREZZA™ during an eight-week treatment period to assess the safety, tolerability, and efficacy in adults with TS. The primary endpoint of the study was the change in baseline of placebo vs. active scores utilizing the YGTSS at the end of Week 8.

While unable to share many details, during the conference call to discuss the results management did highlight a few broad themes from the study, including: the placebo arm behaved as expected, which according to the literature would suggest a 15-25% responder rate; the treatment effect was both dose-dependent and improved over time; adverse events were similar in TS patients as in healthy volunteers; and the company was very pleased with the use of the YGTSS by the investigators. We anticipate additional results from the study being shared at scientific conferences later in the year.

While disappointing that the study did not achieve the primary endpoint, the company never intended to initiate a Phase 3 program in TS in adults. The purpose of this exploratory study was to simply learn more about TS in adults (since very few placebo controlled trials have been conducted in adults with TS), the proper dosing for this population, and the use of the YGTSS in a placebo controlled clinical trial.

Conclusion

While unsure of the exact reasons, due to the very fact that it continues on into adulthood, TS in adults is different from TS in children and adolescents, as 80% of children with TS will not suffer from the condition as adults. Thus, we don't believe the fact that the T-Forward study missed the primary endpoint can be used as a read-through for the T-Force GREEN study. While the company certainly would have preferred if the T-Forward study achieved the primary endpoint, given the fact that the company never intended to move forward to a Phase 3 program of INGREZZA™ in adults with TS, these results do not have any material impact on our valuation.

During the conference call, the company indicated that all adolescents have been enrolled in the T-Force GREEN study and the final children are being screened and randomized. Once the final child is enrolled the company will be able to better estimate when the data from the T-Force GREEN study will be available, but we continue to estimate it will be in the second quarter of 2017. In addition, we remind investors that the PDUFA data for INGREZZA™ for the treatment of tardive dyskinesia is April 11, 2017. Both of these events could have a material impact on our valuation. Our probability adjusted discounted cash flow model currently yields a valuation for Neurocrine's shares of $75, and we continue to view Neurocrine as a solid core holding for any biotech investor.

PROJECTED FINANCIALS

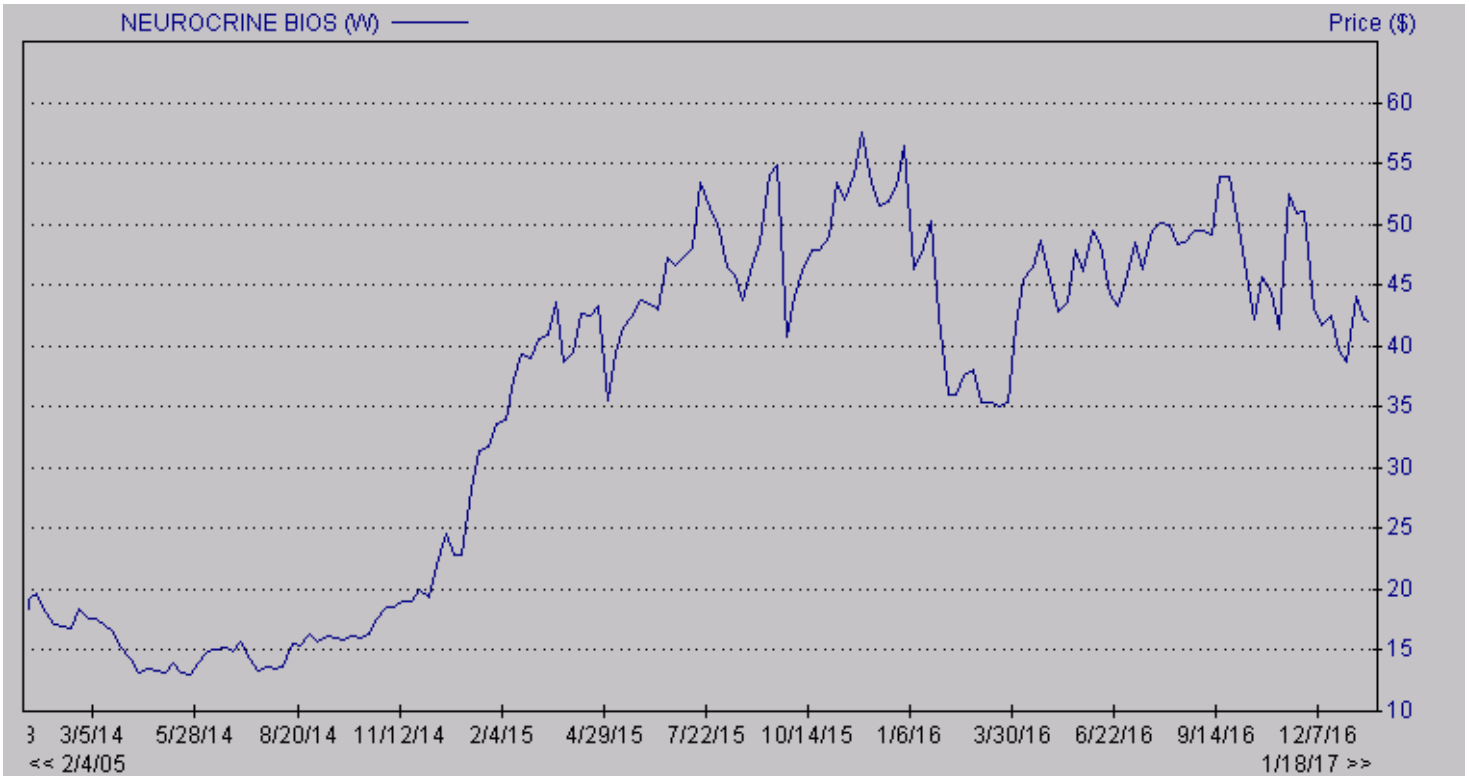
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
R&D / Milestones & Fees	**$19.8**	**$15**	**$0**	**$0**	**$0**	**$15.0**	**$50.0**	**$100.0**
YOY Growth	-	-	-	-	-	-	-	-
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$23**
YOY Growth	-	-	-	-	-	-	-	-
NBI-640756	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
NBI-98854 (VMAT2)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$34**	**$297**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$19.8**	**$15.0**	**$0**	**$0**	**$0**	**$15.0**	**$84.0**	**$420.0**
YOY Growth	-	-	-	-	-	-	*460.0%*	*400.0%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$5	$45
Gross Margin	-	-	-	-	-	-	-	-
SG&A	$32.5	$12.0	$15.0	$17.5	$20.0	$64.4	$120.0	$140.0
R&D	$81.5	$23.9	$26.9	$20.9	$24.0	$95.7	$100.0	$105.0
Operating Income	($94.2)	($20.9)	($41.8)	($38.4)	($44.0)	($145.1)	($141.1)	$130.5
Operating Margin	-	-	-	-	-	-	-	-
Interest / Other Income	$5.3	$1.6	$1.5	$1.5	$1.3	$6.0	$5.5	$5.3
Pre-Tax Income	($88.9)	($19.3)	($40.3)	($36.9)	($42.7)	($139.1)	($135.6)	$135.8
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*30%*	*0%*	*0%*	*0%*	*0%*	*30.0%*	*30.0%*	*30.0%*
Net Income	($88.9)	($19.3)	($40.3)	($36.9)	($42.7)	($139.1)	($135.6)	$135.8
YOY Growth	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.05)**	**($0.22)**	**($0.46)**	**($0.43)**	**($0.49)**	**($1.59)**	**($1.51)**	**$1.48**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	84.5	86.5	86.7	86.8	87.0	87.5	90.0	92.0

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2017, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.