Zacks Small-Cap Research

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Neurocrine Biosciences, Inc. (NBIX - Nasdaq)

NBIX: P2 Study in Tourette's Syndrome Does Not Meet Primary Endpoint; P2b Study to Start Before End of 2017…

Based on our probability adjusted DCF model that takes into account potential future revenues from INGREZZA® in TD and TS along with elagolix in endometriosis and UF, NBIX is valued at $80/share. This model utilizes a 11% discount rate and is highly contingent upon continued clinical and commercial success of both INGRESSA® and elagolix. It will be adjusted accordingly based upon future clinical results.

Current Price (05/25/17)	$48.89
Valuation	**$80.00**

OUTLOOK

On May 23, 2017, Neurocrine Biosciences, Inc. (NBIX) announced that the T-Force GREEN study of INGREZZA® in Tourette syndrome (TS) did not meet its primary endpoint, which was the change from baseline between placebo and active groups in the Yale Global Tic Severity Scale (YGTSS) at Week 6.

The company believes that INGREZZA® was not dosed at a high enough concentration for a majority of the patients. An exposure-response analysis showed that for subjects with pharmaceutical exposure in the appropriate range, there was a substantial reduction in tics while for subjects with sub-therapeutic exposure tic reduction was comparable to placebo. The company intends to take what was learned from this study and initiate a Phase 2b study in children and adolescents with TS before the end of 2017.

SUMMARY DATA

52-Week High	**$55.38**
52-Week Low	**$37.35**
One-Year Return (%)	**6.68**
Beta	**1.77**
Average Daily Volume (sh)	**1,379,050**
Shares Outstanding (mil)	**88**
Market Capitalization ($mil)	**$4,306**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**97**
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)
2016	15.0 A	0 A	0 A	0 A	15.0 A
2017	0 A	0 E	34.0 E	13.0 E	47.0 E
2018					164.0 E
2019					395.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.22 A	-$0.46 A	-$0.43 A	-$0.51 A	-$1.05 A
2017	-$0.90 A	-$0.62 E	-$0.28 E	-$0.58 E	-$2.50 E
2018					-$1.66 E
2019					$0.94 E

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WHAT'S NEW

Business Update

T-Force Green Study Does Not Meet Primary Endpoint

The T-Force GREEN study was a Phase 2 study designed to evaluate the safety, tolerability, and efficacy of INGREZZA™ in children and adolescents with Tourette syndrome (TS) (NCT02679079). It was a randomized, double blind, placebo controlled, multi-dose, parallel group trial of approximately 90 children and adolescents. Patients received once-daily dosing of INGREZZA™ or placebo in a 1:1:1 fashion during a six-week treatment period. The primary endpoint of the study was the change in baseline of the Yale Global Tic Severity Scale (YGTSS) between placebo and active groups at the end of six weeks.

On May 23, 2017, the company announced that the T-Force GREEN study did not meet the primary endpoint, however the company still believes it was a successful study as a large amount of data was compiled that will likely lead to future clinical success. An exposure-response analysis showed that the selected doses (which were not disclosed by the company) were below the therapeutic range for adequate tic reduction in the majority of patients. For those subjects with adequate exposure to drug there was a substantial reduction in tics (-11.3 to -13.7 points on the YGTSS). For subjects that did not have adequate exposure to drug, the reduction in tics was similar to placebo (-4.7 to -8.3 points on the YGTSS).

Management is confident that with the knowledge gained from this trial they will be able to better design the next study to maximize the chance for a positive outcome. The company is hopeful to get a Phase 2b study underway before the end of 2017 that will likely include more patients and the same endpoint, but those parameters won't be known for sure until after the company meets with the FDA to finalize the protocol. While the T-Force GREEN study took approximately one year to fully enroll, management believes that the next study could likely be enrolled in approximately six months, as there will not be any delays in getting study sites on-line as there was for the T-Force GREEN study. Administrative delays caused a number of sites to not be available to enroll patients until a few months after the T-Force GREEN study initiated, and since those same sites are likely to be used in the next study those delays will not be an issue.

Conclusion

We're disappointed that the T-Force GREEN study did not meet the primary endpoint, however we are encouraged by how hopeful the company sounds in regards to what was learned from the study that can be applied to the next trial. We have pushed the timelines for approval in TS back by a year due to what we view as a minor setback, however we believe TS continues to represent a significant opportunity for the company and are confident in management's ability to optimize the next trial design for success. We have slightly lowered our fair value estimate to $80 per share, and view any pullback in the stock price as a good opportunity for long-term investors to acquire shares.

PROJECTED FINANCIALS

Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2016 A	Q1 A	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
R&D / Milestones & Fees	**$15.0**	**$0**	**$0**	**$30**	**$0**	**$30.0**	**$30.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$23**	**$77**
YOY Growth	-	-	-	-	-	-	-	-
NBI-640756	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
NBI-98854 (VMAT2)	**$0**	**$0**	**$0**	**$4**	**$13**	**$11**	**$78**	**$346**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$15.0**	**$0**	**$0**	**$34**	**$13**	**$41.0**	**$131.0**	**$423.0**
YOY Growth	-	-	-	-	-	*173.3%*	*219.5%*	*222.9%*
CoGS / Royalties	$0	$0	$0	$0	$0	$2	$12	$52
Gross Margin	-	-	-	-	-	-	-	-
SG&A	$68.1	$28.1	$30.0	$35.0	$40.0	$133.1	$150.0	$160.0
R&D	$94.3	$51.9	$25.0	$25.0	$25.0	$126.9	$110.0	$120.0
Operating Income	($147.4)	($79.9)	($55.0)	($26.0)	($52.0)	($220.6)	($140.7)	$91.1
Operating Margin	-	-	-	-	-	-	-	-
Interest / Other Income	$6.3	$1.6	$1.5	$1.5	($4.3)	$0.4	($6.6)	($6.6)
Pre-Tax Income	($141.1)	($78.3)	($53.5)	($24.5)	($56.3)	($220.2)	($147.3)	$84.5
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*30.0%*	*0%*	*0%*	*0%*	*0%*	*30.0%*	*30.0%*	*30.0%*
Net Income	($141.1)	($78.3)	($53.5)	($24.5)	($56.3)	($220.2)	($147.3)	$84.5
YOY Growth	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.63)**	**($0.90)**	**($0.61)**	**($0.28)**	**($0.64)**	**($2.50)**	**($1.66)**	**$0.94**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	86.7	87.3	88.0	88.2	88.5	88.0	89.0	90.0

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

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