Zacks Small-Cap Research

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Neurocrine Biosciences, Inc. (NBIX - Nasdaq)

NBIX: AdComm Meeting for INGREZZA™ Cancelled by FDA…

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 (01/06/17)	$41.38
Valuation	**$75.00**

OUTLOOK

On January 5, 2017, Neurocrine Biosciences, Inc. announced that the Food and Drug Administration (FDA) has cancelled the Psychopharmacologic Drugs Advisory Committee meeting that was originally scheduled for Feb. 16, 2017 after further review of the INGREZZA™ New Drug Application (NDA). The FDA informed the company that the Priority Review of the NDA for INGREZZA™ for the treatment of tardive dyskinesia was continuing as planned with the previously announced Prescription Drug User Fee Act (PDUFA) date of April 11, 2017. We do not view this action by the FDA in a negative light, as management indicated that all interactions with the agency thus far have been very positive, and we continue to believe that INGREZZA™ is likely to gain approval.

SUMMARY DATA

52-Week High	**$54.77**
52-Week Low	**$32.19**
One-Year Return (%)	**-13.32**
Beta	**0.57**
Average Daily Volume (sh)	**865,390**
Shares Outstanding (mil)	**87**
Market Capitalization ($mil)	**$3,595**
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

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WHAT'S NEW

Business Update

On January 5, 2017, Neurocrine Biosciences, Inc. announced that the Food and Drug Administration (FDA) has cancelled the Psychopharmacologic Drugs Advisory Committee meeting that was originally scheduled for Feb. 16, 2017 after further review of the INGREZZA™ New Drug Application (NDA). The FDA informed the company that the Priority Review of the NDA for INGREZZA™ for the treatment of tardive dyskinesia (TD) was continuing as planned with the previously announced Prescription Drug User Fee Act (PDUFA) date of April 11, 2017.

During the conference call to discuss the situation, management indicated that they have had nothing but positive interactions with the FDA up to and during review of the NDA and that they were not aware of any issues with the review of the NDA. Following the notification about cancellation of the Advisory Committee meeting, the FDA indicated to the company that the NDA review is still on track. Thus, we do not believe there is any cause for concern with the Advisory Committee meeting being cancelled and we continue to believe that INGREZZA™ is likely to gain approval. In addition, this is likely to remove any type of overhang there may have been on the stock in the time leading up to the Advisory Committee meeting.

Plans for INGREZZA™ Following Approval

In addition to commenting on the cancellation of the Advisory Committee Meeting, management also touched on the pre-commercialization activities that have been occurring leading up to the planned approval for INGREZZA™, assuming approval. The company is continuing to meet with both private and public payers to discuss coverage of the drug and making sure as many patients as possible have access. In addition, the medical affairs team has been preparing presentations and publications to showcase data from the company's clinical trials of INGREZZA™ as well as meeting with Key Opinion Leaders (KOLs) and patient advocacy groups to raise awareness of the drug prior to launch. On the sales side, the National Sales Manager has been hired along with regional directors, who have been building a sales team of approximately 140 representatives. Contracts for sales representatives are being prepared, which will be contingent upon INGREZZA's approval. Following approval, the sales representatives will give their two weeks notice at their current positions, will have two weeks of home study, and then have two weeks of on-site study at Neurocrine headquarters. Thus, if approved, we anticipate a full commercial launch of INGREZZA™ in the beginning of June 2017.

New President and Chief Operating Officer

On November 6, 2016, Neurocrine announced the hiring of David-Alexandre Gros, M.D. as President and Chief Operating Officer. Dr. Gros previously served as Senior Vice President, Chief Business Officer, and a member of the Management Board at Alnylam Pharmacueticals where he was responsible for strategy, finance, business development, communications, and investor relations. Prior to Alnylam, Dr. Gros was Chief Strategy Officer at Sanofi. Dr. Gros holds an M.D. from The Johns Hopkins University School of Medicine and an M.B.A. from Harvard Business School. Dr. Gros' vast experience will be important to Neurocrine as it transitions to a commercial-stage company.

Conclusion

There is nothing to cause us concern about the cancellation of the Advisory Committee meeting for INGREZZA™, as there do not appear to be any review issues regarding the NDA and the company has stated that all interactions with the FDA in regards to the NDA have been positive. We are not anticipating hearing any additional news about INGREZZA™ until the PDUFA date, and we continue to believe that approval is highly likely. We currently model for peak sales of INGREZZA™ in TD of $1.6 billion. As a reminder, Phase 2 data from the study of adults with Tourette syndrome (TS) is expected in the third or fourth week of January 2017, and Phase 2 data from the study of TS in children and adolescents is expected near the end of the first quarter of 2017. We view TS as an additional billion-dollar opportunity. Our probability adjusted discounted cash flow model 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*

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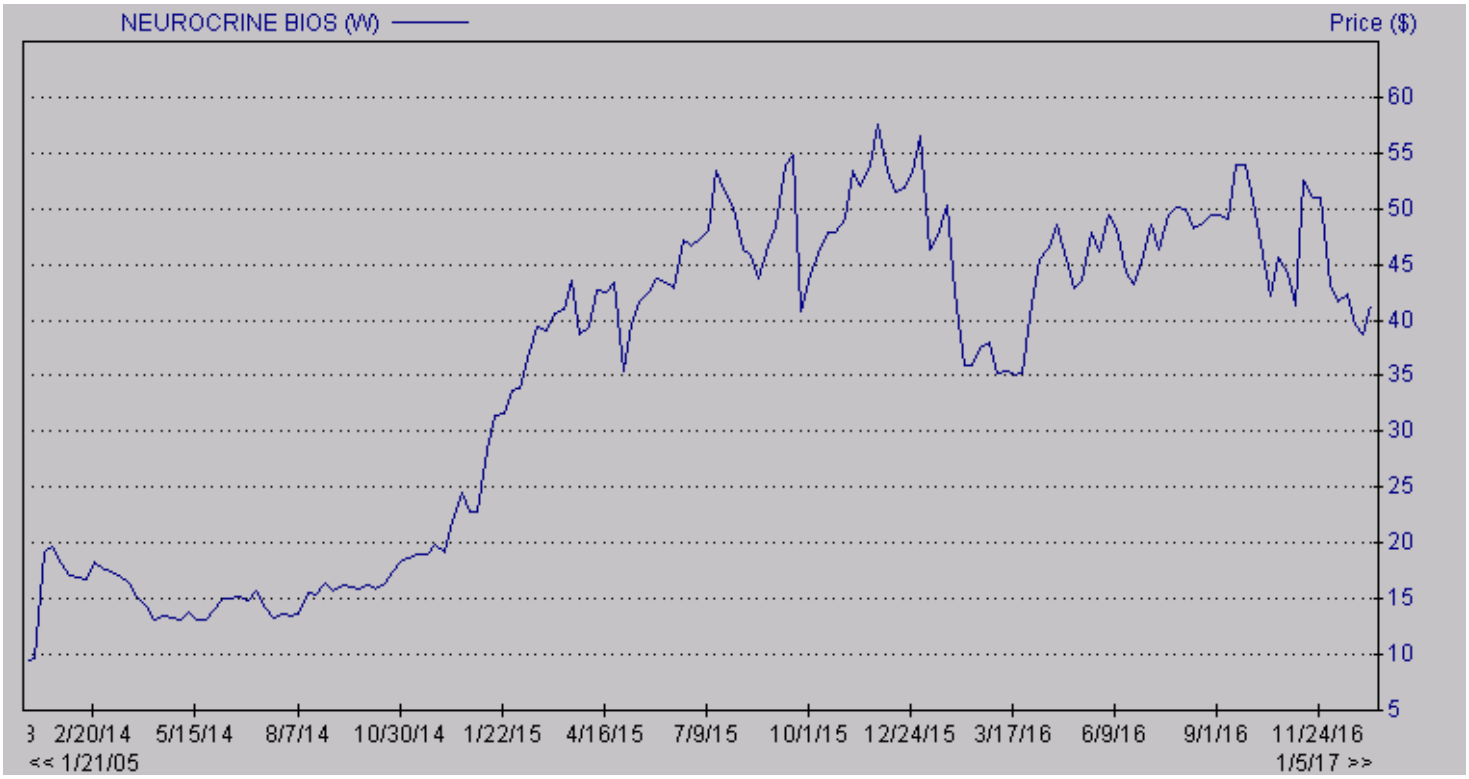

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