Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

February 16, 2018
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: Will File an NDA for Opicapone in 1H19…

Based on our probability adjusted DCF model that takes into account potential future revenues from INGREZZA® in TD and TS, elagolix in endometriosis and UF, and opicapone NBIX is valued at $90/share. This model utilizes a 11% discount rate and is highly contingent upon continued clinical and commercial success of INGREZZA®, elagolix, and opicapaone. It will be adjusted accordingly based upon future clinical results.

Current Price (02/16/18)	$85.57
Valuation	**$90.00**

OUTLOOK

On February 13, 2018, Neurocrine Biosciences, Inc. (NBIX) announced financial results for the fourth quarter and full year 2017 and provided a business update. Fourth quarter revenues for INGREZZA® were $64.5 million with approximately 9,100 prescriptions. For 2017, the company reported revenues of $161.6 million, which included $116.6 million in revenue from INGREZZA® and $45 million in milestone payments. In the fourth quarter of 2017 the company reported net income of $6.9 million, or $0.07 per share, while net loss for 2017 was $142.5 million, or $1.62 per share.

The company recently announced that it plans to file a new drug application (NDA) with the U.S. FDA for the approval of opicapone in the first half of 2019. Upcoming milestones in the first half of 2018 include data from Phase 3 studies of elagolix in uterine fibroids (1Q18), a PDUFA date for elagolix in endometriosis (2Q18), and data from NBI-74788 in CAH patients.

SUMMARY DATA

52-Week High	**$90.67**
52-Week Low	**$40.24**
One-Year Return (%)	**98.31**
Beta	**0.26**
Average Daily Volume (sh)	**1,007,060**
Shares Outstanding (mil)	**89**
Market Capitalization ($mil)	**$7,639**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
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/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Large-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue

(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0 A	6.3 A	60.8 A	94.0 A	161.6 A
2018	70.0 E	87.0 E	149.0 E	124.0 E	430.0 E
2019					648.0 E
2020					978.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.90 A	-$0.68 A	-$0.13 A	$0.07 A	-$1.62 A
2018	-$0.27 E	-$0.19 E	$0.48 E	$0.09 E	$0.12 E
2019					$2.11 E
2020					$5.11 E

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

Business Update

Opicapone NDA to be Filed in 1H19

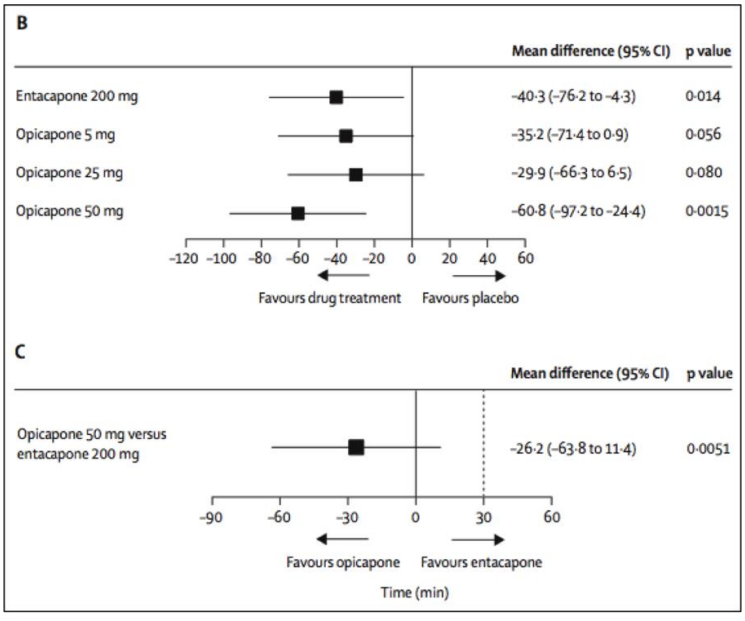
On Feb. 14, 2018, Neurocrine Biosciences, Inc. (NBIX) announced the company will file a new drug application (NDA) for opicapone in the first half of 2019 following receipt of the meeting minutes from the January 2018 meeting with the FDA. During that meeting, the FDA did not request that Neurocrine conduct an additional Phase 3 study for opicapone prior to filing the NDA. We model for peak revenues of opicapone in the U.S. of approximately $150 million.

Opicapone is a peripherally-acting and highly selective inhibitor of catechol-o-methyltransferase (COMT) to be used as an adjunct therapy to levodopa/DOPA decarboxylase inhibitors in patients with Parkinson's disease (PD). It decreases the conversion of levodopa into 3-O-methyldopa, thus reducing the "off-time" period and increasing the "on-time" period of Parkinson's patients.

Opicapone is a third-generation COMT inhibitor with a highly favorable pharmacodynamics profile. Preclinical data showed that opicapone was nontoxic in an *in vitro* assay (Kiss *et al*., 2010) suggesting that it was unlikely to have liver toxicity, unlike tolcapone (another COMT inhibitor). Interestingly, while opicapone is rapidly cleared from plasma (Cmax at 1.5-3.5 hours following a single dose and 1-2.5 hours after multiple doses), the half-life of opicapone-induced COMT inhibition in erythrocytes is >100 hours (Rocha *et al*., 2013). This is due to opicapone's very slow dissociation rate from COMT.

The clinical efficacy of opicapone was shown in two Phase 3 clinical trials, BIPARK I (NCT01568073) and BIPARK II (NCT01227655).

BIPARK I (Ferreira *et al*., 2016): This was a randomized, double blind, placebo controlled, and active controlled trial of opicapone as an adjunct to levodopa in patients with Parkinson's disease with end-of-dose motor fluctuations. A total of 600 patients were randomly assigned 1:1:1:1:1 to receive placebo, entacapone, 5 mg opicapone, 25 mg opicapone, or 50 mg opicapone. The following charts show that patients in the 50 mg opicapone group were significantly more likely to experience less time in the 'off' state compared to placebo (panel B; *P*=0.0015) and that 50 mg opicapone was non-inferior to entacapone (panel C; *P*=0.0051). Opicapone was well tolerated, with a very low percentage of patients discontinuing due to treatment-emergent adverse events and ≤7% of patients in all groups experiencing serious treatment-emergent adverse events, of which 35% were deemed unrelated to study drug.



Source: Ferreira *et al*., 2016

BIPARK II (Lees *et al*., 2016): This was a randomized, double blind, placebo controlled trial to evaluate the safety and efficacy of opicapone as adjunct to levodopa therapy. A total of 427 patients were randomized 1:1:1 to receive placebo, 25 mg opicapone, or 50 mg opicapone for a total duration of 14-15 weeks. This was followed by a 52-week open label extension phase. At the end of the double-blind phase, the mean change in 'off' time was -64.5 min for placebo group, -101.7 min for the 25 mg opicapone group, and -118.8 min for the 50 mg opicapone group. The adjusted treatment difference compared with the placebo group was significant for the 50 mg opicapone group (*P*=0.008), but not for the 25 mg opicapone group (*P*=0.11). 'Off' time reduction was sustained through the open label extension phase as the adjusted mean change from start to finish of the open label phase in 'off' time was -18.3 min. Overall, opicapone was well tolerated with most adverse events being mild or moderate in intensity. The most common adverse events were dyskinesia, constipation, and dry mouth. There were no relevant liver function findings in either phase of the trial.

Numerous Readouts Ahead in 2018

Neurocrine enjoyed a very successful 2017 and will look to keep the momentum going in 2018 with a number of important readouts throughout the year.

- AbbVie is expected to release Phase 3 data for elagolix in the treatment of uterine fibroids in the first quarter of 2018. Based on strong Phase 2 data we anticipate positive results from the Phase 3 study.

- A PDUFA decision for elagolix in the treatment of endometriosis is expected in the second quarter of 2018.

- Neurocrine is currently conducting a Phase 2, proof-of-concept study of NBI-74788 in adults with classic, 21-hydroxylase deficiency congenital adrenal hyperplasia (CAH). The study is evaluating how NBI-74788 exposure correlates with specific steroid hormone levels. We anticipate data in the first half of 2018.

- Late in 2018 we anticipate results from the Phase 2 T-Force GOLD study of INGREZZA® in pediatric patients with Tourette syndrome (TS). This is a multicenter, randomized, double blind, placebo controlled Phase 2b study that expects to enroll approximately 120 pediatric patients ages 6-18. While the T-Force GREEN study did not meet the primary endpoint (change in the Yale Global Tic Severity Scale, YGTSS), we believe the T-Force GREEN study has a higher probability of being positive as the company will be using a higher dose of INGREZZA® based on exposure-response analysis from the T-Force GREEN study.

Financial Update

On February 13, 2018, Neurocrine announced financial results for the fourth quarter and full year 2017. The company reported revenues for INGREZZA® of $64.5 million for the fourth quarter of 2017 and $116.6 million for the full year 2017 (INGREZZA® was launched May 1, 2017). In addition, the company recorded $30 million of milestone revenue from AbbVie in the fourth quarter of 2017 and $45 million in milestone revenue for the full year for total 2017 revenues of $161.6 million. Net income for the fourth quarter of 2017 was $6.9 million, or $0.07 per share, while the net loss for 2017 was $142.5 million, or $1.62 per share.

For 2017, R&D expenses were $121.8 million, compared to $94.3 million for the same period in 2016. The increase was primarily due to a $30 million payment in the first quarter of 2017 to BIAL for the development and commercialization of opicapone in the U.S. and Canada. SG&A expenses in 2017 totaled $169.9 million, compared to $68.1 million for the same period in 2016. The increase was due primarily to commercialization activities for INGREZZA®.

As of Dec. 31, 2017, the company had cash, cash equivalents, and investments of approximately $763.3 million. Neurocrine has guided for total operating expenses in 2018 of $365 million to $395 million, with approximately $50 million in stock-based compensation. The company did not give guidance for INGREZZA® sales in 2018 while we are currently forecasting sales of $390 million.

Conclusion

Neurocrine continues to impress with the launch of INGREZZA®. There were some concerns that revenues would lag in the fourth quarter of 2017 due to converting patients over to the 80 mg capsule (which was essentially completed by the end of 2017), however this was more than offset by the strong growth in prescriptions. We believe revenue and prescription growth will remain strong in 2018. Our valuation now stands at $90 per share, and we believe that Neurocrine would make a solid core holding for any biopharmaceutical investor.

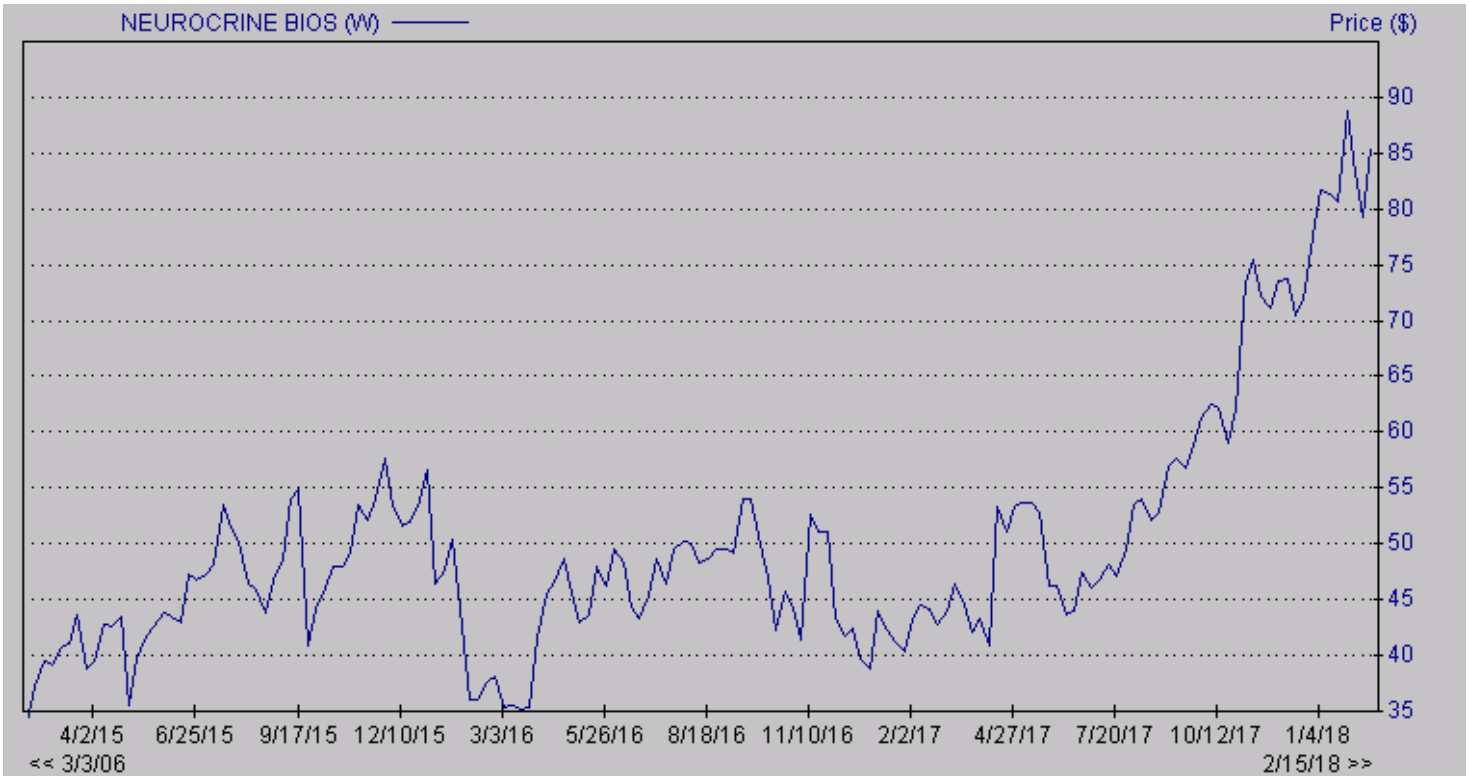
PROJECTED FINANCIALS

Neurocrine Bio	2017 A	Q1 E	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
R&D / Milestones & Fees	**$45.0**	**$0**	**$0**	**$40**	**$0**	**$40**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$18**	**$78**
YOY Growth	-	-	-	-	-	-	-	-
Opicapone	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$8**
YOY Growth								
CAH Program	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
INGREZZA	**$117**	**$70**	**$87**	**$109**	**$124**	**$390**	**$630**	**$900**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$161.6**	**$70**	**$87**	**$149**	**$124**	**$430.0**	**$648.0**	**$978.0**
YOY Growth	*977.5%*	-	-	-	-	*166.0%*	*50.7%*	*50.9%*
CoGS / Royalties	$1.3	$5	$7	$10	$11	$33	$52	$79
Gross Margin	*99.2%*	*92.9%*	*92.0%*	*93.3%*	*91.1%*	*92.3%*	*92.0%*	*91.9%*
SG&A	$169.9	$58.0	$60.0	$62.0	$64.0	$244.0	$260.0	$280.0
R&D	$121.8	$30.0	$31.0	$33.0	$35.0	$129.0	$130.0	$135.0
Operating Income	($131.4)	($23.0)	($11.0)	$44.0	$14.0	$24.0	$206.0	$484.0
Operating Margin	-	-	-	-	-	-	-	-
Interest / Other Income	($11.2)	($1.0)	($5.8)	($1.0)	($5.8)	($13.6)	($14.0)	($14.0)
Pre-Tax Income	($142.5)	($24.0)	($16.8)	$43.0	$8.2	$10.4	$192.0	$470.0
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0%*	*0%*	*0%*	*0%*	*0.0%*	*21.0%*	*21.0%*
Net Income	($142.5)	($24.0)	($16.8)	$43.0	$8.2	$10.4	$192.0	$470.0
YOY Growth	-	-		-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.62)**	**($0.27)**	**($0.19)**	**$0.48**	**$0.09**	**$0.12**	**$2.11**	**$5.11**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	88.1	89.2	89.8	90.4	91.0	90.1	91.0	92.0

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

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2018, 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.