Zacks Small-Cap Research

October 21, 2016
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: AbbVie Presents Positive Phase 3 Data for Elagolix in Endometriosis…

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 (10/21/16)	$45.67
Valuation	**$75.00**

OUTLOOK

On October 19, 2016, AbbVie and Neurocrine Biosciences, Inc announced detailed results from two pivotal Phase 3 clinical trials evaluating the efficacy and safety of elagolix in premenopausal women suffering from endometriosis. The results show that patients treated with elagolix reported statistically significant reductions in scores for menstrual pain and non-menstrual pelvic pain associated with endometriosis. Abbvie is planning a 2017 NDA filing for elagolix in endometriosis.

Neurocrine filed the NDA for valbenazine in tardive dyskinesia in August 2016, which was accepted for priority review by the FDA with a PDUFA date of April 11, 2017. Two additional data readouts for valbenazine in adults and children with Tourette syndrome are expected in late 4Q16 or 1Q17.

SUMMARY DATA

52-Week High	**$57.63**
52-Week Low	**$32.19**
One-Year Return (%)	**-3.79**
Beta	**0.42**
Average Daily Volume (sh)	**886,160**
Shares Outstanding (mil)	**87**
Market Capitalization ($mil)	**$3,962**
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)
2015	19.8 A	0 A	0 A	0 A	19.8 A
2016	15.0 A	0 A	0 E	0 E	15.0 E
2017					174.0 E
2018					542.0 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	-$0.59 E	-$0.62 E	-$1.90 E
2017					-$0.86 E
2018					$2.11 E

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

AbbVie Presents Positive Data For Elagoiix in Endometriosis

On October 19, 2016, AbbVie (ABBV) announced in cooperation with Neurocrine Biosciences, Inc. (NBIX) the presentation of results from two pivotal Phase 3 clinical trials evaluating the efficacy and safety of elagolix in premenopausal women who suffer from endometriosis at the 72nd American Society for Reproductive Medicine Scientific Conference & Expo (ASRM). The data show that patients treated with elagolix had a statistically significant reduction in scores for both menstrual pain (dysmenorrhea, DYS) and non-menstrual pelvic pain (NMPP). AbbVie is planning to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in 2017.

Phase 3 Trial Design

The first pivotal Phase 3 trial (NCT01620528) was a 24-week, multinational, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of elagolix in 872 women, age 18 to 49, with moderate-to-severe endometriosis-associated pain. The trial was conducted at 175 sites in the United States, Puerto Rico and Canada. An extension study allowed for some patients to continue treatment for an additional six months.

The primary endpoint was a dual-endpoint in reduction in DYS and NMPP for women on two doses of elagolix (150 mg QD & 200 mg BID) vs. placebo in a 1-1-2 randomization over six months. Efficacy was assessed by a responder analysis for statistical evaluation. The inclusion of a higher dose allows for a potential full label with dose titration and prescribing options post approval.

The second Phase 3 trial (NCT01931670) was similar in design to the first trial and included 815 women age 18-49 with moderate to severe endometriosis-associated pain. The study was conducted across 226 sites in 13 countries, with equal representation of enrollment between U.S. and ex-U.S. countries.

Trial Results

AbbVie had previously announced positive top-line data for the two Phase 3 trials in Jan. 2015 and Feb. 2016. Detailed results from the trials were presented through five poster presentations and three oral presentations. The data show that both doses of elagolix resulted in a statistically significant improvement in DYS and NMPP ($P<0.001$).

In the first study, 46% and 76% of patients taking 150 mg once daily and 200 mg twice daily, respectively, were classified as DYS responders after three months of treatment. This compares to 20% of patients taking placebo. In addition, 50% and 55% of patients taking 150 mg once daily and 200 mg twice daily, respectively, were classified as NMPP responders, compared to 36% taking placebo.

Results from the second study were similar to the first study. After three months, 43% and 72% of patients taking 150 mg once daily and 200 mg twice daily, respectively, were classified as DYS responders, compared to 23% of those taking placebo. Fifty percent and 58% of patients taking 150 mg once daily and 200 mg twice daily, respectively, were classified as NMPP responders, compared to 37% taking placebo.

The safety profile of elagolix was consistent across both Phase 3 studies and was similar to what had been seen in prior studies of elagolix. The most common adverse events following six months were hot flush, headache, and nausea. Discontinuation rates due to adverse events in study 1 and study 2 occurred in 5.9% and 6.1% for placebo, 6.4% and 4.4% for 150 mg once daily, and 9% and 10% for 200 mg twice daily, respectively.

Based upon its mechanism of action, a loss in bone mineral density (BMD) is a potential side effect of elagolix treatment. AbbVie presented the following results regarding BMD in a poster presentation title "*The Effect of Elagolix On Bone Mineral Density: Safety Results From Two Randomized, Placebo-Controlled Studies in Women With Endometriosis-Associated Pain*".

Lumbar Spine Bone Mineral Density	STUDY1, Placebo N=282	STUDY1, Elagolix 150 mg QD N=186	STUDY1, Elagolix 200 mg BID N=182	STUDY2, Placebo N=269	STUDY2, Elagolix 150 mg QD N=174	STUDY2, Elagolix 200 mg BID N=180
Mean at BL, g/cm^2	1.18	1.17	1.18	1.18	1.17	1.18
Z-score at BL[a]	0.47	0.56	0.54	0.46	0.26	0.41
Mean (95% CI) percentage change from BL to M6	0.47 (0.16, 0.79)	-0.32 (-0.70, 0.07)	-2.61 (-3.00, -2.22)	0.49 (0.20, 0.78)	-0.71 (-1.07, -0.35)	-2.45 (-2.81, -2.10)
Mean (95% CI) difference from placebo in mean percentage change from BL to M6		-0.79 (-1.29, -0.30)**	-3.08 (-3.58, -2.59)***		-1.20 (-1.67, -0.74)***	-2.95 (-3.41, -2.49)***
Number (%) of participants, categories of percentage change from BL to M6						
No change or increase	165 (59)	87 (47)	34 (19)	152 (57)	64 (37)	33 (18)
Decrease ≤ 3%	100 (35)	78 (42)	65 (36)	104 (39)	86 (49)	68 (38)
Decrease >3, ≤ 5%	12 (4.3)	14 (7.5)	45 (25)	10 (3.7)	20 (11)	49 (27)
Decrease >5 , < 8%	4 (1.4)	6 (3.2)	29 (16)	b	b	b
Decrease ≥ 8%	1 (0.4)	1 (0.5)	9 (4.9)	b	b	b

BL = baseline; M=month; CI=confidence interval. Statistical significance vs. placebo is indicated for P<0.01 (**), P≤0.001 (***). a. Study 1 n: placebo=288, elagolix 150 QD=190, elagolix 200 BID = 188; Study 2 n: placebo=359, elagolix 150 QD=226, elagolix 200 BID=229. b. Due to the blinding status of individual participant treatment assignments, these data are unavailable until the presentation.

Source: Archer *et al.*, 2016

The results show that there is a minimal average decrease in BMD in the 150 mg once daily group, however there is a more sizeable decrease in the 200 mg twice daily cohort, which is similar to what was reported for Lupron (average loss in BMD of 3.2%, Lupron prescribing information). We do not believe that the 150 mg once daily dose will have any type of restrictive labeling based on loss in BMD. However, the 200 mg twice daily dose is likely to be restricted to shorter term use, at least initially until Abbvie submits additional data on the use of add-back hormonal therapy. Results from the use of elagolix in women suffering from uterine fibroids showed that the use of add-back therapy attenuated the reduction in BMD.

Conclusion

The data presented by AbbVie confirm our belief that elagolix is likely to be a blockbuster treatment for endometriosis, as we model for peak sales of elagolix in endometriosis of $1.5 billion worldwide. Using a composite 20% royalty rate, we estimate peak royalties to Neurocrine of approximately $300 million from sales in endometriosis.

For elagolix in uterine fibroids, we estimate an NDA filing would most likely not occur until the end of 2018, putting approval for elagolix in UF in 2019. We estimate that peak sales of elagolix in uterine fibroids could top $2.6 billion worldwide. Using a composite 20% royalty rate, we estimate peak royalties to Neurocrine of over $500 million from sales in UF.

As a reminder, Neurocrine recently filed the NDA for valbenazine (INGREZZA®) for the treatment of tardive dyskinesia (TD) and was assigned a PDUFA date of April 11, 2017. For valuation purposes, we assume U.S. approval of valbenazine in TD will target roughly 150,000 of the total patients in the U.S. that are moderate-to-severe in disease state. For modeling purposes, we estimate the yearly cost of valbenazine will be $20,000. If Neurocrine can capture 33% market share, which we believe is reasonable given the superior characteristics of valbenazine vs. generic tetrabenazine, then peak sales estimates are approximately $1.6 billion in this indication in the U.S. alone.

Lastly, we anticipate results from two Phase 2 studies of valbenazine in adults and children with Tourette Syndrome (TS) late in the fourth quarter of 2016 or in the first quarter of 2017. With an estimated 200,000 patients (both children and adults) with TS severe enough to require treatment in the U.S., a 15% peak market share represents another billion-dollar opportunity for valbenazine.

We continue to believe the future is bright for Neurocrine and that the stock would make a solid core holding in the portfolio of any investor interested in the biotechnology sector. We have built a probability adjusted discounted cash flow model that yields a current valuation for Neurocrine's shares of $75.

PROJECTED FINANCIALS

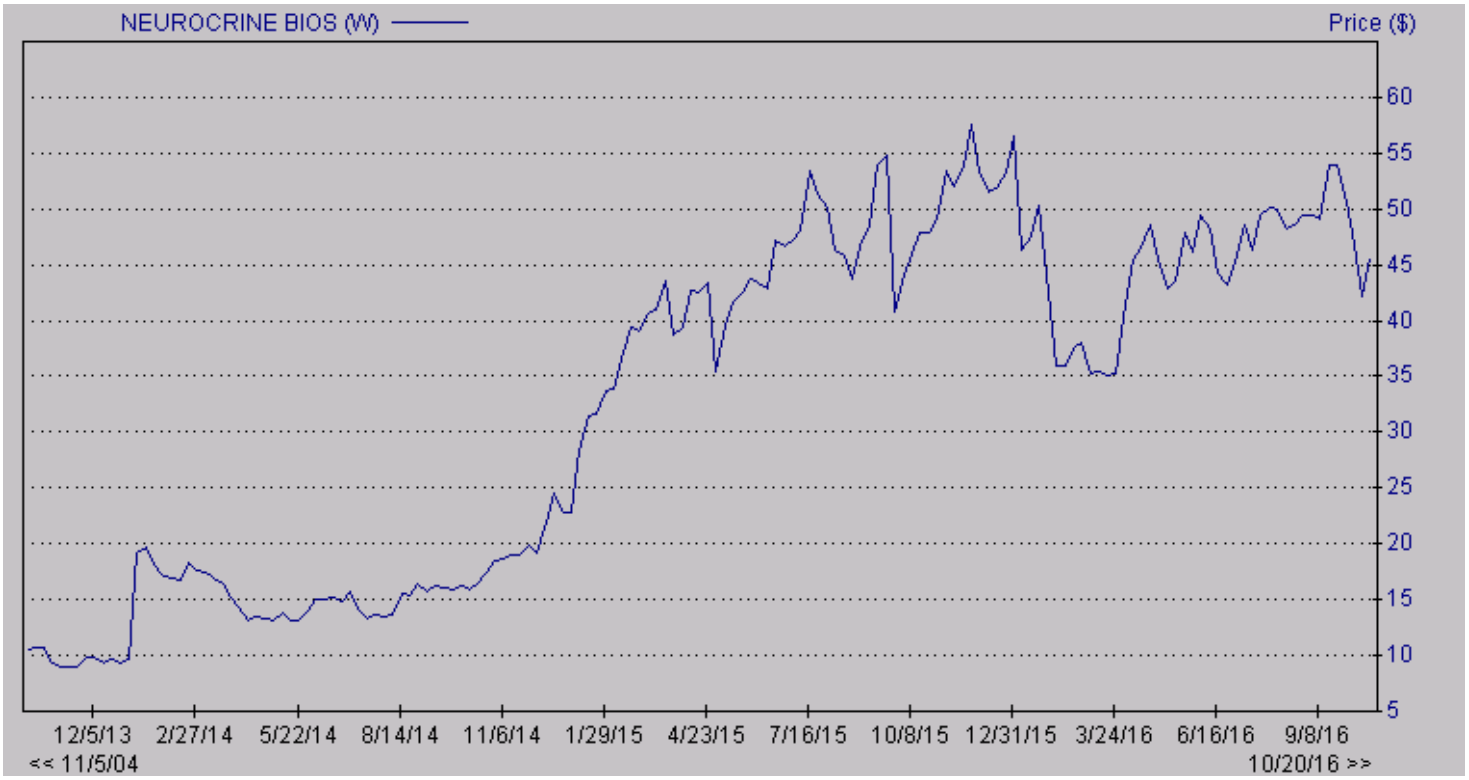
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2015 A	Q1 A	Q2 A	Q3 E	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**	**$103**	**$371**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$19.8**	**$15.0**	**$0**	**$0**	**$0**	**$15.0**	**$153.0**	**$494.0**
YOY Growth	-	-	-	-	-	-	*920.0%*	*222.9%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$15	$56
Gross Margin	-	-	-	-	-	-	-	-
SG&A	$32.5	$12.0	$15.0	$28.0	$30.0	$84.9	$120.0	$140.0
R&D	$81.5	$23.9	$26.9	$25.0	$26.0	$101.8	$100.0	$105.0
Operating Income	($94.2)	($20.9)	($41.8)	($53.0)	($56.0)	($171.7)	($82.5)	$193.4
Operating Margin	-	-	-	-	-	-	-	-
Interest / Other Income	$5.3	$1.6	$1.5	$1.3	$1.3	$5.7	$5.5	$5.3
Pre-Tax Income	($88.9)	($19.3)	($40.3)	($51.7)	($54.7)	($165.9)	($77.0)	$198.7
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)	($51.7)	($54.7)	($165.9)	($77.0)	$198.7
YOY Growth	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.05)**	**($0.22)**	**($0.46)**	**($0.59)**	**($0.62)**	**($1.90)**	**($0.86)**	**$2.11**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	84.5	86.5	86.7	87.5	88.0	87.5	90.0	94.0

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

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2016, 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.