Zacks Small-Cap Research

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Neurocrine Biosciences, Inc. (NBIX - Nasdaq)

NBIX: INGREZZA® Revenues Way Ahead of Forecasts In 3Q17…

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 $85/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 (11/02/17)	$60.93
Valuation	**$85.00**

OUTLOOK

On November 1, 2017, Neurocrine Biosciences, Inc. announced financial results for the third quarter of 2017. The company reported $45.8 million in revenues from the sale of INGREZZA®. This was well ahead of the consensus forecast of approximately $11 million. The company also received a $15 million milestone payment from partner Mitsubishi Tanabe for the initiation of a pivotal trial of INGREZZA® in Asia.

In October, AbbVie submitted a New Drug Application (NDA) for elagolix for the treatment of endometriosis. This triggered a $30 million milestone payment, which Neurocrine will receive in the fourth quarter of 2017. Neurocrine has initiated a Phase 2b study (T-Force GOLD) of valbenazine for the treatment of pediatric Tourette syndrome, an indication that the FDA has granted the company orphan drug designation. We anticipate results from this study at the end of 2018.

SUMMARY DATA

52-Week High	**$62.56**
52-Week Low	**$37.90**
One-Year Return (%)	**43.16**
Beta	**0.32**
Average Daily Volume (sh)	**747,853**
Shares Outstanding (mil)	**88**
Market Capitalization ($mil)	**$5,392**
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/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	6.3 A	60.8 A	80.0 E	147.1 E
2018					220.0 E
2019					364.0 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	-$0.68 A	-$0.13 A	-$0.06 E	-$1.75 E
2018					-$1.05 E
2019					-$0.08 E

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WHAT'S NEW

Business Update

INGREZZA® Launch Continues to Impress

On November 1, 2017, Neurocrine Biosciences, Inc. (NBIX) announced financial results for the third quarter of 2017 and provided a business update. The company reported $45.8 million in revenues from the sale of INGREZZA® for the treatment of tardive dyskinesia (TD), which was way ahead of even the most optimistic expectations. The company reported 745 prescriptions filled during the second quarter of 2017 and 5,100 prescriptions filled in the third quarter of 2017.

On October 5, 2017, the company announced that the FDA approved the 80 mg capsule of INGREZZA®. Most patients are prescribed 80 mg of INGREZZA® per day, and up to this point had been taking two 40 mg capsules each day. The 40 mg capsules were priced at $5,275 for 30, thus in essence patients had been paying the equivalent of ~$126,000 for a year's supply. The 80 mg capsules will be priced at $6,225 for 30, or approximately $75,000 per year. This pricing issue did contribute somewhat to the company's very successful third quarter, but we believe the tremendous quarter-over-quarter growth in prescriptions was a greater factor. Looking ahead to the fourth quarter, management indicated that transitioning patients to the 80 mg capsules will impact revenue, however we believe that continued strong prescription growth will help to offset this. Additional headwinds in the fourth quarter include competition from Teva's AUSTEDO® (which was approved for TD in late August 2017) and a new sampling program (patients can try INGREZZA® free for up to five weeks). Based on these factors, we now forecast fourth quarter revenue to be up only slightly quarter-over-quarter at $50 million, and have increased our estimate for 2018 to $190 million.

T-Force GOLD Study Underway

On October 25, 2017, Neurocrine announced the initiation of the T-Force GOLD study of valbenazine 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. The primary endpoint of the study is the change in baseline of the Yale Global Tic Severity Scale (YGTSS). We anticipate topline data near the end of 2018.

This study follows up the T-Force GREEN study, which the company announced earlier this year did not meet the primary endpoint (also the change in the YGTSS). However, management believes that the GREEN study was valuable as it provided a wealth of information, including exposure-response analysis that indicated selected doses used in the trial were below the therapeutic range. Thus, the company will be using a higher dose of valbenazine in the GOLD study. Should this trial prove successful, management will approach the FDA to inquire about what would be necessary to file a supplementary new drug application (sNDA), as the company has already completed all preclinical pediatric safety studies.

Elagolix Update

On Nov. 1, 2017, AbbVie announced positive Phase 3 extension study data for elagolix for the treatment of endometriosis. In both extension studies, treatment with elagolix resulted in a sustained reduction in average monthly menstrual pelvic pain and non-menstrual pelvic pain through the 12-month treatment period for greater than 50% of subjects at both the 150 mg and 200 mg dose (Taylor *et al*., 2017). There were no new safety signals reported in the extension studies and dose-dependent average changes in bone mineral density (BMD) were -0.6% and -1.1% for the 150 mg dose and -3.6% and -3.9% for the 200 mg dose, however the mean BMD Z-scores were all within the normal range. AbbVie also recently announced that the FDA granted priority review for elagolix in the treatment of endometriosis and we expect the PDUFA date to be in the second quarter of 2018.

Opicapone Update

On February 9, 2017, Neurocrine Biosciences, Inc. (NBIX) announced an exclusive license agreement with BIAL for the development and commercialization of opicapone (ONGENTYS®) in North America. ONGENTYS® is a once-daily, highly-selective catechol-O-methyltransferase (COMT) inhibitor that was approved in June 2016 by the

European Medicines Agency (EMA) as an adjunct therapy along with levodopa/DOPA decarboxylase inhibitors for adults with Parkinson's disease.

Management has indicated that they will need to meet with the FDA in order to determine whether any additional trials will be necessary prior to filing for approval in the U.S., with a meeting scheduled to take place in January 2018. Right now, we are assuming that at least one Phase 3 trial in the U.S. will be required, thus we view approval in 2021 as the most likely outcome, however we will know more after the company receives the official minutes from the meeting in February 2018. Following approval, the drug will be sold using the company's sales force that was assembled for INGREZZA™ with no additional reps necessary.

Congenital Adrenal Hyperplasia Update

NBI-74788 is a non-peptide corticotropin releasing factor 1 (CRF-1) receptor antagonist being developed for the treatment of congenital adrenal hyperplasia (CAH). CAH typically results in poor cortisol production, which leads to rising levels of adrenocorticotropic hormone (ACTH), due to cortisol feedback being responsible for inhibiting ACTH production. Without treatment, the steady rise in ACTH can result in salt wasting, dehydration, and eventually death. Corticosteroids are used for treatment, however the amount needed to suppress ACTH production results in serious side effects such as bone loss, growth impairment, and metabolic syndrome.

CRF is a peptide released directly from the hypothalamus in the central nervous system into a discrete network of blood vessels where it functions via specific G-Protein Coupled Receptors on cells in the anterior pituitary gland to regulate the release of pituitary hormones. One such hormone is ACTH. By blocking CRF receptors at the pituitary gland with NBI-74788, Neurocrine is hoping to decrease the release of ACTH and thus decrease production of adrenal steroids along with decreasing the amount of exogenous corticosteroids necessary for treatment.

The company has successfully completed a Phase 1, open label, two period crossover study to evaluate the pharmacokinetics (PK) and safety of NBI-74788 in 16 healthy adults. The next step is a Phase 2, proof-of-concept study examining the PK and safety of NBI-74788 in adult CAH patients along with the relationship between NBI-74788 exposure and specific steroid hormone levels. That trial is initiating soon and topline data should be released in the first half of 2018.

We believe the U.S. CAH population is between 20,000 and 30,000 individuals. Given the potential for strong pricing due to CAH being an orphan indication and limited competition, we believe NBI-74788 could have peak sales in the billion-dollar range (5,000 patients x $200,000 per year), however we are not including it in the model yet until after the proof-of-concept data is released.

Financial Update

The company reported $45.8 million in revenue from the sale of INGREZZA®. In addition, the company received a $15 million milestone payment from partner Mitsubishi Tanabe from the initiation of a pivotal trial of valbenazine in Asia.

Net loss for the third quarter of 2017 was $11.1 million, or $0.13 per share. R&D expenses were $22.5 million, compared to $20.9 million in the third quarter of 2016. The increase was primarily attributed to a higher headcount and increased stock-based compensation. SG&A expenses for the third quarter of 2017 were $43.9 million, compared to $17.5 million during the third quarter of 2016. The increase was due to the commercial launch of INGREZZA®, which included higher personnel costs, market research, commercial launch activities, and other professional services.

The company exited the third quarter of 2017 with approximately $772.5 million in cash, investments, and receivables, which included $502.8 million raised net of expenses through the sale of 2.25% convertible senior notes due 2024. The note will be convertible into cash, shares of common stock, or a combination of cash and shares based on an initial conversion rate of 13.1711 shares per $1,000 principal amount ($75.92 per share).

We anticipate the company receiving an additional milestone payment of $30 million in the fourth quarter of 2017 from AbbVie, due to the filing of the New Drug Application (NDA) for elagolix for the treatment of endometriosis.

Conclusion

Neurocrine is off to a tremendous start with the launch of INGREZZA® and we have made additional upward adjustments to our revenue forecast for 2017 and 2018. We believe that revenues will be essentially flat in the

fourth quarter of 2017 before ramping up again in 2018 and we are even more confident now in our initial call for peak revenues >$1 billion.

In addition to TD, Neurocrine is also testing INGREZZA® in TS, with the T-Force GOLD Phase 2b study now underway. With approximately 200,000 patients in the U.S. with TS, even a conservative 15% peak market shares represents another billion-dollar opportunity for INGREZZA®.

Now that AbbVie has filed the NDA for elagolix for endometriosis and received priority review, we believe approval will occur in the second quarter of 2018. 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 UF, we estimate that the topline data from the Phase 3 program will be available in 2018, thus an NDA filing would most likely not occur until 2019, putting approval for elagolix in UF in 2020. We estimate that peak sales of elagolix in UF 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.

We 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 $85.

PROJECTED FINANCIALS

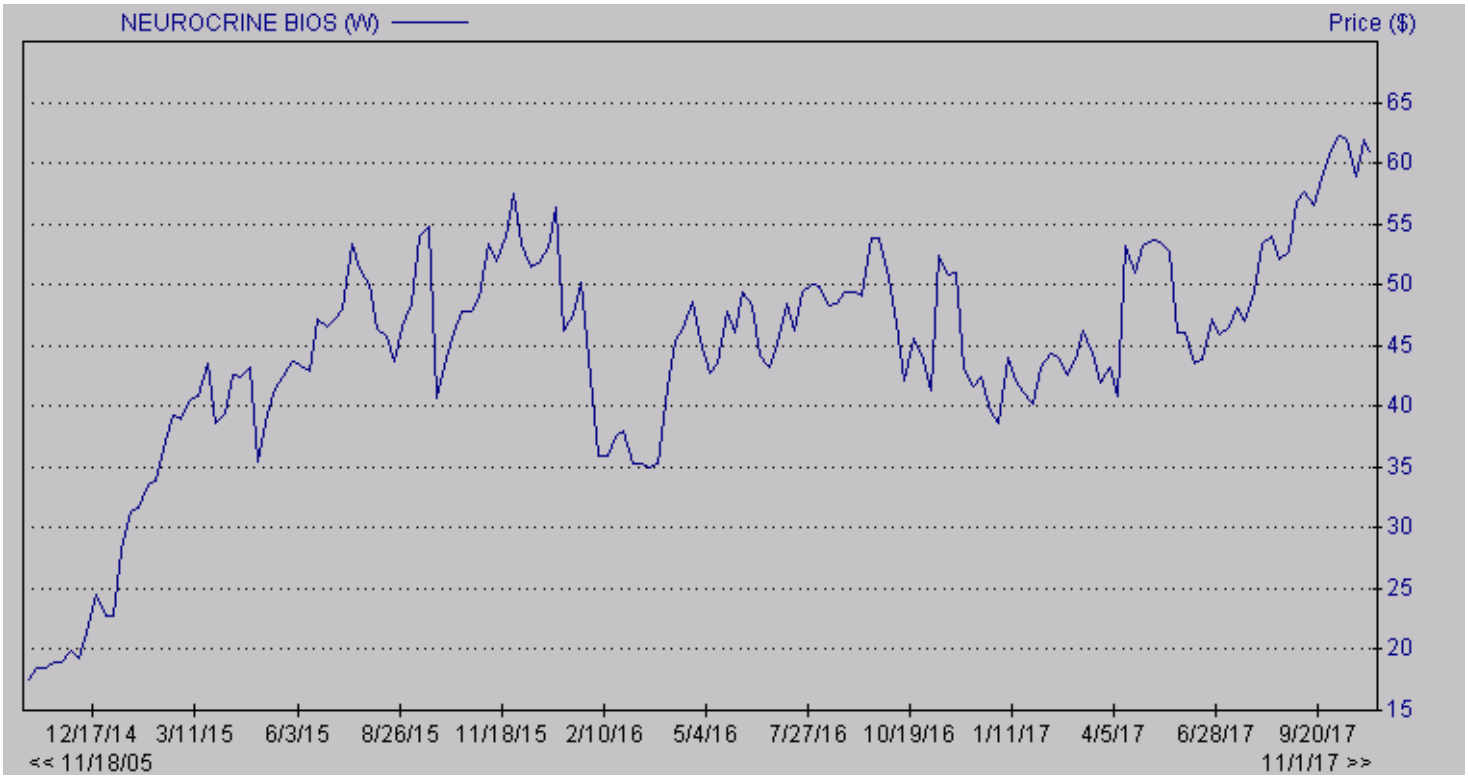
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 E
R&D / Milestones & Fees	**$15.0**	**$0**	**$0**	**$15**	**$30**	**$45.0**	**$30.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$18**
YOY Growth	-	-	-	-	-	-	-	-
NBI-640756	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
NBI-98854 (VMAT2)	**$0**	**$0**	**$6**	**$46**	**$50**	**$102**	**$190**	**$346**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$15.0**	**$0**	**$6**	**$61**	**$80**	**$147.1**	**$220.0**	**$364.0**
YOY Growth	-	-	-	-	-	*880.7%*	*49.5%*	*65.5%*
CoGS / Royalties	$0	$0	$0	$0	$3	$3	$17	$55
Gross Margin	-	-	*99.0%*	*99.3%*	*96.3%*	*97.6%*	*92.3%*	*84.9%*
SG&A	$68.1	$28.1	$41.7	$43.9	$47.0	$160.6	$170.0	$180.0
R&D	$94.3	$51.9	$21.9	$22.5	$22.0	$118.2	$120.0	$130.0
Operating Income	($147.4)	($79.9)	($57.3)	($6.0)	$8.0	($135.2)	($87.0)	($1.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest / Other Income	$6.3	$1.6	($2.7)	($5.1)	($13.0)	($19.2)	($6.6)	($6.6)
Pre-Tax Income	($141.1)	($78.3)	($60.0)	($11.1)	($5.0)	($154.4)	($93.6)	($7.6)
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)	($60.0)	($11.1)	($5.0)	($154.4)	($93.6)	($7.6)
YOY Growth	-	-		-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.63)**	**($0.90)**	**($0.68)**	**($0.13)**	**($0.06)**	**($1.75)**	**($1.05)**	**($0.08)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	86.7	87.3	88.1	88.3	88.5	88.0	89.0	90.0

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

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