Zacks Small-Cap Research

May 11, 2017
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Neurocrine Biosciences, Inc. (NBIX - Nasdaq)

NBIX: INGREZZA™ Launch Commences…

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 (05/11/17)	$53.42
Valuation	**$85.00**

OUTLOOK

On May 9, 2017, Neurocrine Biosciences, Inc. (NBIX) announced financial results for the first quarter of 2017. The company reported a net loss of $78.3 million, or $0.90 per share, and exited the first quarter of 2017 with approximately $273.3 million in cash, cash equivalents, and marketable securities. Subsequent to the end of the quarter, Neurocrine completed a private offering of $517.5 million in 2.25% convertible senior notes due 2024.

On May 1st, Neurocrine officially launched INGREZZA™ and is currently focused on getting physicians educated on recognition of tardive dyskinesia and proper diagnosis while engaging with payors to hopefully begin reimbursement within the next six to 12 months.

SUMMARY DATA

52-Week High	**$54.77**
52-Week Low	**$37.90**
One-Year Return (%)	**25.25**
Beta	**0.66**
Average Daily Volume (sh)	**1,406,246**
Shares Outstanding (mil)	**88**
Market Capitalization ($mil)	**$4,705**
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

Financial Update

On May 9, 2017, Neurocrine Biosciences Inc. (NBIX) announced financial results for the first quarter of 2017 and provided a business update. As expected, the company did not report any revenue during the first quarter of 2017, compared with a $15 million milestone that was paid by AbbVie during the first quarter of 2016. Net loss for the first quarter of 2017 was $78.3 million, or $0.90 per share. R&D expenses were $51.9 million for the first quarter of 2017 compared to $23.9 million for the first quarter of 2017. The increase was driven by a $30 million payment to BIAL to inlicense opicapone partially offset by a decrease in VMAT2 spending due to the wind down of the Phase 3 clinical program of INGREZZA™ in tardive dyskinesia (TD). G&A expenses totaled $28.1 million in the first quarter of 2017 compared to $12.0 million for the same period of 2016. The increase was due to higher personnel related costs and external costs related to market research and commercial launch preparation for INGREZZA™.

Neurocrine exited the first quarter of 2017 with approximately $273 million in cash, cash equivalents, and marketable securities. Subsequent to the end of the quarter, Neurocrine sold $502.2 million in net proceeds of 2.25% convertible senior notes due 2024, which included $67.5 million in notes that were sold pursuant to the exercise of the initial purchasers' option to purchase additional notes. 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).

Business Update

INGREZZA™ Launch Commences

Neurocrine officially launched INGREZZA™ for the treatment of TD with its 160 member sales force on May 1st, 2017. The sales team has begun calling on movement disorder neurologists, psychiatrists, and mid-level providers in private practice settings along with community mental health centers across the country. One of the most important aspects of the initial launch will be educating health care practitioners about the full range of presentations of TD across the various body regions as well as the various patients that develop TD. In addition, the sales team is introducing customers to the INBRACE program so they can better understand the full suite of patient support services available to initiate and maintain treatment. The payor accounts team has been meeting with a range of health plan decision makers from Medicare Part D and Medicaid plans to better familiarize them with the underlying clinical data as well as pricing. We anticipate formulary reviews to occur toward the end of the year at which time we'll know more about coverage and reimbursement. Neurocrine set the wholesale acquisition cost for a 30-count bottle of INGREZZA™ 40 mg capsules at $5,275 ($63,300/yr). The company will be filing an sNDA for the 80 mg capsule, which should be priced similarly to the 40 mg capsule, which we anticipate will be approved by the end of the year.

Data from T-Force Green Study in May 2017

The T-Force GREEN study is a Phase 2 study designed to evaluate the safety, tolerability, and efficacy of INGREZZA™ in children and adolescents with Tourette syndrome (TS) (NCT02679079). It is a randomized, double blind, placebo controlled, multi-dose, parallel group trial of approximately 90 children and adolescents. Patients are receiving once-daily dosing of INGREZZA™ or placebo in a 1:1:1 fashion during a six-week treatment period. We anticipate data being released before the end of May 2017. The primary endpoint of the study is the change in baseline of the Yale Global Tic Severity Score (YGTSS) between placebo and active groups at the end of six weeks.

The company is also conducting a long-term Phase 2 clinical study of INGREZZA™ in patients with TS. The study is an open label, fixed dose study of up to 180 patients (90 children/adolescents and 90 adults) with the primary purpose being the assessment of long-term safety and tolerability of INGREZZA™. Enrollment is limited to subjects who completed either the T-Forward or T-Force GREEN studies. Patients are receiving once daily dosing of INGREZZA™ for a 24-week treatment period.

Neurocrine Acquires North American Rights to ONGENTYS®

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 likely to take place in late 2017. 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. Following approval, the drug will be sold using the company's sales force that is being built for INGREZZA™ with no additional reps necessary.

Elagolix Update

AbbVie is currently evaluating elagolix in women with uterine fibroids (UF) in two replicate Phase 3 randomized, double blind, placebo controlled trials that are expected to enroll 400 subjects for an initial six-month placebo-controlled dosing period followed by an additional six-month dosing period in a safety and efficacy extension study. The primary efficacy endpoint of the studies is an assessment of the change in menstrual blood loss utilizing the alkaline hematin method comparing baseline to month six. We anticipate top-line efficacy data to be reported in late 2017.

AbbVie remains on track to file an NDA for elagolix in endometriosis in the third quarter of 2017. Upon filing of the NDA, Neurocrine will earn a $30 million milestone payment.

Essential Tremor Update

Neurocrine has successfully completed a Phase 1 single site, randomized, double blind, placebo controlled, sequential dose escalation, pharmacokinetic study to assess the safety and tolerability of a single dose of NBI-640756 in up to 32 healthy volunteers. Based on the results of that study, the company has initiated a second Phase 1, single site, randomized, double blind, placebo controlled, multiple dose, sequential dose escalation study to evaluate the safety, tolerability, and pharmacokinetics of NBI-640756 in up to 30 healthy volunteers over a week of continuous dosing. We anticipate data from this study later in 2017. Since the compound is just starting out in clinical trials we are not yet including it in our financial model, however with a patient population totaling 10 million, there is certainly a large potential opportunity for the company in ET.

Conclusion

Neurocrine appears to have all the pieces in place to make INGREZZA™ a commercial success in the treatment of TD. We have incorporated the yearly cost of INGREZZA™ into our model, and assume that the 80 mg dose will be priced similarly to the 40 mg dose. We believe sales of over a billion dollars are possible, and we will be keeping a close eye on uptake, particularly once payor coverage and reimbursement is sorted out.

In addition to TD, Neurocrine is also testing INGREZZA™ in TS, with data from the T-Force GREEN study in children and adolescents with TS set to be released in May 2017. 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™.

We anticipate AbbVie filing an NDA for elagolix for endometriosis in the third quarter of 2017 and approval occurring in 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 at the end of 2017, 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

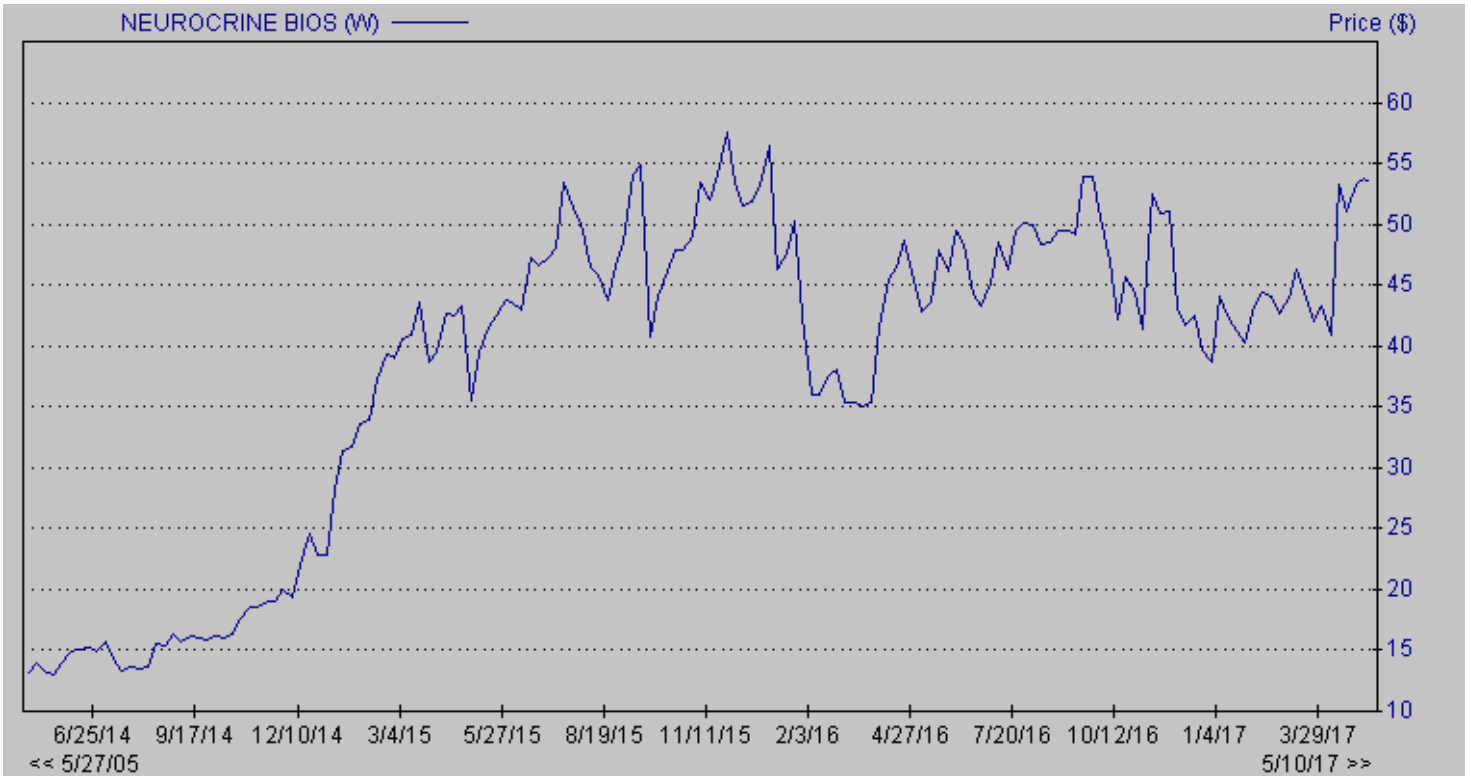
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2016 A	Q1 A	Q2 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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