Zacks Small-Cap Research

April 12, 2017
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# Neurocrine Biosciences, Inc. (NBIX - Nasdaq)

## *NBIX: INGREZZA™ Approved by the FDA…*

Based on our probability adjusted DCF model that takes into account potential future revenues from INGRESSA™ in TD and TS along with elagolix in endometriosis and UF, NBIX is valued at $82/share. This model utilizes a 11% discount rate and is highly contingent upon continued clinical success of both INGRESSA™ and elagolix. It will be adjusted accordingly based upon future clinical results.

| | |
|---|---|
| Current Price (04/12/17) | $41.48 |
| **Valuation** | **$82.00** |

## OUTLOOK

On April 11, 2017, Neurocrine Biosciences, Inc. (NBIX) announced that the U.S. Food and Drug Administration has approved INGREZZA™ for the treatment of tardive dyskinesia. Importantly, there is no "black box" warning in the product's label, thus immediately differentiating it from Teva's AUSTEDO™, which is approved for the treatment of chorea associated with Huntington's disease and is under review by the FDA for the treatment of tardive dyskinesia. The company plans to officially launch INGREZZA™ on May 1, 2017, at which time the price will be announced as well.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$54.77** |
| **52-Week Low** | **$37.90** |
| **One-Year Return (%)** | **-7.25** |
| **Beta** | **0.70** |
| **Average Daily Volume (sh)** | **1,074,186** |
| **Shares Outstanding (mil)** | **87** |
| **Market Capitalization ($mil)** | **$3,613** |
| **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 E | 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 | -$0.56 E | -$0.62 E | -$0.28 E | -$0.58 E | -$2.06 E |
| 2018 | | | | | -$1.21 E |
| 2019 | | | | | $0.80 E |

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## WHAT'S NEW

**Business Update**

*INGREZZA™ Approved by the FDA*




On April 11, 2017, Neurocrine Biosciences, Inc. (NBIX) announced that the U.S. Food and Drug Administration (FDA) approved INGREZZA™ for the treatment of tardive dyskinesia (TD). INGREZZA™ is the first medicine to be approved by the FDA for the treatment of TD, and is the culmination of over a decade of work since the compound was discovered in Neurocrine's laboratory.

TD is a disorder that results in involuntary movements of the tongue, lips, face, trunk, and extremities that occur in patients treated with long-term dopaminergic antagonist medications. People with schizophrenia and other neuropsychiatric disorders are particularly vulnerable to developing TD after treatment with conventional neuroleptics, anticholinergics, substances of abuse, and other agents. TD is most common in patients with schizophrenia, schizoaffective disorder, or bipolar disorder who have been treated with antipsychotic medications for a long period of time.

INGREZZA™ was approved based in part on the results of the Phase 3 Kinect 3 clinical trial, which was a randomized, parallel group, double blind, placebo controlled trial testing INGREZZA™ in moderate to severe TD patients with underlying schizophrenia, schizoaffective disorder, or mood disorder. A total of 234 patients were randomized and results showed a highly significant change from baseline in the Abnormal Involuntary Movement Scale (AIMS) at Week 6 ($p<0.0001$). Importantly, the drug's label does not include any type of 'black box' warning, which is in contrast to potential competitor AUSTEDO™, which was recently approved for the treatment of chorea in patients with Huntington's disease and is under review for the treatment of TD.

The company plans to officially launch INGREZZA™ with its 160 member sales force on May 1, 2017, which will coincide with an extensive education program to increase awareness about TD and the availability of INGREZZA™ for patients with the condition. Neurocrine did not disclose the price for INGREZZA™, but said that pricing will be announced May 1, 2017. AUSTEDO™, which is marketed by Teva Pharmaceuticals (TEVA), is priced at approximately $90,000 per year for Huntington's disease (which corresponds to approximately $60,000 per year if approved for TD), and Neurocrine's management indicated they are aware of AUSTEDO's™ price and will price INGREZZA™ "competitively".

**Conclusion**

The treatment of TD is a very meaningful market opportunity for Neurocrine. There are an estimated 500,000 TD patients in the U.S. with no real treatment options besides tetrabenazine, although AUSTEDO™ may gain approval later this year. We estimate that Neurocrine will target roughly 150,000 of the total TD patients in the U.S. that are moderate-to-severe in disease state. For modeling purposes, we estimate the yearly cost of INGREZZA™ will be $20,000, which could end up being conservative, as management has guided for the cost to be $20,000 to $60,000 per year. We will find out the price of INGREZZA™ on May 1, 2017. If Neurocrine can capture 33% market share,

which we believe is reasonable given the superior characteristics of INGREZZA™ vs. both generic tetrabenazine and AUSTEDO™, then peak sales estimates are approximately $1.6 billion in this indication in the U.S. alone.

In addition to TD, Neurocrine is also testing INGREZZA™ in Tourette syndrome (TS), with data from the T-Force GREEN study in children and adolescents with TS set to be released in May 2017. While the T-Forward study of INGREZZA™ in adults with TS did not achieve the pre-specified primary endpoint, we don't believe there is much read-through for the T-Forward GREEN study, and we continue to believe there is a good chance for positive results. 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 believe AbbVie will file an NDA for elagolix for endometriosis in the third quarter of 2017 and approval will occur 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 $82.

## PROJECTED FINANCIALS

**Neurocrine Biosciences Inc.**
Income Statement

| Neurocrine Bio | 2016 A | Q1 E | 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** | **$17** | **$111** | **$318** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$15.0** | **$0** | **$0** | **$34** | **$13** | **$47.0** | **$164.0** | **$395.0** |
| *YOY Growth* | - | - | - | - | - | *213.3%* | *248.9%* | *140.9%* |
| CoGS / Royalties | $0 | $0 | $0 | $0 | $0 | $3 | $17 | $48 |
| *Gross Margin* | - | - | - | - | - | - | - | - |
| SG&A | $68.1 | $25.0 | $30.0 | $35.0 | $40.0 | $130.0 | $150.0 | $160.0 |
| R&D | $94.3 | $25.0 | $25.0 | $25.0 | $25.0 | $100.0 | $110.0 | $120.0 |
| Operating Income | ($147.4) | ($50.0) | ($55.0) | ($26.0) | ($52.0) | ($185.6) | ($112.7) | $67.3 |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Interest / Other Income | $6.3 | $1.5 | $1.5 | $1.5 | $1.5 | $6.1 | $5.0 | $5.0 |
| Pre-Tax Income | ($141.1) | ($48.5) | ($53.5) | ($24.5) | ($50.5) | ($179.5) | ($107.7) | $72.3 |
| 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) | ($48.5) | ($53.5) | ($24.5) | ($50.5) | ($179.5) | ($107.7) | $72.3 |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($1.63)** | **($0.56)** | **($0.62)** | **($0.28)** | **($0.58)** | **($2.06)** | **($1.21)** | **$0.80** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Shares Outstanding | 86.7 | 86.8 | 86.9 | 87.0 | 87.1 | 87.0 | 89.0 | 90.0 |

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

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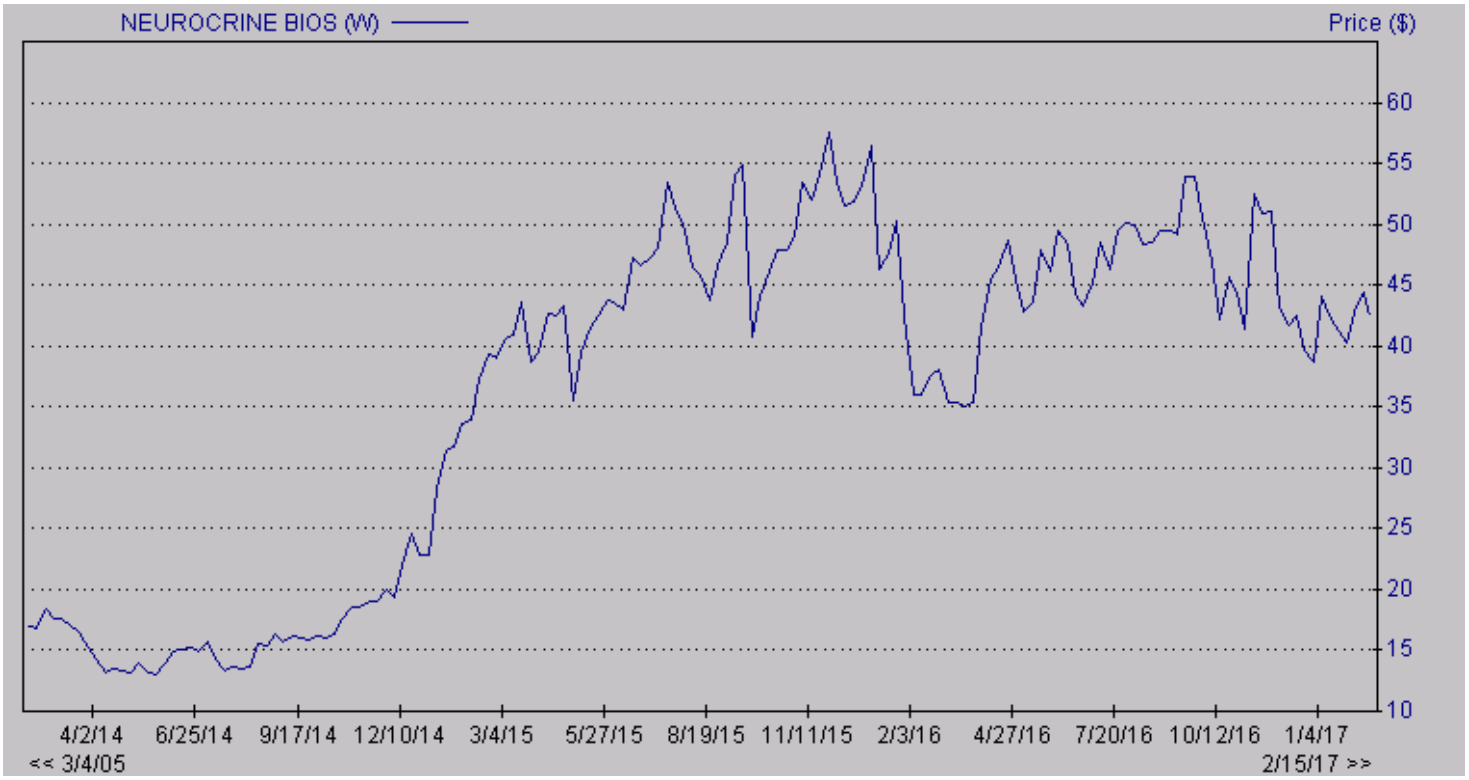
## HISTORICAL STOCK PRICE

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