Zacks Small-Cap Research

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# Neurocrine Biosciences, Inc. (NBIX - Nasdaq)

## *NBIX: Strong Start to INGREZZA® Launch…*

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 $80/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 (08/04/17) | $48.84 |
| **Valuation** | **$80.00** |

## OUTLOOK

On August 3, 2017, Neurocrine Biosciences, Inc. announced financial results for the second quarter of 2017. The company reported $6.3 million in revenues from the sale of INGREZZA®, which was launched on May 1, 2017. While still very early, we consider this to be the sign of a successful initial launch, particularly in light of management's comments that they do not believe the revenue number was heavily influenced by stockpiling of product.

The company exited the second quarter of 2017 with $739.6 million in cash, investments, and receivables, which includes $502.8 million raised, net of expenses, through the convertible notes offering on May 2, 2017. We anticipate a $15 million milestone payment in the third quarter of 2017 from partner Mitsubishi Tanabe for the initiation of a pivotal trial of INGREZZA® in Asia, and a $30 million payment from partner AbbVie in the fourth quarter of 2017 following the submission of the NDA for elagolix in the third quarter of 2017.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$54.77** |
| **52-Week Low** | **$37.90** |
| **One-Year Return (%)** | **-2.48** |
| **Beta** | **0.42** |
| **Average Daily Volume (sh)** | **811,159** |
| **Shares Outstanding (mil)** | **88** |
| **Market Capitalization ($mil)** | **$4,302** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **96** |
| **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 | 24.0 E | 43.0 E | 73.3 E |
| 2018 | | | | | 108.0 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 | -$0.55 E | -$0.45 E | -$2.61 E |
| 2018 | | | | | -$2.31 E |
| 2019 | | | | | -$0.08 E |

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## WHAT'S NEW

**Financial Update**

On August 3, 2017, Neurocrine Biosciences, Inc. (NBIX) announced financial results for the second quarter of 2017. The company reported $6.3 million in revenue from the sale of INGREZZA®, which was officially launched on May 1, 2017 following its approval by the U.S. Food and Drug Administration (FDA) in April 2017. We consider the initial two months of sales to be quite encouraging, particularly in light of managements comments that they do not attribute much of that revenue to stocking of product (<$1 million). In support of this, during the conference call to discuss the quarterly results, management indicated that the pharmacies keep less than 1 week of INGREZZA® in inventory.

Net loss for the second quarter of 2017 was $60.0 million, or $0.68 per share. R&D expenses were $21.9 million, compared to $26.9 million in the second quarter of 2016. The decrease was primarily attributed to the costs in 2016 associated with preparing the NDA filing for INGREZZA® that were not incurred in 2017. SG&A expenses for the second quarter of 2017 were $41.7 million, compared to $15.0 million during the second quarter of 2016. The increase was due to the commercial launch of INGREZZA® in May 2017, which included higher personnel costs, market research, commercial launch activities, and other professional services.

The company exited the second quarter of 2017 with approximately $739.6 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 two additional milestone payments this year. In the third quarter of 2017, Neurocrine should receive a $15 million milestone payment from Mitsubishi Tanabe, which is expected to initiate a pivotal trial for INGREZZA® in Asia. In the fourth quarter of 2017, the company should receive a $30 million payment from AbbVie, which is expected to file a New Drug Application (NDA) for elagolix for the treatment of endometriosis in the third quarter of 2017.

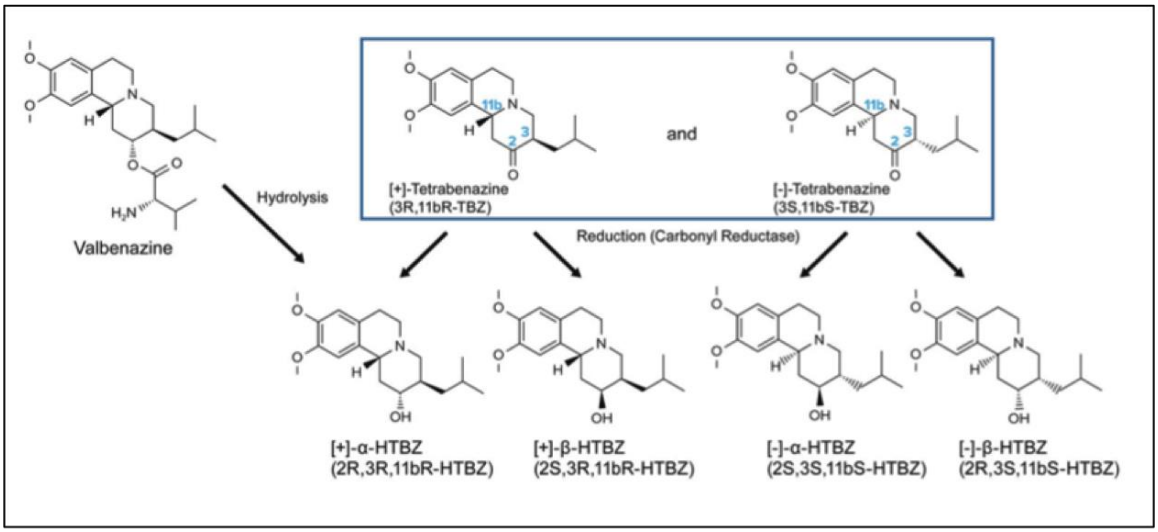
**Business Update**

*INGREZZA® Launch Off to a Good Start*

Neurocrine officially launched INGREZZA® for the treatment of tardive dyskinesia (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. The $6.3 million in revenue was well above our estimate for the quarter, and we are hopeful this is a positive sign of things to come. The company revealed that there were 745 prescriptions written during the second quarter of 2017, but is not releasing any other prescription metrics at this time. While the company is unable to confirm this for certain, since the identities of patients both in the clinical trials and receiving prescriptions can't be determined, there does not appear to be any pent-up demand that was driving the early revenue numbers, for instance from patients that had been part of the clinical program and were transitioning to being on prescription. Based on these results we have slightly increased our revenue target for the year from $23 million to $28 million, and we will continue to monitor the progress of the INGREZZA® launch as better than expected results again next quarter may warrant more significant upward estimates for future revenues.

*Publication Shows Clear Differences Between Tetrabenazine and Valbenazine Metabolism*

AUSTEDO™ (deuterated tetrabenazine) is being developed by TEVA Pharmaceuticals and is currently approved for the treatment of Huntington's disease and has a PDUFA date of Aug. 30, 2017 for the treatment of TD. Like valbenazine (INGREZZA®), tetrabenazine (TBZ) is a known VMAT2 inhibitor, and its activity is thought to be due to the four isomeric dihydrotetrabenazine (HTBZ) metabolites ([+]-α-HTBZ, [+]-β-HTBZ, [-]-α-HTBZ, [-]-β-HTBZ). Valbenazine only has one metabolic product shared with tetrabenazine ([+]-α-HTBZ), as shown in the following figure.

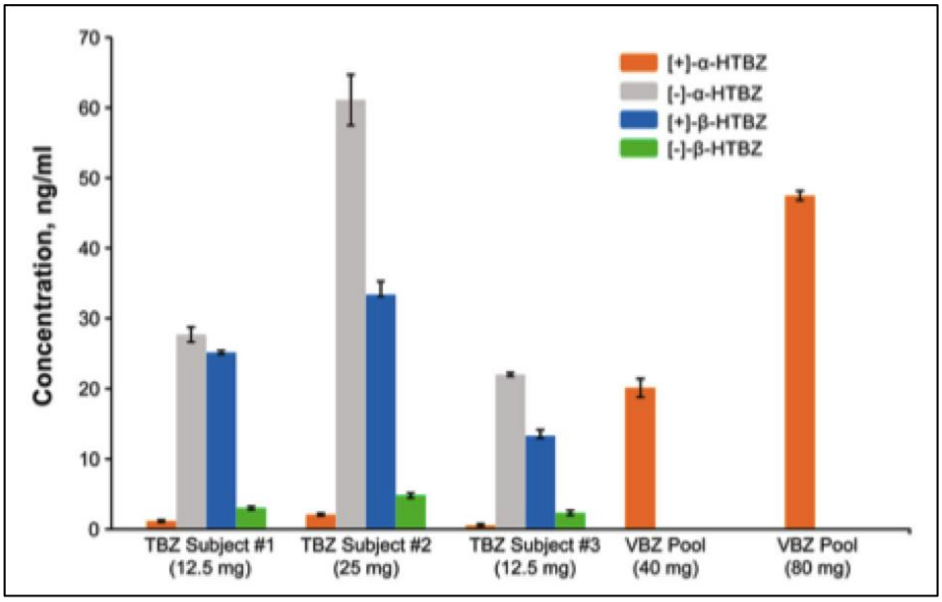



*Source*: Skor *et al*., 2017

Neurocrine recently published a research paper describing the development of a method to quantitate the four isomers of HTBZ (Skor *et al*., 2017). In the study, the researchers were able to quantitate the four metabolites in patient samples from three individuals taking TBZ for the treatment of Huntington's disease and from pooled samples of five patients each taking either 40 mg or 80 mg valbenazine.

No previous study had ever quantified the circulating levels of the four different HBZT metabolites, and published data has only reported the combined concentrations of the enantiomeric pairs (e.g., α-HTBZ, which consists of both [+]-α-HTBZ and [-]-α-HTBZ, and β-HTBZ, which consists of [+]-β-HTBZ and [-]-β-HTBZ). Since valbenazine only forms the [+]-α-HTBZ isomer, and both valbenazine and TBZ are in clinical use for movement disorders, determining the level of HTBZ isomers in patients taking each of those medications is warranted.

Unsurprisingly, the results showed that [+]-α-HTBZ was the only HTBZ metabolite found in samples from those taking valbenazine. However, what was surprising was the fact that the two major metabolites seen in patients taking tetrabenazine were [-]-α-HTBZ and [+]-β-HTBZ, with little to no {+}-α-HTBZ seen. These results are summarized in the following graph.




*Source*: Skor *et al*., 2017

Traditionally, it had been thought that the VMAT2 inhibition caused by TBZ was the result of the [+]-α isomer, with no biological activity seen with the [-]-α isomer and no analysis of the role of the β isomer (Kilbourn *et al*., 1997). In light of the results shown above, it can be assumed that the majority of the biological activity for TBZ likely comes from [+]-β-HTBZ. Thus, TBZ and valbenazine inhibit VMAT2 through different circulating metabolites, which may

influence how the two drugs are utilized in the clinic. With AUSTEDO™ set to potentially enter the market as a direct competitor to INGREZZA® in September 2017, these results are highly relevant to Neurocrine as they may sway physicians' opinions on which product to use in TD patients given the level of other metabolites seen with TBZ treatment. While we won't know for some time how this will effect prescribing habits, if at all, what is clear is that valbenazine is a completely differentiated product from TBZ with a unique active VMAT2 inhibiting metabolite without the presence of additional isomers that confer unwanted side effects.

*T-Force Gold Study to Initiate in Oct. 2017*

While the T-Force GREEN study of INGREZZA® in children and adolescents with Tourette syndrome (TS) did not meet its primary endpoint, the company still believes it was a successful study as a large amount of data was compiled that will likely lead to future clinical success. An exposure-response analysis showed that the selected doses (which were not disclosed by the company) were below the therapeutic range for adequate tic reduction in the majority of patients.

To follow up on the results of the T-Force GREEN study, the company is planning to initiate the T-Force GOLD study in October 2017, with a targeted data read out toward the end of 2018. Additional details from the study will be available when the study protocol is put on clinicaltrials.gov at the time of study launch.

*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 or early 2018.

In May 2017, AbbVie presented data from the Phase 3 studies of elagolix in premenopausal women who suffer from endometriosis at the 13th World Congress on Endometriosis. Following those presentations, the company published an article in *The New England Journal of Medicine* detailing the findings from the two Phase 3 trials (Taylor *et al.*, 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, which we anticipate to be paid in the fourth quarter of 2017.

*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 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 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.

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.

*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 in the third quarter of 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 be off to a great start with the launch of INGREZZA® and we have made slight upward adjustments to our revenue forecast for 2017. However, if the company reports another better than expected quarter next month, the revenue forecast may need to be revised even higher. We have always believed that revenues >$1 billion are possible, and the strong launch, while still very early, gives us added confidence in that estimate.

In addition to TD, Neurocrine is also testing INGREZZA® in TS, with the T-Force Gold Phase 2b study set to get underway in October 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 $80.

## PROJECTED FINANCIALS

**Neurocrine Biosciences Inc.**
Income Statement

| Neurocrine Bio | 2016 A | Q1 A | Q2 A | Q3 E | 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** | **$9** | **$13** | **$28** | **$78** | **$346** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$15.0** | **$0** | **$6** | **$24** | **$43** | **$73.3** | **$108.0** | **$364.0** |
| *YOY Growth* | - | - | - | - | - | *388.9%* | *47.3%* | *237.0%* |
| CoGS / Royalties | $0 | $0 | $0 | $1 | $1 | $4 | $17 | $55 |
| *Gross Margin* | - | - | *99.0%* | *97.9%* | *97.7%* | *94.2%* | *84.3%* | *84.9%* |
| SG&A | $68.1 | $28.1 | $41.7 | $44.0 | $47.0 | $160.7 | $170.0 | $180.0 |
| R&D | $94.3 | $51.9 | $21.9 | $22.0 | $22.0 | $117.8 | $120.0 | $130.0 |
| Operating Income | ($147.4) | ($79.9) | ($57.3) | ($42.5) | ($27.0) | ($209.4) | ($199.0) | ($1.0) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Interest / Other Income | $6.3 | $1.6 | ($2.7) | ($6.0) | ($13.0) | ($20.1) | ($6.6) | ($6.6) |
| Pre-Tax Income | ($141.1) | ($78.3) | ($60.0) | ($48.5) | ($40.0) | ($229.5) | ($205.6) | ($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) | ($48.5) | ($40.0) | ($229.5) | ($205.6) | ($7.6) |
| *YOY Growth* | - | - | | - | - | - | - | - |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($1.63)** | **($0.90)** | **($0.68)** | **($0.55)** | **($0.45)** | **($2.61)** | **($2.31)** | **($0.08)** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Shares Outstanding | 86.7 | 87.3 | 88.1 | 88.2 | 88.5 | 88.0 | 89.0 | 90.0 |

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

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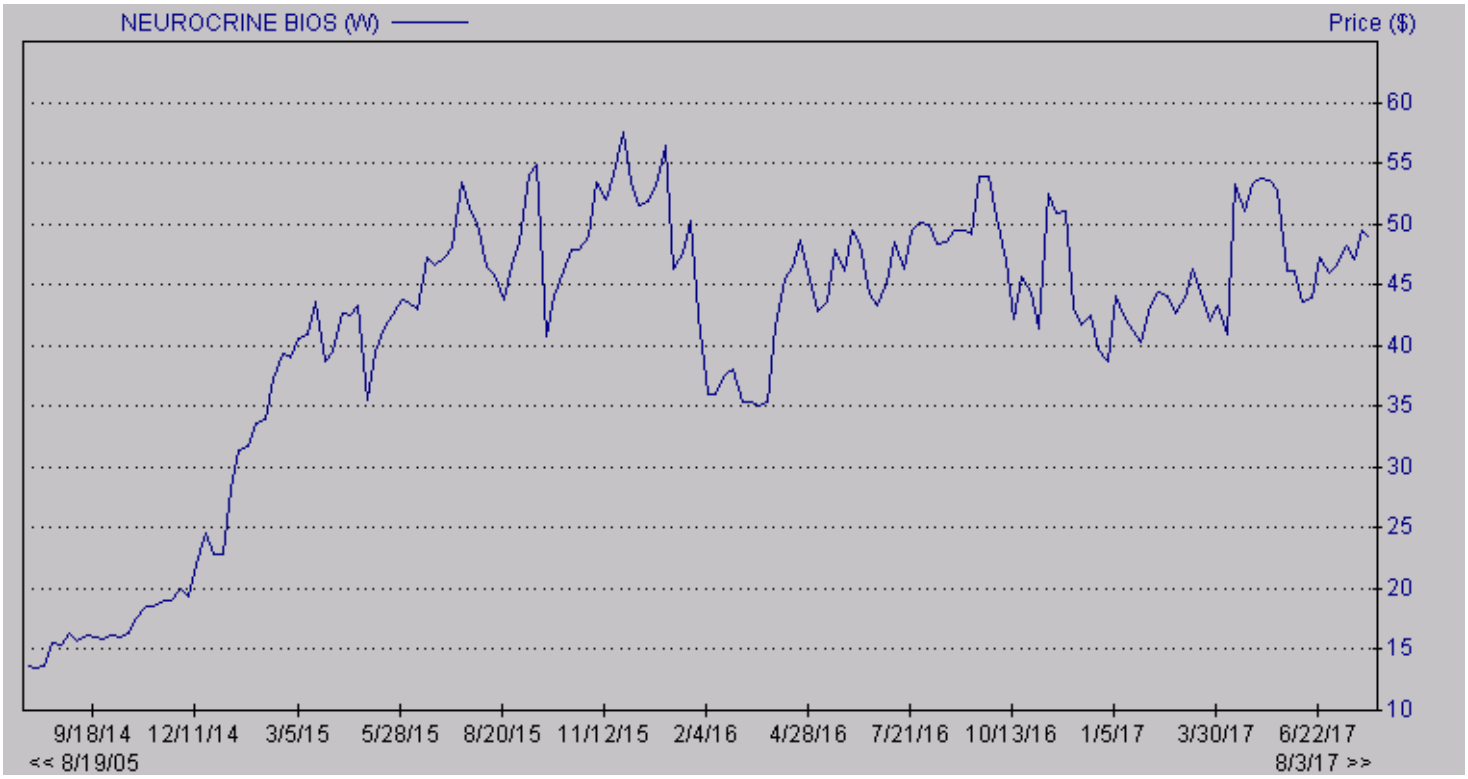
## HISTORICAL STOCK PRICE

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