Zacks Small-Cap Research

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Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: All Systems Go For Phase 3 Program With Elagolix…

UPDATE

With a strong financial position, we believe Neurocrine is in an outstanding position to build shareholder value over the next several years. The company exited the first quarter 2011 with over $121 million in cash and investments, with the potential to earn several hundred million more as clinical development progresses. The company's dramatically improved financial position affords management the opportunity to push forward the development of internal pipeline candidates, including VMAT-2, as well as in-license new pre-phase 2 molecules within the company's core CNS focus. We recommend accumulating the stock at today's price, up to our $12 target.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (05/03/11)	$7.91
Target Price	**$12.00**

SUMMARY DATA

52-Week High	**$8.53**
52-Week Low	**$2.48**
One-Year Return (%)	**161.77**
Beta	**0.41**
Average Daily Volume (sh)	**359,500**
Shares Outstanding (mil)	**55**
Market Capitalization ($mil)	**$421**
Short Interest Ratio (days)	**7.13**
Institutional Ownership (%)	**77**
Insider Ownership (%)	**2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-36.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**127.8**
P/E using 2011 Estimate	**10.8**
P/E using 2012 Estimate	**N/M**
Zacks Rank	**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)
2010	0.8 A	4.6 A	14.4 A	13.7 A	33.5 A
2011	12.5 A	15.0 E	21.0 E	27.5 E	76.0 E
2012					50.0 E
2013					50.0 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.18 A	-$0.09 A	$0.06 A	$0.04 A	-$0.15 A
2011	$0.05 A	$0.10 E	$0.19 E	$0.30 E	$0.64 E
2012					$0.16 E
2013					$0.13 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

Financial Results

On May 3, 2011, Neurocrine Bio reported financial results for the first quarter 2011. The company reported total revenues in the quarter of $12.5 million, which consisted of $2.9 million in sponsored R&D and reimbursement from Abbott Labs and $0.4 million from Boehringer Ingelheim (BI), and $9.2 million in amortization of upfront payments from Abbott, BI, and Dainippon Sumitomo Pharma (DSP). As a reminder, Neurocrine signed two research collaborations in the second quarter 2010, one with Abbott for elagolix that included $75 million cash up-front and the potential for $530 million in milestones, and one with BI for GPR119 that included $10 million upfront and the potential for $225 million in milestones. Neurocrine reported net income for the first quarter of $2.9 million, or 5 cents per diluted share. This was just below our expectations, as we had anticipated slightly higher sponsored R&D work from BI than the $0.4 million recorded.

The company's balance sheet on March 31, 2011 reflected total assets of $134.0 million, including cash and short-term investments of $121.6 million. Management expects to have a net cash burn from operations of approximately $3 to $6 million for the full year 2011; meaning cash at the end of the year will still exceed $120 million. We believe this is sufficient cash to fund operations, including the in-house development of Uro-2, VMAT-2, and the remaining preclinical work on elagolix for which Neurocrine is still responsible, for the foreseeable future.

We are expecting revenues in 2011 of $76.0 million (Guidance: $75 to $80 million), which includes amortization of up-front license fees of approximately $36 million and anticipated milestones earned under collaboration agreements of approximately $30 million. We see net income in 2011 of $36.2 million (Guidance: $34 to $39 million), which equates to $0.64 per share (Guidance: $0.62 to $0.71 cents per share).

Elagolix Phase 3 To Start 2H-2011

On March 28, 2011, Neurocrine Bio met with the U.S. FDA's Division of Reproductive Products for a formal end of phase 2 (Type-B) meeting. The purpose of the meeting was to confirm the design of the planned phase 3 program to start in the fourth quarter 2011. Management reported the meeting was "productive and positive" on the first quarter conference call. We expect that the pivotal phase 3 program will include two large-scale (n~500) patient programs with co-primary Dysmenorrhea and Non-Menstrual Pelvic Pain endpoints, testing 150mg elagolix QD. The exploratory Dyspareunia endpoint may also be tested, as well as Patient Global Impression of Change (PGIC) in the phase 3 program. There will also be a long-term (n~400) safety program. Efficacy will be assessed by a responder analysis for statistical evaluation. We are expecting this program to be up and running by the fourth quarter 2011. Additionally, Abbott plans to start a phase 2 dose-ranging program in uterine fibroids to start in the third quarter 2011.

VMAT-2 IND Shortly

In early April 2011, Neurocrine released data from an open-label phase 2a study designed to assess the efficacy, safety and tolerability of NBI-98854 in schizophrenia patients with moderate to severe Tardive Dyskinesia over 12 days. The data showed a mean Abnormal Involuntary Movement Scale (AIMS) score decreased to 8.4, a reduction of 41.3%. Results show a reduction in abnormal involuntary movements across multiple assessment points. After the seven-day washout period most patients' AIMS scores returned to their baseline levels.

We anticipate Neurocrine filing an IND application in the second half 2011. Neurocrine plans to meet with the FDA's Division of Psychiatry to discuss in June 2011. This should be followed by the initiation of a phase 2 (placebo-controlled, cross-over design in ~50 patients) program in the U.S. in the third quarter. If successful, we anticipate Neurocrine moving into a larger-scale (n=150, 3-month dosing) phase 2b program during the first half of 2012.

INVESTMENT THESIS

DAISY Program Offers Positive Results

On May 24, 2010, Neurocrine Bio announced that the Daisy PETAL (Study-901) program provided statistically significant results in all top-line primary and secondary endpoints testing the company's proprietary, orally-active nonpeptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix, in patients with endometriosis. In addition, the company confirmed that the daily scales for menstrual and non-menstrual pelvic pain, developed with extensive input from the U.S. FDA and patients, functioned well in a clinical trial setting. The phase 2b Daisy PETAL (901) study enrolled 137 women with endometriosis into one of two treatment groups; elagolix 150 mg (n=66) or placebo (n=66) once daily for two months of treatment, in a double-blind design.

Top-line results at week 8 (ITT) confirm that elagolix is associated with statistically significant reduction in the two co-primary endpoints, Dysmenorrhea (severe uterine pain during menstruation) and Non-Menstrual Pelvic Pain (NMPP), and an exploratory endpoint, Dyspareunia (painful intercourse), when compared to placebo.

Data at Week 8	Baseline	Elagolix	Placebo
Change in Baseline (ITT population) of…			
Dysmenorrhea (mean, 0-3)	2.1 / 2.1	-1.13	-0.37
Non-Menstrual Pelvic Pain (mean, 0-3)	1.4 / 1.3	-0.47	-0.19
Dyspareunia (pain, 0-3)	1.6 / 1.3	-0.61	-0.23
All p<0.01			

Management also conducted a responder analysis that demonstrated clinically meaningful improvement of 30% or greater from baseline on all three endpoints (ITT population).

Data at Week 8	Elagolix	Placebo
Responder Analysis (>30%)…		
Dysmenorrhea	63% [1]	33%
Non-Menstrual Pelvic Pain	63% [1]	33%
Dyspareunia	58% [2]	34%
1 = p<0.01 2 = p<0.05		

Secondary endpoints also demonstrated statistically significant improvement from elagolix subjects versus the placebo on validated efficacy outcome assessments.

Data at Week 8	Elagolix	Placebo
Secondary Efficacy Endpoints (ITT population) on…		
Patient Global Impression of Change (PGIC) "much" or "very much improved"	60%	30%
Endometriosis Health Profile 5 (EHP-5) Related-Pain Assessment, 0-100	-28 pts	-13 pts
Composite Pelvic Signs & Symptoms Scale (CPSSS) Reduction from Baseline (9.5), 0-15)	-4.45 pts	-2.19 pts
All p<0.001		

On November 22, 2010, management provided a follow-up to the active (placebo-controlled) dosing portion of the program at week 24. The data included open-label placebo crossover patients for the next 16 weeks and demonstrated further decrease in all three endpoints, NMPP, Dysmenorrhea, and Dyspareunia for the 150mg elagolix arm, as well as reductions in pain scores for placebo patients during the open-label crossover portion.

Data at Week 24	Elagolix	Crossovers
Secondary Efficacy Endpoints (ITT population) on…		
Patient Global Impression of Change (PGIC) "much" or "very much improved"	86%	74%
Endometriosis Health Profile 5 (EHP-5) Related-Pain Assessment, 0-100	-36 pts	-30 pts
Composite Pelvic Signs & Symptoms Scale (CPSSS) Reduction from Baseline (9.5), 0-15)	-5.5 pts	-4.5 pts

The continued improvement in the active 150mg elagolix group is highly encouraging. However, we are even more impressed by the strong results from the placebo crossover group. In our view, the data from Daisy PETAL clearly shows that elagolix is working.

We are also encouraged by the fact that during the phase 2b Daisy PETAL program, the elagolix demonstrated excellent safety and tolerability. Discontinuation due to adverse events (AEs) was low at 4.4% for elagolix vs. 1.4% for the placebo during the first eight weeks of the program. The discontinuation rate increased to only 5.1% at week 24. The most common adverse event reported more often with elagolix than with placebo was nausea (~10% of the subjects). This was consistent with what we saw in previous clinical studies. Importantly, there were no elagolix treatment-related serious adverse events (SAEs).

…Collaboration With Abbott Labs…

In June 2010, Neurocrine signed a collaboration agreement to develop and commercialize elagolix with Abbott Labs. Abbott received worldwide exclusive rights to develop and commercialize elagolix and all next-generation GnRH antagonists for women's and men's health. This includes potential indication beyond endometriosis pain, such as uterine fibroids, adenomyosis, premenstrual dysphoric disorder (PMDD), polycystic ovarian syndrome (PCOS), breast cancer, or benign prostatic hypertrophy (BPH).

Abbott made an upfront payment of $75 million and will fund all ongoing development activities. Neurocrine is eligible to receive additional milestone payments of approximately $530 million from Abbott for the achievement of certain development, regulatory and commercial milestones. Neurocrine will also receive funding for certain internal collaboration expenses, plus royalty payments (we model 20%) on any future product sales. CEO Kevin Gorman has previously noted that the “vast majority” of the $530 million milestones are for development, about 2/3rd of which are for endometriosis and uterine fibroids and about 1/3rd for other indications such as prostate and breast cancer. This gives us confidence that Neurocrine will recognize a significant portion of these milestones prior to potential FDA approval in 2013 or 2014. Company guidance is for revenues in 2011 totaling $75 to $80 million. The IND has since been transferred to Abbott. Neurocrine will continue to handle the CMC and commercial scale-up for elagolix, which will be funding by Abbott Labs.

It’s a ‘home run’ deal in our view for Neurocrine Bio. Abbott is the pioneer and market leader in GnRH antagonists with Lupron (leuprolide) for the treatment of hormone-responsive cancers such as prostate cancer or breast cancer. The drug is also used by Ob/Gyns for the treatment of endometriosis and uterine fibroids, as well as to treat precocious puberty, and to control ovarian stimulation in In-Vitro Fertilization (IVF). Abbott has a strong appreciation for the GnRH mechanism and the company is clearly committed to see elagolix a success with Lupron expected to lose patent protection in 2015. Abbott’s Lupron sales in 2010 were $748 million ($483 million U.S.). We believe that Abbott will look to replace Lupron in the Ob/Gyn market with elagolix thanks to superior efficacy and tolerability, as well as patent protection.

…A Billion-Dollar Opportunity…

Endometriosis is a medical condition characterized by growth of the endometrium (uterine tissue) outside of the uterus, most usually on the pelvis, that affects an estimated 100 million women of reproductive age worldwide, or about 5-10% of the female population according to the World Endometriosis Foundation. There are an estimated 10 million women affected by endometriosis in the U.S. Endometriosis also occurs in a small percentage (2-4%) of postmenopausal women. Symptoms of endometriosis are severe recurring pain that can include dysmenorrhea (menstrual pain), dyspareunia (painful sex), dyschezia (painful bowel movements) and dysuria (painful urination).

From a sales standpoint, we think peak U.S. sales are around $1.5 billion. Abbott's upfront payment of $75 million in June 2010 (and $530M backend) seems to validate this forecast. We remind investors that Abbott owns the worldwide rights to elagolix, including in Europe, were we see another 10 million potential users. We arrive at this figure as follows:

- 10 million women in the U.S. with endometriosis…
- 65% with moderate-to-severe seeking treatment options beyond oral contraceptives…
- 50% seek alternatives to Lupron / DMPA…
- 40% turn to elagolix (market share)…
- Elagolix costs $5 per pill, with 6-month on / 3-month off Rx pattern…
- 10 million * 65% * 50% * 40% * 240 pills/year * $5 per pill = $1.5 billion

Endometriosis is caused by an excess of the hormone estrogen, and thus can manifest during peak reproductive years. Hereditary and environmental factors, as well as associated infections (such as HPV), can increase incidence and severity. The disease is often treated, ineffectively, by a number of medications. NSAIDs are used to treat mild-to-moderate pain associated with endometriosis. Progesterone or progestin and hormonal contraceptives are used to regulate estrogen levels when appropriate. In fact, industry data shows that almost 20% of all oral contraceptives prescribed are written specifically for the treatment of endometriosis. Steroids and aromatase inhibitors are used to block estrogen levels and endometrium growth. However, these have significant negative side-effects. Lupron, an injectable gonadotropin depo shot, is used to lower estrogen levels and slow endometrium growth. However, Lupron shuts down estradiol production and puts the body into "medicated menopause", resulting in significant side effects such as hot flashes and a reduction in bone mineral density. In the most severe cases, a hysterectomy is performed.

Elagolix, a gonadotropin-releasing hormone (GnRH) antagonist has efficacy characteristics similar to Lupron for the treatment of endometriosis, but with less potential for bone mineral density loss. It is also the first oral small molecule GnRH antagonist. The drug works by blocking the action of GnRH and suppressing luteinizing hormone and follicle-stimulating hormone. There are a few other GnRH molecules on the market, but none that are oral in dosing or have amassed the clinical data of elagolix. Therefore, we believe that Neurocrine can achieve significant market share gains with elagolix upon commercialization. Most women shy away from Abbott's Lupron due to side-effects. Nevertheless, Abbott is still the market leader in this category. As such, we believe that Neurocrine has the ideal pharmaceutical partner to further develop and commercialize elagolix in Abbott Labs. We believe a specialty Ob/Gyn sales force of 200 to 250 representatives can effectively target greater than 90% of the market.

…Phase 3 To Start In Q4…

In late March 2011, Neurocrine and Abbott met with the U.S. FDA's Division of Reproductive Products for a formal end of phase 2 (Type-B) meeting. In total, Neurocrine and Abbott sat down with the FDA and offered up data from 12 phase 1 programs and 6 phase 2 programs (2 phase 2a and 4 phase 2b) on roughly 1,000 patients. The purpose of the meeting is to confirm the design of the planned phase 3 program to start in the fourth quarter 2011. We note the preclinical toxicology and carcinogenicity programs are all ongoing.

We expect that the pivotal phase 3 program will include two large-scale (n~500) patient programs with co-primary Dysmenorrhea and Non-Menstrual Pelvic Pain endpoints. The exploratory Dyspareunia endpoint may also be tested, as well as Patient Global Impression of Change (PGIC) in the phase 3 program. There will also be a long-term (n~400) safety program. Efficacy will be assessed by a responder analysis for statistical evaluation. Abbott also plans a separate phase 3 program for the European submission. This program may include a head-to-head non-inferiority arm vs. Lupron.

…Uterine Fibroids…

Beyond endometriosis-pain, uterine fibroids represent an attractive second indication for elagolix. Uterine fibroids or adenomyosis are benign tumors that form on the wall of the uterus. They are the most common type of growth found in a woman's pelvis and are most common in women aged 30-40 years. While many women do not have symptoms, depending on the size, location and number, uterine fibroids can cause heavy menstrual bleeding, can put pressure on the bladder and rectum, and can cause pain and nausea. Symptoms can also include miscarriages and infertility. Depending on the symptoms, treatment sometimes requires surgery. This is a potential billion-dollar market in the U.S. given the significant number of women affected and the lack of pharmaceutical options available. Abbott is doing the necessary work to design a phase 2 dose-ranging program here with elagolix. We expect this trial may start during the third quarter of 2011.

…Benign Prostatic Hypertrophy…

In men's health, elagolix has potential in benign prostatic hypertrophy (BPH). BPH is defined by enlargement of the prostate gland. As the prostate grows larger and presses against the urethra, normal flow of urine is hindered. A competitor is developing an injectable peptide GnRH antagonist currently in phase III trials. However, Neurocrine Bio believes that a significant advantage may be provided by oral non-peptide GnRH antagonist, such as elagolix. Moderate to severe BPH affects an estimated 21 million men in the U.S. Additionally, more than 40% of all men over the age of 60 suffer from the symptoms of BPH. Worldwide sales of current treatments for BPH exceeded $3 billion in 2006.

VMAT-2 Moving Forward

Neurocrine is current working on a vesicular monoamine transport 2 (VMAT-2) inhibitor, dubbed NBI-98854, which could play an important role in treating or preventing hyperkinetic movement disorders. Tardive dyskinesia (TD) is characterized by involuntary bodily movements as seen in patients suffering from Huntington's disease, Parkinson's disease, or as a side effect of dopamine modulation in patients suffering from schizophrenia. VMAT-2 is a protein concentrated in the human brain that is essential for the transmission of nerve impulses between neurons. Neurocrine identified a highly selective VMAT-2 inhibitor that is effective in regulating the levels of dopamine release during nerve communication, while at the same time having minimal impact on the other monoamines thereby reducing the likelihood of "off target" side effects.

…Phase 1…

In August 2009, management began a phase 1 single ascending dose study in healthy male volunteers conducted in Canada. Preliminary data show that NBI-98854 was generally safe and well tolerated. In October 2010, Neurocrine Bio announced that it has successfully completed a second phase 1 clinical trial. The program tested repeated dosing in healthy volunteers looking for favorable signs of safety, tolerability, and pharmacokinetics. During the phase 1 program there were no serious adverse events, clinically significant drug-related laboratory abnormalities or clinically significant ECG findings. The characteristics of the compound met the pre-specified pharmacokinetic requirements: dose proportionality, low maximum concentration (Cmax) with adequate area-under-curve (AUC) for drug exposure, low variability, and a half-life which supports once per day dosing.

Management now plans to push forward into a phase IIa dose exploration (titration) program in 10 patients with moderate-to-severe Tardive Dyskinesia (TD) in Canada. The 12-day, open-label program will test escalating doses (12.5mg, 25mg, and 50mg) of NBI-98854 looking for signs of efficacy and safety in patients on stable doses of anti-psychotic medications. The primary analysis will be an analysis based on the Abnormal Involuntary Movement Scale (AIMS), with data expected in April 2011.

…Phase 2…

In October 2010, Neurocrine moved NBI-98854 into an open-label phase 2a study designed to assess the efficacy, safety and tolerability in schizophrenia patients with moderate to severe Tardive Dyskinesia over 12 days. The dosing regimen consisted of three, four-day periods of NBI-98854 at increasing doses of 12.5mg, 25mg and 50mg administered once daily. After discontinuation of NBI-98854, a seven-day washout period was followed by a final assessment. Efficacy will be assess utilizing the Abnormal Involuntary Movement Scale (AIMS). At baseline, the mean AIMS score was 14.3 for the six patients enrolled in the trial.

In early April 2011, Neurocrine released data showing the mean AIMS score decreased to 8.4, a reduction of 41.3%. Results show a reduction in abnormal involuntary movements across multiple assessment points. After the seven-day washout period most patients' AIMS scores returned to their baseline levels. The adverse events reported during administration of study drug were transient and mild or moderate including one subject with dizziness and one with restlessness. One subject became anxious and agitated seven days after stopping the study medication due to return of baseline-intensity dyskinesia. All trials were conducted in Canada.

…Next Steps…

We anticipate the IND filing in the second half 2011. Neurocrine plans to meet with the FDA's Division of Psychiatry to discuss in June 2011. This should be followed by the initiation of a phase 2 (placebo-controlled, cross-over design in ~50 patients) program in the U.S. in the third quarter. If successful, we anticipate Neurocrine moving into a larger-scale (n=150, 3-month dosing) phase 2b program during the first half of 2012.

In addition, NBI-98854 may well be useful in other disorders, such as Huntington's chorea, schizophrenia, Tourette's syndrome, and Tardive Dystonia. We are particularly excited about the VMAT-2 program at Neurocrine. It represents significant upside and diversification from elagolix. VMAT-2 is a protein concentrated in the human brain that is primarily responsible for re-packaging and transporting monoamines (dopamine, norepinephrine, serotonin, and histamine) among nerve cells. Neurocrine's molecule, NBI-98854, is a novel, highly-selective VMAT2 inhibitor that modulates presynaptic dopamine release during nerve communication, while at the same time having minimal impact on the other monoamines thereby reducing the likelihood of "off target" side effects. NBI-98854 is designed to provide low, sustained, plasma and brain concentrations of the active drug to minimize side effects associated with excessive dopamine depletion.

Looking to Monetize Urocortin-2

Another important mid-stage program is the Urocortin-2 program for mild to moderate congestive heart failure (CHF). Previous phase II data with Urocortin-2 has demonstrated the candidate to be generally well tolerated and that the predicted hemodynamic effects on systolic and diastolic blood pressure, heart rate, cardiac work and, most importantly, cardiac output occurs over the entire 4-hour infusion. Management recently completed some preclinical formulation, toxicology and safety work to support a longer-term duration infusion – potentially up to 14 days. Neurocrine has partnered with academic laboratories to move Urocortin-2 forward.

These collaborations include one with the Christchurch Cardioendocrine Research Group (CCRG) at the University of Otago, New Zealand, Christchurch School of Medicine and Health Sciences. CCRG has initiated enrollment in a 50-person pilot study with Urocortin-2, called Unicorn, in patients with acute decompensated heart failure (ADHF). As of mid-January 2011, 43 patients have been enrolled in the study so far. Data from all 50 patients is expected around the middle of 2011. Neurocrine is supplying drug and logistical support to CCRG.

The Centre for Cardiovascular Sciences at The University of Edinburgh, through a British Heart Foundation grant, is also conducting clinical-stage trials on Urocortin-2. Management noted that nine studies will be conducted in both healthy volunteers and patients with stable congestive heart failure to determine the impact of Urocortin-2 infusions on biomarkers of cardiovascular function and dysfunction. The first of these studies are currently underway.

Neurocrine has always been focus on drugs primarily for neurological and endocrine diseases and disorders. We believe that management will look to out-license Urocortin-2 to a pharmaceutical partner focused on cardiovascular disease. This could bring upfront cash perhaps in 2011 or 2012.

Teaming Up With Boehringer Ingelheim

In June 2010, Neurocrine Bio announced a worldwide collaboration with Boehringer Ingelheim to research and develop small molecule GPR119 agonists for the treatment of Type-2 diabetes and other indications, with BI responsible for the global development and commercialization. Under the terms of the agreement, Neurocrine Bio received a $10 million upfront payment, research funding to support discovery efforts and is eligible to receive up to $225 million in milestone payments based on the achievement of development, regulatory and commercial goals as well as royalty payments on any future product sales. BI is currently conducting preclinical studies looking at candidate selection for an IND. We anticipate an IND in 2012.

GPR119 is a G-protein coupled receptor (GPCR) that has been implicated as a novel target for the treatment of Type II diabetes. The activation of GPR119 receptors located in the digestive system stimulates incretins, resulting in increased insulin production, while activation of GPR119 receptors located on pancreatic islet beta cells also stimulates insulin secretion.

RECOMMENDATION

Neurocrine Looks Well Positioned for the Future

We continue to very positive on Neurocrine Bio. The basis for our optimism is our belief that the collaboration deal with Abbott Labs for elagolix was a 'Homerun'. Neurocrine received $75 million upfront and has the potential to earn an additional $530 million in future milestones, of which CEO Kevin Gorman noted the "vast majority" are for development. This gives us confidence that Neurocrine will recognize a significant portion of these milestones prior to potential FDA approval in 2013 or 2014. Abbott is the pioneer and market leader in GnRH antagonists with Lupron (leuprolide) for the treatment of hormone-responsive cancers such as prostate cancer or breast cancer. The drug is also used by Ob/Gyns for the treatment of endometriosis and uterine fibroids. Abbott has a strong appreciation for the GnRH mechanism and the company is clearly committed to see elagolix a success with Lupron expected to lose patent protection in 2015. Abbott's Lupron sales in 2009 were $800 million ($540 million U.S.). We believe that Abbott will look to replace Lupron in the Ob/Gyn market with elagolix thanks to superior efficacy and tolerability, as well as patent protection.

Since that time, the company has signed a second deal with Boehringer Ingelheim and successfully completed phase 2a studies on VMAT-2. This has allowed us to raise our target price to $12 per share.

The collaboration with BI focuses on the research and development of G-protein coupled receptor (GPCR) small molecules for the treatment of Type-2 diabetes. The activation of GPR119 receptors located in the digestive system stimulates incretins, resulting in increased insulin production, while activation of GPR119 receptors located on pancreatic islet beta cells also stimulates insulin secretion. As part of terms of the collaboration, Neurocrine received another $10 million upfront milestone payment for research funding, and is eligible to receive up to $225 million in future milestone payments based on the achievement of development, regulatory and commercial goals. Again, CEO Kevin Gorman noted that a "substantial amount" can be achieved in clinical development.

The company's balance sheet on March 31, 2011 reflected total assets of $134 million, including cash and investments of roughly $121 million. Management expects to end the year with roughly $120 million in cash and investments. Revenues are expected to increase to approximately $75 million in 2011, which includes amortization of up-front license fees of approximately $36 million and anticipated milestones earned under collaboration agreements of approximately $30 million. Management believes net income for 2011 will be $34 to $39 million, or $0.62 to $0.71 cents per share. We currently forecast net income in 2011 at $36.2 million, with EPS at $0.64.

The company should see its lead product candidate, elagolix, enter phase 3 trials during the fourth quarter of 2011. Our market research shows elagolix as a $1.5 billion drug in the U.S., potentially $2-3 billion worldwide. Meanwhile, phase 2 programs with Uro-2 and VMAT-2 are also moving forward with little cost to the company. We believe Neurocrine is in an outstanding position to build shareholder value over the next several years based on these factors. We recommend accumulating the stock at today's price, up to our $12 target.

PROJECTED FINANCIALS

Neurocrine Biosciences Inc.
Income Statement

	2010 A	Q1A	Q2E	Q3E	Q4E	2011 E	2012 E	2013 E	2014 E	2015 E
R&D / Milestones & Fees	**$33.5**	**$12.5**	**$15.0**	**$21.0**	**$27.5**	**$76.0**	**$50.0**	**$50.0**	**$40.0**	**$30.0**
YOY Growth	*1034.5%*	*1561.6%*	*223.1%*	*45.3%*	*101.4%*	*126.9%*	*-34.2%*	*0.0%*	*-20.0%*	*-25.0%*
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$25.0**	**$75.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
VMAT-2	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$40.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$33.5**	**$12.5**	**$15.0**	**$21.0**	**$27.5**	**$76.0**	**$50.0**	**$50.0**	**$65.0**	**$105.0**
YOY Growth	*1034.5%*	*1561.6%*	*223.1%*	*45.3%*	*101.4%*	*126.9%*	*-34.2%*	*0.0%*	*30.0%*	*61.5%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$0	$0	$0	$6.0
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*94.3%*
SG&A	$16.1	$3.3	$3.4	$3.5	$3.5	$13.7	$14.5	$15.0	$16.0	$17.0
% SG&A	*48.0%*	*26.0%*	*22.7%*	*16.7%*	*12.7%*	*18.0%*	*29.0%*	*30.0%*	*24.6%*	*16.2%*
R&D	$31.2	$7.3	$7.0	$7.5	$8.0	$29.8	$30.0	$30.0	$30.0	$30.0
% R&D	*93.0%*	*58.5%*	*46.7%*	*35.7%*	*29.1%*	*39.2%*	*60.0%*	*60.0%*	*46.2%*	*28.6%*
Operating Income	($13.7)	$1.9	$4.6	$10.0	$16.0	$32.5	$5.5	$5.0	$19.0	$52.0
Operating Margin	-	-	-	-	-	*42.8%*	*11.0%*	*10.0%*	*29.2%*	*49.5%*
Interest / Other Income	$5.8	$0.9	$0.9	$0.9	$0.9	$3.6	$3.5	$3.0	$2.5	$2.5
Pre-Tax Income	($8.0)	$2.9	$5.5	$10.9	$16.9	$36.2	$9.0	$8.0	$21.5	$54.5
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$1.1	$8.2
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5.0%*	*15.0%*
Net Income	($8.0)	$2.9	$5.5	$10.9	$16.9	$36.2	$9.0	$8.0	$20.4	$46.3
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	*47.6%*	*18.0%*	*16.0%*	*31.4%*	*44.1%*
Reported EPS	**($0.15)**	**$0.05**	**$0.10**	**$0.19**	**$0.30**	**$0.64**	**$0.16**	**$0.13**	**$0.33**	**$0.71**
YOY Growth	-	-	-	-	-	-	*-75.5%*	*-14.8%*	*145.1%*	*118.1%*
Stock Options	*$3.1*	*$0.7*	*$0.9*	*$0.9*	*$0.9*	*$3.4*	*$4.0*	*$4.5*	*$5.0*	*$5.0*
EPS Impact of FAS-123R	*$0.06*	*$0.01*	*$0.02*	*$0.02*	*$0.02*	*$0.06*	*$0.07*	*$0.08*	*$0.08*	*$0.08*
Shares Outstanding	52.8	56.1	56.5	56.7	56.8	56.5	57.5	60.0	62.5	65.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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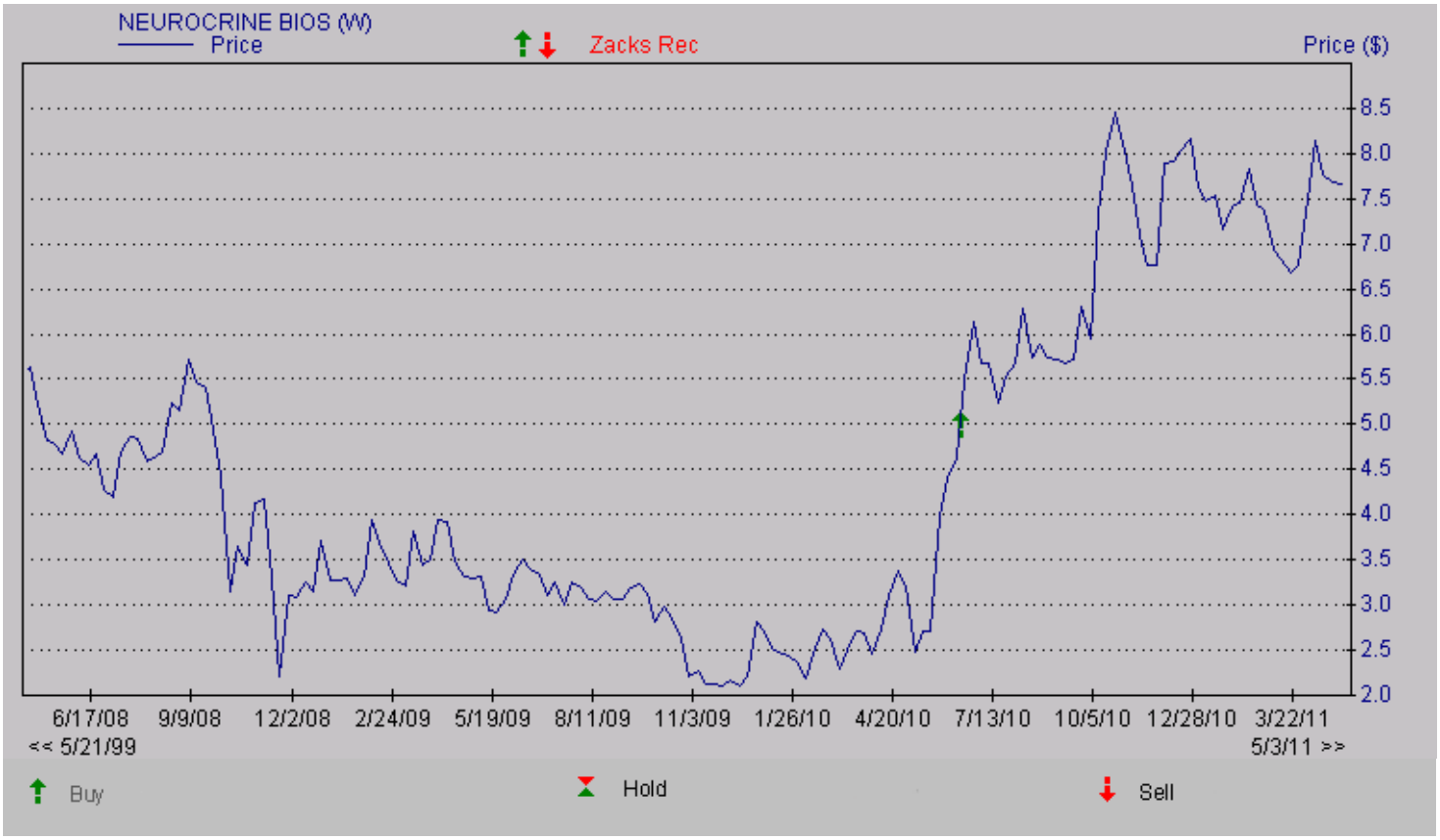

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