Zacks Equity Research

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Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

www.zacks.com
111 North Canal Street, Chicago, IL 60606

Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

UPDATE

NBIX: Positive DAISY-PETAL Data Sends Shares Higher…Next Up, Schedule A Meeting With The FDA…

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	12/13/2007
Current Price (05/25/10)	$3.70
Six- Month Target Price	**$5.00**

Neurocrine's phase II program on elagolix is nearing an end. The final program, DAISY-901, recently met all primary and secondary endpoints in the placebo-controlled portion of the trial. The next step is for management to request an end of phase II meeting with the FDA, and then submit a special protocol assessment (SPA) for the phase III program. We expect this will take place in late June 2010. We also expect that the company will secure a development and commercialization partnership shortly after the first submission of the SPA. The elagolix story is moving forward, and Neurocrine is squarely on our radar as a name-to-watch once the phase III program begins late 2010 / early 2011.

SUMMARY DATA

52-Week High	**$3.51**
52-Week Low	**$2.00**
One-Year Return (%)	**-6.83**
Beta	**0.70**
Average Daily Volume (sh)	**393,003**
Shares Outstanding (mil)	**53**
Market Capitalization ($mil)	**$145**
Short Interest Ratio (days)	**4.15**
Institutional Ownership (%)	**47**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-62.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Below Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**
Zacks Rank in Industry	**16 of 77**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	0.7 A	0.7 A	0.7 A	0.7 A	3.0 A
2010	0.8 A	0.7 E	0.7 E	0.7 E	3.0 E
2011					15.0 E
2012					24.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-$0.51 A	-$0.39 A	-$0.21 A	-$0.20 A	-$1.30 A
2010	-$0.18 A	-$0.21 E	-$0.18 E	-$0.17 E	-$0.74 E
2011					-$0.58 E
2012					-$0.46 E

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

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WHAT'S NEW

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. Daisy PETAL (901) study enrolled 137 endometriosis subjects 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 confirm that elagolix is associated with statistically significant reduction in the two co-primary endpoints, Dysmenorrhea and Non-Menstrual Pelvic Pain, and the exploratory endpoint, Dyspareunia, when compared to placebo based on the ITT population.

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		

During the phase II program, the elagolix demonstrated encouraging safety and tolerability. Discontinuation due to adverse events (AEs) was low at 4.4% for elagolix vs. 1.4% for the placebo. The most common adverse event reported more often with elagolix than with placebo was nausea (7.4% elagolix; 2.9% placebo). This was consistent with what we saw in previous clinical studies. Importantly, there were no elagolix treatment-related serious adverse events (SAEs). We note that subjects are continuing for an additional four months of open-label elagolix treatment and assessments program. This 24-week open-label data should be available in late August 2010.

…Next Step – Meet With The FDA…

Now that the top-line data from Daisy PETAL has been reported, management will request an end of phase II (Type-B) meeting with the Division of Reproductive Products at the FDA. We expect this request (filing) will take place in late June 2010. The FDA usually responds within 60 days, and our best guess is that the meeting will take place in late August / early September 2010.

In total, Neurocrine should be able to sit down with the FDA and offer up data from 6 phase II programs (2 phase IIa and 4 phase IIb) on roughly 1,000 patients. Concurrent to the end of phase II meeting request, management will file a draft proposal for a special protocol assessment (SPA) for the phase III design. The company believes that the first round of discussions on the proposed SPA will take place with the agency at the end of phase II meeting. The final SPA agreement should be in hand by late in the Q3-2010. This should allow management, and its partner, to begin a phase III program before the end of the year.

We expect that the pivotal phase III 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 in the phase III program. There will also be a long-term (n~400) safety program. Depending on management's European strategy, one of the two phase III programs may include a head-to-head non-inferiority program vs. Lupron for the European submission.

Neurocrine is actively seeking a development and commercialization partner on elagolix. Our best guess is that management will be able to secure this partnership this summer, in-time for the partner to get involved in the end of phase II meeting and SPA discussions with the FDA. This is the most significant catalyst to drive the shares higher. Potential partners are firms that have strong Women's health focus, including market leaders Pfizer, Abbott, or J&J. Although the product could also be very effectively marketed by a specialty pharmaceutical company given that a small specialty Ob/Gyn sales force of 200 to 250 representatives can effectively target greater than 90% of the market.

…Background Info on Endometriosis…

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 8 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). 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, a 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. 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 Lupron due to side-effects. Market research so far has been encouraging. Management noted that they are beginning to receive requests from physicians to prescribe elagolix on a compassionate basis. It is possible the FDA will allow elagolix compassionate use once phase III trials begin in 2010. Peak market sales opportunity is roughly $500 million.

PROJECTED FINANCIALS

Neurocrine Biosciences Inc.
Income Statement

	2009 A	Q1A	Q2E	Q3E	Q4E	2010 E	2011 E	2012 E	2013 E	2014 E
R&D / Milestones & Fees	**$3.0**	**$0.8**	**$0.7**	**$0.7**	**$0.7**	**$3.0**	**$15.0**	**$15.0**	**$10.0**	**$10.0**
YOY Growth	*-25.7%*	*0.8%*	*1.0%*	*1.0%*	*0.0%*	*0.7%*	*404.5%*	*0.0%*	*-33.3%*	*0.0%*
indiplon Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$9.0**	**$25.0**	**$47.3**
YOY Growth	-	-	-	-	-	-	-	-	-	-
CRF Receptor Antagonists	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Urocortin 2	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
VMAT-2	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$3.0**	**$0.8**	**$0.7**	**$0.7**	**$0.7**	**$3.0**	**$15.0**	**$24.0**	**$35.0**	**$57.3**
YOY Growth	*-25.7%*	*0.8%*	*1.0%*	*1.0%*	*0.0%*	*0.7%*	*404.5%*	*60.0%*	*45.8%*	*63.6%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$14.9	$3.2	$3.2	$3.2	$3.3	$12.9	$14.0	$15.0	$16.0	$17.0
% SG&A	*505.2%*	*424.8%*	*432.4%*	*432.4%*	*445.9%*	*433.9%*	*93.3%*	*62.5%*	*45.7%*	*29.7%*
R&D	$35.8	$7.6	$7.8	$6.2	$5.5	$27.1	$30.0	$32.5	$35.0	$35.0
% R&D	*1212.7%*	*1006.1%*	*1054.1%*	*837.8%*	*743.2%*	*910.7%*	*200.0%*	*135.4%*	*100.0%*	*61.1%*
Operating Income	($47.8)	($10.0)	($10.3)	($8.7)	($8.1)	($37.0)	($29.0)	($23.5)	($16.0)	$5.3
Operating Margin	-	-	-	-	-	-	-	-	-	-
Interest / Other Income	($3.3)	$1.5	($0.3)	($0.3)	($0.4)	$0.5	($1.4)	($1.8)	($2.1)	($2.1)
Pre-Tax Income	($51.0)	($8.5)	($10.6)	($9.0)	($8.5)	($36.5)	($30.4)	($25.3)	($18.1)	$3.2
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($51.0)	($8.5)	($10.6)	($9.0)	($8.5)	($36.5)	($30.4)	($25.3)	($18.1)	$3.2
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-
Reported EPS	**($1.30)**	**($0.18)**	**($0.21)**	**($0.18)**	**($0.17)**	**($0.74)**	**($0.58)**	**($0.46)**	**($0.31)**	**$0.05**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Stock Options	*$6.1*	*$0.6*	*$0.8*	*$1.0*	*$1.5*	*$3.9*	*$4.5*	*$5.0*	*$5.5*	*$6.0*
EPS Impact of FAS-123R	*$0.16*	*$0.01*	*$0.02*	*$0.02*	*$0.03*	*$0.08*	*$0.09*	*$0.09*	*$0.10*	*$0.10*
Shares Outstanding	39.1	46.6	49.5	50.0	50.5	49.2	52.5	55.0	57.5	60.0

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

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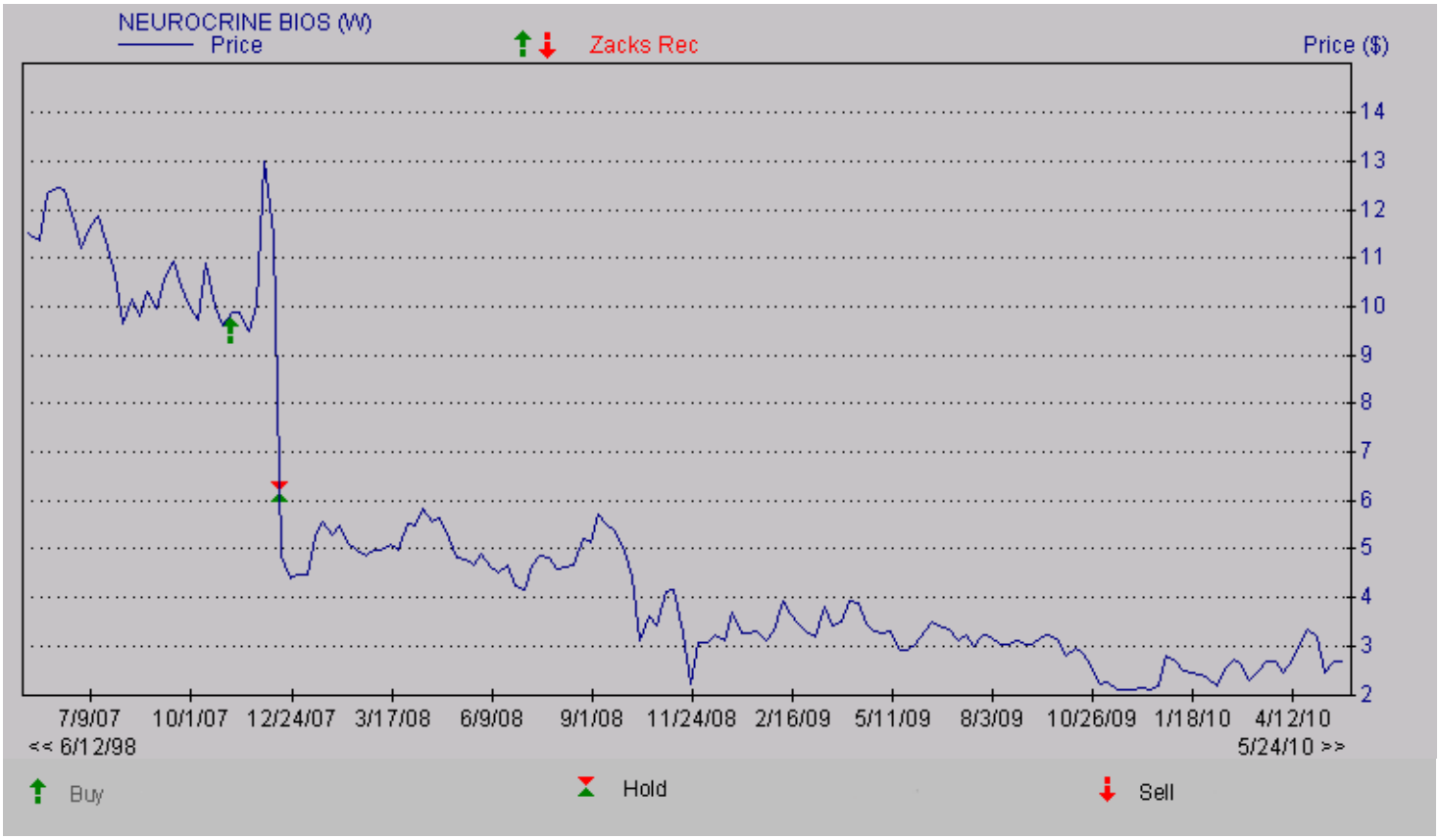
HISTORICAL ZACKS RECOMMENDATIONS



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