Zacks Small-Cap Research

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Neurotrope, Inc. (NTRP - OTC)

NTRP: Bryostatin Receives Orphan Designation for FXS While We Wait for Phase 2b Initiation for AD…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	10/20/2014
Current Price (05/15/15)	$0.87
Target Price	**$2.00**

UPDATE

Neurotrope, Inc. (NTRP) announced positive top-line results from the Phase 2a study of bryostatin-1 in Alzheimer's Disease patients in February 2015. Additional pharmacokinetic information was released in March 2015.

In other news, Neurotrope received orphan drug designation for bryostatin in the treatment of Fragile X Syndrome (FXS) by the U.S. FDA in April 2015. The company also received a research grant from the FRAXA Research Foundation to provide full funding for a pre-clinical FXS study.

Below, we will give a brief overview of bryostatin-1, the Phase 2a study, and the next steps in the development of bryostatin-1 for Alzheimer's Disease. We also touch briefly on an additional potential indication for the drug, which could become a more significant driver of the stock later in the year.

SUMMARY DATA

52-Week High	**$1.45**
52-Week Low	**$0.50**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**22,303**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$25**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**51**
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/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 E	0 E	0 E	0 E
2016					0 E
2017					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.08 A	-$0.09 A	-$0.14 A	-$0.11 A	-$0.42 A
2015	-$0.09 A	-$0.08 E	-$0.09 E	-$0.11 E	-$0.39 E
2016					-$0.38 E
2017					-$0.39 E

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WHAT'S NEW

Financial Update

On May 15, 2015, Neurotrope, Inc. filed form 10-Q with results from the first quarter of 2015. As expected the company did not report any revenues. Net loss for the quarter was $2.4 million, compared to $1.7 million for the corresponding quarter of 2014. This was in-line with our expectations. The increase in loss was primarily due to increased activities and new employee hiring.

Research and development expenses included $0.6 million of related party expenses in the first quarter of 2015 versus $0.7 million for the first quarter of 2014. These expenses are related to the company's alliance with Blanchette Rockefeller Neurosciences Institute (BRNI) for ongoing research and development related to potential therapeutic and diagnostic products. In addition, the company incurred $0.5 million of internal research and development expenses in the current quarter compared to $0 for the first quarter of 2014. These expenses were related to producing and storing drug product for clinical trials, the company's Phase 2a clinical trial, licensing payment amortization, orphan drug development costs, and the development of alternative drug supply. Related party general and administrative expenses for the first quarter of 2015 totaled $27k and were similar to those incurred in the first quarter of 2014. Other general and administrative expenses during the current quarter totaled $1.2 million versus $0.8 million for the first quarter of 2014.

The company exited the first quarter of 2015 with $5.5 million in cash and cash equivalents. We estimate that this will be sufficient to fund activities into the fourth quarter of 2015.

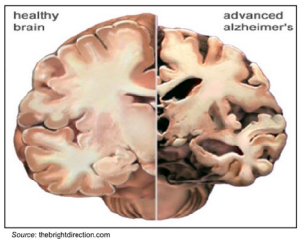
An Update on Bryostatin-1 in AD

On February 24, 2015, Neurotrope, Inc. (NTRP) announced positive top-line results from the Phase 2a study of bryostatin-1 in Alzheimer's Disease patients. Additional pharmacokinetic information was released a month later. Below, we give a brief overview of bryostatin-1, the Phase 2a study, the next step in the development of bryostatin-1 for Alzheimer's Disease.

…A Brief Overview of Alzheimer's Disease…

Alzheimer's Disease (AD) is a progressive, neurodegenerative disease that causes memory loss and dementia. In fact, it accounts for 60-70% of all dementia in older adults. The most common early symptom of AD is a gradually worsening ability to remember new information. This is due to neurons associated with forming new memories dying off first. As neurons in other parts of the brain die, individuals experience different symptoms, which include:

- Memory loss that disrupts daily life
- Inability to plan or solve problems
- Difficulty completing familiar tasks
- Confusion with location and time
- Difficulty with visual images and spatial relationships
- Problems with words in speaking or writing
- Withdrawal from social activities
- Changes in mood, including apathy and depression



The root cause of Alzheimer's is still unknown; however, it is likely to involve a number of different factors as opposed to being due to one single cause. These factors are likely a combination of genetic, environmental, and lifestyle. Deposits of extracellular beta-amyloid, a fragment of the larger protein amyloid precursor protein (APP), are readily identifiable by microscopy in the brains of AD patients (Tiraboschi *et al*., 2004), thus anti-beta-amyloid therapies have dominated AD clinical trials. However, none of these therapies has proven beneficial, with the only current treatment options available being acetylcholinesterase inhibitors and an NMDA receptor antagonist. AD drug development from 2002 to 2012 had a failure rate of 99.6%, thus there exists a pressing need for more and better treatment options.

Memory loss is the most characteristic clinical manifestation of AD and occurs early in the course of the disease

when an inability to retain recent information is primarily affected (Petersen *et al*., 1994). Past research into memory formation has shown that the enzyme Protein Kinase C (PKC) activates multiple targets during memory acquisition and storage (Olds *et al*., 1993). Once activated, PKC plays an important role in intracellular signaling cascades, with the PKC isozymes PKCα and PKCε being important for synaptogenesis, or the development of new synapses between neurons. There is a high abundance of PKCε in the presynaptic nerve fibers, suggesting the protein plays an important role in neurite outgrowth, synapse formation, and neurotransmitter release (Shirai *et al*., 2008). In addition, activation of PKCα and PKCε has been shown to prevent synaptic loss in pathogenic mouse models (Sun *et al*., 2008, 2009). Using specific PKC isozyme inhibitors showed that PKCε as the isozyme that most effectively suppresses the production of beta-amyloid (Zhu *et al*., 2001).

…***Neurotrope's Bryostatin-1 for AD…***

Neurotrope is developing bryostatin-1, a natural compound isolated from the marine organism *Bugula neritina*, a filter-feeding creature approximately 1 mm in length that resides in ocean waters around the world for the treatment of AD. The compound activates PKC, specifically the isoforms PKCα and PKCε, both of which have been shown to be important for synaptogenesis (the creation of new synapses in the brain) and could potentially alleviate a number of the pathological processes of AD by decreasing the levels of beta-amyloid, decreasing neuron death, and increasing synaptic function. Initially, bryostatin-1 was tested for its anti-neoplastic activity, but due to a number of clinical trial failures those efforts have mostly ceased. Nevertheless, the compound was tested in over 1200 patients, thus there is a significant amount of data related to toxicity, dosing, and pharmacokinetics.

There have also been a number of preclinical studies published that support the use of bryostatin-1 as a treatment for AD. The results from these and other studies point to a central role of PKCε in maintaining neuron structure and function. Thus, activators of PKCε, such as bryostatin-1, may work not just to alleviate the symptoms of AD, but could delay the progression of the disease through both synaptogenesis (formation of new synapses in the brains of AD patients) and through a decrease in the amount of beta-amyloid.

Phase 2a Results Show Bryostatin-1 is Well-Tolerated in AD Patients

The Phase 2a clinical trial (NCT02221947) was designed to evaluate the safety of a single dose of bryostatin-1 in patients with AD. This was a randomized, double-blind, placebo controlled, single dose study with a total of nine patients; six patients were randomized to receive bryostatin-1 through intravenous infusion and three received a matching placebo control. The primary objective of the trial was to assess the safety and tolerability of a single dose of bryostatin-1. The secondary objectives of the study were the preliminary evaluation of the efficacy of a single dose of bryostatin-1, the pharmacokinetics of the drug, and to correlate the changes in PKCε with plasma levels of bryostatin-1 and with improvement in cognitive function.

The study consisted of screening evaluations and on study evaluations divided into two segments, an inpatient segment and an outpatient segment. The four-day inpatient segment consisted of baseline evaluations and a 1-hour IV infusion of study drug followed by multiple evaluations over the first 72 hours post dose. During the outpatient segment, patients were followed for adverse events and had a final evaluation two weeks post dose and at the end of the fourth week were contacted via telephone for a safety follow up.

For the study, patients had to have a mini mental state exam (MMSE) score between 16 and 26. The mini mental state exam is a 30-point questionnaire test that is used to screen for cognitive impairment (Folstein *et al*., 1975). It includes simple questions and problems in a number of areas (arithmetic, language use and comprehension, basic motor skills) and is scored on a 30-point scale. A score greater than 27 indicates normal cognition, 19-26 points indicates mild cognitive impairment, 10-18 points indicates moderate cognitive impairment, and scores ≤ 9 indicate severe cognitive impairment (Mungas, 1991). Thus, Neurotrope selected patients with mild to moderate cognitive impairment for inclusion in the Phase 2a trial.

The results from the Phase 2a study showed that it met the primary endpoint demonstrating safety and tolerability of bryostatin-1, with no serious adverse events reported. All adverse events that occurred were considered mild and resolved spontaneously. As a secondary objective, the Phase 2a safety study examined the correlation of the changes in PKCe with plasma levels of bryostatin after a single dose. Preliminary assessment of PKCe levels in peripheral monocytes demonstrated a significant increase in total PKC protein levels at the end of the bryostatin infusion consistent with target engagement. An additional secondary objective of the study was the evaluation of efficacy following a single dose of bryostatin using the Hopkins Verbal Learning Test-Revised™ (HVLT-R™; Brandt, 1991; Benedict *et al*., 1998). However, as expected with a single dose of bryostatin, there was no measurable improvement in cognition in this mildly impaired patient population.

We were pleased to see that bryostatin-1 was shown to be safe and well tolerated in AD patients, although this was not entirely unexpected as the compound has been tested previously in over 1,200 patients through various clinical trials at the National Cancer Institute, which showed the compound to be generally safe and well tolerated. However, this was a necessary first step in order to proceed to a larger clinical trial in AD.

With positive results from the Phase 2a trial, Neurotrope is now ready to initiate a larger, multi-dose Phase 2b trial in AD patients with moderate to severe AD. This will be a multi-site, double-blind, placebo controlled trial of approximately 150 patients with moderately severe to severe AD. The company is currently working on finalizing the protocol for submission to the FDA, which we believe will include the cognitive tests such as the HVLT-R mentioned above, in addition to evaluating safety and pharmacokinetics. On March 30, 2015, Neurotrope signed a letter of intent with Worldwide Clinical Trials to commence pre-patient enrollment activities, and thus we estimate that the trial will begin sometime during the middle of 2015, take approximately nine months to enroll, with patients being dosed for six months. We are still expecting data from the Phase 2b study to be available in late 2016.

…Compassionate Use Continues in 2015…

Bryostatin-1 is also available to select advanced Alzheimer's Disease patients via the company's enhanced access program, formerly known as compassionate use. Three patients have been treated thus far, two of which were treated under the Investigational New Drug Application (IND) cleared by the FDA that is held by the Blanchette Rockefeller Neurosciences Institute (BRNI). The study has concluded for one of these patients while the other patient is still being treated after 6 months on the protocol. Neurotrope went to great lengths in the filing to say that the study is an open-label study with no placebo control, thus it does not meet accepted scientific standards of a rigorous double blind placebo controlled trial. However, it is useful in supplying important information to help Neurotrope optimize ongoing clinical trial efforts. In addition, we believe it is an encouraging sign that the enhanced access program is being expanded and that one of the patients has been on protocol for over six months. Additional patients would most likely not be allowed to participate, nor would a patient stay on treatment for so long, were the drug shown to have any type of safety issues.

On March 20, 2015, researchers at BRNI and the Marshall University Joan C. Edwards School of Medicine announced findings from a new study titled, *"PSEN1 Variant in a Family with Atypical AD."* Researchers believe that that a patient with severely advanced Alzheimer's Disease, with a rare variant of the PSEN1 gene, was responsive to treatment with bryostatin-1. The patient was treated with IV bryostatin infusion that was provided by the National Cancer Institute once a week for the first three weeks of each month. According to BRNI, within two weeks, the patient showed clinical improvements related to speech, focus, and motion that lasted approximately eight weeks, even though the patient had to be intubated and hospitalized for four weeks due to severe pneumonia. Results of the study will be printed in the *Journal of Alzheimer's Disease* shortly (Denvir, *et. al*, 2015). Although these results are encouraging, we believe that clinical trials are necessary in order to demonstrate safety and efficacy of bryostatin treatment in AD patients.

Additional Orphan Indications

On April 23, 2015, Neurotrope announced that based upon its work in orphan drug indications, it was invited to join the National Organization for Rare Disorders (NORD) as a member of the NORD Corporate Council. NORD is an independent, non-profit organization that is committed to the identification, treatment, and cure of rare disorders, such as Niemann-Pick Type C Disease (NPC) and Fragile X Syndrome (FXS).

In addition to AD, Neurotrope is developing bryostatin-1 as a potential therapy for additional orphan diseases. Neurotrope has signed a world-wide, exclusive license agreement with the Icahn School of Medicine at Mount Sinai for the use of bryostatin-1 in the treatment of Niemann-Pick Type C Disease (NPC), a rare disease that mostly affects children who are afflicted with Alzheimer's-like symptoms. NPC is an orphan disease as it affects approximately 3,000 individuals in the U.S, and the majority of patients affected with the disease die between the ages of 10 and 25 years. The disease is part of a group of inherited metabolic disorders known as lysosomal storage diseases. Normally, lipids are broken down to provide energy; however, in NPC harmful quantities of lipids accumulate in the spleen, liver, lungs, and brain. Symptoms include brain degeneration, loss of muscle tone, feeding and swallowing difficulties, and slurred speech. Since PKC is involved in synaptogenesis, bryostatin-1 treatment has the potential to obviate the neuronal degeneration seen in NPC patients. The company has initiated pre-clinical work with bryostatin for the treatment of Niemann-Pick Type C, and the company plans to file for orphan drug designation for the disease.

Neurotrope is also investigating the use of bryostatin-1 in other neurodegenerative diseases such as Fragile X syndrome (FXS), a genetic condition that results in a range of developmental problems including learning disabilities, cognitive impairment and/or intellectual disabilities. Speech and language development delays as well as a variety of physical and behavioral characteristics are commonly seen in individuals with the disease. FXS is the most common cause of inherited intellectual disability, and the most common known genetic cause of autism or autism spectrum disorders. The condition affects approximately 1 in 4,000 men and 1 in 8,000 women in the U.S. Nearly all cases of FXS are caused by a mutation in the FMR1 gene, which encodes the fragile X mental retardation protein (FMRP). FMRP is thought to play a role in synaptic plasticity, which is the ability of synapses to form new connections in the processes of learning and memory. Activation of Protein Kinase C (PKC) by bryostatin-1 could represent a novel treatment option for these patients through the induction of synaptogenesis.

On April 9, 2015, it was announced that Neurotrope received orphan drug designation for bryostatin in the treatment of Fragile X Syndrome by the U.S. FDA. Neurotrope is developing bryostatin under a licensing agreement with the Blanchette Rockefeller Neuroscience Institute (BRNI). Management is encouraged by the pre-clinical data that was acquired in a Fragile X mouse study at BRNI regarding synaptogenesis. It was then announced that the company received a research grant from the FRAXA Research Foundation to provide full funding of a pre-clinical Fragile X Syndrome study to evaluate the behavioral effects of bryostatin-1 in a Fragile X Syndrome mouse model over a thirteen-week period at FRAXA's purpose built laboratory located at the University of Chile in Santiago, Chile. Founded in 1994 by three parents of children with FXS, FRAXA supports scientific research aimed at finding a treatment and a cure for FXS, and has funded more than $24 million in scientific research around the globe.

Orphan drug designation allows for a host of incentives becoming available including the following:

- ✓ The FDA must provide the sponsor with “written recommendations for the non-clinical and clinical investigations (based on the information available at the time of the request)… that would be necessary for approval of such drug for such disease or condition…”

- ✓ For a period of seven years post-approval, the FDA may not approve an application from a different sponsor for the “same drug” for the same disease or condition. For biological treatments, the FDA defines same drug to mean one that contains the “same principle molecular features.” The 7-year exclusivity period conferred by orphan drug status is important because patent protection and Hatch-Waxman data exclusivity have limited effectiveness in excluding competitors from introducing equivalent drugs with slightly different structures. An exception is provided by any change that leads to improved safety or efficacy.

- ✓ Grants and contracts are available to defray the costs of development. For 2013-17, the amount appropriated is $30 million per year, which is a fairly modest sum but could make a significant difference for a small company such as Neurotrope.

- ✓ A tax credit in the amount of 50% of qualified clinical testing expenses is established by related legislation (Title 26 Part 1-28). The tax credits can be rolled forward by up to 15 years for companies that have no tax liability in the year in which expenses are occurred (e.g., pre-revenue biotech companies).

- ✓ Waiver of PDUFA fees. For FY 2014, these are $2.17 million for full NDAs, a huge benefit for a company with limited financial resources.

Diagnostic Division

Neurotrope also has a diagnostic test for AD that has been tested in a total of 140 individuals, including AD patients, patients with mixed dementia, patients with non-AD dementia, and healthy controls. The total also includes 51 patients with autopsy-confirmed diagnoses. Results showed sensitivity (correctly diagnosing AD) ≥ 97% and specificity (correctly identifying individuals without AD) ≥ 96%, both of which compare quite favorably with other published diagnostic tests.

We have not included the AD diagnostic test in our valuation model as Neurotrope has limited resources and thus it is unclear to us at this time whether the company will move forward with development. However, particularly given the impressive data shown thus far, we believe this asset decreases the risk associated with an investment in Neurotrope and offers some upside should the company decide to focus on its development or otherwise monetize it through a licensing or partnership deal.

Financial Position

As of March 31, 2015, the company held $5.5 million in cash and investments and burned $2.5 million in the first quarter. We find this to be sufficient to fund operations into the fourth quarter. We believe the company will require additional funds to conduct the planned Phase 2b study with Bryostatin-1 in AD, as well as conduct new Phase 1 studies in Fragile-X and Niemann Pick. From January 1, 2015 through March 20, 2015, the company entered into private placement transactions with investors to convert a total of approximately 2.581 million shares of the company's Series A Preferred Stock (issued in 2013) into 2.581 million shares of common stock. Additionally, from January 1, 2015 through March 26, 2015, the private placement investors exercised common stock warrants (issued August 23, 2013) resulting in the issuance of a total of 0.181 million shares of common stock. From April 1 through May 7, 2015, private placement investors converted a total of 614,500 shares of the Company's Series A Preferred Stock (issued in 2013) into 614,500 shares of common stock.

Conclusion

Should bryostatin-1 prove to be an effective AD treatment the upside potential is enormous, as there are few treatment options available for AD patients today. We believe a safe and efficacious AD drug would easily generate sales in excess of $1 billion in the U.S. alone. With the positive safety results in hand from the Phase 2a trial, the company is now ready to initiate a larger Phase 2b trial, which should give an indication as to whether bryostatin-1 will show efficacy in AD patients. The company is also continuing to use bryostatin-1 on a limited basis in the "enhanced access program", formerly known as compassionate use, in patients with advanced AD. While the company is not allowed to discuss the results from this program specifically, there is encouraging preliminary anecdotal evidence demonstrated by significantly improved activities of daily living in the program. We are also intrigued by the fact that patients have been on bryostatins-1 for a significant period of time, suggesting that physicians are seeing response with the drug and it is worth continuing therapy.

We model that upon successful completion of the Phase 2b study in 2016 will lead to a registration program in 2017. If all goes well, we anticipate a U.S. NDA filing in 2019, with potential approval in 2020. We forecast that bryostatin-1 will cost $8,000 per year, which is a slight premium to the branded AD treatments that are currently available. We believe peak sales of the drug in AD are $3.2 billion. We apply an aggressive 25% discount rate to future earnings and give a probability of success at 15%. Lastly, we forecast free cash flow as 60% of gross revenues. This leads to a value of approximately $95 million for bryostatin-1 in AD along. At this time, our valuation for additional programs in Fragile-X and Niemann Pick is minimal at only $20 million ($10 million each), but we do view the news of Neurotrope receiving orphan drug designation for bryostatin in the treatment of Fragile X Syndrome to be promising. We look forward to hearing more about the company's work as it relates to the orphan indications.

Neurotrope currently has approximately 27.5 million common shares outstanding with 18.1 million shares of convertible preferred stock and 6.1 million options and warrants. This leads to a fully diluted share count of approximately 51.7 million. Dividing the value we assign to bryostatin-1 by the fully diluted share count leads us to a fair value of approximately $2.00 per share. Thus, we assign a 'Buy' rating to the stock.

PROJECTED FINANCIALS

Neurotrope, Inc.
Income Statement

Neurotrope, Inc.	2013 A	2014 A	Q1 A	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 E
Bryostatin	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Licensing & Other Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-	-
R&D	$1.4	$3.5	$1.1	$1.0	$1.2	$1.5	$4.8	$6.0	$7.0
SG&A	$6.2	$5.8	$1.3	$1.3	$1.4	$1.6	$5.6	$6.2	$6.5
Other expenses	$0	$0	$0.0	$0	$0	$0	$0	$0	$0
Operating Income	($7.6)	($9.3)	($2.4)	($2.3)	($2.6)	($3.1)	($10.4)	($12.2)	($13.5)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($7.6)	($9.3)	($2.4)	($2.3)	($2.6)	($3.1)	($10.3)	($12.2)	($13.5)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($7.6)	($9.3)	($2.4)	($2.3)	($2.6)	($3.1)	($10.3)	($12.2)	($13.5)
Reported EPS	**($0.35)**	**($0.42)**	**($0.09)**	**($0.08)**	**($0.09)**	**($0.11)**	**($0.39)**	**($0.38)**	**($0.39)**
YOY Growth	-	-						-	-
Shares Outstanding	21.7	22.1	25.0	27.5	28.0	29.0	26.8	32.0	35.0

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

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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