



NTII

Neurobiological Technologies, Inc.

Company Alert

September 20,
2005

Mid-Quarter
Update

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Disclosures Section
At the end of this review

Neurobiological Sells Brain Tumor Compound, XERECEPT® Rights for \$33 Million

NTII announced today the signing of a definitive agreement with a subsidiary of Celtic Pharma Holdings L.P. for the sale of rights in XERECEPT®, a synthetic preparation of the natural human peptide, Corticotropin-Releasing Factor, which is in Phase III clinical trials as a treatment for swelling associated with brain tumors (peritumoral edema).

Under the terms of the agreement, NTII will receive \$33 million in upfront payments, of which, \$20 million will be paid upon closing. NTII may receive up to an additional \$15 million upon the achievement of certain regulatory objectives. NTII is also eligible to receive profit-sharing payments on sales of XERECEPT® in the United States, if the product receives regulatory approval, and royalties on any sales elsewhere in the world. Celtic Pharma's subsidiary will assume responsibility for product development and pay all product development expenses. NTII will provide services relating to the current clinical trials of XERECEPT®. Celtic expects the transaction to close on 9/30/05.

NTII developed XERECEPT®, as a synthetic preparation of the natural human peptide Corticotropin-Releasing Factor (CRF), for reduction of cerebral edema associated with brain cancer (peritumoral brain edema). In April 1998, XERECEPT® received orphan drug designation from the FDA for peritumoral brain edema.

Orphan drug designation provides the first product approved for a given indication with seven years market exclusivity and makes the recipient eligible to receive Orphan Drug Grants to fund clinical research. NTII has completed animal toxicology studies for XERECEPT®, and, in April 2004, NTII began enrollment in one of two pivotal clinical trials for XERECEPT®, which has a target enrollment of 200 patients. A third long-term safety trial is ongoing and offers an extended use option for patients already enrolled in either clinical trial.

XERECEPT® could be as effective as dexamethasone but with reduced side effects. For FDA approval, Celtic Pharma will not need to prove that XERECEPT® is more effective than dexamethasone (it does not expect that it will), but it has fewer side effects.

We are increasing our FY06 price target from \$5.25-\$6.00 to \$6.50-\$7.00. We are basing this price target on the continuous revenue stream from Namenda sales, the expected initiation of patient enrollment for the Phase III trial for Viprinex™, the expected FRX/Merz decision on a potential Phase III trial for Diabetic Neuropathy, the new XERECEPT® deal and the recent \$10 m credit facility.

Mid-Quarter Financial Metrics

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Price (as of 9/19/05)	\$3.32
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New FY06 Price Target	\$6.50-\$7.00
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52 – Week Range	\$2.71-\$5.05
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Market Capitalization (9/19/05)	\$89.81 m
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Shares Outstanding	27.08 m
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Institutional Holdings	24.8%
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Insider Holdings	16.8%
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Avg. Daily Volume (3 mo.)	39,527
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Cash (6/30/05)	\$8.54 m
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LT Debt (6/30/05)	0
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Fiscal Year Results for 2004

Highlighting the CEO's assessment of the agreement

Paul E. Freiman, president and CEO of NTII said, "We believe that this is an exciting opportunity for a product candidate that we have worked diligently to bring to this stage of clinical development. If the ongoing trials are successful, brain cancer patients around the world will have access to a useful product in reducing the debilitating swelling around their tumors. Celtic provides both an attractive financial vehicle and an experienced pharmaceutical management team to realize the global potential of XERECEPT®. From a financial standpoint, I expect that the upfront payments will offset the costs of our complete Viprinex™ Phase III clinical program for ischemic stroke. Subsequent payments, dependent on approval, plus profit sharing and royalty payments will provide NTII with an opportunity to maintain a financial interest in the success of XERECEPT® on an ongoing basis. Upon closing, NTII will be in a stronger financial position to support its programs while having its burn rate reduced. This will also provide us with an opportunity to continue to expand our pipeline."

FY 2006 Prospects and accomplishments

1. Improved progress in the XERECEPT® Phase III trials
2. Initiation of enrollment in Phase III trial for Viprinex™
3. FRX/Merz (Sept) decision on potential Phase III trial for Diabetic Neuropathy
4. Expanded liquidity of NTII on a **Non-Dilutive** basis by the recent \$10 m credit facility, the \$33 m deal structure and a favorable royalty structure
5. Cut in the expense of clinical trials which we estimate to be \$4-5 m which will now be assumed by Celtic Pharma. Celtic Pharma will pick up further clinical development costs and responsibilities, although Neurobiological Technologies (will) provide support for the studies. NTII had invested \$24 million in the drug.

Investment Thesis

NTII, a late stage development company, is undervalued and we expect for some of this undervaluation to disappear over the next few months, and clarity from clinical outcomes over the next year should aid toward a fair market valuation. **Viprinex™ acquired fast track status from the FDA, which allows NTII to meet with the agency in an open door fashion. If Viprinex™ is approved; NTII would likely become a mid-cap stock.** Approximately 560,000 people suffer from ischemic stroke annually. Potentially, 20-25% of the population that suffers from ischemic stroke could receive Viprinex™, if it is FDA approved and found effective. tPA, the current therapy for ischemic stroke, currently costs \$2,000 an injection and has only a three hour window. If 125,000 people received only one injection of Viprinex™, assuming a cost of \$2,000, then that would mean annual sales of \$250 m (conservative estimate). **Viprinex™ has the potential to be a blockbuster drug that, if FDA approved, could easily find a marketing partner.**



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Company Description

NTII was founded in 1988 and went public in February 1994. **NTII is now (8/15/05) located in Emeryville, California (formerly Richmond, CA) employing twenty-five full-time employees.** The new phone number is 1.510.595.6000 and the fax is 1.510.595.6006. In 1995, NTII acquired commercial rights to Memantine, an orally available neuroprotective agent that acts to modulate the N-methyl-D-aspartate ("NMDA") receptor in the central nervous system. NTII licensed the rights to Memantine to development partners, but retained royalty rights from the sale of Memantine (Namenda). In April 1998, NTII entered into a strategic research and marketing alliance with Merz to further the development and commercialization of Memantine. Merz has marketed Memantine in Germany since 1989 with the labeling "dementia syndrome." Memantine received European marketing approval in May 2002 for the treatment of moderate to severe Alzheimer's disease. In June 2000, Merz + Co. entered into an agreement with Forest Laboratories, Inc. for the development and marketing of Memantine in the United States for the treatment of Alzheimer's disease, Neuropathic pain, and AIDS-related dementia. In August 2000, Merz + Co. entered in an agreement granting H. Lundbeck A/S exclusive rights to market Memantine in certain European markets and in Canada, Australia and South Africa and semi-exclusive rights to co-market Memantine with Merz + Co. in other markets worldwide excluding the United States. Lundbeck's strategic partner, Forest Laboratories, Inc., holds the right to the U.S. market for Memantine. Forest Laboratories, the U.S. marketer, filed a New Drug Application with the FDA which was approved in September 2003 for the use of Memantine in the treatment of Alzheimer's disease. In Japan, Memantine is under development by Merz's collaborative partner Suntory/Dai-Ichi Ltd.

NTII's Memantine has demonstrated positive results in treating patients suffering from painful diabetic neuropathy. The Neuropathic pain of diabetes is a chronic disorder that affects an estimated 16 million Americans. One of its most common complications is nerve damage, particularly damage to peripheral nerves that send sensory signals from the extremities to the central nervous system, or CNS. This condition, referred to as peripheral diabetic neuropathy, or PDN, is a large, unmet medical need. This condition most frequently damages nerves in the feet, making walking or standing painful and difficult. We estimate that approximately 800,000 patients in the US currently receives treatment for the symptoms of PDN, including severe, chronic pain known as Neuropathic pain (persistent pain in the absence of an obvious stimulus).

Viprinex™ (Fast track status granted by FDA 1/28/2005), the recent NTII PIII compound acquisition, is a thrombin-like enzyme that is highly specific to fibrinogen. A U.S. Phase III clinical study was completed in 1998 to evaluate the safety and efficacy of Viprinex™ in 500 patients. In this study, Viprinex™ was shown to be effective in preserving neurological function in this patient population. A separate Phase III study was completed in Europe in 2000, enrolling patients within six hours of onset of acute ischemic stroke. The trial was stopped after a planned interim analysis indicated lack of efficacy and increased incidence of intracranial hemorrhage. The higher dosing levels in the European trial and the protocol criteria are thought to have contributed to the trial's failure. A review of the positive U.S. findings versus the European findings has suggested the need for a revised Viprinex™ dosing strategy, which will be integrated into the new Phase III study.

Neurobiological Technologies Inc.'s [Corporate Governance Quotient \(CGQ®\)](#) as of 1-Sep-05 is better than **70.4%** of CGQ Universe companies and **44.6%** of Pharmaceuticals & Biotechnology companies (Institutional Shareholder Services).



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