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NTI Sells Xerecept Rights To Celtic Pharma For \$48M

By Karen Pihl-Carey
Staff Writer

Neurobiological Technologies Inc. signed a definitive agreement to sell the rights of its Phase III product Xerecept to a subsidiary of Celtic Pharma Holdings LP for up to \$48 million.

Xerecept is a synthetic preparation of the natural human peptide, corticotropin-releasing factor (CRF). It works to reduce peritumoral edema, or an abnormal increase in brain water content, which can lead to brain ischemia, herniation and death.

Emeryville, Calif.-based NTI will receive \$33 million in up-front money, of which \$20 million will be paid at closing, expected by Sept. 30. It also can receive up to \$15 million more by achieving certain regulatory milestones. If the therapy reaches the market, NTI would receive profit-shar-

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Clinical Data Scooping Up Icoria For \$12.5M In Stock

By Randall Osborne
West Coast Editor

To wed biomarkers with molecular diagnostics, Icoria Inc. is being taken over by Clinical Data Inc. in an all-stock deal worth about \$12.5 million, based on the former's closing price last Friday – and one that comes months after Clinical Data disclosed its plan to buy out Genaisance Pharmaceuticals Inc. (OTC BB:ICOR).

Icoria's shares closed Tuesday at 26 cents, up 8 cents, or 45 percent, and Newton, Mass.-based Clinical Data's stock (NASDAQ:CLDA) ended the day at \$21.06, down \$1.06.

Barry Buzogany, chief operating officer and general counsel for Icoria, noted that the firm had alerted investors months ago that "our cash position was in jeopardy," with only enough to last through the second quarter of 2006.

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Bio Mid-America VentureForum 2005

Midwest Venture Conference Opens Today In Minneapolis

By Jennifer Boggs
Staff Writer

Representatives from venture capital firms and both biotech and medical device companies will converge at the Hilton Hotel in Minneapolis this evening to kick off the third annual BIO Mid-America VentureForum.

"We have a great lineup" of panels and presenters, said Ray Frost, senior vice president of Medical Alley/MNBIO, the life sciences and biotech association for Minnesota, which is co-hosting the event with the Biotechnology Industry Organization (BIO). Eight other state associations – Colorado, Iowa, Indiana, Illinois, Michigan, Missouri, Ohio, and Wisconsin – are co-sponsoring.

The three-day event begins with a reception this evening, and will feature presentations from more than 60

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Axonyx Reports 'Expected' Miss With Phenserine In AD

By Jennifer Boggs
Staff Writer

Axonyx Inc. reported disappointing, though not unexpected, results from its final two Phase III trials of Phenserine in mild to moderate Alzheimer's disease patients.

The New York-based company said top-line data failed to show statistical significance over placebo, as measured by standard cognition scales. Those results confirmed findings reported in February from the first Phase III study of Phenserine, a selective acetylcholinesterase inhibitor, in which the drug failed to meet its cognition endpoint of improved memory in 375 patients. (See *BioWorld Today*, March 15, 2005.)

"We kind of knew we would probably not achieve statistical significance" in the two additional Phase III trials, said Colin Neill, chief financial officer of Axonyx, since

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INSIDE: PARALYZED MICE SHOW BENEFIT; STEM CELLS INC.'S SHARES JUMP2
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Paralyzed Mice Show Benefit; Stem Cells Inc.'s Shares Jump

By **Randall Osborne**
West Coast Editor

Shares of Stem Cells Inc. jumped 12.2 percent on news of a published study showing the firm's neural stem cells restored function in paralyzed mice, which is the first research to establish a causal link between the transplanted cells and recovery of long-term motor ability.

Company officials couldn't be reached, but the Palo Alto, Calif.-based firm's stock (NASDAQ:STEM) closed Tuesday at \$5.53, up 60 cents.

When the cells were taken out of some of the mice, their previously improved motor function was lost. The study was conducted at the Reeve Irvine Research Center at the University of California at Irvine and published online Tuesday in the early edition of the *Proceedings of the National Academy of Sciences*. The work will appear in the Sept. 27, 2005, print issue.

In the experiment, human neural stem cells were transplanted into mice nine days after a spinal cord crush injury that resulted in hind-limb paralysis. The mice were then watched and tested for 16 weeks after the transplant, and showed significant improvement in their ability to walk compared to mice in two control groups, a benefit that persisted during the full term of the study.

Treated mice had better weight-bearing ability and coordinated stepping using their hind limbs, and data gathered during the study shows the neural stem cells survived, produced new neural cells that integrated into the mouse spinal cord and reversed hind-limb paralysis.

Specifically, the neural cells transplanted into the mouse spinal cord become specialized new cells called oligodendrocytes that make myelin, which forms the myelin sheath that insulates nerve fibers. The newly formed oligodendrocytes not only made new myelin sheaths around damaged mouse axons, but also new human neurons were generated that were shown to form synapses.

The study is likely to be carefully weighed in the days to come. News of progress in mice has caused a major stir before, notably in 1998 when Rockville, Md.-based Entremed Inc.'s stock quadrupled after a feature in *The New York Times* highlighted the company's progress in rodents with angiogenesis inhibitors. (See *BioWorld Today*, May 5, 1998.)

Farther back, Centocor Inc., of Malvern, Pa., once had positive results in mice afflicted with medicine's big-time bugaboo, sepsis – which many other firms also have tried, and are trying, to tackle – but the work did not translate well to humans. ■

OTHER NEWS TO NOTE

- **Alnylam Pharmaceuticals Inc.**, of Cambridge, Mass., said it will to delay the development of ALN-VEG01, its vascular endothelial growth factor (VEGF)-targeting drug to treat age-related macular degeneration. President and CEO John Maraganore attributed the decision to an “increasingly competitive landscape for VEGF-targeting AMD therapeutics on the market and in late-stage human trials.” Instead, the company plans to allocate its resources to advancing ALN-RSV01, an RNAi therapeutic candidate for treating respiratory syncytial virus infection. Alnylam now plans to file an investigational new drug application for ALN-RSV01 by the end of the year, rather than during the first half of 2006, as originally scheduled.

- **Avantogen Ltd.**, of Sydney, Australia, formerly Australian Cancer Technology, and **Innovate Oncology**, of San Diego, said encouraging clinical results from a study of RPI01 in patients with pancreatic cancer were presented at the 2nd International Conference on Tumor Progression and Therapeutic Resistance in Burlington, Mass. Avantogen and Innovate have jointly licensed RPI01 from RESprotect GmbH, of Dresden, Germany, and intend to sponsor clinical trials in the U.S. in early 2006. Results presented showed that 10 of 13 patients survived at least one year following treatment. Median survival was 447 days.

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APPOINTMENTS AND ADVANCEMENTS

4SC AG, of Martinsried, Germany, appointed Enno Spillner chief financial officer.

Aastrom Biosciences Inc., of Ann Arbor, Mich., appointed Stephen Sudovar to its board.

Ablynx, of Ghent, Belgium, appointed Hennie Hoogenboom chief scientific officer.

Acorda Therapeutics Inc., of Hawthorne, N.Y., appointed Gerard Cignarella vice president of business development, and Herbert Henney vice president of medical affairs.

Adaltis Inc., of Montreal, promoted Raymond Tong to chief operating officer.

AdipoGenix Inc., of Boston, appointed Richard Bergman, George Bray and Manuel Navia to its scientific advisory board.

Adventrx Pharmaceuticals Inc., of San Diego, appointed Keith Meister to its board.

Affymax Inc., of Palo Alto, Calif., appointed Philip Haworth vice president of business development.

Altachem Pharma Ltd., of Edmonton, Alberta, appointed Ron Moore, Gilles Lauzon and Ki-Jun Hwang to its scientific advisory board.

Amarin Corp. plc, of London, appointed Anthony Clarke vice president of clinical development at Amarin Neuroscience. It also appointed Prem Lachman nonexecutive director.

ARCH Venture Partners, of Seattle, appointed Steven Gillis venture partner.

ARYx Therapeutics, of Fremont, Calif., appointed Keith Leonard to its board.

BioMarin Pharmaceutical Inc., of Novato, Calif., pro-

moted Jeffrey Cooper to chief financial officer.

Cambridge Biostability Ltd., of Cambridge, UK, appointed John Lambert nonexecutive director of its board.

Cell Therapeutics Inc., of Seattle, promoted Jade Brown to executive vice president and chief business officer, and Scott Stromatt to executive vice president, clinical development and regulatory affairs.

CeMines Inc., of Golden, Colo., appointed Pauline Gee vice president and general manager of the BioSystems division.

Cephalon Inc., of Frazer, Pa., said board member Gail Wilensky was appointed to the World Health Organization's Commission on Social Determinants of Health.

CereMedix Inc., of Maynard, Mass., appointed John Norris to its board.

ChemGenex Pharmaceuticals Ltd., of Melbourne, Australia, appointed Patrick Burns and Peter Bradfield to its board.

Chemokine Therapeutics Corp., of Vancouver, British Columbia, appointed Shahin Rafii to its scientific and clinical advisory boards.

CMEA Ventures, of San Francisco, appointed William Haseltine senior life sciences adviser.

Connetics Corp., of Palo Alto, Calif., appointed Scott Meggs senior director, corporate counsel.

Dendreon Corp., of Seattle, appointed Michelle Burren senior vice president and chief financial officer.

Dynavax Technologies Corp., of Berkeley, Calif., appointed Stanley Plotkin to its board.

Eisai Inc., of Teaneck, N.J., appointed Douglas Snyder vice president and general counsel.

Gemin X Biotechnologies Inc., of Montreal, appointed Timothy Barberich and Wayne Roe to its board.

Genentech Inc., of South San Francisco, appointed Ian Clark senior vice president, commercial operations. Myrtle Potter will serve as a consultant.

OTHER NEWS TO NOTE

- **AVI BioPharma Inc.**, of Portland, Ore., initiated patient enrollment in Germany for the company's Appraisal Phase II study. The trial is designed to evaluate AVI's Resten-MP in the prevention of cardiovascular restenosis when delivered intravenously in conjunction with the placement of one or more bare-metal stents. Resten-MP is AVI-4126 delivered via intravenous injection using AVI's microparticle delivery technology.

- **Celera Genomics Group**, of Rockville, Md., initiated Phase I testing for cathepsin S inhibitor CRA-028129 for the treatment of psoriasis. In the Phase I trial, healthy volunteers will be randomized to receive orally administered CRA-028129 or placebo. About 70 subjects will be enrolled in the trial.

- **Cytokinetics Inc.**, of South San Francisco, presented

a poster on CK-1827452, a small-molecule activator of cardiac myosin, Tuesday at the 2005 Annual Heart Failure Society of America Meeting. CK-1827452 is the first drug candidate produced from Cytokinetics' cardiac myosin activator program and is in a Phase I trial.

- **Geron Corp.**, of Menlo Park, Calif., said underwriters of its public offering exercised their overallotment option in full to purchase 900,000 additional shares, resulting in an additional \$8.1 million to the company. That adds to the \$72 million raised through the sale of 8 million shares at \$9 each, including 2 million shares sold to Whitehouse Station, N.J.-based **Merck & Co. Inc.**, relating to a telomerase vaccine collaboration signed in July. (See *BioWorld Today*, Sept. 19, 2005.)

- **GTC Biotherapeutics Inc.**, of Framingham, Mass., will be producing MM-093, a recombinant version of human alpha-fetoprotein, for Cambridge, Mass.-based **Merrimack Pharmaceuticals Inc.** Merrimack is conducting a Phase II study of MM-093 in patients with rheumatoid arthritis. No further details of the agreement were disclosed.

Conference

Continued from Page 1

companies Thursday and Friday. More than 400 people have pre-registered for the event, and Frost said additional registrants are expected on site.

Last year's event, held in St. Louis, drew about 450 attendees, and companies that presented during the conference collectively secured about \$89 million in venture funding over the last year.

Frost said organizers chose Minneapolis for several reasons. The city offers a central location, is easy to get to and is home to a number of medical technology and medical device companies that, for the first time, will be invited to join biotech at the Mid-America conference.

"Minnesota is a major capital of medtech," Frost said, "So it seemed logical to hold the conference here."

While the biotech industry in the Midwest has not built up as quickly as it has along the east and west coasts, it has developed a solid foothold in the region.

Icoria

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"As a management team and board of directors, we had to look at other options," he said, and those included possibly going private or getting acquired.

Under the terms, Icoria shareholders will get 0.0139 shares of Clinical Data stock for each share of Icoria they own. At the close of trading Friday, that represented a price of 32 cents per share of Icoria stock. Should the price of Clinical Data shares change before the transaction closes, the aggregate purchase price could fluctuate, but it won't go below \$10 million or exceed \$12.5 million.

Based on the current share price of Clinical Data and including the impact of the expected acquisition of New Haven, Conn.-based Genaisance – a \$56 million all-stock deal announced in June – Icoria shareholders will own about 7.6 percent of the combined company upon the close of the Icoria transaction. (See *BioWorld Today*, June 22, 2005.)

The idea is to pair Research Triangle Park, N.C.-based Icoria's biomarker discovery platform with Clinical Data's molecular diagnostics business model, as well as Icoria's metabolomics and genomics capabilities with the growing pharmacogenomics expertise of Clinical Data. Whether Icoria will lose staff in the deal is uncertain, Buzogany said.

In the Genaisance/Clinical Data merger, approved by both boards and expected to close in the fourth quarter,

"We have some of the largest research institutions," Frost said, listing the University of Minnesota, the University of Michigan and Michigan State, to name a few. "We also have some top-notch research hospitals, like the Mayo Clinic and the Cleveland Clinic."

He added that the nine-state region could easily compete with the country's biggest biotech hubs.

"When all of us pull our resources together, which is something we do well in Midwest," he said, "then we have a lot of what is needed to be successful and to build success."

BIO began the annual event in 2003 to bring together young biotech firms from the Midwest and other areas, along with investors and other industry leaders. This year, Minnesota Gov. Tim Pawlenty is expected to speak following opening remarks by James Greenwood, president and CEO of BIO. Keynote speakers include Leon Moulder, president and CEO of Minneapolis-based MGI Pharma Inc., and Joshua Boger, chairman, president and CEO of Cambridge, Mass.-based Vertex Pharmaceuticals Inc. ■

Genaisance stockholders would get, at a fixed exchange ratio, 0.065 shares of Clinical Data for each share of Genaisance. Based on the two firms' closing prices just before the deal was made public, the amount represented a price of \$1.33 per share of Genaisance's common stock.

Genaisance's preferred shareholders would exchange their shares for Clinical Data preferred shares, and owners of Genaisance would have about 40 percent of the combined company.

"[Clinical Data's] vision for the three companies is that they will become one of the leaders of personalized medicine in the clinical setting," Buzogany told *BioWorld Today*.

"If you look at the biomarker element, I think it's on the rebound, or winning more and more favor in terms of the science behind using them to diagnose this disease."

Icoria's board has unanimously approved the Clinical Data transaction and will recommend to Icoria's stockholders that they do the same.

"Certainly, it could come apart, as any of these deals can, since we need our shareholders to approve the deal," Buzogany said, citing "all the standard kinds of potential issues that could cause the deal to go down, but we're confident that's not going to happen."

New York-based Needham & Co. LLC served as financial adviser to Icoria. ■

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NTI

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ing payments on sales in the U.S., and royalties on sales for the rest of the world.

In response to the deal, the company's stock (NASDAQ:NTI) rose more than 23 cents, to close at \$3.55.

Hamilton, Bermuda-based Celtic, a private equity firm, will take over all product development, while NTI will provide services relating to the current clinical trials of Xerecept.

The up-front payments should offset the costs of NTI's Viprinex (ancrod) Phase III program for ischemic stroke, which the company gained through its July 2004 acquisition of Empire Pharmaceuticals Inc., of Greenville, N.Y. A Phase III trial is expected to start any day. The deal also enables NTI to reduce its burn rate, while it still maintains a financial interest in Xerecept.

The Xerecept Phase III program represents about \$3 million in expenses a year to NTI, said Jonathan Wolter, the company's vice president and chief financial officer.

In addition, NTI's \$10 million revolving credit facility, joined with the \$33 million up front from the Celtic deal "puts in place \$43 million of non-dilutive liquidity" for NTI, Wolter told *BioWorld Today*, "which we think positions the company very well to proceed with our trials and look at expanding our pipeline."

NTI developed Xerecept after licensing the product from the Salk Institute in 1988. It is a synthetic mimic of the naturally occurring human neuroendocrine hormone CRF, which is thought to be a key hormone involved in regulating the release of natural corticosteroids by the pituitary and adrenal glands.

Xerecept appears to block vascular permeability by inducing up-regulation of blood-brain barrier specific structural proteins.

NTI has invested \$24 million in the compound's development. Celtic intends to develop the product globally, starting trials in Europe in the near term. It recently formed a strategic alliance with CMIC, Japan's leading contract research organization, which could become involved in the development of Xerecept in Asia.

The market for Xerecept is not huge, but brain tumor patients have few options for treatment. About 35,000 patients are diagnosed each year with primary brain tumors in the U.S., and another 170,000 patients with metastatic brain tumors.

Xerecept received orphan drug designation for peritumoral edema from the FDA in April 1998. NTI has completed animal toxicology studies and began enrollment of 200 patients in April 2004 in a pivotal trial for the chronic treatment of peritumoral brain edema. (See *BioWorld Today*, April 21, 2004.)

A second pivotal trial for acute peritumoral brain edema will begin enrolling 120 patients later this year. Each trial is expected to last about 18 months, meaning a new

drug application filing for Xerecept could come in 2007.

"Enrollment has been slower than initially anticipated," Wolter said, "but we are successfully enrolling in that [first] trial. I'd say that 18 months is a reasonable estimate, but it is certainly possible we could extend beyond that, but not substantially."

A third long-term safety study of the intravenous therapy began in August, providing an extended use option for patients enrolled in the two other trials.

Xerecept represents the fourth late-stage product acquired this year by Celtic. Clinical data have shown that Xerecept could have better efficacy and safety than high-dose synthetic corticosteroids, specifically dexamethasone, the current standard of care for edema. Corticosteroid therapy is linked with several adverse effects, such as hyperglycemia, gastritis, gastrointestinal bleeding, weight gain, osteoporosis, psychosis, immunosuppression and skin fragility.

Nevertheless, dexamethasone – which is sold under the names Decadron, Dexameth, Dexone and Hexadrol as an oral therapy – is effective in treating brain tumors, Wolter said.

"We are hopeful that our trials will demonstrate the same efficacy with Xerecept, but with a far improved quality of life, without the side effects caused by the steroid," he said.

Several Phase I/II trials have shown Xerecept to be safe with mild side effects, such as flushing, minor nausea, nasal congestion, headache and tingling. The early studies also showed patient improvement in neurological function and the ability to enhance radiation therapy for brain tumors.

Aside from developing Xerecept and Viprinex, NTI receives revenues from its one marketed product – Namenda (memantine HCL), which received FDA approval in October 2003 for Alzheimer's disease. ■

OTHER NEWS TO NOTE

• **IBEX Technologies Inc.**, of Montreal, signed two new distribution agreements for its glycobiology enzymes. Beginning this quarter, Associates of Cape Cod Inc., a subsidiary of Tokyo-based **Seikagaku Corp.**, and **Prozyme Inc.**, of San Leandro, Calif., will begin marketing and distributing the IBEX enzymes to customers worldwide.

• **Illumina Inc.**, of San Diego, has signed an agreement with the Max-Planck Institute of Psychiatry in Munich, Germany, to supply Illumina's Sentrix BeadChips and Infinium assay reagents for a large-scale genotyping study. The study will be performed by MPI's Center for Applied Genotyping to identify genetic variations that predispose people to specific disorders and to further determine the impact of genetic variants on disease pathogenesis.

OTHER NEWS TO NOTE

• **Intranasal Technology Inc.**, of Lexington, Ky., changed its name to **Intranasal Therapeutics Inc.** to reflect its new business strategy to develop and market nasally delivered products that address unmet medical needs. The company intends to focus on commercializing certain products with its own sales force, while working with marketing partners on other products, including some in its development pipeline.

• **Isis Pharmaceuticals Inc.**, of Carlsbad, Calif., initiated Phase II development of ISIS 301012 for lowering of high cholesterol. ISIS 301012 is a second-generation antisense drug that targets apoB-100, the protein component of low-density lipoprotein cholesterol. It is a double-blinded, placebo-controlled study, and patients will be followed for six months.

• **MerLion Pharmaceuticals Pte. Ltd.**, of Singapore, and **Cancer Research Technology Ltd.**, of London, entered a large-scale screening program to identify new cancer drug candidates derived from natural product chemistry. MerLion will screen its natural compound collection against high-throughput screens developed by scientists at CRT in order to isolate new therapeutic compounds against validated cancer targets. The results of the collaboration will be jointly owned.

• **Mesoblast Ltd.**, of Melbourne, Australia, enlisted **Cambrex Corporation Inc.**, of East Rutherford, N.J., for large-scale production of its proprietary adult stem cells. The cells are being evaluated for the treatment of a range of orthopedic and cardiovascular conditions and will be used in U.S.-based clinical trials.

• **Monsanto Co.**, of St. Louis, and **Targeted Growth Inc.**, of Seattle, agreed to develop and commercialize a yield enhancement gene developed by TGI. Terms include exclusive licensing rights to one of TGI's gene enhancing technologies in applicable Monsanto crops, in return for up-front, milestone and royalty payments. In other news, Monsanto also entered a licensing agreement for rights to a nitrogen use efficiency technology in canola developed by **Arcadia Biosciences Inc.**, of Davis, Calif. Monsanto will pay Arcadia an up-front fee, along with milestones and royalties.

• **Nabi Biopharmaceuticals**, of Rockville, Md., initiated a repeated dosing study designed to evaluate the ability of StaphVAX (*Staphylococcus aureus* Polysaccharide Conjugate Vaccine) to provide continuous protection in patient populations who are at high chronic risk for *S. aureus* infections. The trial will evaluate StaphVAX in end-stage renal disease patients on dialysis who are at high risk of contracting an *S. aureus* infection during their invasive and long-term treatment.

• **Nastech Pharmaceutical Co. Inc.**, of Bothell, Wash.,

said the *International Journal of Obesity* published preclinical results relating to the administration of PYY to treat obesity. The major finding is that the treatment group receiving 205 ug/kg of PYY intravenously once daily over 14 days had lower average weight, compared to the control group. Researchers also observed a trend in reduced food consumption in rabbits provided with fixed daily food allotment.

• **Procyon Biopharma Inc.**, of Montreal, said results of research describing the mechanism of action of PCK3145, its therapeutic peptide in clinical trials for the treatment of advanced prostate cancer, are set to be published in three scientific journals and one prostate cancer journal. Data show that the drug acts as a signal transduction inhibitor with anti-angiogenic and antimetastatic effects. Procyon has filed an investigational new drug application for PCK3145, and has an ongoing pilot study expected to be a lead-in to a North American Phase II trial.

• **Sequenom Inc.**, of San Diego, received a letter from the Nasdaq staff on Sept. 16 indicating that the company does not comply with the \$1 minimum bid price requirement for continued listing set forth in the Marketplace Rules. Sequenom will have 180 days, or until March 15, to regain compliance.

• **SIGA Technologies Inc.**, of New York, entered an agreement with St. Louis University for the continued development of SIGA's oral smallpox drug, SIGA-246. The agreement is funded through the National Institutes of Health. SIGA will receive about \$1 million to support specific aspects of the preclinical development of SIGA-246. SIGA will receive the revenue over the next six months.

• **Somaxon Pharmaceuticals Inc.**, of San Diego, began enrolling patients in its second Phase III study of Silenor (doxepin hydrochloride) for the treatment of insomnia. That trial will evaluate the drug's safety and efficacy over a three-month period in elderly patients diagnosed with primary chronic insomnia, with the primary endpoint of wake after sleep onset. Somaxon initiated the Phase III program in June after completing a \$65 million Series C financing. (See *BioWorld Today*, June 10, 2005.)

• **Speedel Holding Ltd.**, of Basel, Switzerland, said **Novartis AG**, also of Basel, released positive Phase III results of SPPI00 (Aliskiren) as a monotherapy and in co-administration with the diuretic hydrochlorothiazide in treating hypertension. Novartis said it is on track for its first regulatory submission of SPPI00 in the U.S. in early 2006, and in the European Union in the fourth quarter of 2006. The latest results confirmed previous findings from clinical studies conducted by Speedel, which in-licensed the compound from Novartis and developed SPPI00 through Phase I and II before Novartis exercised a license-back option in 2002.

Axonyx

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those trials involved "the same immediate-release formulation" at the same 10 mg and 15 mg dosage levels.

Shares of Axonyx (NASDAQ:AXYX) lost 15 cents Tuesday to close at \$1.09 (or 12.1%).

The studies initially were designed to enroll 450 patients each, with a 26-week treatment period. But, after the first Phase III miss, the company halted recruitment and cut the treatment period by more than half. The combined studies evaluated a total of 255 patients and cut the treatment period to 12 weeks.

Patients were assessed throughout the trial period using the Alzheimer's Disease Assessment Scale (cognitive subscale) and Clinical Interview-Based Impression of Change with caregiver input. Since neither dose of Phenserine met the primary endpoint, no secondary outcomes were analyzed.

Results "were very much as we expected," Neill told *BioWorld Today*. But the company still is hoping for some positive news from a Phase IIb study of Phenserine, which will measure the reductions in beta amyloid levels in the patients' brains, as well as evaluate standard cognition.

Phenserine, licensed from the National Institutes of Health in Bethesda, Md., is designed with a dual mechanism of action, focusing both on improving cognition and reducing the levels of beta amyloid in the brain, which is believed to be a cause of Alzheimer's. However, the Phase III studies did not look at changes in beta amyloid levels. The Phase

IIb study will measure the level of beta amyloid in patients' cerebral spinal fluid at baseline and six months.

That trial is almost fully enrolled, and data are anticipated around the end of the first quarter of 2006.

In the meantime, efforts have been ongoing to reformulate Phenserine as an extended-release drug.

The immediate-release formulation "powers into the brain and dissipates," he said. The aim of reformulating Phenserine is to "get more of the drug into the brain."

Axonyx hopes to complete the reformulation in the early part of 2006, though it plans to seek partners to co-develop the product, Neill said.

The company now is focusing on two other products in its pipeline, both for treating Alzheimer's Disease. Posiphen, a disease-modifying drug aimed at disease progression, recently began a Phase I trial in healthy volunteers. Posiphen is a positive isomer of Phenserine and targets only the reduction of beta amyloid. Preclinical studies showed a lack of toxicity, which might allow the drug to be administered at higher doses than Phenserine. Posiphen is for mild to moderate Alzheimer's patients.

A third drug, BisNorCymcerine, is in late preclinical studies as a potentially symptomatic treatment of moderate to severe Alzheimer's disease.

Axonyx reported a net loss of \$8.2 million for the second quarter of 2005. Its research and development costs for the quarter totaled about \$7.4 million. As of June 30, the company had cash and cash equivalents of \$70.3 million. ■

OTHER NEWS TO NOTE

• **U.S. BioDefense Inc.**, of City of Industry, Calif., received its first stem cell line as a part of an agreement with the University of British Columbia. The company will begin evaluation of the neural crest stem cell line before beginning production of a commercial line that will be available for research use by universities and other biotech companies. U.S. BioDefense also will evaluate the use of this line for human transplantation in collaboration with the FDA. Further development of the cell line could lead to a treatment for brain neurodegeneration and spinal cord repair.

• **VION Pharmaceuticals Inc.**, of New Haven, Conn., initiated a Phase II trial of Cloretazine in small-cell lung cancer. The objectives of the study are to determine the response rate and toxicity of Cloretazine in patients with locally advanced or metastatic small-cell lung cancer who have either not responded to or relapsed following initial treatment for the disease.

• **Vyteris Holdings Inc.**, of Fair Lawn, N.J., said data

from a Phase I study of Actyve transdermal drug technology showed that the product could be used to provide controlled delivery of zolmitriptan in humans. The study compared zolmitriptan pharmacokinetics following transdermal iontophoretic delivery and oral administration. Zolmitriptan is the active ingredient in Zomig, a treatment for migraine.

• **XOMA Ltd.**, of Berkeley, Calif., will collaborate with **Cubist Pharmaceuticals Inc.** to develop new processes to manufacture the two-antibody biologic HepeX-B. The processes are needed to produce enough quantities of the biologic to conduct Phase III trials. XOMA will begin work on the project immediately and will negotiate a longer-term agreement with the Lexington, Mass.-based Cubist. HepeX-B has orphan drug status in the U.S. and the European Union.

• **Zimmer Holdings Inc.**, of Warsaw, Ind., acquired worldwide, exclusive distribution rights for genetically engineered xenogeneic tissues for regenerative therapies from **Revivicor Inc.**, of Blacksburg, Va., which has an advanced transgenic technology platform for the production of tissues, cells and whole organs for therapeutic applications. Zimmer initially plans to develop the technologies for orthopedic applications.