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PAGE 1 OF 7

High Number Of Dropouts Spoil Oxytrex Phase III Trial

By Aaron Lorenzo
Washington Editor

Shares in Pain Therapeutics Inc. lost nearly 20% of their value on news that a Phase III study of Oxytrex was inadequate due to patient dropouts, meaning another trial is in order.

The number of those who completed the osteoarthritis study was lower than expected, and statistical significance was not reached in reducing opioid-related physical dependency, the trial's primary endpoint. The South San Francisco-based company had expected that up to 40 percent of patients would drop out before completing the study's three-month treatment period, but in fact dropout rates were 48 percent to 60 percent in the drug arms and 37 percent among placebo patients.

On Tuesday, its stock (NASDAQ:PTIE) sank \$1.61, or 18.9
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Point Therapeutics Offering Gets \$22.2M For Talabostat

By Randall Osborne
West Coast Editor

Continuing its roughly once-a-month news trend, Point Therapeutics Inc. priced an offering of about 8.1 million shares of common stock at \$3 per share to raise \$24.2 million, with net proceeds expected to total about \$22.2 million.

Boston-based Point's stock (NASDAQ:POTP) closed Tuesday at \$3.53, up 38 cents, or 12 percent.

Word of the stock pricing comes a month after the company started its Phase III program to evaluate the lead product, talabostat, in metastatic non-small-cell lung cancer, and that disclosure came less than a month after details about advances with the Phase II study testing the same drug for leukemia. (See *BioWorld Today*, Oct. 17, 2005.)

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Antitrust Hearing Could Lead To Changes In Merger Review

By Aaron Lorenzo
Washington Editor

WASHINGTON – Mergers and acquisitions are a fact of life in the biotech industry, driving growth and expansion, and even fostering innovation. But the transactions aren't easy to complete, and not simply because financial terms can be hard to agree upon.

In some circumstances, government regulations around M&A activity can prove particularly burdensome. That was the case for Cephalon Inc.'s buyout of CIMA Labs Inc., a transaction that took months to close because of an exhaustive antitrust review by the federal government.

As a result, that deal served as an anecdotal backdrop at a recent hearing held by the Antitrust Modernization Commission, a special committee convened by Congress last year to review current antitrust analysis that is largely

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Nurel, Diamyd Combine GAD Technologies Through Merger

By Jennifer Boggs
Staff Writer

Swedish company Diamyd Medical AB is picking up a gene therapy program involving glutamic acid decarboxylase (GAD) to go along with its protein-based GAD portfolio through its merger with Nurel Therapeutics Inc.

Diamyd will pay Nurel about \$1.5 million in a stock transaction, issuing Nurel shareholders 223,208 Diamyd B

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Holiday notice

BioWorld's offices will be closed on Thursday, Nov. 24, and Friday, Nov. 25, in observance of the Thanksgiving Day holiday in the U.S. No issues will be published those days. The next issue of *BioWorld Today* will be published Monday, Nov. 28.

INSIDE: OTHER NEWS TO NOTE (NICOX GETS €2M FROM PFIZER)2-7

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OTHER NEWS TO NOTE

• **Cell Genesys Inc.**, of South San Francisco, and **Genzyme Corp.**, of Cambridge, Mass., said that Genzyme acquired Cell Genesys' manufacturing operation in San Diego to support the growth of Genzyme's gene therapy programs. Genzyme will pay Cell Genesys \$3.2 million in cash for the assets contained in the 47,000-square-foot leased facilities. Most of the approximately 40 employees formerly employed by Cell Genesys became Genzyme employees.

• **Cellegy Pharmaceuticals Inc.**, of Brisbane, Calif., licensed to **New Harbor Corp.**, under Cellegy's Chinese patent, the rights to develop, manufacture and market a nitric oxide donor product for the treatment of anal disorders. New Harbor will work through Beijing-based **PUMC Pharmaceuticals Co. Ltd.**, which will cover all development, regulatory, manufacturing and marketing costs. Cellegy will receive a royalty on any product sales. Cellegy's Chinese patent was issued in May 2003 and expires in April 2015.

• **ChemoCentryx Inc.**, of Mountain View, Calif., filed an investigational new drug application with the FDA to begin clinical studies of a small-molecule inhibitor of the CCR2 chemokine receptor with which it expects to complete Phase I studies in 2006. CCX915 belongs to a new class of synthetic compounds that are chemically distinct from all known inhibitors of CCR2, the company said.

• **Cubist Pharmaceuticals Inc.**, of Lexington, Mass., reported that it will hire an additional 36 sales professionals for its anti-infective acute care U.S. sales organization. The sales organization will be realigned effective Jan. 1 with the objective of increasing both depth and breadth of coverage prior to the decision by the FDA on a potential label expansion for Cubicin.

• **CyGenics Ltd.**, of Sydney, Australia, intends to investigate the listing of its tissue banking business, predomi-

nantly held under its subsidiary, CordLife Pte. Ltd., on an Asian stock exchange. The listing seeks to raise additional funds for both investment and working capital and would create a second equity position for existing and potential shareholders, the company said. CordLife is a regional cord blood bank that operates a facility in Singapore and a separate facility in Hong Kong.

• **EntreMed Inc.**, of Rockville, Md., said the FDA accepted its investigational new drug application for ENMD-1198, a tubulin-binding agent for which EntreMed intends to pursue clinical development with a Phase I study in 2006. ENMD-1198 is a new chemical entity based on a modified chemical structure of 2ME2 designed to increase antitumor and antiangiogenic properties and improve metabolism.

• **Genesis Bioventures Inc.**, of New York, said its wholly owned subsidiary, Biomedical Diagnostics LLC, in Ann Arbor, Mich., signed an agreement for **Harlan Bioproducts for Science Inc.**, of Indianapolis, to assist in the research and development of monoclonal antibodies for potential use in Biomedical's Mammastatin Serum Assay, a blood test designed to assess women's breast health. Financial terms were not disclosed.

• **Immutep SA**, of Orsay, France, initiated a Phase I trial of its lead product, ImmuFact, IMP321 in metastatic renal-cell carcinoma. ImmuFact IMP321 is a natural human T-cell immunostimulatory factor designed to amplify the T-cell immune response through activation of dendritic cells and more efficient antigen presentation to T cells. It is a single-center, open-label, escalating-dose study.

• **Large Scale Biology Corp.**, of Vacaville, Calif., and **Growers Research Group LLC**, of Soledad, Calif., entered an agreement for GRG to access to LSBC's Geneware plant and gene expression technology to accelerate development of new products for use in agriculture. The companies said the exclusive, worldwide license should enable GRG to discover approaches to crop protection. The agreement also provides an option for commercial rights to Geneware technology that can be negotiated at GRG's request.

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THOMSON



Pain

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percent, to close at \$6.90.

Still, there were encouraging and positive trends in the 775-patient trial, which began in March of last year.

"It's a classic case where the drug worked and the trial failed," Pain Therapeutics President and CEO Remi Barbier told *BioWorld Today*. "Clearly, the clinical effect is here. We saw it, and we've seen it before, in two large trials, animal data and the mechanism of action. Why the heck we did not see it here is just a shame."

Oxytrex, a combination of oxycodone with ultra-low-dose naltrexone, reduced physical dependency by 28 percent compared to an equivalent dose of oxycodone, exceeding Pain Therapeutics' expectation of such a reduction by 25 percent or more, but well below the statistical significance threshold. The trial did hit statistical significance in a subgroup analysis, as Oxytrex reduced physical dependency by 75 percent in patients older than 50 ($p=0.04$).

Barbier said the company chose not to exclude patients younger than 50, though, because of the potential of label restrictions. But he blamed the study's high dropout rate on its inclusion of younger patients, many of whom aren't typical osteoarthritis patients but nonetheless appeared to have enrolled soon after last year's market withdrawal of the COX-2 inhibitor Vioxx (rofecoxib, Merck & Co. Inc.).

"We believe that a fair number of patients who used to be on Vioxx were inappropriately enrolled in our study," he said, "and if Vioxx treats your pain, you're not a good candidate for opioid therapy, and vice-versa."

Still, the study met its pre-defined secondary endpoint, as Oxytrex was non-inferior to oxycodone during the three-month treatment period. Specifically, Oxytrex patients reported slightly better pain relief than oxycodone patients and significantly better analgesia than placebo patients. In contrast, oxycodone did not separate from placebo, given the high dropout rate and placebo response.

However, Barbier acknowledged that another trial would be necessary, although he noted that it wouldn't significantly delay the pain drug's eventual market entry given that required open-label safety studies remain ongoing until the third quarter of next year. He predicted a potential six-month setback.

"I think what we're seeing [with the company's stock drop] today is not so much a reaction to our timelines as much as investors' collective sentiments to the 'P' word – pain," Barbier said. "I think investors are just tired of these pain trials, not just by us, but every pain company out there, which have at one point or another published disappointing trial results."

He attributed negative data to trial design rather than the inability of pain drugs to work. Studies fail to take into

account that a single dose of particular drug works differently for different patients, high placebo effects (especially among younger patients) and difficult side-effect profiles among opioids, he said.

"So when you have no happy dose, large placebo responses and side effects," Barbier said, "it becomes very difficult to prove in a statistically meaningful way the value of a drug."

The just-reported trial was the second of two Phase III studies on which the company planned to file for approval. It enrolled 719 patients with severe, chronic lower-back pain, and those on the investigational drug reported about 50 percent fewer symptoms of physical dependence and withdrawal after stopping high-dose opioid use compared to patients on oxycodone. (See *BioWorld Today*, March 25, 2005.)

Pain Therapeutics plans to talk with the FDA early next year on designing clinical trials and titration studies that pre-screen patients to overcome the statistical limitations imposed by high dropout rates.

"I think this study proves almost definitively that fixed-dose studies rarely work with opioid painkillers," Barbier said, adding that the first Phase III trial of Oxytrex followed a titration design. "Going forward, not just us, but I think the whole industry will be looking toward titration designs."

Pain Therapeutics said the setback would not impede the closing of its recently reported alliance with King Pharmaceuticals Inc., of Bristol, Tenn., and thanks to that deal, Pain Therapeutics expects to move into next year with more than \$200 million in cash. Looking into 2006, the company is eyeing a net cash burn rate of less than \$15 million.

The new agreement with King is related to Remoxy, a long-acting oral oxycodone, and other abuse-resistant opioid painkillers. Terms include an up-front cash payment of \$150 million to Pain Therapeutics, payable upon closing.

Elsewhere in the company, Pain Therapeutics said it remains on track to soon report results of a Phase III trial of PTI-901 in 600 women with irritable bowel syndrome. ■

OTHER NEWS TO NOTE

• **Life Therapeutics Ltd.**, of Sydney, Australia, started an early stage project to develop a specialty immune globulin for influenza. It is a multiyear program to immunize selected donors with the flu vaccine, and collect their hyperimmune blood plasma for use in a therapeutic drug to combat infection caused by the influenza virus. The company expects that a new supply of influenza hyperimmune will be produced each year to combat the latest influenza strain.

Point

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A spokeswoman from Point said the company was in a quiet period and could not comment. But there's no shortage of uses for the cash raised.

The pair of Phase III trials, involving as many as 800 patients at about 100 sites in North America, are giving the drug to patients afflicted with Stage IIIb/IV NSCLC who have failed platinum-based chemotherapy. Results are due at the end of 2007.

In the first study, Point is trying oral talabostat in combination with docetaxel vs. docetaxel with placebo. The second uses the drug in combination with pemetrexed vs. pemetrexed with placebo. Docetaxel and pemetrexed are the current standard of care in that advanced patient population.

Progression-free survival is the primary endpoint in both trials, with secondary endpoints including overall survival, objective response rate, complete response, duration of response and quality of life.

Point has a two-year orphan products development grant of \$600,000 from the FDA to fund its Phase II study of talabostat in combination with rituximab in advanced chronic lymphocytic leukemia. In the first quarter of next year, after finishing the Phase II trial (which completed its first stage in September), the company will decide whether to move into Phase III.

Talabostat, which inhibits DPP enzymes to boost IL-1b

and promote immune response, also is being studied in two Phase II trials against Stage IV melanoma, as a single agent and with cisplatin, with a decision likely at the end of this year whether to start Phase III.

Earlier this month, Point said results of one 42-patient Phase II study in patients with Stage IV melanoma showed that two patients had a response to talabostat, as defined by RECIST (a 30 percent or greater reduction in tumor size), and one of those patients got a complete response. The Kaplan-Meier estimates for single-agent talabostat are 7.1 months for median survival and 1.5 months for median progression-free survival. Results from the trial were presented at the International Society for Biological Therapy of Cancer meeting in Alexandria, Va.

There's more. In June, Point began a Phase II trial with the compound combined with gemcitabine against metastatic pancreatic cancer, which could be the quickest route to approval if the data prove strong enough, but the push for now is on NSCLC.

Last month, Point made public its plan to sell 6 million shares but backed off a week later, citing market conditions. In the priced offering of about 8.1 million shares, which is expected to close Nov. 28, Point has granted underwriters an option to buy up to about 1.2 million more shares to cover over-allotments, if any. Pacific Growth Equities LLC, of San Francisco, is the sole book-runner, with CIBC World Markets Corp., of New York, acting as a co-lead manager. ■

OTHER NEWS TO NOTE

- **MedMira Inc.**, of Halifax, Nova Scotia, closed an equity line financing that would allow it to require Cornell Capital Partners to purchase up to C\$10 million (US\$8.5 million) of MedMira common shares in a series of draw-downs over a 58-month period, which began Nov. 22 and ends Sept. 6, 2010. Share price will be determined at the time of any draw-down. In addition, MedMira agreed to pay a C\$100,000 implementation fee to Cornell at closing by issuing 185,426 shares at C\$0.54 each. MedMira develops in vitro flow-through rapid diagnostic tests designed to detect antibodies in human serum, plasma or whole blood for diseases such as HIV and hepatitis C.

- **Microlslet Inc.**, of San Diego, and Mayo Foundation for Medical Education and Research in Rochester, Minn., entered a long-term strategic supply agreement, under which Mayo will supply Designated Pathogen Free Pigs to Microlslet for use in the development of Microlslet-P, a vialled suspension of microencapsulated porcine islets for transplantation by injection into the abdominal cavity in patients with insulin-dependent diabetes. Under the terms, Mayo will supply substantially all of its nontransgenic pig islet production for a period of three to seven years, and also granted Microlslet exclusive use of its DPF pigs for research and treatment during the term of the agreement. Financial terms were not disclosed.

State Of The Industry Report Looks At Status Of Med-tech

The *Medical Device Daily State of the Industry Report 2005*, a 504-page look at the status of the medical technology sector as of mid-year 2005, is now available.

The book has several overview chapters dealing with activity in the executive/legislative and regulatory arenas, deal-making and financing, and efforts undertaken by industry associations. It also has 15 sector-specific chapters, ranging from Cardiovascular to Women's Health, with a special closing section on Emerging Sectors/Companies.

"This is a substantial compilation of material," said *MDD* Executive Editor Jim Stommen. "Our goal was to provide a snapshot of where the med-tech sector stood as of mid-2005, and I think we have gathered what amounts to an overflowing album showing just that."

Along with BioWorld's *Biotechnology State of the Industry Report 2005*, and *Clinical Trials State of the Industry Report 2005*, these three publications provide a comprehensive view of the health care landscape.

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Antitrust

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carried out these days by the Federal Trade Commission and the Department of Justice. The bipartisan, independent commission includes 12 members who are charged with issuing a final report in the spring of 2007.

"The main question is whether the antitrust laws, some of which are now over 100 years old, are fully capable of addressing these [new economy] industries, which may have somewhat different economic underpinnings than the types of industries in existence when the antitrust laws were first passed," explained Andrew Heimert, the commission's executive director and general counsel. Traditional antitrust analysis includes a measure of skepticism over mergers, given that economic theory says combinations might diminish competition.

The hearing, one of several incorporated into the commission's schedule, included Frazer, Pa.-based Cephalon's senior vice president and general counsel, John Osborn, who emphasized that mergers are an integral part of the life sciences. He asked the commission to consider "whether mergers among some segment of the life sciences industry can have a positive impact on ultimate consumer value by enabling mid-cap or larger-cap firms to bring things to market."

That's assuming, of course, that the buying company already has clinical, medical, regulatory, marketing and distribution resources that the smaller firm lacks, so a merger would allow a smaller company's product to advance more efficiently. In its merger, Cephalon wanted CIMA's then-investigational OraVescent fentanyl product as an add-on to its own already-marketed fentanyl product known as Actiq, acquired by Cephalon a few years earlier. With a pathway already forged by Actiq, Cephalon thought it could progress OraVescent fentanyl more capably than Eden Prairie, Minn.-based CIMA's resources alone would allow.

"Companies the size of Cephalon, or maybe a little smaller or bigger, are looking at these opportunities not to try to monopolize a market but to try to adequately commercialize products and bring them to consumers," Osborn said. "It is one of the underlying premises on which the industry is built."

But the antitrust review process established under the Hart-Scott-Rodino Act "almost by definition creates a burden on the companies that are proposing a merger to demonstrate that there is no anticompetitive impact," Osborn added, and antitrust regulators viewed the acquisition more conservatively, only allowing the deal to move forward after Cephalon out-licensed Actiq's rights to Barr Laboratories Inc., of Woodcliff Lake, N.J.

Osborn, who acknowledged that while "our experience didn't seem to be a particularly good one," stressed that his testimony was not meant to rehash those happenings but rather to lend perspective on behalf of the industry. "I can't believe that we're the only firm that has had this sort of

review issue," he said, adding that while divestiture compromises might sometimes be appropriate (such as in large-cap mergers), in other circumstances (such as those involving one-product companies) divestitures undermine the purpose of the merger. Osborn also noted that antitrust reviewers' tendencies to broadly exercise caution on approving prospective mergers has led to "risk-avoidance behavior" and an accompanying failure "to examine whether there might be pro-consumer benefits" by defining product markets too narrowly.

"And if this continues over time," he said, "I think you will start to see firms question whether or not it's really worth doing these things."

At the hearing, several commissioners talked about the possibility of issuing more explicit guidelines to the government's antitrust review agencies, which Osborn said "could include some recognition of the value in certain cases of mergers."

Such advice is one possible outcome of the commission's work, said Heimert, who added that final recommendations could call for explicit legal changes, suggestions or no changes at all. The final report will go to Congress and the president and will contain the commission's findings and conclusions, along with recommendations for legislative or administrative action. Heimert said both the House and Senate seem hopeful for a report to provide a basis for antitrust law updates, and the commission could advocate legislative change by way of specific statutory language or recommendations on ideas with which to amend existing laws. The commission also might recommend ways for the two primary antitrust review agencies to improve their work, including guidance that would either be specific or more broadly suggestive.

Osborn said he hoped that in the end, the commission's recommendations lead to "a slightly more balanced review when the agencies are considering issues like product market definition and the likelihood and impact of product entry by other third parties.

"We're not gobbling up potential competitors," he concluded. "We're trying to acquire products that we believe have great potential, but might not otherwise reach that potential if they remain in the hands of the smaller, less-developed firm." ■

OTHER NEWS TO NOTE

• **Migenix Inc.**, of Vancouver, British Columbia, a developer of drugs for infectious and degenerative diseases, initiated enrollment in a Phase IIb combination therapy clinical trial of celgosivir, supported in part through an agreement with Schering-Plough. Celgosivir is an orally administered, first-in-class alpha glucosidase I inhibitor, in development for the treatment of chronic hepatitis C virus infections. Results of the study are expected in mid-2006.

Nurel

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shares valued at SEK55 (US\$6.80) each, representing a 15 percent premium to the closing price on Nov. 21. Diamyd also will issue an additional 110,000 shares against convertible loans previously used to finance Nurel.

The deal "primarily came about because of complementary technologies," said Michael Christini, CEO of Pittsburgh-based Nurel, specifically the work both companies have done using their GAD platforms.

Founded in 2003 by Christini and University of Pittsburgh professor Joseph Glorioso, Nurel develops products based on a drug-delivery technology derived from an inert herpes simplex virus, designed to deliver therapeutic proteins through local injections into the peripheral nervous system. A single injection is intended to deliver medicine over a period of months.

The company's lead product, NG2 (HSV-GAD) is in late-stage preclinical development for the treatment of chronic pain due to diabetes. The product could work well with Diamyd's platform, which is developing compounds targeting GAD65 to treat diabetes. That product has completed a Phase II study and is being evaluated in an ongoing Phase II/III trial in Type II diabetic patients.

Diamyd therapies are "protein-based to treat diabetes, while ours is a gene-based therapy that's intended to treat complications from diabetes," such as neuropathy and nerve degeneration, Glorioso said. So the two companies' products are a "good fit in terms of patients."

NG2 is expected to enter the clinic within the next 18 months. Behind it, Nurel has a second product aimed at protecting nerve cells from degradation caused by diabetes.

The advantage of using the inert herpes virus to administer the therapeutic is that the product is delivered locally, without leading to some of the systemic toxicities seen in protein-based drug candidates. The virus also is engineered to prevent replication, so the number of viral particles in the body does not suddenly increase.

Early studies have shown that the product "blocks pain in animal models for several weeks," Christini told *BioWorld Today*.

In addition to diabetic neuropathy, Nurel's early candidates also have been investigated in models of pain caused by spinal cord injury.

Development of another Nurel compound, NC3, a cancer drug targeting glioblastoma multiforme, is being supported with grant funding. Nurel has received \$1.4 million in federal money to help with Phase I trials for that product, the first of which is scheduled to begin in 2007.

To date, Nurel's financing has come from convertible debt funding from Pittsburgh-based investment firms, such as UPMC Health Ventures, Innovation Works, and support from the Pittsburgh Life Sciences Greenhouse, a public/private partnership aimed at building the life science industry.

Nurel outsources its work, relying heavily on its relationship with the University of Pittsburgh, which handles "engineering for our gene therapy products, and has an established facility of animal models, particularly in neuropathic pain and spinal cord pain," Christini said.

At the close of the deal, Nurel's office in Pittsburgh is expected to remain operational, with Christini at the helm. Glorioso will stay on board in a consulting role to continue working on the science.

Diamyd will retain its corporate headquarters in Stockholm.

The merger is expected to have little effect on Diamyd's financial position, and the company said it anticipates little change to its burn rate.

For the three months ending Aug. 31, Diamyd reported a net loss of SEK11.9 million, or SEK1.3 per share. The company ended the quarter with cash, cash equivalents and short-term investments totaling SEK115.5 million.

Shares of Diamyd, listed on the Stockholm Stock Exchange (OMX:DIAMB) rose SEK1.30 Tuesday to close at SEK48.50. ■

OTHER NEWS TO NOTE

- **Myriad Genetics Inc.**, of Salt Lake City, and **Abbott Laboratories**, of Abbott Park, Ill., extended their strategic alliance in pharmacogenetics to focus on identifying human genetic variation around drug targets in various stages of development. Abbott will fund the research, and Myriad will use its high-throughput sequencing technologies and mutation screening software to analyze samples from various populations to identify genetic polymorphisms. Results of the collaboration could assist Abbott's drug discovery program. Financial terms were not disclosed.

- **Neose Technologies Inc.**, of Horsham, Pa., received a milestone payment from **Novo Nordisk A/S**, of Bagsvaerd, Denmark, under the license agreements entered in November 2003 to use Neose's GlycoPEGylation technology to develop next-generation versions of three marketed therapeutic proteins. It is the second of the three proteins Novo is developing using the Neose technology for which a milestone payment has been received.

- **Neurobiological Technologies Inc.**, of Emeryville, Calif., enrolled the first patient in the first of two Phase III studies of Viprinex (ancrod) Injection in patients with acute, ischemic stroke. The two trials are expected to run concurrently and will enroll 650 patients each. The primary endpoint of the first trial is the proportion of patients alive and independent in day-to-day functions at 90 days, as measured with the Barthel Index, while the second trial will evaluate function using the dichotomized modified Rankin Scale as the primary endpoint. (See *BioWorld Today*, Aug. 23, 2005.)

OTHER NEWS TO NOTE

• **Neurochem Inc.**, of Laval, Quebec, enrolled the first patient in its European Phase III trial of Alzhemed (3-amino-1-propanesulfonic acid, 3APS) for the treatment of Alzheimer's disease. The study is designed to investigate the safety and efficacy of the drug in 930 mild to moderate AD patients randomized to receive either Alzhemed or placebo over an 18-month treatment period, in addition to regular treatment with one of a number of acetylcholinesterase inhibitors. Meanwhile, the company is continuing its North American Phase III study of Alzhemed, following the third positive recommendation from the independent safety review board on the safety and tolerability of the drug. Enrollment in that trial recently completed, with 1,052 patients at centers in the U.S. and Canada. (See *BioWorld Today*, June 22, 2004.)

• **NicOx SA**, of Sophia Antipolis, France, said New York-based **Pfizer Inc.** selected a development candidate from the companies' collaboration focusing on nitric oxide-donating compounds in ophthalmology. Under the terms, Pfizer will pay €2 million (US\$2.3 million) to NicOx, in exchange for an exclusive worldwide license to NicOx compounds. Including the recent payment, NicOx has received a total of €4 million in connection with this agreement, and stands to receive an additional €33 million, plus royalties.

• **Oscient Pharmaceuticals Corp.**, of Waltham, Mass., submitted a supplemental new drug application for use of Factive (gemifloxacin mesylate) tablets (320 mg once daily) for the five-day treatment of acute bacterial sinusitis, and five-day treatment of mild to moderate com-

munity-acquired pneumonia (CAP). Factive is approved for the five-day treatment of acute bacterial exacerbations of chronic bronchitis and seven-day treatment of mild to moderate CAP.

• **Peregrine Pharmaceuticals Inc.**, of Tustin, Calif., said that its wholly owned manufacturing subsidiary, Avid Bioservices Inc., entered a manufacturing agreement with the Sidney Kimmel Cancer Center in San Diego. Avid will provide process development services to SKCC and will perform cGMP manufacturing of a therapeutic antibody for preclinical studies and clinical trials. The antibody is initially being tested for lung cancer.

• **PharmaMar SA**, of Madrid, Spain, said data from two research projects show that patients with a defined pattern of tumor DNA repair efficiency have a higher probability of better survival, which is expected to affect the optimization of Yondelis in studies in solid tumors. Results also showed molecular evidence that correlates extreme in vitro sensitivity to Yondelis with mutation of the *p53* gene. Yondelis is a marine-derived compound in development to treat soft-tissue sarcomas and ovarian cancer. The data were presented at the 11th annual Connective Tissue Oncology Society meeting in Boca Raton, Fla.

• **Sinovac Biotech Ltd.**, of Beijing, said the China State Food and Drug Administration approved the start of clinical trials for its pandemic influenza (H5N1) vaccine. The regulatory authority fast-tracked Sinovac's application in October in response to a potential avian flu pandemic, and cut the clinical trials process from three to two. Building on safety data from preclinical testing, scientists will use clinical trials to further examine safety and immunogenicity in humans, and to establish the ideal dosage and immunization schedule. Preliminary testing for the first clinical stage is expected to take about three months.

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