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## Preparing To File Satraplatin NDA, GPC Brings In \$44M

**By Jennifer Boggs**  
Staff Writer

Four months after GPC Biotech AG's satraplatin met its endpoint in a pivotal prostate cancer study, the company pulled in €33.6 million (US\$43.7 million) to pave the way for the compound's anticipated commercialization.

"We're working very hard to complete the [new drug application] filing as soon as possible," said Laurie Doyle, director of investor relations and corporate communications for GPC. FDA submission is expected "in the next few weeks," she added. If the NDA succeeds in gaining priority review, the agency could reach a decision around the middle of the year, and pending approval, satraplatin "could be on the market shortly thereafter."

Satraplatin, an oral platinum-based compound, demonstrated highly statistically significant results over placebo

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## Renovis Cuts Staff As Focus Moves To Preclinical Programs

**By Jim Shrine**  
Staff Writer

Renovis Inc. is reducing its staff by 40 percent in a move to trim costs following the Phase III failure of its lead compound nearly three months ago.

The South San Francisco-based company was left with no products in clinical development when its neuroprotectant compound NXY-059 (Cerovive) failed to demonstrate efficacy in the 2,300-patient SAINT II Phase III trial in stroke. Partner AstraZeneca plc ended development of the product following those results. Renovis had ended clinical development of two earlier-stage clinical compounds in 2005.

Renovis President and CEO Corey Goodman told *BioWorld Today* that the company ended 2006 with nearly \$100 million in cash – enough to fund operations at least

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*The Contractile Dynamic Duo*

## Paper Recasts Alzheimer's As Cardiovascular Disorder

**By Anette Breindl**  
Science Editor

A paper in the Jan. 16, 2007, issue of the *Proceedings of the National Academy of Sciences* casts Alzheimer's disease against type – as a cardiovascular disorder at its root.

Reduced blood flow is a well-known symptom of Alzheimer's disease, but that is viewed as an effect of the disorder.

Senior author Berislav Zlokovic described the prevailing opinion as "well, the brain is atrophying because of the disease, so not as much blood as usual is needed." But he believes that the opposite cause-and-effect relationship is true: "The brain [may be] dying because of the reduced blood flow."

The scientists studied the role of two cardiovascular proteins, serum response factor, or SRF, and myocardin,

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## New WARF Stem Cell Rules To Benefit Biotech Research

**By Aaron Lorenzo**  
Washington Editor

Embryonic stem cell research should advance a bit more freely because of policy changes announced this week by a major patent holder in this area, the Wisconsin Alumni Research Foundation (WARF). The move could clearly benefit biotech companies and possibly negate for now some criticism that the organization has endured.

"It creates a little more comfort in academic research institutions," explained Tom Quinlan, an attorney in the San Francisco office of Reed Smith LLP. He added that the new guidelines would provide "an increased opportunity to get research going or continue." It also would delay questions on "whether the WARF patents are going to continue to be challenged or should have been issued in the first place," he added.

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## GPC

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in progression-free survival as a second-line chemotherapy treatment in 950 hormone-refractory prostate cancer patients.

Data from that Phase III study showed that patients receiving satraplatin in combination with prednisone had a 40 percent reduction in the overall risk of disease progression compared to those receiving prednisone plus placebo. (See *BioWorld Today*, Sept. 26, 2006.)

With those results in hand, "we were really able to accelerate the building of a commercial infrastructure in the U.S.," Doyle told *BioWorld Today*. The recent financing "will assist us in aggressively moving forward with those commercialization activities and, in addition, allow us to expand the development of satraplatin in other cancer settings."

GPC privately placed about 1.6 million shares priced at €21.50 each with institutional investors. Those shares, following the placement, represent about 4.5 percent of GPC's total shares outstanding.

The company, which reported a cash position of €114 million as of Sept. 30, was "pretty well funded" prior to the latest financing, Doyle said. "This extra amount will keep us going for a good chunk of time and help us continue to move forward with satraplatin."

More money is expected to come into GPC later this year by way of a milestone payment triggered by the acceptance of a marketing authorization application for satraplatin in Europe by marketing partner Pharmion Corp., as per the companies' potential \$270 million licensing agreement signed in 2005. Pharmion, of Boulder, Colo., anticipates filing for European approval sometime in the second quarter. (See *BioWorld Today*, Dec. 21, 2005.)

GPC retains marketing rights to satraplatin in the U.S., as well as Asian territories, including Japan, though Doyle said the company is not planning to handle any ex-U.S. commercialization itself.

Recently, Spectrum Pharmaceuticals Inc., which licensed satraplatin to GPC in 2002, filed a demand for arbitration against GPC alleging that the company has not used "commercially reasonable efforts" to gain regulatory approval of the product in Japan, and asked to be reimbursed for €9 million in past development expenses. In response, GPC said claims made by Waltham, Mass.-based Spectrum are without merit and denied that it defaulted on any obligation under the licensing agreement.

Pending approval in all territories, worldwide sales of satraplatin are estimated to reach about \$500 million in annual peak sales, Doyle said, and GPC also is investigating the compound in other indications, such as non-small-cell lung cancer.

The company has an ongoing Phase II study of satraplatin in combination with Taxol (paclitaxel, Bristol-Myers Squibb Co.) in patients with NSCLC and another ongoing Phase II study of satraplatin plus Tarceva (erlotinib, Genentech Inc. and OSI Pharmaceuticals Inc.) in elderly NSCLC patients.

Behind satraplatin, GPC is working to advance its early stage pipeline of internally discovered compounds, starting with ID09C3, a monoclonal antibody aimed at treating relapsed or refractory B-cell lymphomas, such as non-Hodgkin's lymphoma and chronic lymphocytic leukemia. That product is in Phase I testing, and preliminary results presented last month at the American Society of Hematology meeting in Orlando, Fla., suggested that ID09C3 is well tolerated, with hints of antitumor activity observed in two patients.

"We hope to finish Phase I around the middle of the year," Doyle said, with plans to begin a Phase II trial shortly after that.

GPC, which is based in Martinsried, Germany, with offices in Waltham, Mass., and Princeton, N.J., also has an "active discovery group," she added, with a focus on kinase inhibitors for multiple cancer indications.

Shares of GPC (NASDAQ:GPCB) closed at \$28.60 Wednesday, down 22 cents. ■

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## Renovis

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through 2009. That gives it a number of options going forward, the first of which is moving its late-stage preclinical compounds into human trials, he said.

"By significantly reducing our burn, we have the cash to take these programs into the clinic and get proof-of-concept data before we'd have to raise money again," Goodman said. "It puts us in a position of strength. We are in control of our own destiny in taking these forward."

Goodman did not discount other strategic options, such as finding a merger partner, in-licensing compounds, out-licensing preclinical programs or other arrangements. "All those things are on the table," he said, and will be evaluated in terms of what is best for shareholders and building value.

Renovis had about 115 employees when the SAINT II trial data were released. It now will have about 70. It expects to take a restructuring charge of about \$1 million this quarter.

Its stock (NASDAQ:RNVS) fell 70 percent Oct. 26 on the SAINT II data, to close at \$3.43. It gained 17 cents Wednesday to close at \$3.62.

The nearest-term clinical program at Renovis is from its collaboration with Pfizer Inc. focused on vanilloid receptors (VRI). Renovis said Pfizer is on track to initiate clinical development this year on that program, which initially targets pain and urinary incontinence. Behind that Renovis has the unpartnered programs P2X7 and P2X3, antagonists of purinergic receptors, scheduled to enter the clinic in 2008. And Renovis has a collaboration with Genentech Inc. on another preclinical program.

Bret Holley, an analyst at CIBC Work Markets Corp., said the staff reductions at Renovis did not come as "that big of a surprise. The company's timelines for commercialization are a lot longer now. That [SAINT II trial result] significantly changed the profile of the company."

Its cash position gives Renovis some breathing room, Holley said. "They can make a lot of progress internally if they decide to go that route, but strategic options are always open to a biotech company."

Mark Monane, an analyst at Needham & Co. LLC, suggested one such option at Renovis would be exploration of merger opportunities. "Rather than in-license late-stage compounds, we believe management is more likely to explore an M&A route to expand the company's pipeline," he wrote in a research note. "In the meantime, Renovis plans to pursue development of [the] three preclinical programs."

Work with Pfizer focuses on developing small-molecule inhibitors of vanilloid receptor 1 for treating inflammatory pain, neuropathic pain, urinary incontinence and other disorders. Renovis got \$10 million up front and \$7 million in research funding from that May 2005 collaboration, which also could yield up to \$170 million to Renovis in milestone payments per product, plus low-double-digit royalties on resulting sales. (See *BioWorld Today*, June 1, 2005.)

One internal program at Renovis is development of

antagonists of the P2X3 purinergic (ATP) receptor, which it expects will have applications in treating chronic, persistent pain. Another is on inhibition of P2X7, a potential target in inflammatory disease that could yield compounds for rheumatoid arthritis, inflammatory bowel disease and chronic obstructive pulmonary disease. Renovis said it has selected a clinical candidate from the P2X7 program and plans to begin investigational new drug application-enabling studies in the first half of this year.

The deal with Genentech dates to late 2003, and focuses on development of therapeutics in the areas of angiogenesis and nerve growth. Most of the effort in that program now is Genentech's development of monoclonal antibodies for cancer that inhibit angiogenesis, which could complement its Avastin franchise. Renovis is entitled to modest milestone and royalty payments on resulting products, Goodman said. Renovis also has certain rights in that collaboration to develop products in the area of nerve growth. ■

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## OTHER NEWS TO NOTE

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• **Affymetrix Inc.**, of Santa Clara, Calif., and the Vanderbilt-Ingram Cancer Center in Nashville, Tenn., have entered into a three-year translational research collaboration to analyze genomic information across a large number of patient samples. Researchers at Vanderbilt-Ingram and Vanderbilt University Medical Center will use Affymetrix GeneChip microarray technology to develop new applications for translational research. The Affymetrix Human Mitochondrial Resequencing Array 2.0 will be used as a research tool to identify genetic variants that may make some patients more susceptible to adverse effects of certain drugs. The results of the study potentially will help clinicians select the most appropriate drug therapy for each patient, avoiding those most likely to cause toxicity. Such a tool could have applications for HIV/AIDS treatment in both affluent and resource-limited settings, and for other diseases.

• **Allon Therapeutics Inc.**, of Vancouver, British Columbia, has received funding from The Michael J. Fox Foundation for Parkinson's Research to evaluate the effectiveness of Allon's lead drug, AL-108, in pre-clinical models of Parkinson's disease. Gordon McCauley, president and CEO of Allon, said the preclinical studies will start immediately and, if successful, Allon could begin a Phase II clinical trial to evaluate the drug's effectiveness in patients as early as 2008. AL-108 has been shown in preclinical animal studies to prevent deterioration of neurons through interaction with tubulin, the protein that forms microtubules. Assembly of microtubules is essential for the ongoing regeneration of the nervous system and for combating neurodegenerative diseases. AL-208 also is being evaluated in a Phase II trial to prevent and treat the mild cognitive impairment that commonly occurs after coronary artery bypass graft.

## Alzheimer

*Continued from page 1*

which are the chief regulators of arterial contraction. The scientists found that both are overexpressed in tissues from patients with late-stage Alzheimer's disease.

"We don't know exactly why," Zlokovic told *BioWorld Today*, adding that hypoxia or a genetic polymorphism are just two possibilities. But the result is clear. "Blood flow regulation is disrupted." And that disruption, in turn, may be a contributing factor in the dementia that makes Alzheimer's so devastating. "Normally, with attention there is an increase in blood flow to parts of the brain," Zlokovic explained. But with high levels of myocardin and SRF, blood vessels are no longer able to dilate to accommodate blood flow. And that state of affairs "doesn't support brain function."

The work was done by Zlokovic, a professor of neurological surgery, and his colleagues from Rochester, N.Y. biotech start-up Socratech Research Laboratories, the University of Rochester Medical School in Rochester, N.Y., and the State University of New York at Stony Brook.

The researchers first did tissue studies and found that both myocardin and SRF genes are more highly expressed in vascular smooth muscle cells from the brains of Alzheimer's patients than in control brains, and that such high expression led to arterial wall muscles contracting more than usual.

The scientists next did in vivo studies – a somewhat challenging task in this case. Knockouts lacking either gene never make it past early embryonic development, since they have severe cardiac abnormalities, and overexpressing the Srf gene is lethal for the same reason.

Zlokovic and his colleagues got around that by delivering genes to the brain surface via a cranial window, which, as Zlokovic explained, is "not gene transfer to the brain itself" but targets the blood vessels on the brain surface.

Using that technique they found that when either gene was expressed more strongly than usual, blood flow in the brain was reduced, much like it is in Alzheimer's disease. Conversely, when they used short hairpin RNAs to silence SRF, the phenomenon was reversed, and blood flow increased.

Exposing cells to A-beta peptides, which form amyloid plaques, did not lead to increased expression of serum response factor, suggesting that increases in blood vessel contractility cause the protein accumulations, rather than the other way around. The technology has been licensed to Socratech LLC, a spinout from the University of Rochester where Zlokovic is chief scientific officer.

The company, which Zlokovic said has identified gene targets and currently is doing high-throughput screening to find molecules that are active against those targets, is focused on new treatments for Alzheimer's and stroke. ■

## OTHER NEWS TO NOTE

- **BioServe Biotechnologies Ltd.**, of Laurel, Md., entered an agreement to perform DNA purification and genotyping on tissue samples collected from 750 school children in Chennai, India, who have been exposed to lead pollutants. The effort is part of a study by Harvard University and the University of Michigan on how genetics and environmental lead pollution interact to affect children's intellectual and behavioral functioning.

- **Celgene Corp.**, of Summit, N.J., filed a lawsuit in the U.S. District Court of New Jersey seeking to prevent Woodcliff Lake, N.J.-based **Barr Laboratories Inc.**, a subsidiary of Barr Pharmaceuticals Inc., from proceeding with the commercialization of a generic version of Celgene's Thalomid (thalidomide) capsules, 50 mg, 100 mg and 200 mg. Barr filed an abbreviated new drug application for the generic version in September 2006, claiming that the patents protecting Thalomid from generic competition are invalid, unenforceable or not infringed by Barr's product.

- **Crucell NV**, of Leiden, the Netherlands, received a €2.4 million (US\$3.1 million) grant from the European Union to advance the development of a two-component pediatric malaria vaccine. The funding, which was awarded to a Crucell-led consortium of six universities and companies in the field of malaria research, will finance preclinical studies.

## CLINIC ROUNDUP

- **Addex Pharmaceuticals SA**, of Geneva, began a double-blind Phase IIa study in the U.S. of ADX10061 for smoking cessation. Smokers will receive the drug or placebo for seven weeks, with counseling. Endpoints include abstinence measures, nicotine craving and withdrawal, and mood scores. ADX10061 is a selective antagonist of the dopamine D1 receptor.

- **Lexicon Genetics Inc.**, of The Woodlands, Texas, began a Phase I trial of LX1031, an oral drug candidate for irritable bowel syndrome and other gastrointestinal disorders. The single-dose trial will evaluate safety, tolerability and pharmacokinetics in 40 healthy volunteers, and is expected to be followed by a similar trial evaluating multiple doses. LX1031 is designed to act locally in the gastrointestinal tract by reducing the serotonin available for receptor activation.

- **Merck Serono**, of Geneva, a unit of Merck KGaA, began the Phase II ONWARD trial to evaluate oral cladribine added to a new formulation of the multiple sclerosis product Rebif for treating MS patients with active relapsing disease. The two-year trial in the U.S. and Europe will evaluate the combination in 260 MS patients who have experienced at least one relapse while taking Rebif (interferon beta-1a). Oral cladribine already is being evaluated as a monotherapy in a fully enrolled Phase III pivotal trial (the CLARITY study) for first-line treatment of relapsing forms of MS. The new formulation of Rebif is under review by regulatory authorities in Europe, the U.S. and elsewhere.

## Stem Cells

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Those thoughts were echoed by John Wetherell, a lawyer in the San Diego office of Pillsbury Winthrop Shaw Pittman LLP. He told *BioWorld Today* that the new policies would enhance stem cell research and also “should eliminate conflict” between WARF and its critics.

WARF, the technology transfer arm of the University of Wisconsin in Madison, has made three specific licensing changes “to move the science forward,” said Andy Cohn, its director of government relations and public relations, by increasing opportunities for private funding and collaboration. “We certainly have heard from universities that this change would be helpful,” he told *BioWorld Today*. “They are our customers, and we’re listening to our customers.”

First, WARF will no longer charge license fees for industry-sponsored research at academic or nonprofit institutions, regardless of location and intellectual property rights passing from the research institution to the company. That removes a high-cost hurdle to companies, some of which WARF had been charging up-front and annual maintenance payments that totaled well into six figures for funding academic lab research.

Up to now, the industry has been slow to bend to such tripartite agreements, considering the high cost of doing business with WARF on what essentially amounts to basic research, several years before commercialization efforts come into play. So there has been little industry-sponsored research on embryonic stem cells in the U.S., due in part to those fees but more so the result of President Bush’s limits on federal funding for the research. So instead, those activities have moved overseas, where the patents hold no clout and more government backing is available.

Of course, returning stateside with therapies developed overseas but based on discoveries underlying the WARF patents would bring some sort of license back into play, Quinlan told *BioWorld Today*. The patents expire in 2015.

Some industry sources told *BioWorld Today* that the new policy doesn’t go far enough – WARF said companies still will need a license when they want to conduct internal research, which potentially is debatable given recent Supreme Court rulings on patent law, or develop a product for the market. But those same critics nonetheless feel that the overall bent of the change in attitude represents a positive step.

Cohn said 15 companies have licenses to its patents, along with more than 365 academic groups. He said commercial license costs are variable, while independent researchers pay nothing more than \$500 for processing and delivering cells.

Another new WARF policy should allow California’s state-funded embryonic stem cell organization, the California Institute for Regenerative Medicine, to move forward without worrying about WARF challenges. Previously, WARF

planned to charge the California agency for using its patents because the state expected to generate royalties from groups to which it grants money: 25 percent from universities and nonprofit institutions on commercial applications, and a lower but not yet determined figure for companies’ commercial products. That prompted a good deal of opposition and has led the U.S. Patent and Trademark Office to re-examine the WARF patents.

Now WARF has acquiesced, indicating that it will not press the California institute to remit any payments received from its grantees. Lastly, WARF is changing the cell transfer provisions in its academic and commercial licensing to allow easier and simpler cost-free cell transfers among researchers.

The intellectual property held by WARF includes three broad patents related to a method to isolate and define human embryonic stem cells discovered by a researcher at the school, James Thomson. Should the ongoing re-examination process uphold the patents – a decision that Quinlan said could come later this year – it’s possible that a court challenge could then arise, another tack to question their validity. Wetherell speculated that the less-restraining policies “will make it less likely” that such litigation would arise.

Many detractors believe that WARF has long been too restrictive in all those research areas, and essentially greedy, hampering progress on embryonic stem cells. The more cynical among them believe WARF is opening its doors a bit to foster the science before it misses potential commercial opportunities.

But outside of feelings about WARF, many with interests in advancing embryonic stem cells believe there remains the aforementioned White House obstacle. Sean Tipton, president of an organization called the Coalition for the Advancement of Medical Research, called WARF’s new policies “a positive development” for broadening research opportunities and noted that such scientists “are doing their best” working within the confines of “a fundamentally flawed system.”

Senate passage of a bill to circumvent the president’s restrictions is expected next month, following on the House of Representatives’ vote in favor of such legislation two weeks ago. ■

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## OTHER NEWS TO NOTE

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• **Durect Corp.**, of Cupertino, Calif., amended its development and commercialization agreement with **Voyager Pharmaceutical Corp.**, of Raleigh, N.C., related to Memryte, an investigational drug for Alzheimer's disease. Going forward, Durect will receive a royalty rate ranging from 10 percent to 14 percent of net sales, double the original amount, and also would receive 10 percent of any up-front, milestone and other fees received by Voyager, should it sublicense the product. In return, Durect will pay Voyager \$1 million in cash and forgive about \$725,000 that was owed for previously provided services. Memryte is based on Durect's Durin biodegradable implant technology.

• **Inflazyme Pharmaceuticals Ltd.**, of Vancouver, British Columbia, has entered into a private placement agreement to issue 17.6 million units at \$0.17 per unit for gross proceeds of C\$3 million (US\$2.54 million). The company expects the placement to close within three business days. Each unit will comprise one common share of Inflazyme stock and one-half of one share purchase warrant. Each whole warrant will have a 12-month term from the date of closing and an exercise price of \$0.29 per share. The private placement is a nonbrokered deal and is subject to TSX and any other regulatory approvals. Inflazyme is currently on track to report on two sets of clinical results this quarter. The first is the results of the Phase IIb asthma study with IPL512,602 in moderate to severe asthma. The company announced completion of patient enrollment in the study Nov. 8, 2006. The second set of clinical results will be the Phase IIa proof-of-concept study with IPL455,903 in Age-Associated Memory Impairment. This study is being conducted and paid for by Helicon Therapeutics of New York under a limited license agreement. Helicon has advised Inflazyme that the results of this trial will be available this quarter.

• **Isis Pharmaceuticals Inc.**, of Carlsbad, Calif., completed a private debt placement of \$125 million worth of 2 5/8 percent convertible subordinated notes due 2027, and issued an additional \$37.5 million of such debt pursuant to the purchasers' full exercise on additional notes. The company plans to use its \$157.6 million in net proceeds to repurchase, retire or repay its existing 5.5 percent convertible subordinated notes due 2009, of which \$125 million remains outstanding. Isis already has agreed to repurchase about \$44.1 million of that total, and intends to use its remaining proceeds for general corporate and working capital purposes.

• **Molecular Insight Pharmaceuticals Inc.**, of Cambridge, Mass., entered a worldwide, exclusive licensing agreement with Basel, Switzerland-based **Novartis Pharma AG** to develop and sell Onalta (previously known as OctreoTher or Y-90 SMT-487), a radiolabeled peptide, for

metastatic pancreatic neuroendocrine and carcinoid tumors in patients whose symptoms are not controlled by somatostatin analogue therapy. Onalta is intended to complement Azedra, the company's other clinical-stage radiotherapeutic candidate for neuroendocrine tumors. Under the terms, Molecular Insight will pay Novartis a licensing fee, plus additional payments upon completion of certain regulatory milestones. Novartis will receive royalties upon the product's commercialization. The deal marks Molecular Insight's second in-licensing this month. The company previously acquired rights to Solazad, a small-molecule benzamide compound for melanoma tumors, from Berlin-based Bayer Schering AG. (See *BioWorld Today*, Jan. 18, 2007.)

• **Neurocrine Biosciences Inc.**, of San Diego, was awarded a grant from The Michael J. Fox Foundation to study the potential neuroprotective effects of adenosine A2A receptor antagonists in models of Parkinson's disease. Neurocrine will evaluate the neuroprotective effects of A2A antagonists in preclinical models of Parkinson's disease, specifically to assess their potential to modify early disease progression. This may also help guide the preclinical selection of drug candidates in which both symptom relief and neuroprotective actions have been optimized. A2A receptor antagonists have been shown to be effective at relieving symptoms in preclinical models of Parkinson's disease and in clinical trials with Parkinson's disease patients.

• **Proneuron Biotechnologies Inc.**, of Los Angeles, has initiated a program to develop Proneuron's PN277 neurorestorative therapy for Parkinson's disease. The Michael J. Fox Foundation for Parkinson's Research is providing \$430,000 for the project under its Therapeutics Development Initiative. The goal is to examine PN277's ability to prevent degeneration of dopaminergic neurons and to reverse dopamine loss in relevant preclinical models. PN277 is an oligopeptide that has been found to have significant immune-mediated neurorestorative activities. PN277 is being developed by Proneuron to treat various CNS disease conditions, of which ischemic stroke is in the most advanced state. PN277 already completed most required studies in support of a planned Phase I study for stroke. Company representatives have met the FDA to present its pre-IND file, and the company intends to pursue a Phase I study during 2007.

• **The Medicines Co.**, of Parsippany, N.J., said it will not proceed with its pending public offering due to prospective administrative activity that might occur in the near term regarding the company's application for an extension for the principal patent covering Angiomax (bivalirudin). At this time, the company said, it does not know whether any action will be taken, or whether such action would be favorable or unfavorable. The Medicines Co. had planned to sell 6 million shares, which would have raised about \$200 million. Shares of the company (NASDAQ:MDCO) dropped \$1.16 on the news Wednesday, to close at \$29.25.



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