

# BIOWORLD® TODAY

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## InterMune Divesting Infergen For \$135.5M, Cuts Work force

**By Randall Osborne**  
West Coast Editor

Six months after selling its anti-infective drug Amphotec to Three Rivers Pharmaceuticals LLC, InterMune Inc. has agreed to dispense U.S. and Canadian rights to its hepatitis C compound Infergen to Valeant Pharmaceuticals International Inc. for about \$135.5 million in cash.

Dan Welch, president and CEO of Brisbane, Calif.-based InterMune, said the latest move came as a result of having too many opportunities and not enough money to pursue them all.

"We had alternatives," he said. "We could go out and raise a great sum of money that would be highly dilutive to shareholders, and/or partner pifenedone [the Phase III compound for idiopathic pulmonary fibrosis] and the protease inhibitor [in preclinical study also for HCV]. Or we  
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## Axonyx Pins Partnering Hopes On Better Phenserine Findings

**By Aaron Lorenzo**  
Washington Editor

Still hoping to find a partner for its Alzheimer's disease drug Phenserine, Axonyx Inc. released positive data supporting further studies at higher doses that could spark a deal.

"It's really the [total] data package that we will have available that should be of interest to [potential partners]," Colin Neill, the company's chief financial officer, told *BioWorld Today*. "What the new data show, really, is that the drug potentially can work."

The results stem from an additional analysis of two curtailed Phase III trials of the selective acetylcholinesterase inhibitor, which has been in development for mild to moderate forms of the neurodegenerative disease. Those studies, labeled AX-CL-09 and AX-CL-010, had  
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## Series A Brings CeNeRx \$18.5M For Depression, Anxiety Drugs

**By Jennifer Boggs**  
Staff Writer

Within the last month, start-up firm CeNeRx BioPharma Inc. in-licensed a series of compounds aimed at central nervous system disorders and raised \$18.5 million in its first financing round.

The Series A round was led by New York-based Perseus-Soros BioPharmaceutical Fund, and also included participation by L Capital Partners, also of New York; A.M. Pappas & Associates, of Research Triangle Park, N.C.; and Wistar Morris.

Co-founder and CEO Barry Brand said the company was "delighted to be working with top-tier life science investors." Funds will be used to support the company's business growth initiatives, including research and development work involving its first compounds to treat  
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## Actelion: Pursuing Bosentan In Pulmonary Fibrosis Despite Miss

**By Jennifer Boggs**  
Staff Writer

Actelion Ltd. discontinued studies of its dual endothelin receptor agonist bosentan in one indication, but intends to move forward with the drug in idiopathic pulmonary fibrosis (IPF) despite missing the primary endpoint in an earlier study.

Bosentan, which is marketed as Tracleer for pulmonary arterial hypertension (PAH), recently completed two trials testing it against IPF and pulmonary fibrosis related to systemic sclerosis. In both trials, the drug failed to show an effect on the primary endpoint of exercise improvement, as measured by the six-minute walk test. But when the secondary endpoints of morbidity and mortality in IPF patients were examined, "we've seen a clear trend in favor of bosentan," Isaac Kobrin, head of develop-  
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THOMSON

## OTHER NEWS TO NOTE

• **Accentia Biopharmaceuticals Inc.**, of Tampa, Fla., introduced its CRSFungal Profile diagnostic test for chronic rhinosinusitis. The product allows doctors to test for the specific protein marker, eosinophil major basic protein (eMBP), as well as one of the fungi that causes chronic sinusitis.

• **Advanced BioHealing Inc.**, of New York, closed its Series B private placement, raising \$8 million. The investment follows a \$2.4 million Series A financing completed with angel investors in October 2004. Funds will support the commercialization of the company's lead product Celaderm within 12 to 18 months. The product is designed to accelerate healing in partial-thickness burns. Canaan Partners and Wheatley Partners co-led the financing, which also included existing investors. Stephen Bloch from Canaan and David Dantzker from Wheatley will join Advanced BioHealing's board.

• **Agilent Technologies Inc.**, of Palo Alto, Calif., acquired privately held **Molecular Imaging Corp.**, of Tempe, Ariz., a developer and manufacturer of nanotechnology measurement tools. The company is known for its atomic force microscopes, which are used to measure the shape and properties of materials at the nanometer scale. Financial terms were not disclosed.

• **AnorMed Inc.**, of Vancouver, British Columbia, announced the enrollment of HIV patients into its clinical trial of AMD070, the first anti-HIV drug candidate that targets the HIV entry co-receptor CXCR4. The use of CXCR4 by HIV is known to occur in up to 40 percent of patients, especially those with more advanced disease and those failing other treatment options. The open-label, dose-finding study may include up to four cohorts of 12 patients each, with one cohort receiving 200 mg of AMD070 twice daily for 10 days.

• **Aspreva Pharmaceuticals Corp.**, of Victoria, British Columbia, completed enrollment of 176 patients in the Phase III study to assess the safety and efficacy of mycophenolate mofetil (MMP, CellCept) to maintain or improve symptom control with reduced corticosteroids in patients with myasthenia gravis. The randomized, double-blind, placebo-

controlled clinical trial is designed to evaluate the efficacy and safety of MMF in maintaining or improving symptom control with reduced corticosteroids in patients with myasthenia gravis over a treatment period of 36 weeks. The company expects to complete the trial in late 2006.

• **Biovail Corp.**, of Toronto, launched Glumetza, a once-daily, extended-release formulation of metformin, on the Canadian market. The product, developed in partnership with Menlo Park, Calif.-based **Depomed Inc.** received FDA approval in June to treat Type II diabetes. Earlier this year, Depomed sued Biovail for breach of contract, alleging that Biovail failed to launch Glumetza in the U.S. and Canada within a certain time period following regulatory approval. Depomed is entitled to royalties on Glumetza sales. Shares of Depomed (NASDAQ:DEPO) climbed 13.3 percent, or 70 cents on Tuesday, to close at \$5.98.

• **Celtic Pharma Holdings LP**, a private equity firm in Hamilton, Bermuda, closed on its acquisition of exclusive worldwide rights to Xerecept, a Phase III clinical compound for treatment of peritumoral brain edema, from **Neurobiological Technologies Inc.**, of Emeryville, Calif. The closing of the transaction, originally announced Sept. 20, follows the receipt of certain third-party consents and the satisfaction of other closing conditions. At closing, NTI received \$20 million and will receive an additional \$13 million, payable in installments through January 2007. Celtic Pharma and NTI will collaborate on the ongoing clinical development of Xerecept in the United States.

• **Dendreon Corp.**, of Seattle, plans to publicly offer 10 million shares of common stock as part of a shelf registration statement filed with the SEC. It also intends to grant underwriters – Banc of America Securities LLC, JMP Securities and Lazard Capital Markets – an overallotment option for an additional 1.5 million shares. In a separate release, the company said it reached an agreement with the FDA under the special protocol assessment procedure to amend the design of its ongoing Phase III trial of Provenge, its active cellular immunotherapy to treat advanced prostate cancer. Patients now will be eligible to enroll in the study regardless of their Gleason score, and the primary endpoint is now overall survival, with time to objective disease progression a secondary endpoint. The trial will enroll 500 men.

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## InterMune

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could divest Infergen for lots of money, and avoid the dilutive capital and partnering.”

InterMune's stock (NASDAQ:ITMN) closed Tuesday at \$15.24, down 45 cents.

Some “might have expected the shares would be punished today, but what we saw was a lot of volume and the share price was very stable,” Welch said, predicting a “little shakeout period” in the coming months during which investors will analyze the value of changes made at InterMune.

Valeant's deal for Infergen (interferon alfacon-1) is expected to close by the end of this year. Under the terms, Costa Mesa, Calif.-based Valeant will make an up-front payment of \$113.5 million, a fixed cash payment of €2 million (US\$2.35 million) to be paid in 2007, and milestone cash payments in 2007 and 2009 that could total up to \$20 million. Also, Valeant will buy about \$6.5 million in inventory. The fixed cash payment is expressed in Euros because it's related to a manufacturing deal for Infergen with Boehringer Ingelheim GmbH, of Ingelheim, Germany, Welch said.

“For a product [such as Infergen] that's growing, depending on the profitability, you tend to see anywhere from two times [annual] revenues to five times” as the sale price for rights, he noted.

“The value of this deal is roughly four times the revenues, so it's on the high end of the multiples,” Welch told *BioWorld Today*. “For Valeant, the strategic value is very high. They have a Phase III [HCV] program, the results of which they will have in 2006, so they would tend to pay more than someone who doesn't have an interest” in the disease.

Valeant's oral Virmidine, a nucleoside analogue, is undergoing two pivotal Phase III trials for use in combination with pegylated interferon to treat chronic HCV in treatment-naïve patients.

InterMune also is letting 160 full-time employees go, and expects to see operating expenses drop by about \$50 million per year, as the firm reduces money put into awareness programs related to idiopathic pulmonary fibrosis (IPF), for which InterMune has Actimmune (interferon gamma-1b) in Phase III trials.

Approved by the FDA in 1990 for infections associated with chronic granulomatous disease and in 2000 for delaying the time to disease progression in patients with severe, malignant osteopetrosis, Actimmune sales were \$125 million last year.

Data are expected from the Actimmune IPF trials in early 2008 and from the pirfenidone trials in early 2009. Actimmune also is being studied in Phase III trials testing the drug in combination with standard of care therapy against ovarian cancer, with an interim analysis expected in the first quarter of next year.

Also in 2006, InterMune plans to file an investigational new drug application for the HCV protease inhibitor, which the company has resolved not to partner yet.

“We decided to keep it through the next major milestone,” Welch said. “At the end of Phase Ib, we could very well make the decision [to partner]. At that time, we'll take a look at whether shareholders would be better off if we partnered it or continued through Phase II on our own,” although “finances and a whole host of other things” will figure into the equation, he said.

“There is an evolution going on, and changes in the HCV marketplace,” Welch said. “We felt we wanted to invest in the small molecule side of things. Interferons will continue to have a role in the future,” he added, but probably not the same as before.

Welch was referring in part to eye-opening interim data from the Phase Ib trial evaluating VX-950, the oral protease inhibitor for HCV from Vertex Pharmaceuticals Inc., disclosed this spring – results that helped the Cambridge, Mass.-based firm raise \$152.8 million in a stock sale the following month. (See *BioWorld Today*, May 11, 2005, and June 9, 2005.)

Suddenly, InterMune's protease inhibitor looked a lot more valuable. Add to this the go-ahead from the FDA and European regulators for the pirfenidone Phase III program, and InterMune – with Actimmune work under way as well – had a full plate.

“Infergen's growth was another place to invest, and frankly, we ran out of money,” Welch said. Hence, the deal with Valeant, for which talks began over the summer.

What about partnering pirfenidone? By divesting Infergen, “we don't need to anymore, and we can be more choosy” about potential hookups. After taking a restructuring charge of \$6 million to \$10 million associated with the latest changes, InterMune expects to finish 2005 with more than \$200 million in cash.

If an alliance for pirfenidone could be found with an overseas firm, Welch said, “I'd probably do that. We don't have a European infrastructure. But the huge pharmas that have a presence over there unfortunately want the U.S., too, and we don't want to give up anything in the U.S. on pirfenidone.”

In May, InterMune sold Amphotec (amphotericin B cholesteryl sulfate complex for injection) to Three Rivers, based in Cranberry Township, Pa., as part of InterMune's decision to back away from infectious diseases. Amphotec is approved for invasive aspergillosis, a fungal infection that occurs in patients with compromised immune systems. (See *BioWorld Today*, May 26, 2005.)

The firm still is looking to be rid of oritavancin, the Phase III, hospital-based glycopeptide antibiotic acquired more than four years ago from Indianapolis-based Eli Lilly and Co. (See *BioWorld Today*, Sept. 21, 2001.)

“That's one remaining piece of the refocusing program that we started a couple of years ago,” Welch said. ■

## CeNeRx

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depression and anxiety.

Brand previously served as a vice president for London-based GlaxoSmithKline plc before he and CeNeRx president Mark Baric founded the company. Based in Research Triangle Park, N.C., CeNeRx focuses on acquiring and developing early-stage compounds for central nervous system diseases, including depression, anxiety and bipolar disorder, as well as Parkinson's and Alzheimer's disease.

Early this month, the company licensed from Krenitsky Pharmaceuticals Inc., of Durham, N.C., a series of preclinical and early clinical compounds known as reversible inhibitors of monoamine oxidase, or RIMAs, for treating depression and anxiety. RIMAs are functionally related to monoamine oxidase inhibitors (MAOIs), which are known

to be effective in treating depression but can cause potential hypertensive side effects when taken with foods rich in tyramine. Since RIMAs are reversible in the presence of tyramine, they are not believed to carry the same risk.

RIMAs also are designed to work on all three neurotransmitters, serotonin, norepinephrine and dopamine, which provide more effective treatment than serotonin and noradrenaline reuptake inhibitors (SNRIs).

In addition to RIMAs, the company also is looking to expand its portfolio to include complementary products and programs. CeNeRx aims to take its drug candidates through Phase II development before seeking partners to help with Phase III testing and commercialization.

In connection to the recent financing, Steve Elms and Tony Sun, both of Perseus-Soros, and Ting Pau Oei, of L Capital Partners, joined the company's board. ■

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## OTHER NEWS TO NOTE

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- **Depomed Inc.**, of Menlo Park, Calif., and **Madaus Srl**, of Padova, Italy, entered a distribution and supply agreement for ProQuin XR, Depomed's once-daily, extended-release formulation of the antibiotic ciprofloxacin. Under the terms, Depomed granted an exclusive right to Madaus for the commercialization of ProQuin XR in Europe, and agreed to supply Madaus with ProQuin XR tablets in bulk form. In return, Madaus will pay for the tablets at a prespecified percent of its wholesale ex-factory price, net of packaging costs. Madaus is responsible for securing regulatory approvals in Europe.

- **diaDexus Inc.**, of South San Francisco, and the Methodist DeBakey Heart Center in Houston announced the publication of a landmark study in the American Medical Association's *Archives of Internal Medicine* demonstrating a greater than 11-fold increased risk of ischemic stroke in individuals with high levels of lipoprotein-associated phospholipase A2, an enzyme related to arterial plaque formation, and C-reactive protein, a marker of general inflammation.

- **Edison Pharmaceuticals Inc.**, of San Jose, Calif., closed a \$2.8 million tranche of a Series A offering, raising a total of \$6.2 million. The company also recently brought in \$3.4 million in foundation grants. The funds will be used to advance EPI-A0001 into the clinic for the treatment of inherited mitochondrial diseases. Edison also entered technology transfer and screening agreements with **Galileo Pharmaceuticals Inc.**, of Santa Clara, Calif., and as part of the transaction, Galileo obtained an equity stake in Edison and appointed Peter Morris to Edison's board. The Series A round was led by Paul Avery, who will assume a board position. Hamilton Moses also will join the board as an outside member.

- **Guava Technologies Inc.**, of Hayward, Calif., a privately held developer of cell-analysis systems for life science research, drug discovery, development and clinical diagnostics, announced a \$7 million private venture financing from existing

investors Abingworth Life Science Investment, Granite Global Ventures, HLM Venture Partners, MDS Capital Corp., ProQuest Investments and Skyline Ventures. The company also promoted Lawrence F. Bruder to CEO and elected him to the board. Before joining Guava Technologies in 2004, Bruder was vice president at Applied Biosystems within the functional proteomics division and at Becton Dickinson's biosciences business.

- **Hemispherx Biopharma Inc.**, of Philadelphia, entered into an agreement with Defence R&D Canada – Suffield, an agency of the Canadian Department of National Defence, to evaluate the antiviral efficacy of Ampligen and Alferon for protection against human respiratory influenza virus infection in well-validated animal models. Previous studies have shown certain limitations to using Poly ICLC (an immunomodulating dsRNA) due to its inherent toxicity. In contrast, Ampligen and Alferon have encouraging safety profiles to date and Ampligen shares a similar structure with Poly IC.

- **Immatix Biotechnologies GmbH**, of Tübingen, Germany, began a Phase I study on its product candidate IMA901 for renal cell cancer. Under the study, some two dozen patients suffering from advanced stages of renal cell cancer will be treated in six locations in Germany, the UK and Switzerland. The study comes 22 months after Immatix' first round of funding.

- **Inhibitex Inc.**, of Atlanta, reported that the FDA will consider the licensure of the company's lead drug candidate, Veronate, based upon a subgroup analysis of data from a 2,000-patient pivotal Phase III trial in hospital-associated infections in very low birth weight infants. Specifically, the FDA proposed that if the primary endpoint of preventing *Staphylococcus aureus* bloodstream infections in premature infants weighing between 500 and 1,250 grams at birth is not achieved in the overall study population, but is achieved in a lower birth weight group, approval could be granted for that subgroup. The company also said that the European Medicines Agency issued a favorable opinion to grant orphan drug status for Veronate in Europe for the prevention of late onset sepsis in premature infants of less than 32 weeks gestational age.

## Axonix

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been cut short after an initial Phase III trial failed to hit statistical significance on its primary endpoints.

Neill said it was impossible to tell whether the studies would have hit their endpoints if they had been completed as originally planned. Previously, the three Phase III studies had been moving forward simultaneously.

"We thought the issue was that we were not getting enough drug into the brain with the existing dose," Neill said. "That prompted us to think about reformulating the drug to an extended-release or slow-release formulation."

But now the New York company has said that a subgroup of patients who received 15mg of Phenserine twice daily demonstrated a statistically significant benefit over placebo based on an oft-used measure of the disease, the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog), and also showed a positive trend toward improvement in the Clinical Interview Based Impression of Change (CIBIC+) test. They were treated for more than 12 weeks, and there were no unexpected safety or tolerability concerns associated with Phenserine, so Axonix concluded that the findings support the belief that higher doses could potentially be effective in future potential Phase III trials that last 26 weeks.

Neill added that the findings were "very interesting to include in the data package as we present it to potential marketing partners," though he said there was no imminent agreement forthcoming. Still, reports of the new data increased the company's stock (NASDAQ:AXYX) by 12 cents, to 97 cents.

But since additional trials would be needed to confirm those results, Axonix needs a deal. A month ago, the company indicated it would not commit further resources to the Phenserine program and would seek a partner for the compound. That decision came less than two months after Axonix unveiled top-line results showing that there was no statistically significant benefit associated with Phenserine over placebo after 12 weeks of treatment in either the ADAS-cog or CIBIC+, the primary efficacy endpoints. (See *BioWorld Today*, Sept. 21, 2005.)

Such setbacks aren't uncommon in this space, Neill noted, adding that all four FDA-approved Alzheimer's drugs failed studies during their development. "Nobody gets it right the first time," he said, especially given the subjective nature of study endpoints for Alzheimer's.

The AX-CL-09 and AX-CL-010 trials initially were each designed to enroll 450 patients for a 26-week treatment period, but after the first Phase III miss, the company halted recruitment and cut the treatment duration so they evaluated a total of 255 patients after 12 weeks. That first Phase III trial produced no statistically significant differences between Phenserine and placebo in areas of cognition,

global function, behavior and daily living activities, cutting the company's stock value from more than \$6 at the beginning of this year. (See *BioWorld Today*, Feb. 8, 2005, and March 15, 2005.)

"It's just too expensive to go forward on our own," Neill said. "If the drug has potential, it's going to have to be done in conjunction with somebody else who has a bigger checkbook."

Axonix posted a \$5.7 million net loss for the third quarter ended Sept. 30, at which time it had \$63.2 million in cash, cash equivalents and investments.

The additional analysis was completed as part of the company's efforts to find a partner. It included 182 patients who received 15 mg of Phenserine or placebo for a period longer than 12 weeks but not more than 26 weeks. Patients who received 10 mg of Phenserine twice daily did not show a statistically significant benefit compared to placebo.

Phenserine, which is licensed from the National Institutes of Health in Bethesda, Md., also had been the subject of a Phase IIb study this year, but that trial was stopped as interim data have underscored the efficacy of the twice-daily 15 mg dose.

Going forward, the company has turned its eyes more squarely to two other Alzheimer's products in its pipeline.

Posiphen, a positive isomer of Phenserine that is designed to reduce beta-amyloid precursor protein levels, is in Phase I. Importantly, it lacks Phenserine's limiting side effects of nausea and vomiting, and potentially can be dosed as much as 10 times higher. At an earlier stage of development is BisNorCymersine, a highly selective butyrylcholinesterase inhibitor for moderate to severe Alzheimer's. It is scheduled to begin Phase I next quarter. ■

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## OTHER NEWS TO NOTE

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• **MGI Pharma Inc.**, of Minneapolis, announced results of its tender offer to purchase all outstanding five percent convertible subordinated notes due in July 2008 of Baltimore-based **Guilford Pharmaceuticals Inc.**, which MGI acquired in October. MGI has been advised by the paying agent that \$67.9 million in aggregate principal amount at maturity of notes were validly tendered and not withdrawn in the tender offer.

• **Seattle Genetics Inc.**, of Bothell, Wash., initiated a Phase I/II trial of SGN-40 in patients with chronic lymphocytic leukemia, an indication for which the FDA has granted orphan drug designation. SGN-40 is a humanized monoclonal antibody that targets the CD40 antigen. Seattle Genetics also is conducting ongoing Phase I studies of SGN-40 in multiple myeloma and non-Hodgkin's lymphoma.

## Actelion

*Continued from Page 1*

ment at Actelion, said during a conference call.

In the 158-patient BUILD (Bosentan Use in Interstitial Lung Disease)-1 trial, IPF patients receiving bosentan showed less incidence of death or treatment failure at 12 months (22.5 percent) compared to placebo (36.1 percent) representing a relative risk reduction of 38 percent.

Those results were not statistically significant, but they do provide "a strong rationale" for a morbidity/mortality confirmatory Phase III study in IPF, said Jean-Paul Clozel, CEO of the Allschwil, Switzerland-based company.

"This program is going to become a top priority for the company," he added, "because with these data, we have a light at the end of the tunnel for these patients."

Idiopathic pulmonary fibrosis is a disease that progresses very quickly, and life expectancy following diagnosis is only about three years, Clozel said.

Actelion chose not to start IPF studies focusing on morbidity and mortality because the drug's efficacy in that indication was not known, and those trials typically require large patient populations and extended time periods. The company opted instead to look at exercise improvement.

"But it's clear that the six-minute walk test cannot be

used to evaluate the evolution of pulmonary fibrosis," Clozel said.

The company has not yet released details of the upcoming Phase III study, and Clozel said information would be released after details are finalized with the regulatory authorities.

Results from the BUILD-2 study in pulmonary fibrosis related to systemic sclerosis showed no effect on the secondary endpoints. The company attributed this lack of response to the progression of this disease, which is much slower than for IPF, and said it will not pursue the development of bosentan for the systemic sclerosis patient population.

Actelion has several additional development programs for bosentan, investigating the drug in pediatric PAH, PAH in combination with sildenafil, chronic thrombo-embolic pulmonary hypotension, pulmonary hypertension related to sickle-cell disease, digital ulcers related to scleroderma and melanoma.

The company reported a net profit of CHF37.9 million (US\$28.9 million), or CHF1.70 per share, for the third quarter of 2005. As of Sept. 30, cash and cash equivalents totaled CHF344 million (US\$262 million).

Shares of Actelion on the Swiss Stock Exchange (ATLN) closed at CHF129.20 (US\$98.40) Tuesday, up CHF1.80 (US\$1.37). ■

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## OTHER NEWS TO NOTE

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- **SeraCare Life Sciences Inc.**, of Oceanside, Calif., signed an agreement to purchase the Milford, Mass., diagnostic manufacturing facilities and product lines of the Celliance subsidiary of **Serologicals Corp.** for \$3.7 million in cash plus the assumption of certain liabilities. The acquisition increases SeraCare's portfolio of products in the areas of molecular diagnostic reagents, diagnostic intermediates and substrates. SeraCare expects the acquisition to be accretive to earnings by the first fiscal quarter following its closing, which is expected in January 2006.

- **Stem Cell Therapeutics Corp.**, of Calgary, Alberta, completed the screening and initiation of dosing in its Phase I study of NTx-265, the company's program for the treatment of stroke. The trial, designed to characterize the pharmacokinetic profile of two marketed drugs and to evaluate safety, is being conducted by **Medicon A/S**, of Birkerød, Denmark. In preclinical studies, NTx-265 demonstrated an ability to increase the number of innate adult stem cells that grow in place. SCT has a Phase II trial planned to test NTx-265's safety and efficacy in stroke patients.

- **StemCo Biomedical Inc.**, of Durham, N.C., said its name was changed to **Aldagen Inc.** to reflect the company's focus and progress in regenerative medicine. The

company develops and commercializes products designed to identify populations of adult stem cells with the potential to treat cardiovascular and other degenerative diseases.

- **Tibotec Pharmaceuticals Ltd.**, of Cork, Ireland, is discontinuing its single exploratory Phase II study of TMC125, a non-nucleoside reverse transcriptase inhibitor (NNRTI), in protease inhibitor-naïve HIV patients failing a first-line NNRTI-containing regimen. The company said this move has no impact on its ongoing Phase III registration studies of TMC125, which are enrolling highly treatment-experienced patients.

- **TolerRx Inc.**, of Cambridge, Mass., entered an agreement with Abbott Park, Ill.-based **Abbott Laboratories** for the manufacturing of TolerRx's TRX4 monoclonal antibody. Under the terms, Abbott will perform scale-up and GMP manufacturing of the drug for use in clinical trials, as well as supply commercial-grade material to support regulatory submissions and potential commercial launch. Financial terms were not disclosed. TolerRx is evaluating TRX4 in Type I diabetes and psoriasis.

- **U.S. BioDefense Inc.**, of City of Industry, Calif., met its deadline and submitted an RFQ (request for qualification) to **F. Hoffmann-La Roche Ltd.**, of Basel, Switzerland, in response to the need for greater Tamiflu production. Roche agreed in late October to discuss granting licenses to others to make versions of Tamiflu for emergency use against a potential avian flu pandemic.

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**OTHER NEWS TO NOTE**

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• **Vertex Pharmaceuticals Inc.**, of Cambridge, Mass., announced that five holders of its 5.75 percent convertible senior subordinated notes due 2011 have agreed to exchange \$95 million worth for 6.7 million shares of common stock. The holders will receive 390,000 more shares than they would have received for the bonds under the original terms. The additional shares relate to unpaid and accrued interest through February 2007, when the notes would have been callable by Vertex. The company expects to incur a non-cash charge of approximately \$9.8 million as a result of the exchanges.

• **ViroPharma Inc.**, of Exton, Pa., plans to offer 7 million shares of common stock in a public offering, and to grant underwriters an overallotment option for another 1.05 million shares. The company intends to use net proceeds for working capital and general corporate purposes, and it may use a portion of the funds to repay or prepay all or a portion of its 6 percent subordinated convertible notes due March 2007. Goldman, Sachs & Co. will act as the sole bookrunning manager, while Piper Jaffray & Co. will act as

joint lead manager, and SG Cowen & Co. LLC and Lazard Capital Markets LLC will be co-managers.

• **Vitae Pharmaceuticals Inc.**, of Fort Washington, Pa., initiated a 128-patient Phase II study of VTP-201227 for the treatment of psoriasis. VTP-201227 is a topical agent aimed at selectively inhibiting two enzymes that are active in the skin. The company also began Phase II testing of VTP-195183 to enhance immune cell levels in specific cancer treatments. That study is designed as a proof-of-biology study to determine the effectiveness of VTP-195183 in combination with granulocyte colony stimulating factor to enhance mobilization of peripheral blood progenitor cells in patients for whom high-dose chemotherapy is planned.

• **Y's Therapeutics Co.**, of Tokyo, began a Phase II program of YPSL for prevention of delayed graft function (DGF) in patients undergoing cadaveric kidney transplantation. YPSL is a recombinant molecule resulting from the fusion of P-selectin glycoprotein ligand (PSGL) and human IgG1. **Wyeth**, of Madison, N.J., developed the product, and Y's Therapeutics acquired it in June. In a number of animal models, YPSL has demonstrated its ability to block the selectin/ligand interaction, thereby preventing tissue damage from inflammation.

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