

# BIOWORLD® TODAY

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PAGE 1 OF 7

*\$70M Up Front For Two Programs*

## Infinity, MedImmune Enter Deal With \$500M Potential

**By Randall Osborne**  
**West Coast Editor**

While MedImmune Inc. awaits word from the FDA on the supplemental biologics license application for its flu vaccine and seeks ways to pump sales of Synagis, the firm signed a potential \$500 million deal with Infinity Pharmaceuticals Inc. focused on small-molecule cancer drugs targeting heat-shock protein 90 (Hsp90) and the Hedgehog cell-signaling pathway.

"They had an interest in every program we had in the pipeline," said Arlene Perkins, vice president and chief business officer for Cambridge, Mass.-based Infinity. Her company had not planned to take on a partner so early but found MedImmune's offer hard to refuse.

MedImmune, for its part, "wanted something that  
*See MedImmune, Page 3*

## EPIX's Contrast Agent Vasovist Dealt Another Setback By FDA

**By Aaron Lorenzo**  
**Washington Editor**

The FDA hurt EPIX Pharmaceuticals Inc. again, with news of another regulatory setback for Vasovist (gadofosveset trisodium) knocking 12.9 percent off the company's stock value Monday.

The shares (NASDAQ:EPIXD) traded down 93 cents to close at \$6.28 as a result of the latest in a string of rejections for the blood-pool imaging agent, which already is approved in Europe. In the most recent denial, the FDA turned back a formal appeal from EPIX to approve Vasovist (formerly MS-325), as well as a request for an advisory committee review.

The company, of Lexington, Mass., appealed two prior approvable letters for Vasovist on June 30. Following the latest refusal, EPIX President Andrew Uprichard expressed  
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*Financings Roundup*

## Start-up Zogenix Raises \$60M, Acquires Aradigm's Intraject

**By Jennifer Boggs**  
**Staff Writer**

Formed to develop products for central nervous system disorders and pain, new company Zogenix Inc. raised \$60 million in a Series A round, which covered the costs to acquire the Intraject delivery technology from Aradigm Corp. and will support clinical development of the first product, Intraject sumatriptan, for migraine.

The Intraject technology, which involves the use of a needle-free, disposable, subcutaneous delivery system, has a "long history of development," said Roger Hawley, founder and CEO of Zogenix, who left an executive position with Brisbane, Calif.-based InterMune Inc. in January to start a firm with a CNS, neurology and pain focus.

He founded the company with Chairman Cam Garner,  
*See Financings Roundup, Page 5*

## Taligen's TA106 Could Be Lucky Charm Vs. Asthma

**By Karen Pihl-Carey**  
**Senior Staff Writer**

A friendship that began years ago at the University of Colorado culminated with the start of Taligen Therapeutics Inc. in 2004 – a company focused on the modulation and control of the complement system.

Based in Aurora, Colo., Taligen closed the second and largest tranche of its Series A round in early August, bringing the total amount raised in the preferred stock financing to \$3.75 million. The second tranche was triggered by Taligen's demonstration of in vivo efficacy of a humanized version of its lead compound, TA106.

The company was formed by Woodruff Emlen, its CEO and president, along with his former colleague at the university, Michael Holers.

"Mike and I had known each other for a long time,"  
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## CLINIC ROUNDUP

• **Allos Therapeutics Inc.**, of Westminster, Colo., completed patient enrollment in its pivotal Phase III ENRICH study of Efaproxyn (efaproxiral) in women with brain metastases originating from breast cancer. ENRICH (Enhancing Whole-Brain Radiation Therapy In Patients with Breast Cancer and Hypoxic Brain Metastases) is designed to evaluate whole-brain radiation therapy with supplemental oxygen with or without Efaproxyn. A total of 360 patients were enrolled at 126 participating centers in the U.S., Canada, Europe and South America. The primary endpoint is survival, and secondary endpoints include response rate in the brain.

• **Cellegy Pharmaceuticals Inc.**, of Huntingdon Valley, Penn., said an independent data safety monitoring board recommended discontinuing a Phase III trial of Savvy (C31G vaginal gel) in Nigeria after concluding that the study was not likely to provide convincing evidence that the product protects against HIV in women. The board observed a lower-than-expected rate of HIV seroconversion in the study, which was less than half the expected rate and possibly due to procedures designed to ensure ethical trial design, such as HIV counseling and the distribution of condoms. Last fall, Cellegy halted a similar study of Savvy in Ghana based on low seroconversion rates. (See *BioWorld Today*, Nov. 9, 2005.)

• **Connetics Corp.**, of Palo Alto, Calif., reported results from a Phase III trial of Extina (ketoconazole) Foam, 2 percent, formulated in VersaFoam-HF, for the treatment of seborrheic dermatitis. The four-week, double-blind, active- and placebo-controlled trial included 1,162 patients at 24 centers in the U.S. Based on the Investigator's Static Global Assessment, Extina demonstrated a 56 percent response, compared with a 42 percent response for placebo ( $p=0.0001$ ). The trial also demonstrated noninferiority vs. an active comparator arm of ketoconazole cream.

• **Genentech Inc.**, of South San Francisco, and **Biogen**

**Idec Inc.**, of Cambridge, Mass., said Rituxan (rituximab) met its endpoint in a Phase II study relapsing-remitting multiple sclerosis. Results from the 104-patient trial showed a statistically significant reduction in the total number of gadolinium-enhancing T1 lesions observed on serial MRI scans of the brain at weeks 12, 16, 20 and 24 in the Rituxan-treated group compared to placebo. Patients will continue to be followed for 48 weeks.

• **InSite Vision Inc.**, of Alameda, Calif., said the FDA accepted for filing the new drug application for AzaSite (azithromycin 1 percent ophthalmic solution) indicated to treat bacterial conjunctivitis. AzaSite is formulated with DuraSite, InSite's drug delivery vehicle, which enhances the retention time of the antibiotic on the surface of the target tissue. The NDA contains data from two Phase III trials in which 698 patients were treated with AzaSite, demonstrating the drug provided clinically and statistically significant improvements in clinical resolution of symptoms, and bacterial eradication compared to placebo.

• **Oncolys BioPharma Inc.**, of Tokyo, obtained the FDA's approval to begin a Phase I trial of Telomelysin, an adenovirus therapy, in patients with solid cancers. The study will enroll patients who have been resistant to existing treatment and who have no alternatives. Telomelysin is a conditional-restricted, replication-competent adenovirus designed to replace a transcriptional element of the E1A adenovirus gene with a human telomerase reverser transcriptase (hTERT) gene promoter sequence. Oncolys expects to complete the Phase I study by the end of 2007.

• **Pharmaxis Ltd.**, of Sydney, Australia, said the U.S. Aridol Phase III trial in subjects with suspected asthma has finished recruitment. The trial was conducted in more than 400 subjects in 30 hospitals. It compared Aridol with certain methods for diagnosing airway responsiveness.

• **Sinovac Biotech Ltd.**, of Beijing, said Phase I data on its pandemic influenza vaccine showed that the vaccine with different dosages can induce an immune response. There were no serious adverse events reported with the 120 volunteers. The vaccine is co-developed with the Chinese Centers for Disease Control and Prevention.

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## MedImmune

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could be on the market in the next three or four years," she said.

The lead product in the agreement, intravenous IPI-504, is an Hsp90 inhibitor undergoing Phase I trials in multiple myeloma and refractory gastrointestinal stromal tumors.

Infinity gets \$70 million up front from MedImmune for coexclusive, shared rights to the Hsp90 and Hedgehog programs, and could get up to \$430 million more as milestones are met. The firms will share equally all costs and profits.

For each of the Hsp90 and Hedgehog pathway programs, Infinity is to handle discovery, preclinical development and translational clinical development through proof of concept in humans, with the firms jointly steering clinical work through approval of the first product.

MedImmune, of Gaithersburg, Md., will lead worldwide regulatory strategy, as well as sales and marketing, though Infinity has an option to co-promote in the U.S., contributing up to 35 percent of the total effort.

Hsp90 stabilizes and maintains proteins in the cancer cell. The Hedgehog pathway, normally active during embryo growth, can go wrong in adults and help cancers thrive, including some of the more deadly tumors – those of the pancreas, prostate, lung, breast and brain.

Among those working in the Hsp90 space include San Diego-based Conforma Therapeutics Corp., which Biogen Idec Inc., of Cambridge, Mass., agreed in May to buy for \$150 million, plus as much as \$100 million in milestone payments. Another is Kosan Biosciences Inc., of Hayward, Calif., which provided data in June from three Phase I trials of its two Hsp90 inhibitors, KOS-953 and KOS-1022, under development with Basel, Switzerland-based F. Hoffmann-La Roche Ltd. (See *BioWorld Today*, May 4, 2006.)

"We don't believe there's anyone ahead of us," Perkins said.

Notable in the Hedgehog area is the potential \$240 million partnership entered three years ago by Genentech Inc., of South San Francisco, and Cambridge, Mass.-based Curis Inc., which last month decided not to advance its topical drug for basal-cell carcinoma but will determine another path for approaching the target, and keep working on a systemic antagonist for solid tumors. (See *BioWorld Today*, June 12, 2003.)

In the Hedgehog and the Hsp90, Perkins said, she is confident about the potential for compounds to become "the first in class and the best in class."

Dirk Reitsma, vice president of clinical development in oncology at MedImmune, said the time is too early to predict which cancers might be targeted first, but the three-year to four-year goal to market with a compound is realistic.

"If you pick the correct indications, it's definitely within grasp," he said. "With all the caveats [that go with] being in a dose-escalation trial, I think certainly [a Phase II study] with IPI-504 is reasonable." Infinity is working on an oral formulation of that compound, as well. A drug from the Hedgehog program could be in the clinic in a year or a year and a half, Reitsma added.

Infinity is privately held but not for much longer, thanks to its reverse merger with publicly traded Discovery Partners International Inc., of San Diego, disclosed in the spring. (See *BioWorld Today*, April 13, 2006.)

Infinity will own about 69 percent of the combined business after the merger, will keep the Infinity name and will continue its existing operations, with a post-money valuation of about \$235 million.

"The proxy vote is scheduled for Sept. 12, and we're moving full steam ahead," Perkins said, noting that Infinity viewed the Discovery deal mainly as a financing event that will bring between \$70 million and \$75 million.

Infinity also has a potential \$400 million deal with Basel, Switzerland-based Novartis AG to create natural compounds that modulate the Bcl-2 family of proteins, which includes Bcl-2 and Bcl-xL. The protein family is known to mediate cancer cell survival. (See *BioWorld Today*, March 7, 2006.)

No new alliances are on the horizon, Perkins said.

"Right now, we're going to focus on becoming a public company and capturing the value of these two programs [with MedImmune]," while collaborating with Novartis, she said.

In late July, MedImmune submitted to the FDA the sBLA for use of CAIV-T (cold adapted influenza vaccine, trivalent) in children ages 12 months to 59 months who do not have a history of wheezing or asthma.

CAIV-T is the refrigerator-stable formulation of FluMist, a frozen vaccine approved to prevent influenza in people ages 5 to 49. MedImmune filed for approval of CAIV-T in older subjects about a year ago and received a complete response letter in July from regulators who wanted more information about data already submitted. (See *BioWorld Today*, July 19, 2006.)

Also in July, MedImmune reported a second-quarter loss per share of 27 cents, more than expected by analysts such as Brian Lian with CIBC World Markets in New York, who forecast 22 cents.

The company, which chalked up lighter than predicted revenues from the monoclonal antibody Synagis (palivizumab) for respiratory syncytial virus, "guided flat year-to-year sales growth" with the compound, Lian wrote in a research note.

"We believe the key questions for MedImmune remain how to re-invigorate the RSV franchise and how to drive the adoption of CAIV-T through label expansion to younger (and eventually older) patients," he said.

Lian called the Infinity deal a "modest positive." ■

## EPIX

*Continued from page 1*

frustration and disappointment.

"These are the same issues that were raised in the two approvable letters," he told *BioWorld Today*, "and they're issues that we believe we fully addressed, first in our complete response in May 2005 and more recently in our appeal. There's really nothing new in this response that we got."

Uprichard said that the company already has provided more information relating to the comparator scans used in past clinical trials – non-contrast magnetic resonance angiography (MRA) that the FDA recommended for comparative use prior to the studies – and the statistical treatment of uninterpretable images. That's what the agency wanted in those previous two approvable letters, in addition to requests for more clinical work through another study. (See *BioWorld Today*, Jan. 18, 2005, and Nov. 28, 2005.)

EPIX has yet to conduct any additional human tests, though, and now the FDA has upped that ante. In its most recent letter, its Office of New Drugs suggested that the company would be safer to conduct two new clinical trials to support approval rather than relying on a blinded re-read of previously submitted findings and data from a new study.

Uprichard noted that past studies that have included more than 1,400 patients in 18 trials indicated "that the data speak for themselves."

EPIX could further appeal the review, sending the matter up the chain at the FDA to the director of the Center for Drug Evaluation and Research. Should the company petition to overrule the Office of New Drugs, the subsequent review would take at least 30 days after the appeal is filed, although that could last longer.

"We obviously need time to go over our options," Uprichard said, "but I think it behooves everybody that we reach a decision on where we're going as soon as possible."

He said investors would be apprised quickly of the company's path forward.

The original new drug application included data from four Phase III studies demonstrating Vasovist's significant improvement in diagnostic efficacy compared to non-contrast MRA, and the overall accuracy of Vasovist-enhanced MRA was similar to the individual X-ray reader's inter-reader accuracy. Uprichard, who called non-contrast MRA "obsolete" because of current clinical practice that employs off-label gadolinium as a contrast agent, noted that Vasovist would enter a \$100 million market with FDA approval. EPIX remains committed to bringing the product to the U.S. market, where it has targeted imaging non-coronary vascular disease as an initial indication.

An injectable intravascular contrast agent, Vasovist is partnered with Schering AG. That Berlin-based company has launched it in seven European Union countries, with more to come. It also is approved in Switzerland and was

recently recommended for approval in Australia. Those clearances were based on the same data that the FDA has received.

Uprichard said EPIX expects to earn royalties on the lower end of a \$200,000 to \$800,000 range from those overseas sales this year. In the U.S., the partners would split profits evenly, as well as any additional development costs.

EPIX, which recently merged with Predix Pharmaceuticals Holdings Inc., features five clinical drug candidates in its pipeline behind Vasovist. (See *BioWorld Today*, April 4, 2006.)

The portfolio includes PRX-00023 in Phase III for generalized anxiety disorder, PRX-08066 in Phase II for pulmonary hypertension associated with chronic obstructive pulmonary disease, and PRX-03140 in Phase I for Alzheimer's. EPIX also has collaborations with Amgen Inc., of Thousand Oaks, Calif., and Cystic Fibrosis Foundation Therapeutics Inc., the nonprofit drug discovery and development affiliate of the Cystic Fibrosis Foundation in Bethesda, Md. ■

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## CLINIC ROUNDUP

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• **Synthetic Blood International Inc.**, of Costa Mesa, Calif., completed treatment in its Phase IIa study of Oxycyte in traumatic brain injury, and Oxycyte administration appeared to increase oxygen tension over baseline in all eight evaluable trial patients. The study's primary endpoint is to demonstrate Oxycyte's ability to increase brain oxygen tension and favorably affect other brain chemistries that impact clinical outcome in head injury patients. Preliminary data are expected in the fourth quarter.

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## U.S. PATENT DISCLOSURES

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**AM-Pharma BV**, of Bunnik, the Netherlands, was granted U.S. Patent No. 7,060,677, which claims the use of the hLFI-11 peptide and its derivatives to produce drugs against bacterial, fungal and viral infections.

**Ariad Pharmaceuticals Inc.**, of Cambridge, Mass., was issued U.S. Patent No. 7,091,213, covering its mTOR inhibitors, which include its lead cancer product, AP23573, and the uses of those compounds in cancer and in preventing reblockage at sites of vascular injury following stent-assisted angioplasty.

**Arrowhead Research Corp.**, of Pasadena, Calif., said U.S. Patent No. 7,091,192, titled "Linear Cyclodextrin Copolymers," was issued to the California Institute of Technology. That patent is licensed exclusively to Arrowhead's subsidiary, **Insert Therapeutics Inc.**, and relates to a class of polymers for the delivery of therapeutics.

## Financings Roundup

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who previously formed San Diego-based Xcel Pharmaceuticals Inc. (Later sold to Valeant Pharmaceuticals Inc.)

Before Zogenix's interest, Intraject's development began with Weston Medical Group plc, of Cambridgeshire, UK, which filed for bankruptcy in 2003 after hitting a couple of technical snags with the technology. Hayward, Calif.-based Aradigm then stepped in, paying \$2 million in cash to gain the intellectual property and other assets surrounding Intraject.

"Aradigm's challenge was to fix the technical shortcomings and to build a manufacturing infrastructure that could actually make the product at scale, and they've done that," Hawley told *BioWorld Today*. "The technology has been dramatically improved over the last couple of years."

Since Zogenix's focus is in the CNS space, the company originally considered licensing only the Intraject sumatriptan product. But when Aradigm decided to sell the Intraject technology and related assets in order to concentrate resources on its pulmonary delivery platform, the opportunity was too good for Zogenix to pass up.

"Delivering a needle-free device has been a long time coming," Hawley said, and the deal with Aradigm offered the chance "for us, as a start-up company, to have something that's this far along in development and has the potential, not just for sumatriptan, but for other products as well."

Under the agreement, Zogenix gained global rights to the technology in exchange for a \$4 million up-front fee to Aradigm, and agreed to pay a potential milestone payment and royalties on the migraine product, plus royalties on other products based on Intraject. Those funds will go toward Aradigm's AERx pulmonary platform, which includes internal and partnered programs in asthma, cystic fibrosis, pulmonary hypertension, pulmonary anthrax infections and smoking cessation.

Aradigm, which reported a net loss of \$12.4 million, or 85 cents per share, for the second quarter, had \$8.9 million as of June 30, though that does not include a recent payment of \$27.5 million from Bagsvaerd, Denmark-based Novo Nordisk A/S stemming from a partnership involving the AERx insulin diabetes management system.

Shares of Aradigm (NASDAQ:ARDM) closed at \$1.79 Monday, down 2 cents.

Meanwhile, Zogenix will "develop and commercialize the technology in the CNS, neurology and pain areas," Hawley said, and will seek "to license the technology to other companies that might be interested in the device in areas outside our focus."

The Intraject device offers the ease of self-administration, and the fact that it's disposable after a single use and comes pre-filled it provides increased safety and prevents dosing errors.

Zogenix expects to start clinical development "just as

soon as we can," Hawley said, adding that the company likely will have to conduct only one trial to test bioequivalence, while relying on efficacy data from London-based GlaxoSmithKline plc, which markets sumatriptan under the brand Imitrex.

"So the regulatory path should be fairly quick," he added, though he declined to provide a development timeline prior to meeting with the FDA.

Pending approval, Zogenix expects to create a U.S.-based commercial team with a small sales force with managed care capabilities. Hawley said the firm also anticipates considering a co-promotion arrangement in the U.S. for access to a larger primary care sales team.

But Zogenix is "not going to limit ourselves exclusively to development Intraject products," he said, "if we find some other products that are available for us to complete the development and commercialize in the U.S."

The company of 10 employees has administrative offices in San Diego and operations in Hayward, Calif., though it's looking to consolidate activities and establish headquarters in the East Bay area of San Francisco.

Its management team already is in place. Joining Hawley and Garner is President and Chief Operating Officer Stephen Farr, who previously worked as chief scientific officer at Aradigm. Jonathan Rigby was named vice president of business development, Bret Megargel was named vice president of financing and corporate development and John Turanin will serve as vice president of operations.

The \$60 million Series A round should sustain the company through 2008, Hawley said, though that could change depending on potential licensing and partnership activities over the next couple of years.

That round was co-led by Cambridge, Mass.-based Clarus Ventures and Princeton, N.J.-based Domain Associates LLC, and included investments by Foster City, Calif.-based BA Venture Partners; Stamford, Conn.-based Thomas, Mc Nerney & Partners; and Palo Alto, Calif.-based Life Science Angels Inc.

With the financing, Zogenix appointed several members to its board, including Kurt Wheeler, of Clarus; James Blair, of Domain; Louis Bock, of BA Venture Partners; and Alex Zisson, of Thomas, Mc Nerney & Partners.

In other financings news:

- **Magen BioSciences Inc.**, of Cambridge, Mass., secured \$15.4 million in new Series A funding, led by Highland Capital Partners and included investments from IDG Ventures, QVT Financial LP, Alexandria Real Estate, ARCH Venture Partners, Lux Capital, TVM Capital and Venrock Associates. Proceeds will be used to develop and expand the company's therapeutic programs and operations. Magen, founded in March 2006, focuses on developing products for the dermatology market. In conjunction with the financing, Highland's Robert Higgins will join Magen's board. ■

## Taligen

*Continued from page 1*

Emlen said, adding that he was part of the university faculty about 10 years ago before leaving to work in the biotech industry. "When I moved back here from the Bay area, the two of us founded it together in 2004 and funded it essentially with SBIR grants for the first 16 months."

A little more than \$1 million in grants is "what kept us afloat until we got our Series A," he told *BioWorld Today*.

The first closing of the Series A occurred in August 2005. The financing was led by Sanderling Ventures, of San Mateo, Calif., and included investments from Tango and High Country Venture, both of Boulder, Colo., and the University of Colorado through University License Equity Holdings Inc.

Taligen was founded on technology and intellectual property from the University of Colorado at Denver and Health Sciences Center (UCDHSC), as well as partnering institutions. Emlen formerly served as a professor of medicine and immunology at UCDHSC, and was a member of the original senior management team at InterMune Inc., of Brisbane, Calif.

Holers is an expert in complement biology and has focused his research for 10 years on applications of complement inhibition to disease. He currently serves as professor of medicine and immunology at UCDHSC and is chairman of the division of rheumatology.

The closing of the second Series A tranche will help Taligen move its lead product to the next stage of development.

"The first tranche was relatively small, and this really allows us enough money to get us to or very close to filing an IND," Emlen said.

The investigational new drug application is expected by the middle of next year, and a Phase I trial should start by the end of 2007. Series A funds will cover the manufacturing of TAI06 needed to collect preclinical toxicology data in support of the IND.

TAI06 is a Fab fragment of a monoclonal antibody that regulates complement activation. The complement system is a group of proteins that trigger or initiate the inflammatory response, and is linked with several diseases, such as asthma, rheumatoid arthritis, macular degeneration and immune renal disease.

What makes TAI06 unique is that it has a smaller molecular weight than an antibody and "can be delivered by inhalation at relatively low doses," Emlen said.

"The antibody and the Fab fragment have been shown to be efficacious in animal models of multiple inflammatory diseases," he added.

While other companies are working on complement inhibitors, Taligen's product "doesn't shut off the system," Emlen said. It regulates it "by inhibiting amplification of complement activation."

Taligen initially plans to target severe, persistent

asthma as its first indication for TAI06. While there are about 10 million to 20 million people in the U.S. with asthma, the company's drug candidate would address about 5 percent to 10 percent of the total number of patients, representing those who are resistant to current therapies.

Some of the other indications that TAI06 might address and those for which Taligen has preclinical data – macular degeneration, ischemia reperfusion and immunological renal disease – would represent larger markets.

"I think it's fair to say that several of the indications that we're looking at are potential blockbuster indications," Emlen said.

The company's strategy is to take TAI06 into Phase II trials, reaching proof of concept in humans, and then partnering the product for Phase III trials and commercialization.

While it advances TAI06, it also will focus on an undisclosed preclinical technology that works differently than the lead product but still is based on complement regulation, and it will work toward bringing other technologies in-house.

"We're certainly looking and want to be opportunistic with in-licensing opportunities," Emlen said.

Holers gave Taligen its name based on the word "talisman," which means lucky charm. The company operates as a virtual entity with one part-time and four full-time employees. It is working toward its next financing.

"We're actually just beginning that process," Emlen said, "and our hope would be to close a Series B in the first half or middle part of 2007." ■

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## OTHER NEWS TO NOTE

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• **Accentia Biopharmaceuticals Inc.**, of Tampa, Fla., amended its license with the Mayo Foundation for Medical Research and Education, of Rochester, Minn., to provide Accentia an exclusive worldwide license to all non-prescription products that are intended to treat symptoms associated with chronic sinusitis by suppressing noninvasive fungi in the mucus of patients. The amendment also grants Accentia the right to proceed with commercialization of a first product. Financial terms were not disclosed.

• **BioMarin Pharmaceutical Inc.**, of Novato, Calif., said Orapred ODT (prednisolone sodium phosphate orally disintegrating tablets) has been launched in the U.S. The product is prescribed primarily for acute exacerbations of asthma in children, and also is used to control severe, persistent asthma and to reduce inflammation seen in numerous medical conditions including arthritis and cancer. The first FDA-approved orally disintegrating tablet form of prednisolone, it is marketed by **Alliant Pharmaceuticals Inc.**, of Alpharetta, Ga., pursuant to a North American license and acquisition agreement from earlier this year.

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## OTHER NEWS TO NOTE

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• **Geospiza Inc.**, of Seattle, expanded its year-old platform collaboration agreement with **Applied Biosystems Group**, of Foster City, Calif., and its participation in the latter's Software Community Program. The first product resulting from the expanded collaboration integrates Applied Biosystems' GeneMapper and SeqScape genetic analysis tools with Geospiza's Finch Suite data management system. It is expected to improve customers' ability to scale and automate their information technology infrastructure to meet growing challenges in data analysis and workflow management. Financial terms were not disclosed.

• **Labopharm Inc.**, of Laval, Quebec, said Canadian regulatory authorities accepted its application to market its once-daily formulation of tramadol, and the submission is subject to a 300-day review period. In addition, the company is actively engaged in discussions to establish a marketing partnership in that territory. The pain drug is available in Canada only in an immediate-release formulation that combines tramadol with acetaminophen. The Canadian filing is based on the same data used in a new drug application with the FDA.

• **Lorus Therapeutics Inc.**, of Toronto, filed its final prospectus related to its previously announced transaction with **High Tech Beteiligungen GmbH & Co. KG**, of Dusseldorf, Germany, to issue 28.8 million common shares at 36 cents per share for gross proceeds of \$10.4 million. Also, at the request of the Ontario Securities Commission, Lorus

has refiled its management's discussion and analysis for the year ended May 31, for added disclosure with respect to Lorus' disclosure controls and procedures. None of the numerical items contained in the refiled MD&A has been revised.

• **Millenium Biologix Corp.**, of Kingston, Ontario, closed its previously announced demand loan from one of its existing investors in the amount of \$500,000 at an interest rate of 25 percent yearly. The company also received a commitment from another investor for \$500,000 in debentures. In total, it hopes to bring in between \$1 million and \$3 million.

• **Mylan Laboratories Inc.**, of Pittsburgh, and **Matrix Laboratories Ltd.**, of Hyderabad, India, said Mylan will acquire up to 71.5 percent of Matrix shares outstanding for 306 rupees (US\$6.57) per Matrix share. Specifically, Mylan will purchase 51.5 percent of Matrix's shares outstanding pursuant to an agreement with certain selling shareholders and will make an open offer to Matrix's remaining shareholders to acquire up to an additional 20 percent of Matrix's shares outstanding. Assuming the open offer is fully subscribed, the total purchase price is expected to be about \$736 million. Matrix will remain a publicly traded company in India and will continue to operate independently.

• **Salix Pharmaceuticals Ltd.**, of Raleigh, N.C., said the FDA granted its ulcerative colitis drug, Colazal (balsalazide disodium) capsules 750 mg, additional marketing exclusivity through Jan. 8, 2007. That exclusivity is based upon the agency's acceptance of the clinical package submitted by Salix in June regarding information about the use of Colazal in pediatric patients between the ages of 5 and 17.

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## U.S. PATENT DISCLOSURES

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**AVI BioPharma Inc.**, of Portland, Ore., received a notice for allowance for a patent, titled "Antisense Restenosis Composition and Method," covering the use of AVI-4126 in vascular injury. The company also was issued a notice of allowance for a patent, titled "Microbubble Compositions and Methods for Oligonucleotide Delivery," which covers the administration of drugs, including antisense drugs, via microbubbles to damaged vascular tissue.

**Boston Life Sciences Inc.**, of Hopkinton, Mass., said U.S. Patent No. 7,081,238 was issued to Harvard, the General Hospital Corp. and Organix Inc. that covers methods of diagnosing and monitoring attention deficit hyperactivity disorder by assessing the level of dopamine transporter in at least one region of a patient's central nervous system.

**Echelon Biosciences Inc.**, of Salt Lake City, received a patent covering non-radioactive, competitive phosphatidylinositol 3-kinase assays. PI3-K is a cellular enzyme

that's often altered in diseases leading to abnormal cell growth in cancer and pathological cellular response in inflammation.

**EntreMed Inc.**, of Rockville, Md., received U.S. Patent No. 7,087,592, covering composition of matter for its purified 2-methoxyestradiol product, Panzem NCD, which is in Phase I and Phase II trials for cancer.

**Genera Corp.**, of Plymouth Meeting, Pa., was issued U.S. Patent No. 7,056,698, titled "Nucleic Acids Encoding Interleukin-9 Receptor Variants," which relates to the diagnosis, treatment and methods of discovery of therapeutics for atopic asthma and related disorders based on variants of the IL-9 receptor.

**Generex Biotechnology Corp.**, of Toronto, received a patent, titled "Method for Administering Insulin to the Buccal Region," which relates to an improved delivery system for the administration of large-molecule pharmaceuticals through the oral and nasal membranes. The company also received a patent, titled "Methods of Administering and Enhancing Absorption of Pharmaceutical Agents," covering claims for the delivery of macromolecules via the buccal cavity of the mouth.