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PAGE 1 OF 8

CMS Cites EPO's Bad Rap In Plan To Curtail Reimbursement

By Aaron Lorenzo
Washington Editor

Sales of Amgen Inc.'s blockbuster EPO products are facing a further downturn, this time thanks to the Centers for Medicare & Medicaid Services (CMS), and the company's stock on Tuesday lost 3.7 percent as a result.

Specifically, its shares (NASDAQ:AMGN) fell \$2.06 to \$54.01, well off the stock's 52-week high of \$77.

The agency late Monday publicized its proposal to limit coverage of erythropoiesis-stimulating agents (ESAs) for beneficiaries with certain cancers and related neoplastic conditions, a decision that's the latest in a wave of negativity based on safety questions about the red blood cell boosters.

Last week, members of an FDA advisory committee recommended curbing EPO use, the agency added a black

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Intrexon Follows RheoGene Merger With \$25M Series C1

By Trista Morrison
Staff Writer

Preclinical gene therapy company Intrexon Corp. pulled down \$25 million in a Series C1 round backed entirely by venture capital firm Third Security LLC.

The financing brings the total private equity investment in Blacksburg, Va.-based Intrexon to \$32.3 million, most of it provided through funds managed by Radford, Va.-based Third Security.

Intrexon CEO Robert Beech said the funds will support the company's efforts to advance its lead gene therapy program for melanoma into clinical trials by the end of the year, pending regulatory approvals. A program in glioma is "not far behind," he said, adding that Intrexon is interesting in applying its novel gene therapy approach to other difficult-to-treat indications including prostate and other can-

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Modigene Financing Garner \$11.6M; High Hopes For CTP

By Randall Osborne
West Coast Editor

Modigene Inc. raised \$11.6 million through a complex merger deal steered by Phillip Frost, IVAX Corp.'s former chairman and CEO, and the Modigene's ongoing work with carboxyl terminal peptide technology is led by one of the lead developers of Merck Serono SA's \$1.3 billion multiple sclerosis drug, Rebif.

In late February, the Nevada company LDG Inc. changed its name to Modigene Inc., and in May, Modigene Acquisition Corp., a wholly owned subsidiary of LDG, merged with Modigene Inc., a Delaware corporation, and its Israeli parent firm ModigeneTech Ltd.

As a result of the deal, LDG took over the business of Modigene Delaware and ModigeneTech, and will continue operations with them as wholly owned subsidiaries, under

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CV Therapeutics Files NDA For Regadenoson Use In Stress Tests

Jennifer Boggs
Staff Writer

Armed with positive data from two pivotal studies, CV Therapeutics Inc. filed a new drug application for regadenoson as a stress agent in myocardial perfusion imaging (MPI) tests.

The submission triggers a \$7 million milestone from partner Astellas Pharma U.S. Inc., an affiliate of Tokyo-based Astellas Pharma Inc., which holds exclusive North American rights to commercialize the selective A2A-adenosine receptor agonist. Upon approval of regadenoson, expected in 2008, CVT stands to receive another \$12 million milestone payment. Beyond that, CVT is eligible for "significant royalties" on product sales, said John Bluth, CVT's senior director of corporate communications and investor relations.

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*Financings Roundup***Marcadia Raises \$15M In First Round For Metabolic Programs****By Jim Shrine
Staff Writer**

Marcadia Biotech completed a \$15 million Series A round of financing for development of products for diabetes and obesity.

Marcadia, of Carmel, Ind., has licensed rights to develop and market certain drug candidates for metabolic diseases from Indiana University Research and Technology Corp. Its founders and senior management were former executives at Eli Lilly and Co. and Guidant Corp., both of Indianapolis. The company also sponsors research at Indiana University.

The company's lead compound is a glucagon analogue designed to be supplied in an injector pen, making it available for quick use in emergency treatment of hypoglycemia.

Marcadia has peptide chemistry technologies and other compounds in its discovery and development pipeline.

Frazier Healthcare Ventures and founding investor 5AM Ventures co-led the financing round. Joining them was another founding investor, Twilight Venture Partners. Seed money was provided to Marcadia about a year ago.

In other financing news:

- **BioMS Medical Corp.**, of Edmonton, Alberta, said it entered an agreement with underwriters for the sale of C\$38.5 million (US\$35 million) in stock and warrants. It plans to sell 14 million units at C\$2.75 per unit. Each unit consists of one common share and one-half of one warrant. Each three-year whole warrant would entitle the holder to purchase one common share at C\$4. The underwriting syndicate is co-led by Orion Securities Inc. and Desjardins Securities Inc., and includes Versant Partners Inc., Jefferies & Co. Inc., Janney Montgomery Scott LLC and Rodman & Renshaw LLC. They would have an option to purchase 2.1 mil-

lion additional units. The offering is expected to close May 23. Funds would be used to expand its clinical trial programs in multiple sclerosis and for other corporate purposes.

- **Neosil Inc.**, of Emeryville, Calif., received \$10 million of venture debt financing from Hercules Technology Growth Capital Inc., of Palo Alto, Calif. Neosil is developing two dermatological products. One is a peptide designed to promote hair growth in patients with androgenetic alopecia. It showed benefit in a Phase IIa trial in Germany. Neosil's second product is a broad-spectrum topical antimicrobial agent for acne and anti-infective uses. Neosil in November 2004 received a \$32 million Series A investment from MPM Capital and Burrill & Co.

- **Genomic Health Inc.**, of Redwood City, Calif., said it plans to offer 3 million shares from a shelf registration in an underwritten public offering. J.P. Morgan Securities Inc. is sole book-running manager of the offering, and Lehman Brothers Inc. is co-lead manager. Piper Jaffray & Co. and JMP Securities LLC are co-managers. They would have an option to purchase up to 450,000 additional shares. The company is developing genomic-based clinical diagnostic tests for cancer. Its stock (NASDAQ:GHDX) closed Tuesday at \$14.83, down 96 cents.

- **MonoSol Rx Inc.**, of Warren, N.J., filed a registration statement with the SEC for an initial public offering of up to \$86.25 million. Cowen and Co. is the sole book-running manager for the offering. CIBC World Markets and Susquehanna Financial Group are co-managers. MonoSol Rx is developing drug delivery technology based on its dissolving thin-film technology.

- **SensiGen LLC**, of Ann Arbor, Mich., said Ann Arbor SPARK, which works to establish Ann Arbor as a destination for businesses, approved a \$250,000 investment in SensiGen from the Michigan Pre-Seed Capital Fund. The funds will be used to help SensiGen establish a research laboratory in Ann Arbor and to accelerate development of its gene-based molecular diagnostic technology. ■

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Intrexon

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cers, cardiac failure and progressive neural disorders such as Parkinson's disease.

Intrexon's platform represents an amalgamation of gene therapy technologies developed internally at Intrexon – previously known as Genomatix Corp. – as well as those acquired through a merger with RheoGene Inc., of Norristown, Pa. Financial terms for the merger, which was announced late last year and closed in the first quarter, were not disclosed.

Pre-merger, Intrexon focused on modulating protein-protein interactions in specific, subcellular locations. Beech explained that while small molecules and siRNA also interfere with protein-protein interactions, their “pan-cellular” effects can result in toxicity. Inhibition of a protein, such as the kinase AKT, can cause apoptosis in one location within the cell and promote survival in another location. Differentiating between those locations requires subcellular control that “must be done from the inside of the cell” through gene therapy, he said.

While Intrexon focused on the subcellular proteomics of gene programs, RheoGene was known for gene regulation and integration. Its flagship RheoSwitch Therapeutic System combines external control of gene programs through an activator drug with “the ability to use the body's natural feedback loops in the regulation of the on/off switch,” Breech said. RheoGene's integrase platform allows for precise positioning of the gene programs in safe, stable and transcriptionally active locations within the genome of targeted cells.

Both companies had gene delivery programs, and Intrexon is working with both *ex vivo* approaches using autologous cells that are harvested and transduced outside the patient's body and then re-implanted, and *in vivo* delivery using nonreplicating viruses, biopolymers or biomechanical devices.

Together, those four elements – gene programs, regulation, integration and delivery – are all about “getting in place and controlling exogenous genes,” Beech said.

The resulting preclinical candidates in melanoma and glioma involve “*ex vivo* transduction of autologous dendritic cells with an inducible gene program that is repositioned and timed *in vivo* to deliver the maximum immunotherapeutic response,” he added.

Intrexon's merger with RheoGene grew out of a license agreement, and Intrexon still makes technology licenses outside of human therapeutic applications available through its Quadrant Biosystems division.

Beech said the \$25 million Series CI will be delivered in

two tranches, the second of which is tied to undisclosed milestones. He declined to specify the amount of each tranche.

The Series CI round follows a \$5 million Series C in August 2006, a \$1 million Series BI in March 2006 and a \$500,000 Series B in May 2005, all backed by Third Security's funds. An \$825,000 Series A in May 2004 came from Carilion Health System, the Virginia Tech Foundation, and several angel investors. ■

OTHER NEWS TO NOTE

- **A.P. Pharma Inc.**, of Redwood City, Calif., said Nasdaq is reviewing the company's eligibility for continued listing due to noncompliance with the minimum \$10 million stockholders' equity requirement. The company in April registered to sell up to \$28.8 million in an offering of stock, the successful completion of which would be expected to resolve the deficiency, A.P. Pharma said.

- **Accentia Biopharmaceuticals Inc.**, of Tampa, Fla., made a milestone payment of an undisclosed amount to the Mayo Foundation for Medical Education and Research for a fast-track, pivotal Phase III study of SinuNase, a new formulation of low-dose intranasal amphotericin B being developed for chronic sinusitis. The company has an exclusive worldwide license to the use of the antifungal product in that indication.

- **Anaptys Biosciences Inc.**, of La Jolla, Calif., obtained exclusive licenses to complementary SHM technologies from the UK Medical Research Council and the Albert Einstein College of Medicine of Yeshiva University in Bronx, N.Y. SHM (somatic hypermutation) is a natural process for generating antibody diversity to fight disease, and Anaptys' Omnitrope-SHM System uses the components of SHM to enable the rapid variation and functional selection of evolved proteins with enhanced bioactivities. Financial terms were not disclosed.

- **Biosite Inc.**, of San Diego, said its board of directors has determined that the offer from **Inverness Medical Innovations Inc.**, of Waltham, Mass., to buy Biosite for \$92.50 per share is superior to the \$90 per share offered by **Beckman Coulter Inc.**, of Fullerton, Calif. Inverness's offer is irrevocable and will remain open until 5 p.m., Pacific Daylight Time, on Friday. Beckman Coulter has until 12:01 a.m., Pacific Daylight Time, on Friday to counter, but the company stated it will not increase its offer and will instead take the \$54 million termination fee. (See *BioWorld Today*, April 11, 2007.)



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Amgen

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box warning to the label two months ago, and Congress has continued a longstanding probe into the products.

The CMS proposal could become final by the middle of August, an agency spokesperson told *BioWorld Today*.

Private insurance often follows CMS' lead, and the agency attributed its restrictions to EPO's harmful side effects on a patient's underlying cancer and its belief that the disease increases the risk of adverse events related to EPO use.

Approved as supportive-care drugs to treat anemia in patients on chemotherapy and those with chronic kidney failure, a number of studies have since shed light on safety issues showing that higher-than-recommended doses can lead to multiple complications. Those emerging safety concerns, which include thrombosis, cardiovascular events, tumor progression and reduced survival, prompted CMS to conduct a reimbursement review over the past few months.

Amgen, of Thousand Oaks, Calif., makes all the products in question: Aranesp (darbepoetin alfa), Epogen (epoetin alfa) and Procrit (epoetin alfa). Aranesp alone accounted for \$4.1 billion of Amgen's total product sales last year. Procrit is sold by Johnson & Johnson, of New Brunswick, N.J.

In research notes, several analysts who follow Amgen said they were surprised by the scope and swiftness of the agency's pronouncement, and many have downgraded its shares in recent days given their growing expectation of slumping EPO sales.

Chris Raymond of Robert W. Baird & Co. said between 20 percent and 30 percent "of our already lowered Aranesp estimates are at risk," so he's dropped his revenue estimates to \$3.8 billion, \$3.2 billion, \$3.3 billion and \$3.4 billion over this year and the following three, respectively. During the same time frame, JPMorgan's Geoffrey Meacham predicted Aranesp revenue of \$3.78 billion, \$3.5 billion, \$3.5 billion and \$3.7 billion. Far more pessimistic was Joel Sendek with Lazard Capital Markets LLC, who forecasted \$2.4 billion in revenue next year, followed by \$2.3 billion and \$2.3 billion.

An Amgen spokesperson told *BioWorld Today* that the company is reviewing CMS' proposal and "carefully examining" the scientific evidence underpinning it. The company "believes" that those drugs are safe and effective when used according to their FDA-approved labels, and Amgen officials have long stressed that only such suggested use is promoted.

In proposing its national coverage decision, CMS said that ESA treatment "is only reasonable and necessary" under specified conditions for treating anemia in certain cancers.

Going forward, it would preclude reimbursement for a host of anemia conditions, including anemia of cancer not

related to cancer treatment; in cancer or cancer treatment patients due to deficient levels of folate, B-12 and iron, as well as hemolysis, bleeding or bone marrow fibrosis; in anemic patients with uncontrolled hypertension; from myelodysplasia or myeloid cancers; associated with the treatment of myeloid cancers or erythroid cancers; and associated with radiotherapy.

CMS also would cut coverage in patients treated with anti-angiogenic drugs such as Avastin (bevacizumab, Genentech Inc.) or antibodies directed against the epidermal growth factor receptor like Erbitux (cetuximab, ImClone Systems Inc. and Bristol-Myers Squibb Co.) and Vectibix (panitumumab, Amgen), as well as in patients with thrombotic episodes related to malignancy and those with erythropoietin-type resistance due to neutralizing antibodies.

In addition, the agency would no longer reimburse for prophylactic use to prevent chemotherapy-induced anemia and to reduce tumor hypoxia.

The proposal also said hemoglobin levels immediately prior to starting EPO should be less than 9 g/dL in patients without known cardiovascular disease and less than 10 g/dL in those with ischemic disease that cannot be treated with blood transfusion. Multiple analysts said about half of all chemotherapy-induced anemia patients begin with hemoglobin below 9g/dL.

The products' recently revised labeling includes more conservative prescribing instructions to advise doctors to monitor hemoglobin and adjust doses to maintain the lowest level necessary to avoid blood transfusions, warning that ESAs increase the risk of death and cardiovascular problems when dosed to target hemoglobin levels above 12 g/dL.

CMS also recommended some strict ceilings on EPO use, namely its proposal to cap coverage at 12 weeks per year and to halt reimbursement after four weeks if the treatment is not improving patients' hemoglobin and hematocrit levels.

In addition to use in oncology and anemic renal failure patients, the EPO products also are approved for a few non-renal applications. CMS, which is continuing to review its monitoring policy for their use in kidney disease, might also begin analyzing their non-renal use outside cancer. In addition, the FDA is planning an advisory committee meeting in the fall to discuss the safety of ESA dosing in anemic renal failure patients.

A public comment period on CMS' coverage of EPO in cancer is open until June 13.

The CMS coverage decision on EPO is one of several problems facing Amgen these days. There's possible competition to EPO on the horizon, the Supreme Court has decided against hearing an appeal brought by Amgen on a lower court's patent ruling and the company is facing an SEC investigation into allegedly slow timing of study data disclosure. ■

Modigene

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the publicly traded firm named Modigene Inc.

In the financing, Modigene issued about 6.4 million shares at \$1.50 each, raising about \$9.6 million. Frost and several others – all formerly with IVAX, which Teva Pharmaceuticals Ltd. took over last year – chipped in another \$2 million.

The fund raising also included about 1.6 million warrants that expire in five years and bear an exercise price of \$2.50.

Modigene's stock (OTC BB:MODG) closed Tuesday at \$2.63, up \$1.11, or 73 percent. The management from Delaware and board of directors have assumed control of the merged entity, with Frost as newly appointed board member, along with Jane Hsiao, one of the investors. Modigene officials could not be reached.

Abraham Havron, the company's CEO, not only had a hand in Rebif (interferon beta-1a), but developed the Israeli firm BioTechnology General Ltd.'s human growth hormone Bio-Tropin and the hepatitis B vaccine, Bio-Hep-B, as well as a recombinant insulin that was licensed to Organon, of Oss, the Netherlands (which is being acquired by Schering-Plough Corp., of Kenilworth, N.J., for

about €11 billion in cash, or US\$14.4 billion).

Researchers at Washington University in St. Louis discovered Modigene's CTP technology. CTP occurs naturally in humans, and when attached to a therapeutic protein, extends its efficacy.

Organon has bound the CTP to a follicle-stimulating hormone for fertility, and is testing the product in Phase III trials. Already the firm has shown a single injection of FSH-CTP provided the same clinical effect as seven daily shots with regular FSH.

The Washington license held by Modigene allows the use of CTP with all proteins except four endocrine proteins to which Organon has rights.

So far, Modigene has tested CTP-modified hGH and erythropoietin in animal models for growth failure and anemia, respectively. Experiments have shown interferon-beta-CTP has bioactivity similar to that of interferon-beta.

A longer-lasting growth hormone could help Modigene seize a chunk of the \$2.2 billion market. CTP might create a better Aranesp (the EPO product from Amgen Inc.), which sold \$4.1 billion last year. The approach could improve on therapies for MS, too, where the market size is about \$3.8 billion. ■

OTHER NEWS TO NOTE

- **Cerus Corp.**, of Concord, Calif., said French regulatory authorities published specifications for the Intercept plasma system in the *Official Journal*, authorizing French blood centers to prepare and sell plasma treated with the product. It reduces the risk of transfusion-transmitted diseases. While reimbursement pricing also needs to be established, the company said French blood centers can purchase the plasma system in advance of the reimbursement decision.

- **Commonwealth Biotechnologies Inc.**, of Richmond, Va., and **Tripes Inc.**, of St. Louis, entered into a definitive agreement under which CBI would acquire **Tripes Discovery Research Ltd.** CBI plans to continue to operate TDR from its base in Bude, UK. The deal is structured with an up-front payment of \$350,000 followed by payments of up to \$1.8 million from TDR receivables and billings. TDR, which provides drug discovery services, had revenues in 2006 of about \$6.5 million. The deal is expected to close this month or in early June.

- **Cyto Pulse Sciences Inc.**, of Glen Burnie, Md., and the Cancer Center Karolinska in Stockholm, Sweden, entered a deal with University Hospital Uppsala in Sweden, which will conduct a safety trial of their prostate cancer vaccine. The DNA vaccine, which uses Cyto's Derma Vax delivery system, is designed to stimulate an immune response against prostate cancer cells remaining in the

body after removal or irradiation of the prostate gland. Cyto said it plans to file for Swedish regulatory approval to conduct the study.

- **Gemin X Biotechnologies Inc.**, of Montreal, published preclinical data in the journal *Blood* demonstrating that obatoclox (GX15-070) induced cell death in vitro in mantle cell lymphoma (MCL) cell lines and in primary cells from 11 MCL patients. The drug also sensitized MCL cell lines to Velcade (bortezomib, Millennium Pharmaceuticals Inc.). Obatoclox, a pan-Bcl-2 inhibitor, is being studied in multiple Phase I and Phase II trials in several types of cancer.

- **GeneGo Inc.**, of St. Joseph, Mich., received a \$750,000 Phase II Small Business Innovative Research grant from the National Institute of Environmental Health Sciences to develop functional descriptions for gene expression response to drugs and toxins as part of their MetaTox product line. That money will be used to develop functional descriptors and network models for toxicogenomics data analysis.

- **GPC Biotech AG**, of Martinsried, Germany, and **Spectrum Pharmaceuticals Inc.**, of Irvine, Calif., said the FDA's Oncology Drug Advisory Committee will review the new drug application (NDA) on July 24 for oral platinum drug satraplatin in the second-line treatment of hormone refractory prostate cancer. The NDA is based on an improvement in progression-free survival demonstrated in a Phase III trial conducted under special protocol assessment. An FDA decision is expected by Aug. 15.

CVT

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About 9.3 million patients in 2005 underwent MPI studies, which are used to detect and characterize coronary artery disease by identifying areas of poor blood flow in the heart. In many cases, that is performed in conjunction with an exercise treadmill test, but more than 45 percent of those patients aren't able to take the treadmill test due to medical conditions. Those patients require "a pharmacologic agent that can increase blood flow," mimicking the effects of exercise, Bluth said.

"Right now, Adenoscan is the market leader," he told *BioWorld Today*, referring to the adenosine injection marketed by Astellas, which, in prior years, has generated annual U.S. sales of more than \$300 million. But that product has its drawbacks. Adenosine works by "stimulating all the adenosine receptors, so while it increases blood flow, it also invites some other activities," he said.

Adenoscan has been linked to serious side effects such as second- and third-degree atrioventricular block, cardiac arrest and ventricular tachycardia.

Regadenoson, on the other hand, is more selective, hitting only the A2A-adenosine receptor, which is responsible for coronary vasodilation. In two Phase III trials, the product met its primary endpoint by showing with 95 percent confidence that it is "essentially comparable" to Adenoscan in boosting the blood flow of patient undergoing MPI testing, "but with a profile that is more selective," Bluth said.

Another advantage is that regadenoson can be administered through rapid bolus without requiring any adjustments to the dose based on a patient's weight, which would make it more convenient than Adenoscan's adjusted doses given by infusion.

CVT partnered regadenoson with Fujisawa Pharmaceutical Co. Ltd., which later became Astellas, in 2000. Under the terms, CVT is responsible for managing the clinical development program, with Astellas taking over manufacturing, selling and marketing activities in North America. In addition to milestones and royalties, CVT also is reimbursed for 75 percent of the development costs. (See *BioWorld Today*, July 13, 2000.)

Outside North America, Palo Alto, Calif.-based CVT retains all rights to regadenoson, though it has not yet determined its strategy for overseas regulatory approval and commercialization. "We're still assessing those" options, Bluth said.

If regadenoson gains the FDA's blessing, it would become CVT's first "homegrown product" to reach the market, he added. Regadenoson "really was invented in the late 1990s, and it took less than a decade to get to an NDA."

It also would be CVT's second product approval in two years. The company introduced Ranexa (ranolazine extended-release tablets) early last year for the treatment as a second- and third-line use in chronic angina. Ranexa was licensed from an affiliate of Roche Holdings Ltd. in the

mid-1990s. Sales of the angina product for the first quarter of 2007 totaled about \$12 million.

CVT had hoped to broaden Ranexa's label to treat acute coronary syndrome, but reported in March that Ranexa missed its endpoint in a Phase III study. Results from that trial, however, are expected to enable the company to expand Ranexa's approval as a first-line angina treatment, and "we're looking to have that application submitted this fall," Bluth said. (See *BioWorld Today*, Jan. 31, 2006, and March 8, 2007.)

Elsewhere in its pipeline, CVT has CVT-6883, an oral, selective A2B-adenosine receptor antagonist that is in development for asthma and other pulmonary conditions. That product is in Phase I testing in asthma.

The company, which reported a net loss of \$55.1 million, or 93 cents per share, for the first quarter, had a cash position of \$267.1 million as of March 31.

Shares of CVT (NASDAQ:CVTX) fell 20 cents Tuesday to close at \$9.51. ■

OTHER NEWS TO NOTE

• **Nasdaq Stock Market Inc.**, of New York City, said its semi-annual reshuffling of the Nasdaq Biotechnology Index (NASDAQ:NBI) will go into effect next Monday. Additions include **Akorn Inc.** (NASDAQ:AKRX), of Buffalo Grove, Ill.; **Alexza Pharmaceuticals Inc.** (NASDAQ:ALXA), of Palo Alto, Calif.; **Bio-Mimetic Therapeutics Inc.** (NASDAQ:BMTI), of Franklin, Tenn.; **CombinatoRx Inc.** (NASDAQ:CRXX), of Cambridge, Mass.; **DRAXIS Health Inc.** (NASDAQ:DRAX), of Mississauga, Ontario; **Dynavax Technologies Corp.** (NASDAQ:DVAX), of Berkeley, Calif.; **Medivation Inc.** (NASDAQ:MDVN), of San Francisco; **Sangamo BioSciences Inc.** (NASDAQ:SGMO), of Richmond, Calif.; **Vanda Pharmaceuticals Inc.** (NASDAQ:VNDA), of Rockville, Md.; and **Warner Chilcott Ltd.** (NASDAQ:WCRX), of Rockaway, N.J. As previously announced, **GenVec Inc.** (NASDAQ:GNVC), of Gaithersburg, Md.; **Maxygen Inc.** (NASDAQ:MAXY), of Redwood City, Calif.; and **Osiris Therapeutics Inc.** (NASDAQ:OSIR), of Baltimore, also will be added. Deletions include **Curis Inc.** (NASDAQ:CRIS), of Cambridge, Mass.; **Gene Logic Inc.** (NASDAQ:GLGC), of Gaithersburg, Md.; **Inhibitex Inc.** (NASDAQ:INHX), of Atlanta; and **Threshold Pharmaceuticals Inc.** (NASDAQ:THLD), of Redwood City, Calif.

• **Omxix Biopharmaceuticals Inc.**, of New York, said the FDA approved its supplemental biologics license application to market its liquid fibrin sealant, Evicel, in vascular surgery. The company said the vascular surgery market is about twice the size of the market previously addressed with Evicel's indication in liver surgery. Approval of Evicel for general hemostasis in surgery is expected in the first quarter of 2008, Omrix said. Omrix's marketing partner for the product is **Ethicon Inc.**, a division of New Brunswick, N.J.-based Johnson and Johnson.

OTHER NEWS TO NOTE

• **Proteros Biostructures GmbH**, of Martinsried, Germany, and **Boehringer Ingelheim Pharmaceuticals Inc.**, of Ridgefield, Conn., entered an 18-month deal in the field of protein crystallography. Proteros is entitled to research funding and success payments for the generation and analyses of protein-ligand structures of hits and evolved chemical entities from BI programs. Proteros will use its Free Mounting System and Picodropper technologies in the effort. Terms were not disclosed.

• **Reata Pharmaceuticals Inc.**, of Irving, Texas, said data on RTA 402 were published in the May 2007 issue of *Cancer Research*. Data showed RTA 402, a Phase II development candidate for cancer, was highly effective in an animal model of breast cancer, and that the drug inhibits signaling activity of STAT3, a cancer target. The article was authored by Reata collaborators from the University of Texas MD Anderson Cancer Center.

• **Scynexis Inc.**, of Research Triangle Park, N.C., expanded the scope of its research collaboration with **Merial Ltd.**, of Duluth, Ga., as a result of the success of their two-year-old initial agreement. Terms of the new multiyear agreement call for the partners to significantly increase the capacity of their biological screening, bioanalytical, ADMET and medicinal chemistry efforts directed toward Merial's animal health projects. Financial terms were not disclosed.

• **Sepracor Inc.**, of Marlborough, Mass., said Adrian Adams, president and chief operating officer, has been elected president and CEO. He assumed the CEO role from Timothy Barberich, who was elected executive chairman of the board. Adams joined Sepracor in March. He was president and CEO of Kos Pharmaceuticals Inc. until its acquisi-

tion in December by Abbott Laboratories.

• **SIGA Technologies Inc.**, of New York, reported successful results of a proof-of-concept guinea pig trial of its lead Lassa fever virus drug, ST-193, which showed a significant reduction in mortality at the two doses tested compared to control. Strain 13 guinea pigs were challenged with a lethal dose of Lassa virus and treated with ST-193 once daily for 14 days. At the low dose, 25 mg/kg, 71 percent of the animals survived, whereas all the control animals and those treated with ribavirin succumbed to the disease within 20 days of the challenge. SIGA expects that the guinea pig model is one of the two animal models that will be required to fulfill the FDA's animal efficacy rule. Development of the Lassa antiviral is supported by \$6 million grant awarded by the National Institutes of Health in September 2006.

• **Solstice Neurosciences Inc.**, of Malvern, Pa., entered an agreement with **Eisai Co Ltd.**, of Tokyo, for European commercialization of NeuroBloc (botulinum toxin type B) injectable solution, a purified formulation of the neurotoxin produced by the bacterium *Clostridium botulinum* for treatment of cervical dystonia. Solstice's product, known as Myobloc in the U.S., was approved in the European Union in 2001. Solstice is entitled to receive up to €41 million (US\$55.7 million) in up-front and potential developmental milestone payments in the deal. Solstice and Eisai plan to jointly develop the product for additional indications in the territory. Eisai already had rights in Japan.

• **TriLink BioTechnologies**, of San Diego, said it was awarded a Phase I Small Business Innovation Research grant of about \$100,000. TriLink will use the funds to investigate a new approach for Hot Start activation in PCR. The approach, which uses chemically modified triphosphates to inhibit DNA polymerase activity until a thermal activation step, has shown promise in the reduction of off-target amplification products in PCR.

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CLINIC ROUNDUP

• **AlphaRx Inc.**, of Markham, Ontario, and **Proprius Pharmaceuticals Inc.**, of San Diego, said top-line results from an exploratory Phase II trial of Indaflex 2.5 percent topical indomethacin cream in osteoarthritis of the knee did not meet the primary endpoints. Those were defined as a change from baseline to week six in the global Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score and the subject's global assessment of efficacy – subgroup analysis of patients with moderate to severe pain and more impaired physical function at baseline showed positive trends when treated with Indaflex as compared to placebo or vehicle. The trial enrolled 233 patients. The companies intend to discuss those results with the FDA in preparation of advancing Indaflex into registration trials.

• **Cytos Biotechnology AG**, of Zurich, Switzerland, reported positive results from a Phase II study of different formulations of CYT003-QbG10, an immunotherapeutic product candidate for allergic diseases. The study included 40 patients suffering from mild to moderate allergic rhinitis due to house dust mite allergy and exploratory efficacy was determined by evaluating the allergic disease status of the patients before and after treatment by the conjunctival provocation test. Both formulations of CYT003-QbG10 were safe and well tolerated and demonstrated a statistically significant increase in the median allergen tolerance against baseline in the two treatment arms which comprised QbG10 (i.e. CYT003-QbG10 monotherapy and CYT005-AllQbG10).

• **Pharmaxis Ltd.**, of Sydney, Australia, said the first patients have been enrolled in a Swiss trial evaluating the ability of Aridol to predict the response to inhaled steroids in patients with chronic obstructive pulmonary disease (COPD). The study is designed to test the hypothesis that COPD patients are more likely to have good clinical responses to inhaled steroids if they have a positive Aridol challenge test. It follows two earlier studies – a pilot study and an Australian Phase II trial – and will follow a larger group of patients diagnosed with COPD and receiving

baseline bronchodilator therapy with Spiriva (tiotropium, Boehringer Ingelheim). The trial is expected to conclude in the first half of 2008.

• **Point Therapeutics Inc.**, of Boston, said its board approved an unscheduled interim analysis on the Phase III study of talabostat in combination with pemetrexed (Alimta, Eli Lilly and Co. Inc.) in non-small-cell lung cancer. The study was designed to involve 400 patients who have already failed either one or two prior drug regimens, and to date, about 360 patients have enrolled. The interim analysis will examine about 150 events, defined as either disease progression or death, that already have been recorded and results of that analysis are expected by the end of this month. Talabostat's NSCLC program consists of two randomized, placebo-controlled, double-blind Phase III trials in the second-line and third-line settings, with one trial testing talabostat and pemetrexed vs. placebo and pemetrexed and the second study evaluating talabostat in combination with docetaxel (Taxotere, Sanofi-Aventis). The company has not yet decided whether an interim analysis will be conducted in that second study.

• **Synthetic Blood International Inc.**, of Costa Mesa, Calif., reported positive data from a statistical analysis of its Phase IIa study of Oxybyte in patients with traumatic brain injury. In line with preliminary results announced in December, statistical results confirmed that product met the primary endpoint of increasing patients' oxygen tension levels compared with baseline. Data also showed a decrease in patient glucose and lactate/pyruvate (LP) ratio, consistent with increased glucose metabolism. Patients in the trial were stabilized with either 50 percent or 100 percent oxygen. The company is working to develop a protocol for a Phase IIb trial.

• **Telomerase Activation Sciences Inc.**, of New York, said interim data from a trial of TA-65, a telomerase activator, demonstrated measurable anti-aging benefits in the areas of immune system function, vision, sexual function, skin condition and energy levels. The double-blind, placebo-controlled, 24-week study included 36 male subjects ages 60 to 85. TAS sells TA-65 under an exclusive license from the **Geron Corp.**, of Menlo Park, Calif.

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