

BIOWORLD® TODAY

MONDAY
MARCH 19, 2007

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 18, No. 53
PAGE 1 OF 7

Tracon Licenses D93 Antibody From Micromet

By Trista Morrison
Staff Writer

In a deal worth up to \$100 million, Micromet Inc. licensed the preclinical anti-angiogenesis monoclonal antibody D93 to privately held Tracon Pharmaceuticals Inc.

Micromet's stock (NASDAQ:MITI) soared 50 percent Friday morning before edging back down to close at \$3.25, still managing a gain of 35 cents, or 12 percent, for the day. Christian Itin, Micromet's president and CEO, attributed the stock movement both to the deal and the "substantial amount of progress" discussed in the company's year-end earnings, which also were released on Friday.

Micromet beat fourth-quarter estimates of a 25 cent-per-share loss by posting an 11 cent-per-share gain, due primarily to the receipt of a milestone payment. For the year ended Dec. 31, 2006, the company reported a net loss of
See Micromet, Page 5

A Lifeline Or Just A Lure?

Pfizer, Biogen Idec Launch Incubators To Build Pipelines

By Trista Morrison
Staff Writer

Incubators are nothing new in biotech. They've long helped address the funding gap between basic and clinical research by providing the facilities, leadership and money needed to translate ideas into product candidates.

Often led by universities and economic development groups, incubators traditionally have sought to grow companies to a self-sustainable level. But a new player is poised to enter the game, and the rules may be about to change. Pfizer Inc. and Biogen Idec Inc. are launching the first incubators wholly owned and fully funded by industry, with the end goal of building their pipelines.

Pfizer announced last week that it officially incorporated The Pfizer Incubator LLC (TPI), a wholly owned, fully
See Incubators, Page 4

Alexion Gets FDA Nod For Soliris; First Drug For PNH

By Jennifer Boggs
Staff Writer

Alexion Pharmaceuticals Inc.'s monoclonal antibody product Soliris won FDA approval in paroxysmal nocturnal hemoglobinuria (PNH), making it the first therapy indicated for the rare genetic disorder.

The Cheshire, Conn.-based firm, which already has recruited a 25-member sales team plus 15 medical science liaisons, will waste no time getting the drug to patients. Soliris' launch is expected "within two weeks," said Alexion CEO Leonard Bell.

The news boosted Alexion's shares (NASDAQ:ALXN) \$2.78, or 7.4 percent, Friday, to close at \$40.15, though investors still await the drug's pricing, which analysts have projected from \$100,000 up to \$300,000 in annual costs per patient.
See FDA, Page 3

CEO Retires, Too; Street Baffled

Trimeris Taking Back Rights To Next HIV Fusion Inhibitor

By Randall Osborne
West Coast Editor

Although a takeover still seems possible, Trimeris Inc.'s appeal dipped sharply with the retake of rights to its next-generation HIV fusion inhibitor peptides from Fuzeon partner F. Hoffman-La Roche Ltd. – just six months after the deal was renewed – as well as major changes in top management.

Investors didn't much like the news, trimming Trimeris' shares (NASDAQ:TRMS) by 29.3 percent Friday, when the stock price ended at \$7.12, down \$2.95.

"We actively did negotiate to get all rights back, and we're very pleased to get them back," said management consultant Larry Hill, appointed Thursday as acting president and chief operating officer for Trimeris. He acknowl-
See Trimeris, Page 6

INSIDE: HOUSE SUBCOMMITTEE ADVANCES GENETIC DISCRIMINATION BILL.....	2
INSIDE: CLINIC ROUNDUP.....	6



*News From Washington***House Subcommittee Advances Genetic Discrimination Measure****By Aaron Lorenzo
Washington Editor**

WASHINGTON – A bill to prohibit employers and insurance companies from discriminating because of an individual's genetic makeup is continuing to move through the House of Representatives, with an Energy and Commerce subcommittee approving it last week.

That's the latest hurdle for the legislation, which has always stalled in the past. Still, the measure must clear three panels before it reaches a floor vote in the House. Already the Education and Labor Committee has approved it, and the recent subcommittee endorsement would seem to signal pending success before the Energy and Commerce Committee. Action before the Ways and Means Committee has yet to begin.

The bill, the "Genetic Information Nondiscrimination Act," or H.R. 493, was introduced by Rep. Louise Slaughter (D-N.Y.). It establishes protections against using someone's genetic information in making decisions about health coverage or jobs.

Advocates such as Francis Collins, director of the National Human Genome Research Institute, have testified that without such protections the full potential of genomic research and personalized medicine may never be realized.

A companion bill sponsored by Sen. Olympia Snowe (R-Maine), S. 358, cleared the Senate's Health, Education, Labor and Pension Committee in January. Sharon Terry, president and CEO of the Genetic Alliance, said the Senate is soon expected to bring it to the floor for a vote. Twice before, in 2003 and 2005, the Senate has unanimously passed it, but the House has never voted on the matter.

This year's progress in the House represents a reversal of previous years, when opposition from large employer

groups held up any advances. Of note, President Bush has voiced his support for such legislation.

CMS Looking Into EPO Usage

The Centers for Medicare & Medicaid Services (CMS) last week said it would review all Medicare policies on erythropoiesis-stimulating agents in the wake of the FDA's new black box warnings on the anti-anemia products, and encourage physicians to take the warnings into account when prescribing them.

In addition, CMS is continuing to review its erythropoietin monitoring policy for end-stage renal disease patients who undergo dialysis and has opened a national coverage analysis on the use of the drugs – Aranesp, Epogen and Procrit – for conditions other than end-stage renal disease, a first step toward issuing a national coverage determination.

Those drugs are approved to treat anemia in chronic kidney failure patients and cancer patients whose anemia is caused by chemotherapy, as well as HIV patients using zidovudine and to reduce the number of transfusions in patients scheduled for major surgery, except heart surgery.

The FDA's Oncologic Drugs Advisory Committee is meeting May 10 to further discuss EPO drug issues.

New Bill Aimed At SOX Reform

New legislation has been introduced to reform certain provisions of Section 404 of the Sarbanes-Oxley Act to make compliance more efficient, reducing some of the financial burdens on small- to mid-cap businesses in attesting to the soundness of their internal control functions.

Called the "Compete Act of 2007," or H.R. 1508, its primary sponsor is Rep. Gregory Meeks (D-N.Y.). It seems to follow proposed changes from the SEC, which late last year suggested that auditing standards should be eased for such companies, which have for some time called for scaled reforms to Section 404.

Companion legislation, S. 869, has been introduced by Sen. Jim DeMint (R-S.C.). ■

BioWorld® Today (ISSN# 1541-0595) is published every business day by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305 U.S.A. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. BioWorld® and BioWorld® Today are trademarks of AHC Media LLC, a Thompson Publishing Group company. Copyright © 2007 AHC Media LLC. All Rights Reserved. No part of this publication may be reproduced without the written consent of AHC Media LLC. (GST Registration Number R128870672).

ATLANTA NEWSROOM: Managing Editor: **Glen Harris**.
Staff Writers: **Jennifer Boggs, Trista Morrison, Jim Shrine**.
Senior Production Editor: **Ann Duncan**. Editorial Coordinator: **Tiffany Turner**.

WASHINGTON BUREAU: Washington Editor: **Aaron Lorenzo**.

WEST COAST BUREAU: Editor: **Randall Osborne**.

EAST COAST BUREAU: Science Editor: **Anette Breindl**.

BUSINESS OFFICE: Senior Vice President: **Donald R. Johnston**.
Senior Marketing Product Manager: **Chris Walker**.
Account Representatives: **Steve Roberts, Bob Sobel, Chris Wiley**.

DISPLAY ADVERTISING: For ad rates and information, please call **Stephen Vance** at (404) 262-5511 or email him at stephen.vance@ahcmedia.com.

REPRINTS: For photocopy rights or reprints, call our reprints department at (404) 262-5479.

PRESS MATERIALS: Send all press releases and related information to newsdesk@bioworld.com.

SUBSCRIBER INFORMATION

Please call **(800) 688-2421** to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call **(404) 262-5476**. Our customer service hours are 8:30 a.m. to 6:00 p.m. EST.

Glen Harris, **(404) 262-5408**

Aaron Lorenzo, **(202) 739-9556**

Jennifer Boggs, **(404) 262-5427**

Jim Shrine: **(404) 627-2621**

Fax: **(404) 814-0759**

Randall Osborne, **(415) 384-0872**

Anette Breindl, **(304) 296-1160**

Trista Morrison, **(858) 901-4785**

Senior Vice President

Donald R. Johnston, **(404) 262-5439**

Internet: <http://www.bioworld.com>

**AHC Media LLC**

FDA

Continued from page 1

Bell said disclosure of pricing and other marketing details will be announced by the company later this month during a conference call to outline its U.S. commercialization strategy. However, the company did introduce Soliris OneSource, a treatment support service to educate PHN patients and physicians on the diagnosis and treatment of the disease.

As the first PHN therapy to make it to market, Soliris (eculizumab) is indicated as a treatment for virtually all PHN patients. The disease, which is estimated to affect about 8,000 to 10,000 people across North America and Europe, is characterized by hemolysis, the chronic destruction of red blood cells. By selectively blocking terminal complement, the part of the immune system implicated in PHN red blood cell destruction, Soliris succeeded in reducing hemolysis in every patient treated in the clinic.

"One hundred percent of the patients receiving Soliris had objective responses," Bell told *BioWorld Today*, adding that the drug also was associated with improvement in PHN-associated symptoms, such as anemia, and that patients reported improvements "in their overall quality of life."

Prior to Soliris, the only treatment options for PHN patients have been palliative, such as vitamins, transfusions and blood-thinners. The disorder generally manifests in patients' early 30s, and, once diagnosed, median patient survival is 10 to 15 years. The most common cause of death for PHN patients is blood clots, another area in which Soliris demonstrated positive efficacy. Patients treated with the drug were less likely to suffer thrombosis compared to those on placebo, Bell said.

Data from a 26-week Phase III study, which formed the basis for Alexion's biologics license application submitted in September, showed that Soliris significantly reduced hemolysis in every treated patient, and that reductions occurred within one week of initiating therapy and were sustained for up to 54 months with continued dosing. Preliminary data, reported in January 2006, also showed that the median transfusion rate dropped from 10 units per patient with placebo to 0 units per patient with Soliris, and that hemoglobin stabilization was achieved by 49 percent of patients in the Soliris group compared to none receiving placebo. (See *BioWorld Today*, Jan. 27, 2006, and Sept. 22, 2006.)

According to study data, the most common adverse events were limited to headache, runny nose, back pain and nausea, though Soliris' product label includes a warning about a potential increase in meningococcal infections and recommends that all patients be vaccinated at least two weeks before starting treatment.

Outside of the U.S., Alexion has a pending marketing authorization application in Europe, and expects a regulatory decision "sometime in the summer," Bell said. The company already has started coordinating its commercialization activities there, and plans to handle all marketing itself on a worldwide basis.

"Our objective is to be on the market in 40 countries within three years of launching in the U.S., so around 2010," he said.

Though Alexion has an early stage pipeline, and has done preclinical work on Soliris in additional indications, those programs will take a backseat to Soliris' upcoming launch, Bell said. "We're a small company, so right now all our efforts are focused on that." ■

OTHER NEWS TO NOTE

- **Endo Pharmaceuticals Holdings Inc.**, of Chadds Ford, Pa., and **Vernalis plc**, of Winnersh, UK, said the FDA is requiring an additional three months to review Endo's supplemental new drug application for Frova (frovatriptan succinate) 2.5 mg tablets for the expanded indication of short-term prevention of menstrual migraine. The agency now anticipates completing its review of this application on or before Aug. 19. The original PDUFA date was May 19. The companies said the request relates to the presentation of the data, rather than content, and that no additional data have been requested.

- **Exelixis Inc.**, of South San Francisco, submitted an investigational new drug application for cancer compound XL147, an oral small-molecule phosphoinositide-3 kinase inhibitor. In preclinical studies, the drug slowed tumor growth or caused tumor shrinkage in multiple models, including breast, lung, ovarian and prostate cancers, and gliomas. It also demonstrated an ability to enhance the antitumor effects of several chemotherapeutic agents and an inhibitor of epidermal growth factor receptor in preclinical models.



Add life to your business.

www.LeeCountyBusiness.com

239.338.3161



LEE COUNTY
SOUTHWEST FLORIDA

Adding life to your business.

Incubators

Continued from page 1

funded biotechnology incubator located on its La Jolla, Calif. research and development campus.

Since unveiling the idea at a late 2006 analyst briefing, Pfizer has been busy hammering out the incubator's business model and setting up the 26,600-square-foot facility, which contains eight laboratories and sufficient office space to house between five and eight start-ups. Catherine Mackey, senior vice president of global research and development at New York-based Pfizer, said her company will fund the project with a commitment of \$12.5 million per year for the next five years, to be divided among the facility's nascent biotech occupants.

On the East Coast, Biogen Idec is hatching a similar plan. Although the project has yet to be formally announced, director of public affairs Jose Juves told *BioWorld Today* that his company has identified a facility within its Cambridge, Mass. headquarters to house the Biogen Idec Innovation Incubator. Many details, including the funding commitment, have not been finalized, but Juves said the innovator will be designed to house "a steady rate of four to five companies at any given time."

The notion of industry incubators makes sense on many levels. Researchers need funding to get from the lab to the clinic. Pharmaceutical companies with thinning pipelines are seeking ever earlier access to compounds. Historically, the two groups have joined through licensing deals, or more recently through corporate venture arms such as those offered by pharma like Eli Lilly and Co., of Indianapolis, and Novartis AG, of Basel, Switzerland, or biotech companies like Amgen Inc., of Thousand Oaks, Calif., and MedImmune Inc., of Gaithersburg, Md.

"Incubators are another tool," like licensing and venture arms, Juves said.

But while venture arms tend to be focused on return on investment, industry incubators are purely pipeline driven.

"We're interested in funding emerging technologies that, if successful, could have a significant impact on our portfolio," Mackey said. Juves, too, said the incubator is a way to "supplement the pipeline."

Both companies view acquisition as a possible exit strategy for incubated entities but plan to evaluate them on a case-by-case basis. Another option would be to spin out companies that need more funding than the incubator could provide, while potentially retaining the right to acquire the company or its products later in the game.

That aspect has some venture capitalists concerned.

At a recent conference, Drew Senyei, managing partner with Enterprise Partners, called Pfizer's incubator idea "exciting and useful," but pointed to a need to "understand the economics." He noted that buy-back options could cap the future value of the company or its products and hamper venture capital interest.

Mackey countered that Pfizer's first right of refusal to

acquire would be based on fair market value at the time of the acquisition as determined by a pre-specified, neutral third-party.

But that's easier said than done, according to James Garvey, managing partner with venture firm SV Life Sciences. Companies might want to hold onto their products longer to get a higher market value for them. And the right of first refusal, even at fair-market value, would rule out the bidding wars that have generated so much additional upside for biotech companies of late. "The end game for venture capitalists and pharmaceutical companies is essentially in direct conflict at the exit stage," Garvey said.

Regardless of the exit, Mackey and Juves both pointed out that their incubators would appeal to scientists on the front end by allowing them to focus on science.

"When you start a company, there are 10 million things you need to do that are everything but hardcore, pure science," Mackey said. Pfizer's incubator will have an on-site concierge to address the scientists' needs, providing support with purchasing, shipping and receiving, cleaning, security and regulatory issues.

Management guidance will be available through entrepreneurs in residence, and companies will have access to the incubator's scientific advisory board for help with more technical issues.

Both Pfizer and Biogen Idec are talking actively to start-ups and reviewing proposals from companies interested in a spot on the premises. Both also plan to launch incubator websites – Pfizer later this month and Biogen Idec within the first half of the year.

Pfizer will be looking for companies that fit into one of its 11 areas of therapeutic interest or that have compelling platform technologies. Mackey said she expects the majority of the proposals to come from San Diego research institutes like The Burnham Institute for Medical Research, The Salk Institute for Biological Studies, The Scripps Research Institute and the University of California in San Diego.

Biogen Idec will choose to incubate companies that focus on its core areas of oncology, neurology and immunology as well as other areas of high unmet need served by specialists. Thus far, it has identified potential start-ups predominantly through its network of scientists.

The companies' plan to draw ideas from a broad base of universities and research institutes gives the industry incubators an advantage over university-affiliated incubator programs, which can get "tunnel vision" by focusing only on their own science, Garvey said. A narrowly focused incubator that doesn't filter out the best projects can run into problems given the high failure rate of the industry, he said, adding that industry incubators will be limited by their sponsors' areas of interest.

Both Pfizer and Biogen Idec hope to expand their incubator programs – if they prove successful, Biogen Idec to its San Diego campus and Pfizer to New York, Boston and perhaps the United Kingdom. ■

Micromet

Continued from page 1

\$34 million, or \$1.29 per share, while analysts had expected a loss of only 95 cents per share.

The deal with Tracon will add to Micromet's year-end cash balance of \$24.3 million. Although detailed terms were not disclosed, Micromet will receive both up-front and milestone payments that may top \$100 million, as well as royalties. In exchange, Tracon gets exclusive worldwide rights to develop and commercialize D93.

D93 is a recombinant humanized IgG1 monoclonal antibody that binds to cleaved collagen within the extracellular matrix. The collagen becomes exposed during angiogenesis, and the drug's binding prevents the angiogenic process from progressing.

D93 originally was developed at Los Angeles-based biotech Cell-Matrix Inc., which was acquired by Carlsbad, Calif.-based CancerVax Corp. in 2002. At CancerVax, the program took a backseat to the company's Phase III cancer vaccine, Canvaxin. Yet the Cell-Matrix subsidiary continued preclinical work, demonstrating that D93 suppressed angiogenesis, worked synergistically with Taxol (paclitaxel, Bristol-Myers Squibb Co.), and inhibited tumor growth in animal models of breast cancer, pancreatic cancer and melanoma. (See *BioWorld Today*, Jan. 10, 2002.)

In early 2006, the FDA granted CancerVax's investigational new drug application to start a Phase I trial with D93 in solid tumors. But before that trial was initiated, Phase III failures with Canvaxin lead to CancerVax's demise and eventual merger with Micromet. (See *BioWorld Today*, Apr. 7, 2005; Oct. 5, 2005; and Jan. 10, 2006.)

Although Micromet focuses on antibody-based products for cancer, Itin explained that the Carlsbad, Calif.-based company is licensing out its traditional antibodies so that it can focus on its proprietary BiTE molecules. The clinical-stage cancer antibody MT201 already is partnered with Merck Serono of Geneva, and just last week Micromet licensed another cancer antibody to Morphotek Inc of Exton, Pa. Two preclinical antibodies for inflammation, MT203 and MT204, also are up for sale.

That leaves Micromet with a pipeline of BiTE molecules, which bind a tumor-associated antigen and a T cell, triggering the T cell to recognize and destroy the tumor cell.

Lead molecule MT103 (MEDI-538) is being studied in a European Phase I B-cell lymphoma trial. An interim analysis of four patients showed one complete response and two partial responses, at doses "100,000-fold below Rituxan," Itkin said.

Micromet plans to start a European Phase II trial in acute lymphocytic leukemia in the second half of 2007, and North American partner MedImmune Inc. is planning a U.S. Phase I trial in non-Hodgkin's lymphoma for the first half of this year. Of its preclinical BiTE molecules, Micromet plans to advance MT110, which targets the

EpCAM tumor-associated antigen, into the clinic late this year.

With no time for D93, Micromet licensed the drug to Tracon, which Itkin said he chose because of the team's "excellent track record in developing biologicals and anti-angiogenic focus."

San Diego-based Tracon was founded in April 2005 by Bertrand Liang, who previously served as vice president of development and head of new ventures at Biogen Idec Inc. When Liang decided to start up the San Diego office of New York-based venture capital firm Paramount BioSciences, he stepped back to chairman of Tracon and filled the senior management ranks with executives who had contributed to the development of Rituxan (rituximab, Genentech Inc. and Biogen Idec Inc.), Zevalin (ibritumomab tiuxetan, Schering AG and Biogen Idec Inc.), Sutent (sunitinib, Pfizer Inc.), Macugen (pegaptanib, OSI Pharmaceuticals Inc. and Pfizer Inc.) and other drugs.

"The value of the company is in the people," said Tracon president and CEO Charles Theuer. An interesting point, considering Tracon has only four employees. Like many start-ups today, it's seeking to limit front-end expenditures by in-licensing compounds, handling strategic planning in house, and outsourcing preclinical and clinical development. Theuer added that Tracon can afford to "run lean" because Paramount provides functions like business development, legal and regulatory.

Tracon is exploring a Series A financing, but has survived thus far on convertible debt. Theuer said the company is trying to avoid the "typical multiple VC round" financing model, adding that Paramount companies also tend to obtain financing through the public markets or through PIPEs and reverse mergers.

Even with limited funds, Tracon has built an impressive pipeline. Farthest along is TRCI02, a small molecule that inhibits DNA repair to prevent chemotherapy resistance in cancer cells. A Phase I trial in combination with Temodar (temozolomide, Schering Plough Corp.) is slated for early in the second quarter, with an investigational new drug application for trials in combination with Alimta (pemetrexed, Eli Lilly & Co.) to follow by the end of the year.

Next up is TRCI05, a first-in-class monoclonal antibody that binds CD105. Theuer said he expects the mechanism of action to complement therapies that work through the VEGF pathway, such as Avastin (bevacizumab, Genentech Inc.) and Sutent. An IND filing in cancer is planned for mid-summer, followed by an IND filing in age-related macular degeneration by the end of the year.

Tracon plans to start a Phase I trial with D93 in solid tumors by the end of the second quarter. Preclinical work also is ongoing with TRCI01, a liposomal encapsulation of Taxotere (docetaxel, Sanofi-Aventis Group) and ceramide, an apoptotic factor normally depleted in cancer cells. ■

Trimeris

Continued from page 1

edged during a conference call that, “while there may be risks on the downside in owning it all, we’re now in a position to control that.”

In September, the two firms agreed to extend the research agreement by two years, through 2008. Now, Morrisville, N.C.-based Trimeris has the sole right to continue development of the lead compound in the program, and Roche would pay a “nominal” royalty on TRI-1144, if it reaches the market.

Trimeris still is finalizing the preclinical program, and Hill said officials must “re-think everything” after getting full rights back. Meanwhile, Dani Bolognesi, Trimeris’ CEO and chief scientific officer, has retired and Robert Bonczek, chief financial officer and general counsel, will do the same April 30. Through October 2008, Bolognesi will serve as a scientific consultant.

“We’re not looking for a new CEO at this time,” Hill said, adding that a member of his consulting firm, Hickey & Hill, “will most likely step in as CFO, as soon as Bob brings him up to speed.”

Hill said there is “no term to my engagement,” adding that he has spent his career helping firms through transitions. “My expertise is in right-sizing companies,” he said. Hill came aboard Thursday after serving as advisor for a week, and pledged to “stay around as long as I’m adding value.”

The conference call came as Trimeris disclosed earnings. For the fourth quarter of 2006, the firm earned \$4.7 million, a 25 percent hike over the same period the previous year. Revenue rose 57 percent to \$12.5 million. For the full year, profits reached \$7.9 million, compared to 2005’s \$8.1 million loss. Revenue totaled \$12.5 million, up 57 percent from the year before.

Credit for the increase went mainly to Roche’s strong global sales of Fuzeon (enfuvirtide), which hit \$73.3 million in the fourth quarter, 16 percent higher than the same period the year before. But Wall Street was more interested in why the Roche research changed, and what the management picture might become – especially given that Fuzeon’s growth potential might be “limited,” as ThinkEquity analyst Vinny Jindal pointed out in a research report.

“Overall, the changing of the company’s top executives leaves us scratching our heads, and calling into question the company’s future strategy,” Jindal wrote.

Trimeris’ cash, cash equivalents and investment securities available for sale totaled \$48.6 million at the end of 2006, compared to \$36.9 million when the previous year finished.

“Right now, we’re fairly comfortable with our liquidity and the future cash flow prospects from Fuzeon,” Hill said, and if the company must take TRI-1144 forward alone, “our cash is significant [to] get a fair distance into it.”

Asked whether the company is exploring in-licensing, Hill said he was “aware we are in discussion on one other project.”

Jindal, who questioned “the timing and reasoning behind

both actions” by Trimeris, was “left with little sense of confidence as to [the company’s] future.” He downgraded his rating from “accumulate” to “sell,” with a price target of \$7.

Analysts at First Albany in New York also downgraded Trimeris, from “buy” to “neutral.” Stifel Nicolaus & Co., though, maintained its “hold” rating and raised the earnings per share estimate to 59 cents from 8 cents. ■

CLINIC ROUNDUP

- **Amicus Therapeutics Inc.**, of Cranbury, N.J., completed enrollment in all ongoing Phase II studies of Amigal (migalastat hydrochloride, ATI001) in Fabry’s disease. The four studies are examining various dose levels and frequencies of Amigal to determine the safety and tolerability as the primary objective. The secondary objective is to evaluate certain pharmacodynamic measures of treatment, including effects on alpha-galactosidase A and globotriaosylceramide levels in various cells and tissues of disease. Results of the trials are expected by the end of the year.

- **Diffusion Pharmaceuticals LLC**, of Charlottesville, Va., initiated Phase I testing of trans-sodium crocetininate (TSC), its lead drug candidate designed to enhance the diffusion of oxygen into tissue. The trial will involve 48 healthy volunteers, and pending positive safety data, should allow the company to move into Phase II studies later this year. TSC is being studied as a potential treatment for diseases involving oxygen deprivation at the cellular level.

- **Pharmexa A/S**, of Horsholm, Denmark, initiated a Phase III trial of GVI001, a peptide vaccine, in combination with the chemotherapy compounds gemcitabine and capecitabine (Xeloda) in patients with inoperable pancreatic cancer. The trial will involve 1,110 patients randomized into three groups: the first group to receive gemcitabine and capecitabine in standard treatment, the second to receive initial eight-week treatment with gemcitabine and capecitabine followed by GVI001 and the third to receive gemcitabine and capecitabine concurrently with GVI001. Survival is the primary objective. The study is co-financed by Cancer Research UK, with Pharmexa paying for the vaccine for the trial and Basel, Switzerland-based **F. Hoffmann-La Roche Ltd.** providing Xeloda.

IS YOUR COMPANY FEATURED IN THIS ISSUE?

Promote it on your website or in your investor kit!

For high-quality reprints of articles about your company, please contact Stephen Vance at (404) 262-5511, or stephen.vance@ahcmedia.com

OTHER NEWS TO NOTE

- **MedImmune Inc.**, of Gaithersburg, Md., agreed to lease a portion of **Human Genome Sciences Inc.**'s facility in Rockville, Md., for the development and manufacturing of clinical trial material for cell culture-based seasonal and pandemic influenza vaccine. Financial terms were not disclosed, but MedImmune said the expanded capability will support its commitment to pandemic influenza vaccine development per a five-year, \$170 million contract awarded last year by the Department of Health and Human Services.

- **Neuralstem Inc.**, of Rockville, Md., raised \$5.1 million in a private placement of 2.1 million units priced at \$2.50 each to institutional investors. Each unit consists of one share of common stock and one-half warrant exercisable at \$3 per share. The company plans to use proceeds for its anticipated clinical trials in ischemic spastic paraplegia, as well as for working capital and other general corporate purposes. Neuralstem's technology is designed to produce neural stem cells of the human brain and spinal cord, and the company expects to submit its first investigational new drug application this year. T.R. Winston and Co. acted

as the placement agent.

- **Oncolytics Biotech Inc.**, of Calgary, Alberta, said results of a preclinical study of its reovirus for melanoma showed that it effectively replicated in and killed a range of human melanomas in vitro. Intratumoral injection of the reovirus also significantly delayed tumor growth in a mouse implanted with a human melanoma tumor. In addition, the melanoma cell death caused by reovirus also triggered an immune response leading to additional antitumor activity. Data were presented at the International Conference on Oncolytic Viruses as Cancer Therapeutics in Carefree, Ariz.

- **Titan Pharmaceuticals Inc.**, of South San Francisco, received a commitment of up to \$25 million in common stock equity financing from Azimuth Opportunity Ltd., which may be drawn down, from time to time at Titan's discretion, over the next 24 months in exchange for common stock. Proceeds will be used for product development activities, as well as for general corporate purposes. The company entered that agreement shortly after terminating a September 2005 equity line of credit agreement with Cornell Capital Partners LLC. Under that deal, Titan drew down a total of \$4 million, of a potential \$35 million, but had not drawn down any funds within the last 12 months.

APPOINTMENTS AND ADVANCEMENTS

PPD Inc., of Wilmington, N.C., has named Andy Strayer senior vice president of clinical operations for the Americas and Asia; Sue Stansfield senior vice president of clinical operations and project management for Europe; Mark Roseman vice president for clinical operations; and Randy Marchbanks vice president of business development for the Americas.

Protox Therapeutics Inc., of Vancouver, British Columbia, said James Beesley is joining the company as director of investor relations.

RegImmune Corp., of Mountain View, Calif., and Tokyo, appointed Shirley Liu Clayton as a nonexecutive director.

Sequenom Inc., of San Diego, appointed Paul Hawran

chief financial officer.

Solazyme, of Menlo Park, Calif., has named Donald E. Trimbur senior director of biofuel development.

Stellar Pharmaceuticals, of London, Ontario, has appointed John M. Gregory, CEO of King Pharmaceuticals, a new director.

TaiGen Biotechnology Inc., of Taipei, Taiwan, appointed Luke Lin vice president of clinical research and development.

Tapestry Pharmaceuticals Inc., of Boulder, Colo., appointed Sandra Silberman chief medical officer.

Transgenomic Inc., of Omaha, Neb., has appointed Rodney S. Markin to its board of directors.

Ventures West, of Vancouver, British Columbia, said Kenneth Galbraith joined the firm as venture partner.

VIRxSYS Corp., of Gaithersburg, Md., said Gerard McGarrity joined the company as executive vice president of scientific and clinical affairs.

BIOWORLD PERSPECTIVES

A free, weekly e-zine offering unique viewpoints on developments within the biotechnology industry. Sign-up today and get a fresh outlook on topics that you can't find elsewhere!

Go to BioWorld.com and click on "E-zine Sign-Up"!