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Private Deal Brings \$31M To Memory For Research

By Aaron Lorenzo
Washington Editor

Months after losing part of a partnership, Memory Pharmaceuticals Corp. extended its runway through the end of next year by raising about \$31 million in gross proceeds through a private stock and warrant placement.

The resources will fund the central nervous system-focused company's clinical, preclinical and exploratory research programs, and also be used for other working capital and general corporate purposes. As of June 30, Memory had about \$25.2 million in cash, cash equivalents and marketable securities, and the company posted an \$8.4 million net loss in the second quarter.

"I think this was an appropriate time to get additional funds in order to move our various programs forward," Jzaneen Lalani, Memory's vice president of legal affairs, told

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Mid-America VentureForum

Investors: Regulatory Rules Make Exit Paths Expensive

By Jennifer Boggs
Staff Writer

MINNEAPOLIS – As the FDA focuses on more rigid safety and regulatory guidelines, it is taking more investment capital and a longer time frame for investors to see returns, panelists said during a financing workshop, as the BIO Mid-America VentureForum got under way here Thursday.

Most of the more than 400 attendees filled a ballroom at the Hilton Hotel to hear opening remarks from Biotechnology Industry Organization president and CEO James Greenwood, as well as Tim Pawlenty, the governor of Minnesota, who expounded on the growing biotech sector in the Midwest, an area already known for its medtech and medical device industry.

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Battling The Recurrence Nightmare

Snail's Cancer Role Expands From Metastasis To Relapse

By Anette Breindl
Science Editor

Breast cancer, while scary, is a highly treatable disease, thanks both to clinical advances and to the work of advocates. Indeed, the five-year survival rate after diagnosis of a primary breast tumor now is more than 80 percent.

But in contrast to other types of cancer, which most likely will not recur at all if they have not done so within five years of diagnosis, breast cancer can recur even decades after the original tumor has been vanquished. And it is such recurrence that accounts for many breast cancer deaths, as well as the fear.

The molecular mechanisms of that recurrence have been elusive to date. But in the September 2005 issue of *Cancer Cell*, scientists at the University of Pennsylvania

See Breast Cancer, Page 3

CytRx Starting Phase II With Arimoclomol In ALS Patients

By Karen Pihl-Carey
Staff Writer

More than 64 years after baseball Hall-of-Famer Lou Gherig died of amyotrophic lateral sclerosis – a disease that has since taken on his name – CytRx Corp. has moved its small-molecule drug arimoclomol into a Phase II trial.

"Patients who have Lou Gherig's disease can now go to one of eight to 10 sites around the [U.S.]," said Steven Kriegsman, president and CEO of the Los Angeles-based company. "It's an opportunity to help them because right now there's really nothing available that really does any good. It's a disease that has no effective treatment."

The double-blind, placebo-controlled Phase II trial will enroll 80 ALS patients who will receive one of three dose levels of arimoclomol capsules three times a day for 12 weeks, or a placebo. Researchers are testing the drug

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FDA Request Delays Decision On Avanir's Neurodex In PBA

By Karen Pihl-Carey
Staff Writer

Less than three months after Avanir Pharmaceuticals Inc. completed the rolling submission of a new drug application for its pseudobulbar affect drug, Neurodex, the FDA has requested more information – meaning a decision probably won't come by the end of this year as originally expected.

Specifically, the FDA asked the San Diego-based company to provide an expansion of certain summary analyses in its application to better support new electronic data submission guidelines. Avanir expects to meet with the agency in the next few weeks to discuss the request.

Avanir submitted data to the FDA over a six-month period ending in June, when it completed the rolling NDA filing. It was expecting an FDA decision within six months. (See *BioWorld Today*, July 1, 2005.)

Pseudobulbar affect (PBA) is a neurological condition characterized by an emotional loss of control. It also is known as pathological laughing and crying, emotional lability and emotional incontinence.

Neurodex is made of dextromethorphan and an enzyme inhibitor that slows the otherwise rapid metabolism of dextromethorphan, which might work to control PBA by reducing excessive glutamate excitatory neurotransmission.

The submission included data from two controlled, multicenter Phase III trials of PBA: one in amyotrophic lateral sclerosis patients and the other in multiple sclerosis patients. In the first trial, the Neurodex arm showed statistically and clinically greater improvements than both the dextromethorphan arm and the quinidine arm in the primary efficacy endpoint, change in the Center for Neurological Study Lability Scale. In the second trial, Neurodex patients had a significantly greater reduction in that score than those receiving placebo.

The compound also is being developed in a Phase III

trial to treat diabetic neuropathic pain.

The company's stock (AMEX:AVN) fell 24 cents Thursday to close at \$3.06. ■

OTHER NEWS TO NOTE

- **Acadia Pharmaceuticals Inc.**, of San Diego, said data published in *Journal of Pharmacology and Experimental Therapeutics* show ACP-104, the major metabolite of clozapine, is a partial agonist that causes weak activation of dopamine D2 and D3 receptors, whereas clozapine and most other antipsychotic drugs block those receptors. The company, which is developing ACP-104 for schizophrenia with the added potential benefit of improving cognition, said that the partial agonist properties of ACP-104 might lead to less motoric side effects than seen with most other antipsychotic drugs.

- **AEterna Zentaris Inc.**, of Quebec, started a European multicenter Phase II trial of perifosine in combination with radiotherapy in non-small-cell lung cancer. The exploratory, double-blind, placebo-controlled trial will assess the efficacy and safety of a 150-mg daily dose of perifosine when combined with radiotherapy in 160 patients with inoperable Stage III NSCLC. Patients will receive perifosine daily for five to six weeks, starting seven days prior to radiotherapy, and they will be followed for at least 12 months. The product is partnered in North America with Keryx Biopharmaceuticals Inc., of New York.

- **Archemix Corp.**, of Cambridge, Mass., and **Nuvelo Inc.**, of Sunnyvale, Calif., decided to drop their development of ARCI83, which was being tested as an anticoagulant for potential use in acute cardiovascular settings, such as coronary artery bypass graft (CABG) surgery, and instead will pursue an optimized second-generation molecule. The partners closed a Phase I trial after preliminary results showed that the amount of ARCI83 needed to achieve the desired anticoagulation for use in CABG surgery resulted in a sub-optimal dosing profile.

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THOMSON



Breast Cancer

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School of Medicine and the University of California at Davis report on one protein that appears to underlie such recurrences, at least in an animal model: Snail, an inhibitor of transcription already known to play a role in cancer metastasis. (See *BioWorld Today*, Nov. 2, 2004.)

The difference between recurrence and metastasis, said senior author Lewis Chodosh, vice chair of the cancer biology department at the University of Pennsylvania's Abramson Family Cancer Research Institute, is that for recurrent cancer, there is a period in which the patient is symptom-free. In contrast, "you can have metastasis where there's no break in the action."

The scientists first created a mouse model that can overexpress Her2/neu. That tyrosine kinase is overexpressed in 20 percent to 30 percent of breast tumors and is one characteristic signaling of an aggressive form of the disease. In the animal model, the mice carry a transgene for Her2/neu that is controlled by an antibiotic-inducible promoter. When the mice are given antibiotic, the Her2/neu gene is expressed, and the mice develop tumors; antibiotic withdrawal leads to tumor regression, as Her2/neu is no longer expressed. However, about 85 percent of the mice will develop recurrent tumors within one year of remission.

The scientists first ascertained, through xenograft experiments, that the recurrences were indeed true recurrences of the original tumors rather than new tumors at the same site. While cells from the primary tumor had the characteristics of epithelial cells, the recurrent tumors showed characteristics of another cell type (mesenchymal cells) both in terms of histology and marker expression. Because Snail is prominently involved in the epithelial-to-mesenchymal transition, the researchers further investigated whether it plays a role in the recurrence they observed.

In a series of animal experiments, they demonstrated that Snail is up-regulated in recurrent breast tumors, and that it promotes tumor recurrence. They also showed in cell culture that Snail induced an epithelial-to-mesenchymal transition like that seen in the transition from primary to recurrent breast tumors in their animal model.

In a final analysis, the scientists investigated several microarray expression data sets of human breast cancer tissue samples that reported both Snail expression levels and clinical outcomes. They found that high levels of Snail expression predicted decreased relapse-free survival, and

that the increased risk was independent of other known prognostic factors such as estrogen receptor expression and lymph node involvement.

To Chodosh, that direct validation of the findings of the mouse model in human samples is one of the most remarkable aspects of the paper.

"I could list 30 reasons why this experiment wouldn't work even if [Snail] is involved," he told *BioWorld Today*. "The fact that it worked this robustly is remarkable."

In the clinic, Her2/neu is the target of South San Francisco-based Genentech Inc.'s Herceptin (trastuzumab), approved for the treatment of metastatic breast cancer in 1998 and, as the first humanized monoclonal antibody to be approved by the FDA, one of biotechnology's success stories.

Herceptin is effective at reducing the risk of disease recurrence; earlier this year, two Phase III studies in early stage breast cancer patients were halted prematurely when patients receiving Herceptin showed a more than 50 percent reduction in disease recurrence, compared to those receiving only chemotherapy. And last week, the results of another study were released, again showing significant improvements in disease-free survival for patients who received Herceptin in addition to chemotherapy.

However, Snail is not up-regulated only in Her2/neu overexpressing cancers; indeed, in the animal model, though the primary tumors are induced by Her2/neu overexpression, recurrence also occurs in the absence of overexpression. The human tissue analyses in the *Cancer Cell* paper also confirmed that tumors expressing high levels of Snail have a higher level of recurrence, whether they express Her2/neu or not.

Chodosh and his colleagues are conducting experiments to determine whether it is the epithelial-to-mesenchymal transition itself that causes recurrence, or whether Snail somehow allows residual neoplastic cells to survive. They also are investigating the Snail pathway to determine whether there are targets in it, such as kinases, that might be more tractable drug targets.

"Snail is a transcriptional repressor, and that's a tough nut to crack pharmacologically," Chodosh said.

He and his colleagues are interested in developing industrial partnerships to bring his research to the clinic. He hopes that "in 10 years, disease-free women will be taking a cocktail of drugs to prevent recurrence by wiping out these residual neoplastic cells." ■

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**2005 Survey
Results**

Memory

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BioWorld Today.

In the private placement, which is expected to close today, Montvale, N.J.-based Memory is selling about 16.1 million newly issued common shares at \$1.90 apiece to both new and existing institutional investors and other accredited buyers. Accompanying the stock will be warrants for the purchase of about 5.6 million additional shares exercisable at \$2.22 each.

Its current clinical research efforts are centered on investigational drugs for Alzheimer's disease and schizophrenia, with two compounds in early studies: MEM 1003, an L-type calcium channel modulator for the former, and MEM 3454, a nicotinic alpha-7 agonist for the latter. Other areas of interest for the company include depression, vascular dementia, mild cognitive impairment, Parkinson's disease and memory impairments associated with aging.

Lalani noted that those "multiple compounds and multiple programs," proved important in attracting investor interest.

The deal's definitive agreement was announced just before Wednesday's market close, and the company's stock (NASDAQ:MEMY) dropped 3 cents to \$1.83 by the time trading ended. Yesterday, the shares regained that amount to close at \$1.85. Lalani said the per-share price in the offering was based on a standard formula.

After the financing closes, Memory will file a registration statement covering the resale of the stock issued in the placement, as well as the shares issuable upon the

exercise of the warrants. As of June 30, the company had about 20.9 million shares outstanding.

Going forward, Lalani said Memory would work toward a number of milestones that have been etched into its calendar. The company by the end of this month expects to complete a safety and tolerability study for MEM 1003 and report those results, after which a Phase IIa trial is to begin.

Work also continues on MEM 3454, which is part of a broad nicotinic alpha-7 collaboration with F. Hoffmann-La Roche Ltd., of Basel, Switzerland, with Phase I expected to close shortly down the road. A Phase IIa trial is planned to begin in the first half of next year.

Also down the road, the company expects to make decisions on the future direction of two PDE4 inhibitors previously partnered with Roche: MEM 1414 and its backup, MEM 1917. MEM 1414 previously had been in Phase I.

In April, Roche said it would no longer fund development of the drugs on its own. That news dropped Memory's stock by one-third, but in the amended PDE4 collaboration signed last month, Memory regained all rights to those two compounds.

The agreement is continuing on other advanced leads, and Roche still has an option to get back into developing MEM 1414 and MEM 1917, though Memory is free to partner them elsewhere, as well. In the meantime, the company moves toward the data review of those drugs. (See *BioWorld Today*, Aug. 22, 2005.)

Still in preclinical development at Memory is a PDE10A program, from which it plans to name a drug candidate by the end of this year and seek a partnership. ■

OTHER NEWS TO NOTE

• **Cellerant Therapeutics Inc.**, of San Carlos, Calif., raised \$9 million in a second closing of its Series B round, bringing the total to \$25 million. The first closing was in May. The company is focused on the regulation of the hematopoietic system. (See *BioWorld Today*, May 12, 2005.)

• **Cel-Sci Corp.**, Vienna, Va., said that in connection with the settlement of litigation involving a shareholder and three former investors in Cel-Sci, the judge approved a settlement of the lawsuit that is expected to yield Cel-Sci about \$630,000. Cel-Sci expects to receive the money within the next 10 days. Cel-Sci is developing new immune system-based treatments for cancer and infectious diseases.

• **Cyberonics Inc.**, of Houston, agreed to sell \$125 million in 3 percent convertible senior subordinated notes due 2012 to qualified institutional buyers. The company also granted the initial purchaser a 13-day option for up to \$18.75 million in additional notes. Cyberonics intends to use a portion of the proceeds to purchase \$10 million in shares of its common stock as part of a stock repurchase

program, and to fund separate convertible bond hedge and warrant transactions. The remaining \$98 million is expected to go toward general corporate purposes, including the launch of its treatment-resistant depression product in the U.S. and Europe.

• **Eiffel Technologies Ltd.**, of Sydney, Australia, and **MAP Pharmaceuticals Inc.**, of Mountain View, Calif., signed a development and licensing agreement that provides MAP with the exclusive right to apply Eiffel's intellectual property to developing pharmaceutical products for pulmonary delivery of insulin, pulmonary and nasal delivery of steroids, and pulmonary delivery of combinations of long-acting beta agonists and steroids. Under the agreement, Eiffel will receive \$600,000 up front, as well as potential milestones and royalties.

• **Exelixis Inc.**, of South San Francisco, began a trio of Phase I studies. A trial of XL844 will be conducted in patients with chronic lymphocytic leukemia, and a study of XL184 will be conducted in patients with solid tumors for whom there are no available therapies. At the same time, a repeat-dose trial of XL784 is under way in healthy volunteers in preparation for a Phase II program to test efficacy in patients with renal failure.

Mid-America

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"For the last three years, we've seen the exciting growth of life sciences in this part of the country," Greenwood said, adding that BIO's annual convention will be held in Chicago next year.

Pawlenty, who has supported the growth of the life science industry in his state, said it is "a strategic and economic opportunity," and equated the continuing discovery efforts in biosciences as "going to the moon" for the current generation.

But it is a discovery that does not come cheap, and over the past few years, it has become increasingly difficult for early stage companies to secure much-needed financing.

Bill Kauffman, of Minneapolis-based Oppenheimer Wolff & Donnelly LLP, who moderated the financing workshop, said it is taking significantly more money to reach an exit these days. In 1996, private biotech firms were raising an average of \$26 million before filing for an initial public offering. In 2000, that figure increased to \$49 million, and by 2004, it rose to \$78 million.

However, total VC funds doubled in that time, and about 19 funds represented about two-thirds of the money raised: \$80 million in 1996, \$100 million in 2000 and \$160 million in 2004. So far in 2005, funds have totaled about \$185 million, Kauffman said.

And more money is going to fewer companies, he added.

Part of that is due to the more demanding regulatory requirements coming from the FDA, which is asking for larger clinical trials and longer follow-up periods, said Dale Spencer, who founded the medical device company ev3 Inc., of Plymouth, Minn., and has more than 30 years experience in the business.

He said the best bet is for firms to spend more time designing and executing clinical trials "instead of fighting" the agency's requests for additional data.

Tougher regulatory requirements translate into bigger risks for investors and heightened competition among young companies, particularly those that sport the most innovation.

Aron Knickerbocker, senior director of business development at South San Francisco-based Genentech Inc., said, "What we're seeing is that there's not a lot of venture money going into true venture. We hope that changes because it's really dangerous for the industry," he added.

Partnership Growing Among Biotech

Though investors might be skittish these days about funding new technologies and therapies, biotech firms still have partnership opportunities, though it's no longer "just pharma tapping into biotech," said Dennis Purcell, managing director, Perseus-Soros BioPharmaceutical Fund, in New York, during a partnering workshop. He said that during the last year, 60 percent of the partnerships in the sector were formed between two biotech companies.

"It used to be that a partnership with a company like [Johnson & Johnson] would validate" a firm's product "before going public," he said. "But now, biotech is holding on to its products longer."

Wanting to preserve a larger share of product rights also is turning the traditional licensing deal into a thing of the past.

"You're in it together now," said Denise McGinn, vice president of licensing and new business development of Centocor Inc., of Malvern, Pa., a unit of New Brunswick, N.J.-based Johnson & Johnson. "No one wants to straight out license a product anymore."

Instead, the focus is on securing co-promotion rights, buying equity in a partnering firm or splitting the services and the profits.

McGinn said about 63 percent of J&J's pharma group consists of products that were either in-licensed or acquired. Some of the firms' most successful deals include its collaboration with Cambridge, Mass.-based Millennium Pharmaceuticals Inc. for its protease inhibitor, Velcade, and its partnership with Neurochem Inc., of Laval, Quebec, for Fibrillex, which is being filed as a rolling new drug application to treat amyloid A amyloidosis.

But the company has had partnership troubles, as well, McGinn said, referring to "a legend at J&J" that the firm spent a lot of money in the 1990s to gain a late-stage Phase III product, but made a "fatal flaw" by putting its top executives on the joint product committee rather than the people who were doing the day-to-day work. Now, the company sets aside a day or two at the outset to integrate the work.

"We have an all-hands meeting" to discuss work and plans goals for the collaboration, she said.

"It's hard to look ahead, but you have to be asking the what-ifs and be projecting into the future as much as possible," McGinn said.

And sometimes it's not even the technical or development issues that tear a collaboration apart.

Mark Ungs, vice president of new development and emerging technologies for Boston Scientific Corp.'s cardiovascular division, said trust is one of the biggest issues in collaborations.

"Honesty is the root of the deal," he said, adding that if there's any sign of dishonesty, "I'll just write it off. I won't take the chance." ■

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CytRx

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for its safety and tolerability. Secondary endpoints include a preliminary evaluation of efficacy using an assessment of lung capacity, as well as the revised ALS Functional Rating Scale, which is used to determine a patient's capacity and independence in 13 functional activities.

The trial is expected to be completed in the first half of 2006, and would be followed by a Phase IIb study designed to detect more subtle efficacy responses in about 300 ALS patients at 25 clinical sites. That second trial is expected to take about 18 months.

Lou Gherig's disease, or ALS, is a progressive degeneration of the brain and spinal column nerve cells that control the muscles. It causes increasing muscle weakness, inability to control movement and difficulty speaking, swallowing and breathing.

About half of ALS patients die within 18 months of diagnosis and 80 percent die within five years. The care of one patient costs about \$200,000 a year.

In Europe, ALS is called Charcot's disease, named after the doctor who discovered it in 1874 in Paris. It gained notoriety in the U.S. when New York Yankees first baseman Lou Gherig died of it in 1941 at the age of 37.

In the U.S., an estimated 30,000 people have the disease and almost 6,000 new cases are diagnosed annually, according to the ALS Association.

Patients currently are treated with Paris-based Sanofi-Aventis Group's Rilutek, the only FDA-approved treatment for the disease, which improves patient survival by a few months.

"Our drug, arimoclomol, could be a miracle drug for those people with Lou Gherig's disease who die and suffer a horrendous, debilitating slide to death," Kriegsman told *BioWorld Today*. "Your mind is working perfectly and you can smell and you can taste and you can hear, but everything else shuts down. Eventually, you die of respiratory failure."

Arimoclomol is believed to work by stimulating a normal cellular protein repair pathway by activating "molecular chaperones." Since damaged proteins are thought to play a role in many diseases, CytRx believes that activation of molecular chaperones could have therapeutic efficacy for other afflictions, including Parkinson's, Huntington's, cystic fibrosis and Type II diabetes.

Elemer Piros, an analyst with New York-based Rodman & Renshaw, said arimoclomol's market potential exceeds \$1 billion, if it shows a "significant impact on survival" in ALS. He removed his "under review" rating of CytRx shares Thursday and upgraded the company to "market outperform/speculative risk" with a 12-month price target of \$3.50 per share.

CytRx's stock (NASDAQ:CYTR) rose 2 cents Thursday to close at 87 cents.

In Phase I trials, arimoclomol was well absorbed and well tolerated in healthy volunteers. The FDA granted it orphan drug designation in May for the treatment of ALS. Kriegsman said he didn't know of any other company that has an ALS therapy in Phase II development.

"A lot of trials have been attempted," Kriegsman said. "Amgen did a trial; Cephalon did a trial; Novartis did a trial. But in essence, I think they had the wrong compound. They didn't have the necessary technology at that time."

Arimoclomol is one of the few compounds, out of more than 70 tested in preclinical trials, that has demonstrated a benefit following disease onset, he said.

"In mouse models, the average life span was over 22 percent longer" in those treated with arimoclomol, Kriegsman said, who added that a sister compound, bimoclomol, has been used in more than 300 people for as long as 48 weeks with no serious drug-related adverse events.

CytRx filed its investigational new drug application for the Phase II trial in May, but the FDA placed the study on clinical hold two months later pending review of additional information, namely existing clinical safety data of the related compound bimoclomol. It also had to file an amendment of the protocol to include specific clinical tests to be administered to enrolled patients.

CytRx acquired both compounds, as well as iroxanadine for diabetes and cardiovascular disease, for about \$3 million plus milestone payments in October 2004 from Biorex Research & Development RT, of Veszprem, Hungary, which spent more than \$63 million to develop the drugs. (See *BioWorld Today*, Oct. 6, 2004.)

"I think we have about 94 patents worldwide," Kriegsman said. "We have about 16 years of patent protection. If we get this drug to market, it's potentially a \$2 billion drug worldwide."

Arimoclomol is not partnered, but Kriegsman said several pharmaceutical and large biotechnology companies have shown an interest.

"If an opportunity arises that is good for the shareholders and good for CytRx, we'll obviously consider it," he said. ■

OTHER NEWS TO NOTE

• **GenVec Inc.**, of Gaithersburg, Md., obtained commitments to purchase shares of its common stock in a registered direct offering for gross proceeds of \$14.5 million. Under the terms of the transaction, GenVec will sell about 7.3 million of its common stock at \$2 per share to a group of institutional investors. The closing of the offering is expected to take place on Monday. GenVec estimates net proceeds from the financing to be approximately \$13.4 million after deducting placement agent fees and the estimated costs associated with the offering.

OTHER NEWS TO NOTE

• **Genzyme Corp.**, of Cambridge, Mass., expanded projects in Belgium, Ireland, and the UK to support Genzyme's antibody and protein-based medicines. Together the projects represent capital investments of more than \$500 million over several years. Genzyme also announced today that in addition to producing humanized monoclonal antibodies at its new Geel, Belgium, plant, the facility will be used to meet the anticipated demand for Myozyme (alglucosidase alfa), an enzyme-replacement therapy under review with U.S. and European regulatory authorities for the treatment of Pompe disease.

• **Geron Corp.**, of Menlo Park, Calif., said its public offering of 6.9 million shares of common stock, including 900,000 shares issued upon exercise of an option granted to the underwriters to cover overallotments, closed Sept. 21. The public offering price was \$9 per share and the aggregate gross public offering price, including the shares issued upon exercise of the overallotment option, was \$62.1 million. Concurrent with the closing, **Merck & Co. Inc.**, of Whitehouse Station, N.J., exercised its warrant to purchase 2 million shares of Geron common stock with a total exercise price of \$18 million. The offering was originally announced last week. (See *BioWorld Today*, Sept. 19, 2005.)

• **Hana Biosciences Inc.**, of South San Francisco, received approval to list its common shares on the American Stock Exchange. Hana's common shares will begin trading on the AMEX Thursday under the symbol HBX. Hana acquires, develops, and commercializes innovative products to advance cancer care.

• **Hemosol Corp.**, of Toronto, entered an agreement with an agent under which a syndicate will market a private placement of units consisting of one common share and one common share purchase warrant. The syndicate has a mandate to raise up to \$10 million, with an agents' option to raise up to an additional \$5 million. The company needs to complete the private placement early in the fourth quarter to continue as a going concern.

• **IDM Pharma Inc.**, of San Diego, produced a first lot of Junovan that meets current specifications, as well as the prior specifications for the product to be used in a Phase III study in patients with high-grade non-metastatic osteosarcoma. The company achieved the milestone with its contract manufacturers, Genzyme Pharmaceuticals, of Liestal, Switzerland; NOF Corp., of Tokyo; Ben Venue Laboratories, of Cleveland, Ohio; and Solvias AG, of Basel, Switzerland.

• **llumina Inc.**, of San Diego, signed a commercial, multi-year genotyping services agreement with **GlaxoSmithKline plc**, of London. Illumina will use Sentrix Arrays in conjunction with its GoldenGate and Infinium assays to conduct genetic studies for thousands of samples provided by GSK. The blanket agreement enables multiple projects to be conducted over a period of time. Financial terms were not disclosed.

• **InSite Vision Inc.**, of Alameda, Calif., an ophthalmic therapeutics, diagnostics and drug delivery company, signed a manufacturing supply agreement with Cardinal Health for the manufacture of topical AzaSite (1 percent azithromycin) commercial units. Cardinal Health has manufactured the clinical trial supplies being used in InSite Vision's two Phase III bacterial conjunctivitis trials, and also the registration batches to be used for the AzaSite new drug application filing.

• **Intarcia Therapeutics Inc.**, of Emeryville, Calif., said it would withdraw its initial public offering and accompanying registration statement due to market conditions. The company had filed for an \$86.25 IPO earlier this year to garner funds for its cancer and hepatitis C virus programs. (See *BioWorld Today*, Feb. 8, 2005.)

• **LAB International Inc.**, of Laval, Quebec, successfully completed a Phase I trial of its asthma product LAB CGRP (calcitonin gene-related peptide). The double-blind, placebo-controlled study met its primary endpoints, demonstrating safety and tolerability of the drug.

• **MediciNova Inc.**, of San Diego, said its registration statement was declared effective, through which about 67.3 million of its common shares were registered. The stock may be offered for resale by the stockholders identified therein for their own account, and the specialty pharmaceutical company will not receive any proceeds from such sales.

• **Myogen Inc.**, of Denver, completed its \$125 million public offering. The company said it would use the \$116.4 million in net proceeds to continue the development of its product candidates and research program, including the acceleration and expansion of the darusentan clinical development program, to prepare for the potential commercial launch of ambrisentan and darusentan, as well as to fund working capital and for other general corporate purposes. The transaction included an original 4.7 million newly issued common shares at \$23.25 apiece, and another 700,000 shares for an overallotment. Goldman, Sachs & Co. acted as the offering's sole book-running manager. CIBC World Markets Corp., First Albany Capital Inc. and Lazard Capital Markets LLC acted as co-managers. (See *BioWorld Today*, Sept. 19, 2005.)

• **Myriad Genetics Inc.**, of Salt Lake City, said Phase II findings reported at the Congress of the International Psychogeriatric Association in Stockholm, Sweden, showed that patients with mild Alzheimer's disease who received 800 mg of Flurizan twice daily appeared to stabilize and experience no further decline in cognitive function from months 12 to 15, as measured by the Alzheimer's Disease Assessment Scale cognitive subscale test. Specifically, at 12 months, that dose group had declined an average of 2.8 points on the scale since the beginning of the trial, and after the three additional months on Flurizan, those patients had an average ADAS-cog decline of 2.7 points, indicating that patients did not decline further during the follow-on study and instead demonstrated a small improvement.

OTHER NEWS TO NOTE

- **Nabi Biopharmaceuticals**, of Boca Raton, Fla., received a favorable opinion in Europe regarding orphan medicinal product (OMP) designation for Altastaph to treat *Staphylococcus aureus* bacteremia. The company expects to receive formal OMP designation later this year.

- **National Center for Genome Resources** in Santa Fe, N.M., was awarded \$2.7 million by the National Institute of Allergy and Infectious Disease, part of the National Institutes of Health in Bethesda, Md., to develop diagnostic tests for severe sepsis and community-acquired pneumonia. The program, titled Community Acquired Pneumonia and Sepsis Outcome Diagnostics, involves investigators from five other organizations: Duke University Medical Center in Durham, N.C.; Henry Ford Hospital in Detroit; Eli Lilly and Co., of Indianapolis; Indiana Centers for Applied Protein Sciences in Indianapolis; and ProSanos Corp., of La Jolla, Calif.

- **Nektar Therapeutics Inc.**, of San Carlos, Calif., intends to offer \$200 million aggregate principal amount of convertible subordinated notes due 2012, in a private offering to institutional buyers. Nektar intends to grant the initial purchasers a 30-day option to purchase up to an additional \$50 million of notes to cover overallotments. The notes will be convertible into shares of Nektar's common stock. Proceeds may be used to fund possible repurchases of its outstanding convertible subordinated notes in transactions from a limited number of holders in privately negotiated transactions or in unsolicited open-market transactions, it said. The remaining proceeds will be used for general corporate purposes.

- **Neurogen Corp.**, of Branford, Conn., said its first-in-human, single ascending-dose study of NG2-73, its leading drug candidate for insomnia, produced reports of sleepiness among treated subjects. Also in the Phase I trial, the compound was safe and well tolerated across a broad dose range. NG2-73 selectively modulates receptors of the gamma-aminobutyric acid (GABA) neurotransmitter system. A second study is testing multiple ascending doses in healthy subjects, and a pharmacokinetic/pharmacodynamic study is under way to evaluate its sleep-inducing effects at various dosages in order to establish a range for Phase II.

- **NutraCea**, of El Dorado Hills, Calif., said its SynBiotics-3 product was approved to be added to the formulary at Mercy Hospital of Folsom as adjunctive therapy in the management of recurrent *Clostridia difficile* colitis, or antibiotic-associated diarrhea. The product contains bacteria called *Saccharomyces*, as well as NutraCea's fructooligosaccharide-rich stabilized rice bran derivative "RiSolubles" and other "friendly" bacterial strains.

- **Ortho Biotech Products LP**, of Raritan, N.J., said a study published in the September issue of *The Oncologist* demonstrated that Procrit (epoetin alfa) increased hemoglobin

levels more than Aranesp (darbepoetin alfa) in patients with cancer and anemia caused by chemotherapy. Within four weeks of initiating therapy, 47 percent of patients treated with Procrit achieved the primary endpoint of an increase in hemoglobin of 1 gram or more per deciliter of blood, compared to 33 percent of those treated with Aranesp, which is developed by Amgen Inc., of Thousand Oaks, Calif.

- **Osiris Therapeutics Inc.**, of Baltimore, began distributing Osteocel, a product indicated for the repair, replacement or reconstruction of bone defects. It is an allogeneic bone matrix containing viable stem cells, and provides an alternative to autograft in orthopedic procedures. Blackstone Medical Inc., of Springfield, Mass., will distribute the product under the Trinity brand, while Osiris also will market and distribute the product under the Osteocel brand.

- **ReNeuron Group plc**, of Guildford, UK, held a formal pre-investigational new drug application meeting with the CBER component of the FDA regarding its lead ReN001 stem cell therapy to treat chronic disability after stroke. The company is maintaining its preclinical development timelines and said it will file an investigational new drug application by mid-2006.

- **TransTech Pharma Inc.**, of High Point, N.C., received a milestone payment from its collaboration partner, **Novo Nordisk A/S**, of Bagsvaerd, Denmark, as a result of progress made with a drug candidate resulting from their collaboration. The compound was discovered during their collaboration using TransTech's small-molecule discovery engine, TTP Translational Technology.

- **Vernalis plc**, of London, signed a contract with **Diosynth Biotechnology**, of Research Triangle Park, N.C., for process development, scale-up and manufacturing of VI0153 for Phase III trials. VI0153 is a modified version of human plasminogen, a naturally occurring protein, which, when activated, is responsible for dissolving blood clots in the body.

- **Verus Pharmaceuticals Inc.**, of San Diego, said **Paladin Labs Inc.**, of Montreal, has launched Twinject in Canada. The product is an epinephrine auto-injector indicated for the emergency treatment of severe allergic reactions. Verus and Paladin Labs entered an exclusive agreement in July to commercialize Twinject in Canada.

- **ViaCell Inc.**, of Cambridge, Mass., said the FDA placed a clinical hold on its Phase I trial of CB001, an investigational cord blood product for hematopoietic stem cell transplantation, though the action is not in response to any new events in the study. ViaCell said it suspended enrollment in the study earlier this week, and the company and the agency had an agreement to suspend enrollment after two patients experienced Grade IV acute graft-vs.-host disease, or aGVHD. (See *BioWorld Today*, Sept. 20, 2005.)

- **Vical Inc.**, of San Diego, was awarded funding for a one-year, \$500,000 project for the Defense Advanced Research Projects Agency, of the U.S. Department of Defense. The award will fund feasibility studies of a new approach for rapidly manufacturing large quantities of DNA vaccines.