STEMCELL business news

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Top of the News...

StemCells, Inc., Geron Shares Surge on Promising Stem Cell Findings

Shares of StemCells, Inc. (STEM) skyrocketed $1.04, or 143 percent, to $1.78 in action Friday (as of this writing) on news that it had achieved some success in repairing nerve damage in very early-stage testing on mice, a finding that could point the way to treating spinal cord injuries. (*Story p. 2.*)

StemCells Says Neural SCs Repair Damaged Nerve Cells

(See p. 2…)

Shares of StemCells hit $2.25 at their session high, according to reports.

Geron also benefited from promising news in the stem cell sector, after University of Pennsylvania scientists announced that it may be feasible to coax embryonic stem cells to transform themselves into eggs, opening up the possibility there could be an abundant source of eggs for the research.

Geron (GERN) gained 30 cents, or 6.7 percent, to $4.85.

Some reports said the Penn findings may mean a key ethical barrier to stem cell research will soon be removed because it appears that eggs can be genetically engineered to prevent the production of a cloned baby while still allowing scientists to pursue cloning to harvest stem cells.

However, prevention of a cloned human is not the only ethical problem that bothers pro-life groups.

Creation of any human embryo, by whatever means, for the sole purpose of harvesting stem cells is unethical, they argue, because the embryo is destroyed when stem cells are removed.

StemCells, Inc. Says Neural Stem Cells Repair Damaged Nerve Cells

Scientists from StemCells, Inc. (Nasdaq: STEM), based in Palo Alto, Calif., on May 2 presented promising results of a pre-clinical study that examined the company's human neural stem cell (hCNS-SC) technology as a potential means of regenerating damaged nerve and nerve fibers in patients with spinal cord injuries.

Injured mice transplanted with hCNS-SC showed improved motor function in quantitative tests designed to measure functional recovery from complete hind limb paralysis to normal walking, in comparison with controls, the company said.

A direct link has also been made between the amount of functional recovery and the level of human cell engraftment.

Additionally, the company said, the hCNS-SC does not contribute to scarring due to glial cell proliferation, which normally inhibits neuronal cell growth and recovery.

The findings were reported by Dr. Aileen J. Anderson and Dr. Brian J. Cummings, of the Reeve-Irvine Center at the University of California, Irvine, at the annual conference of the American Society for Neural Transplantation and Repair.

"Loss of myelin, the insulator for nerve cells, is a significant problem after spinal cord injury," said Dr. Anderson. "This data suggests that human neural stem cells could contribute to repairing the nervous system after injury, including the replacement of myelinating cells. We are very excited about the potential for this type of intervention for spinal cord injury."

Dr. Cummings acknowledged that the sample size in the pilot studies was small. "However, we are particularly encouraged by the consistent trend for the transplanted animals to perform better than their controls," Dr. Cummings said. "Our task now is to replicate these studies and to evaluate the potential of these hCNS-SC at different dose levels."

"The potential significance of this study is that we may be able to help those with spinal cord injuries regain their mobility," said CEO Martin McGlynn. "This study elegantly demonstrates recovery of motor ability in a spinal cord injury model, resulting from the presence of human cells rather than spontaneous recovery of endogenous cells. While more testing is needed, we consider these recent findings very encouraging."

McGlynn said the results were "especially pleasing considering they are a recent follow-on to our presentation of positive pre-clinical data from a transplant study using hCNS-SC for the treatment of Batten Disease." (*See SCBN, April 18, 2003.*)

"This study provides us with additional hope that hCNS-SC may eventually improve pa-

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tients' lives by effectively treating a variety of central nervous system diseases and injuries," McGlynn added.

Dr. Aileen Anderson is an assistant professor, Departments of Physical Medicine and Rehabilitation at the University of California-Irvine.

She is also a core professor for The Reeve-Irvine Research Center, part of the College of Medicine of the University of California, Irvine.

Drs. Anderson and Cummings are co-investigators on this study.

The Reeve-Irvine Center, named for quadriplegic actor Christopher Reeve, studies injury and disease of the spinal cord and promotes the coordination and cooperation of scientists seeking a cure for paralysis and amelioration of diseases impacting neurological function.

StemCells, Inc is focused on the discovery, development and commercialization of stem cell-based therapies to treat diseases of the nervous system, liver, and pancreas.

Contact: Martin McGlynn, 650-475-3100, ext. 108, http://www.stemcellsinc.com

Contact: Reeve-Irvine Center, http://www.reeve.uci.edu

Cryo-Cell Delays Quarterly SEC Filing Again

Nasdaq Warns of Possible Stock Delisting

Clearwater, Fla.-based umbilical cord blood bank Cryo-Cell International, Inc. (Nasdaq: CCEL) said on April 22 that there would be a further delay in filing its quarterly SEC report because of "the company's continued assessment of the previously disclosed issues related to certain revenue recognition policies with its auditors."

Because of the continued delay, the company received a Nasdaq staff determination notice that its common stock is subject to delisting from the Nasdaq SmallCap Market for noncompliance with Nasdaq marketplace rule 4310(c)(14).

The company said its financial results for the quarter ended February 28, 2003, are expected to be reported on Form 10-QSB as soon as reasonably practicable following the conclusion of the on-going internal review and consultation with the SEC.

"The company is working to finalize the revenue recognition issues as quickly as possible," said CFO Jill Taymans. "The impact of any revisions that may result from the review are currently expected to be in line with the previously disclosed ranges of guidance."

Nasdaq requires the company to file the delinquent SEC Form 10-QSB within the next seven calendar day period or request a hearing.

In the meantime, the company's common stock will continue to be listed on the Nasdaq SmallCap Market but its symbol "CCEL" will have the fifth character "E" added, which signifies the delinquent filing.

In the event the company is unable to meet the seven calendar day filing requirement, it plans to request a hearing before a Nasdaq listing

qualifications panel to review the staff determination, which will automatically delay delisting of the company's common stock pending the results of the hearing.

There can be no assurance that the panel will grant the company's request for continued listing, the company said.

"Despite the delay in our Form 10-QSB filing, we continue to move forward with the execution of changes that we believe will positively impact the company going forward," said interim CEO Mercedes Walton in a statement.

New Marketing Strategy

In related news, the company on April 23 announced it had put in place a new channel-focused marketing strategy to target major market segments "that strongly influence parents' decisions to bank their newborn's cord blood stem cells at birth."

The company has mainly been marketing directly to expectant parents.

The segments include pre-natal care providers such as physicians, nurse midwives and childbirth educators.

In addition, the company said it is targeting a variety of "non-healthcare" affinity organizations that would particularly benefit from awareness of Cryo-Cell's preservation service.

Cryo-Cell appointed Kathy Notarino and Kris Dekom to oversee the new marketing effort.

Contact: Mercedes Walton, 800-786-7235, http://www.cryo-cell.com

Research Collaborations

Aastrom to Work with European Firms on Bone Graft Trial

Company Dropping Out of Bone Marrow Transplantation Market

Ann Arbor, Mich.-based Aastrom Biosciences, Inc. (NasdaqSC: ASTM) said on April 16 that its wholly owned subsidiary Zellera AG will collaborate with Mathys Medical, Ltd. (Bettlach, Switzerland) and Bergmannsheil University Clinic (Bochum, Germany) on a clinical trial using its tissue repair cells (TRCs) for bone graft applications.

The company also announced it was abandoning the bone marrow transplantation market and shutting down clinical trial efforts in that area.

"With Aastrom's focus shifting to products for these multi-billion dollar [bone grafting] markets, efforts previously directed to the now-declining bone marrow transplantation market are being decreased," the company said in a statement. "Consequently, Aastrom's U.S. SC-I clinical trials are being closed out and there are no current plans to continue this product development activity."

More Lucrative Market

If successful, the company said, the bone graft study may lead to an alternative to the current, highly invasive standard of treatment in the multi-

billion dollar bone graft market.

The study will use Aastrom's proprietary bone-forming TRCs in combination with Mathys' commercial synthetic bone graft matrix to treat patients with serious leg (tibia) fractures that require a bone graft for recovery.

Mathys is a leading supplier of synthetic bone graft matrix for the orthopedic market.

The trial, which expects to accrue five to ten patients, will be conducted at the University, a leading orthopedic treatment center in Germany.

The lead investigator for the trial is Thomas A. Schildhauer, M.D., senior physician of the Traumatology-Surgery Department.

Aastrom's TRCs are produced from small samples of bone marrow (which contain adult stem cells), using the AastromReplicell System, the company's automated platform.

TRCs are enriched for early-stage stem and progenitor cells that can form bone and other tissues.

A typical TRC product contains more than an 80-fold increase in the bone-forming cell types.

To date, TRCs have been safely used in more than 150 patients to generate normal bone marrow, blood and immune system cells.

The company recently announced that in the April 2003 issue of *The Journal of Bone and Mineral Research*, results of a compassionate-use study were published that demonstrated the ability of TRCs to form skeletal bone in a patient with a genetic skeletal disease.

"This collaboration follows a very successful two years of progress in our research program and is an excellent example of the expanding product and collaboration opportunities that Aastrom is pursuing for our proprietary technology," said CEO R. Douglas Armstrong, Ph.D., in a statement.

"Success in this clinical approach may provide the more than one million patients in the United States and Europe who require bone grafting procedures with an efficacious but less invasive, and therefore less morbid, alternative to the current standard procedure. If this approach is successful, it should result in an important product opportunity for the clinical use of TRCs in a major, multi-billion dollar market."

Typical bone grafting procedures include various types of spinal fusions and repair of major fractures such as non-union fractures of legs and arms.

The long-time standard procedure involves surgically chiseling out bone chips and marrow from the patient's hip to obtain the necessary quantities of bone graft material.

This process generally results in substantial acute and chronic pain and complications at the hip collection site.

In an attempt to eliminate this clinical problem, various bone matrix substitutes have been developed and are sometimes used as an alternative to the standard procedure.

They are not as effective, however, because they lack the cellular components needed to generate bone.

In this clinical study, Aastrom's bone-forming TRCs will be combined with Mathys' synthetic bone matrix product, and used by Dr. Schildhauer to augment the repair of serious non-union leg fractures.

Aastrom said it is planning other bone graft trials.

The company has submitted its lead bone graft trial plan to the U.S. Food and Drug Administration (FDA), and is currently in discussion with the FDA to move forward with this clinical track.

Aastrom has demonstrated success with its TRCs in clinical trials for bone marrow transplantation and, on a compassionate-use basis, in a young patient requiring bone generation.

This progress, the company said, has stimulated the company to move toward larger market opportunities, such as bone grafting.

Contact: Mathys Medical, Ltd., http://www.mathysmedical.com.

Contact: Zellera AG, http://www.zellera.de.

Contact: R. Douglas Armstrong, Ph.D., 734-930-5777, http://www.aastrom.com

Analysis

Stem Cell Sector Needs a Viable Product to Spark Investor Interest

If stem cell companies expect to attract serious investor dollars within the next year or two, they'll have to come up with at least one stem cell-based product that meets a genuine market need, investment banker William Kreidel, managing partner of Ferghana Partners Ltd., said this week.

In an interview with *Stem Cell Business News*, Kreidel recapped his presentation at an April conference in which he described the current state of stem cell business and offered a "prescription" for future prosperity.

A primary need among the 115 companies involved in the stem cell research sector, and especially among the 78 that are developing therapeutic products, is funding.

There has been precious little of that in the last year or so, Kreidel said. Financing has come from a few sources: the federal government (i.e., DARPA and NIH), a handful of initial public offerings, and a dozen private placements.

The amount of money raised in the United States through private placements was about $120 million, an amount that Kreidel called "insufficient to support the stem cell sector."

And the public markets "don't look good" either as a viable source of cash, he added.

With investment cash getting tougher and tougher to come by, stem cell companies – they are mostly small operations with fewer than 50 employees and virtually no revenues – tried a variety of tactics to keep their product development activities alive.

Strategic partnering was one tactic; mergers and acquisitions (M&A) was another.

But because the companies involved are so small, M&A activity is like "midgets marrying other midgets to give birth to normal-size progeny," Kreidel said.

To overcome these challenging circumstances and move forward, three key factors will need to come into play in the stem cell sector over the next year, Kreidel said.

These three factors comprise Kreidel's "prescription" for the sector for the near term:

– Smaller stem cell companies will need to consolidate into a few medium-size firms;
– Venture capital firms will need to step in and provide greater support for existing and consolidating companies; and,
– At least one "truly novel and useful therapeutic product" that meets a need that is currently inadequately served in today's market has to be developed and introduced.

In fact, Kreidel said, "until the launch of such a product there will be very little incentive" for investors to pay much attention to the sector, which seems right now to be little more than an "academic oddity" and a "backwater" of the biotechnology industry.

An example of the attitude of some big pharmaceutical firms toward stem cell research can be found in the recent remarks of Merck & Co Inc (MRK) Chairman and CEO Raymond Gilmartin.

In an interview with Reuters, Gilmartin echoed Kreidel's sentiments when he said his company supports stem cell research but isn't involved in it because the research seems too "early stage," thanks in part to the bioethical controversy still stewing in Washington and in state capitals around the country.

"I think there are ways to do [stem cell research] in a highly ethical way, consistent with our values and principles, so therefore it is an important area," Gilmartin said.

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Earnings

Geron Reports $7.9 M First Quarter Loss

Stem cell research pioneer Geron Corporation (GERN), based in Menlo Park, Calif., on April 30 reported a $7.9 million loss for the three months ended March 31, 2003.

The company reported revenue of $262,000 and operating expenses of $8.3 million compared to $626,000 and $11.8 million last year.

The $7.9 million or $0.32 a share loss compared to $10.5 million ($0.43 a share) last year.

The company said it had $7.6 million in cash and about $32 million in marketable securities as of March 31.

Revenues for the first quarter of 2003 represented reimbursement for consulting agreements with various biotechnology companies, royalty revenues under various license agreements with companies for sales of telomerase-based diagnostic kits, shared profits from sales of reagent research products, and license fee revenues recognized from sublicense agreements or license option agreements with various companies for nuclear transfer and telomerase promoter technology, the company said.

Revenues for the first quarter 2002 also included the final payment for the research phase under a collaborative agreement with Kyowa Hakko.

The decline in operating expenses reflected reduced personnel-related costs associated with restructurings in June 2002 and January 2003, the company said.

Also in March 2002, the company acquired patents relating to oligonucleotides containing phosphoramidate backbone linkages from Lynx Therapeutics, Inc. for $2.5 million in a combination of cash and stock.

The company expects its reduced operating costs to absorb a portion of the potential increases in expenses related to manufacturing and testing of GRN163, Geron's telomerase inhibitor drug.

In its 10-Q filing with the Securities and Exchange Commission, Geron was careful to warn investors that the company has had a history of losses, primarily because it still lacks product revenues and continues to spend money on development and clinical testing.

"Substantially all of our revenues to date have been research support payments under collaboration agreements," the company explained. "We may be unsuccessful in entering into any new corporate collaboration that results in revenues. Even if we are able to obtain new collaboration arrangements with third parties the revenues generated from these arrangements may not be sufficient alone to continue or expand our research or development activities and otherwise sustain our operations.

"We are unable to estimate at this time the level of revenue to be received from the sale of diagnostic products and telomerase-immortalized cell lines, and do not currently expect to receive significant revenues from the sale of these products. Our ability to continue or expand our research activities and otherwise sustain our operations is dependent on our ability, alone or with others to, among other things, manufacture and market therapeutic products.

"We may never receive material revenues from product sales or if we do receive revenues, such revenues may not be sufficient to continue or expand our research or development activities and otherwise sustain our operations.

"We will need additional capital to conduct our operations and develop our products, and our ability to obtain the necessary funding is uncertain.

"We will require substantial capital resources in order to conduct our operations and develop our products. While we estimate that our existing capital resources (including the financing completed in April 2003), interest income and equipment financing arrangements will be sufficient to fund our current and planned operations through June 30, 2005, we cannot guarantee that this will be the case."

The company also listed several factors

that could have an impact on the timing and degree of any future capital requirements.

Geron said it intended to obtain additional funding "through strategic collaborations, public or private equity financings, capital lease transactions or other financing sources that may be available," if the financing sources and terms were acceptable.

Geron's product development programs are based upon three patented core technologies: telomerase, human embryonic stem cells and nuclear transfer.

To read Geron's quarterly SEC filing, visit http://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0000886744

Contact: http://www.geron.com.

People

BioMarker Pharmaceuticals, Inc. (Campbell, Calif.): Named Michael West, a founder of Geron Corporation and now CEO of cloning firm Advanced Cell Technology, Inc. (Worcester, Mass.), to it board of directors. BioMarker is using a proprietary, scientifically validated approach to discover and develop safe and effective therapeutics to retard aging.

Contact: Paul Watkins, 408-257-2000, http://www.biomarkerinc.com

Osiris Therapeutics, Inc. (Baltimore, Md.): Named James R. Tobin, president and CEO of Boston Scientific Corporation (BSX), to its board of directors. Prior to joing Boston Scientific, Tobin was CEO of Biogen, Inc. Osiris is focused on adult stem cell therapy for tissue regeneration, using its proprietary mesenchymal stem cell and universal MSC technologies.

Contact: Donald Fallon, 410-522-5005 x341, http://www.osiristx.com