

Tenth Quarterly Update on
Stem Cell Research and Regenerative Medicine -
California and the wider US

**Informal report by the UK Science and Innovation Team, San Francisco,
for UK readers**

This quarterly report highlights recent developments in stem cell research and regenerative medicine in California, following the Proposition 71 initiative* in 2004, and across the United States.

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* In November 2004, Proposition 71 was passed which created the California Stem Cell Research and Cures Act. This authorises and funds stem cell research in California over the next 10 years with a \$3 billion fund. The California Institute for Regenerative Medicine (CIRM) was created to administer and distribute these funds, with oversight from an Independent Citizen's Oversight Committee (ICOC).

California / CIRM

- ***Current Issues***

During May and June, the Facilities Working Group of CIRM held four public workshops to assess the need for new stem cell research laboratories in California. The CIRM has earmarked \$222 million for grants to develop major new research facilities. The Institute expects to begin soliciting grant applications in August, and take funding recommendations to its governing board in the first quarter of 2008. Criteria and scoring for applications were posted in July. A firm timetable has not been set, but Robert Klein, chairman of the Oversight Committee, said he expected to see initial approval of the grants in early January.

After three unsuccessful meetings, the ICOC (the 29-member governing board of CIRM) named Dr. Richard Murphy interim president for CIRM at a fourth meeting on August 8th. On 1 September, Dr. Murphy will take over from Lori Hoffman, who has served as the institute's acting president since May, following the retirement of Dr. Zach Hall in April. As interim president, Dr. Murphy will serve as a consultant for up to six months. He has stated that he does not intend to be a candidate for the permanent position, as he plans to return to the east coast to be closer to family. Dr. Murphy retired as President and CEO of the Salk Institute for Biological Studies in La Jolla, California, on July 1, 2007.

On July 27, Standard Working Group moved to add Japanese stem cell lines to the already approved lines from the UK and Canada. This would mean that research in California using these lines does not have to go through a more lengthy review process. The Japanese lines being considered are those derived under the "Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells." The Standard Working Group's recommendation now needs to be taken up by the Oversight Committee.

On May 31st, California Governor Arnold Schwarzenegger and Canada's Premier Dalton McGuinty signed a deal to boost stem cell research. Schwarzenegger announced collaboration between UC Berkeley's Stem Cell Center and Canada's International Regenerative Consortium to coordinate research and take advantage of each institution's expertise. McGuinty announced the creation of the Cancer Stem Cell Consortium, which will coordinate and fund cancer stem cell research of both Canada and California researchers, universities and private industry. In addition, the Ontario Institute of Cancer Research (OICR) will donate the first \$30 million (Canadian) to fund the Consortium, benefiting both Canadian and Californian researchers.

On 17 May, scientists at the University of California, Merced and the Buck Institute for Age Research in Marin County established a cooperative agreement with UC Davis to meet the oversight requirements of the CIRM for stem cell research. Through the agreement, UC Merced and the Buck Institute will use a

UC Davis Health System medical and ethical standards committee to review any potential human subject research funded by CIRM.

- **Legal Issues**

In June, Senate Bill 771, authored by Senator Sheila Kuehl, Santa Monica, was put off until 2008 to allow the stem cell agency to finish its regulations for intellectual property, the vehicle for determining how to split up potential largess from stem cell products. The bill was introduced in February to increase the return to the state on its stem cell research investment and to provide access to any resultant therapies at (low) Medicaid prices to patients whose care is provided with public funds.

- **CIRM Funding Programmes**

On June 5th, CIRM awarded \$50 mio of the Shared Research Laboratory Grant Program to 17 institutions. The grants will provide funds for the design and renovation of laboratory space, equipment for the new research facilities, and operating expenses for three years. Six of the recipient institutions will receive additional funds to provide training courses for scientists and technical staff in the growth and maintenance of hESCs. A list of successful applicants with links to project summaries can be found at <http://www.cirm.ca.gov/press/pdf/2007/06-05-07.pdf>

On June 28th, CIRM released a call for proposals for the New Faculty Awards Program, totalling \$85 million. The programme will fund up to 25 promising M.D. and Ph.D. scientists in the early stages of their careers as independent investigators. CIRM intends to provide salary and research support for up to five years. Applications are due in August.

Other US State News

Interstate Alliance for Stem Cell Research (IASCR) - A group of state officials from nine states - California, Massachusetts, Connecticut, Illinois, Maryland, New Jersey, New York, Wisconsin and Rhode Island - have forged a coalition to help establish national guidelines and common rules to manage stem cell research initiatives across state lines. The new alliance will focus on avoiding interstate inconsistencies and confusion by establishing standards and common processes for managing intellectual property, tracking stem cell lines and information sharing. Observers from the US S&I Network and from the Canadian consulate also attended the IASCR planning meeting in May.

(http://www.bizjournals.com/masshightech/stories/2007/07/02/story6.html?from_rss=1)

States

Key: ● positive or ● negative development for stem cell researchers

● **Delaware** - Legislation to regulate stem cell research in Delaware was defeated in a House vote on June 30. Senate Bill 5 passed the Senate on a 13-7 vote in March, but received only seven affirmative votes from the House, with 30 representatives voting against it. The surprise vote came after the bill's lead House co-sponsor, Rep. Deborah Hudson, R-Fairthorne, introduced two amendments, one that she said was to "clarify" that the bill did not intend to encourage somatic cell nuclear transfer. This amendment left many representatives uncertain about the bill's scope and whether it would hold back embryonic cell research. The bill is expected to resurface in January. Currently, Delaware has no laws governing stem cell research.

● **Illinois** - On May 31, The Illinois House voted 70-44 to endorse stem cell research and set up an institute to award grants to scientists. The measure now goes to Democratic Gov. Rod Blagojevich, who supports stem cell research. Blagojevich has used his executive powers to provide \$15 million in grants over the past two years without approval from lawmakers. The new legislation would make the grants a formal part of state law.

● **Iowa** - The Iowa 'Stem Cell Research and Cures Initiative' went into effect in July. The bill was signed in February, lifting the ban on "somatic cell nuclear transfer," or therapeutic cloning while prohibiting human reproductive cloning. State funding for the research has not increased.

● **Maryland** - Twenty four researchers were awarded grants on 17 May by the Maryland Stem Cell Research Commission. The 24 were chosen from among 86 applicants. The \$14.5 million state fund was established last year by the legislature to advance stem cell research and to foster Maryland's biotechnology and life sciences industry. An additional \$23 million was appropriated during this year's legislative session to fund awards in 2008. More than half of the grant recipients are affiliated with Johns Hopkins University. Under the Maryland legislation, all of the work must be done in Maryland by Maryland-based institutions.

● **Missouri** - After voters amended the state's constitution to protect stem cell research, conservative Missouri lawmakers have now removed funding for stem cell research, including a \$150 million research center at the University of Missouri in Columbia. In addition, a medical institute in Kansas City, the Stowers Institute, announced it would halt its \$300 million expansion project because of controversy over the research. The research institute also moved a large chunk of its endowment to Delaware, calling the political climate in Missouri too hostile for investment. Sen. Chris Koster announced on July 31 that he was switching from the Republican to the Democratic Party, as he prepares for a likely run for

attorney general. Koster said he has determined that he is more aligned with Democrats than Republicans on several issues, including stem cell research.

- **New Jersey** - In agreement between Gov. Jon Corzine and state legislative leaders will result in a \$450 million bond referendum being put before New Jersey voters this autumn. If approved, the money will be used to augment support for the state's stem cell research initiative over the next 10 years. New Jersey already has committed to spending \$270 million on stem cell research. On the same day the bond issue agreement was announced, the New Jersey Economic Development Authority (NJ EDA) approved \$9.2 million in preconstruction costs for the planned Stem Cell Institute facilities in New Brunswick. Major construction is slated to begin next year and is expected to conclude sometime in 2011.
- **New York** – New York State Legislature passed a budget measure that provides \$600 million over the next 11 years to fund regenerative medicine research, including human embryonic stem cell research. The initiative also provided state funding for the creation of the Empire State Stem Cell Board which will provide state grants for basic, applied, transitional and other research that advances stem cell biology.
- **North Carolina** - The North Carolina House has approved legislation that would authorize the use of state taxpayer dollars to fund human embryonic stem cell research. House Bill 1837, the Stem Cell Research and Wellness Act, passed the House in a 60 to 55 vote on July 27. The House Appropriations Committee approved the measure the day before by a 45 to 35 margin. The measure would provide guidelines for the issuance of grants from the State Health and Wellness Trust Fund to non-profit organizations that would then use the funds to conduct research involving hESCs. A \$10 million appropriation was removed from the bill, with the argument that it could take about a year for the trust fund to set up rules for issuing grants. The bill will be taken up by the Senate now.
- **Oregon** - In June, a vote in the Oregon House derailed a bill that would have put Oregon among the growing number of states exploring public funding for stem cell research. The bill called for spending of about \$160,000 over the next 18 months to support a committee of researchers, medical ethicists, family law specialists and members of the public. The group would be charged with writing guidelines for future state investment in stem cell research, and seeking both public and private donations. The final vote was 30 "yes" votes and 29 "no" votes, but a measure needs at least 31 votes to pass. Rep. Larry Galizio, D-Tigard, then changed his vote, opening the door for the bill to return for one more go-around.

Federal News

On June 20, President Bush vetoed a bill that would have reduced the restrictions on federal funding for embryonic stem cell research. Congress sent the bill to the White House earlier in the month, after the House passed it 247 to 176 and the Senate passed it 63 to 34. The White House said Bush vetoed the bill as a matter of conscience because it would have forced taxpayers to spend money on work that destroyed human embryos.

Federal funding of stem cell research looms as a major issue in the 2008 presidential campaign. All the Democratic candidates support lifting Bush's ban on expanding stem cell research, and the leading Democratic contenders, Sen. Hillary Rodham Clinton of New York and Sen. Barack Obama of Illinois, quickly condemned Bush's veto and pledged to encourage embryonic research if they are elected. Two of the leading Republican candidates, Sen. John McCain of Arizona and former New York City Mayor Rudy Giuliani also have said they would lift the president's ban on federal money for embryonic stem cell research. A recent Washington Post-ABC News poll found that 68 percent of Americans surveyed support embryonic stem cell research.

On July 19, the House of Representatives agreed to the Smith-Davis amendment to the Labor, Health and Human Services Appropriations Bill FY08. Passage of the amendment means the federal government will now allocate \$15 million, instead of the original \$4 million, in FY08 to the National Cord Blood Inventory (NCBI). Smith's "Stem Cell Therapeutic and Research Act of 2005" authorized the collection of 150,000 units of cord blood for the NCBI, with a focus on genetic diversity that is expected to meet the needs of 90% of all patients. These units will be made available through an open registry that will link public cord blood banks nation-wide to simplify searching for a blood match for stem cells. The law mandates that any units of cord blood collected and deemed unsuitable for transplantation be donated for additional cord blood stem cell research.

IP Policy Issues

On May 31, the Wisconsin Alumni Research Foundation (WARF) filed a response refuting the U.S. Patent and Trademark Office (PTO) first office action in the ongoing re-examination of the foundation's patents on human embryonic stem cells. The PTO had released a preliminary decision in April that invalidated three key human embryonic stem cell patents held by WARF, with the argument that the patented cells appeared to be the same as, or clear variations of, cells described in earlier scientific papers or in other patents. In response to the ruling, WARF narrowed its claims, excluding human ES cells from sources other than fertilized eggs, such as cloning. WARF also provided the PTO with statements of support from Colin Stewart, a stem cell researcher from Singapore, and a list of

accolades bestowed upon Thomson at the time he isolated the cell lines, including honours from the American Association for the Advancement of Science. The three WARF patents are being challenged in a process that could reach the federal courts and take several years to resolve.

In July, four prominent stem cell scientists, Harvard researchers Chad Cowan and Douglas Melton, Alan Trounson of Australia's Monash University and Jeanne Loring of the Burnham Institute for Medical Research in San Diego, filed "declarations" in support of a citizens' group that is trying to break the University of Wisconsin's hold on patents for hESCs.

University/Research Institution News

For more detail on news items, click on [•](#) or see Appendix.

Ethics

- A paper by [Dartmouth University](#) Professor Ronald M. Green examines the moral questions and the scientific feasibility of deriving hESC lines in ways that avoid destroying living human embryos. June 2007, Nature Reviews Genetics. *
- A paper by Anne Drapkin Lyerly and Ruth R. Faden presents results of a national survey of patients undergoing fertility treatment in the US, suggesting that 60% of patients would be prepared to donate cryopreserved embryos for research leading to stem cell line derivation. July 6, Science. *

Research

- [University of Pittsburgh](#) investigators have engineered artificial blood vessels from muscle-derived stem cells and a biodegradable polymer suitable for grafting into rats. Tissue Engineering and Regenerative Medicine International Society North America Chapter meeting. *
- Researchers at the [University of Buffalo](#) have also tissue-engineered blood vessels from bone marrow adult stem cells. May, Cardiovascular Research. *
- Researchers at [Harvard](#) have demonstrated that nuclear reprogramming can occur after fertilisation, and were able to use a fertilised egg containing three sets of chromosomes as the recipient for somatic cell nuclear transfer. June 7, Nature. *
- Research groups at the [Whitehead Institute](#), Cambridge, Massachusetts and at the [Harvard Stem Cell Institute](#) in collaboration with scientists at [UC Los Angeles](#) report that they have changed differentiated mouse adult cells into pluripotent stem cells. July 19 issue, Nature, and June 7, Cell Stem Cell. *

- Researchers at the Oregon National Primate Research Center in Portland reported successful somatic cell nuclear transfer using rhesus monkey oocytes. Presentation at annual meeting of the International Society for Stem Cell Research. *
- Researchers at Northwestern University's Feinberg School of Medicine in Chicago conducted the first U.S. study to transplant purified adult stem cells into the heart muscle of patients with severe angina. June 26, *Circulation*. *
- Researchers from the University of California, San Diego grafted human spinal stem cells into paralysed rats and showed improved movement. June 29, *Neuroscience*. *
- Researchers at UC San Francisco published a study showing that adult neural stem cells in the mouse brain are less plastic than previously thought. July 20, *Science*. *
- Scientists at the University of Wisconsin-Madison have shown in rats that it is possible to rescue the dying neurons characteristic of amyotrophic lateral sclerosis (ALS) by secretion of a key growth factor. July 31, *PloSOne* *
- Researchers from UCLA and Howard Hughes Medical Institute at the University of Texas Southwestern Medical Center at Dallas have differentiated hESC cultures into neurons, obtaining a yield of 70-80%, and determine that they had a functional synaptic network. 6 August, online version, *PNAS*. *

Company News

For more detail on news items, click on [•](#) or see Appendix.

Collaborations, Mergers, and Acquisitions

- In May 2007, Advanced Cell Technology of Alameda, California, entered into a letter of intent to acquire Mytogen, Inc., an autologous adult stem cell company with a therapy for cardiovascular disease, for \$5 million in Advanced Cell stock. *
- ThermoGenesis, of Rancho Cordova, California, and the Stem Cell Program at the University of California at Davis entered into a researcher collaboration aimed at developing stem cell therapies based on company's technology. *

Clinical Trials

- Harvest Technologies Corp. of Plymouth, Massachusetts, announced on 30 May that the Food and Drug Administration (FDA) has given approval to commence a 'feasibility' clinical trial using the company's device for concentrating

a patient's own (autologous) bone marrow stem cells to treat patients with Critical Limb Ischemia (CLI). *

Research

- Geron Corporation of Menlo Park, California, reported on May 17 that its scientists and collaborators at the University of Alberta differentiated hESCs into islet-like clusters (ILCs) that secrete insulin in response to elevated glucose levels. August, Stem Cells. *

- Advanced Cell Technology has successfully produced a hESC line without destroying an embryo at its lab in Worcester, Massachusetts. Presentation at meeting of the International Society for Stem Cell Research. *

- On June 15, Invitrogen Corp., of Carlsbad, California, launched a new engineered stem cell line that will allow scientists to monitor the pluripotency of hESCs without sacrificing those cells. *

- Researchers at Lifeline Cell Technology, Walkersville, Maryland, together with a Russian group, announced that they have created human embryonic stem cells by stimulating unfertilized eggs to begin embryonic development (parthenogenetic cell lines). June, Cloning Stem Cells. *

UK Science & Innovation Network activities

In August, S&I secured significant funding through the FCO's Global Opportunities Fund to extend stem cell researcher collaborations between UK and US scientists over the next two years. Part of the programme will be a short term visit scheme (up to 3 months), designed to allow researchers to discuss projects in depth, to learn techniques and to establish long-term collaborations. If you are interested in information on this programme, please e-mail maike.rentel@fco.gov.uk.

The University College of London's Institute of Ophthalmology and its Moorfields Eye Hospital signed a collaboration agreement with the University of Miami's Bascom Palmer Eye Institute in May. Both institutes are world leaders in eye care and research. The groundwork for this agreement was laid during a visit, organised and sponsored by S&I, of Bascom Palmer's Scientific Director and Director of Business to the UK.

S&I represented the UK at a planning meeting for the Interstate Alliance for Stem Cell Research, IASCR (see under 'Other states' above). States currently embarking on stem cell research are in the process of setting down legislation. IASCR meeting participants were well aware of the UK's leadership and eager to draw on UK learning in arriving at consensus approaches. The US S&I Network

will continue to feed into this process. Meeting participants agreed that international observers were welcome at future meetings.

A study released in June marks 4 years of research and a successful collaboration between teams led by Professor Colin McGuckin at the University of Newcastle and Professor Larry Denner at the University of Texas Medical Branch. Their research created human tissue producing insulin from Cord Blood Stem Cells. S&I had been instrumental in setting up the DTI funded Texas-UK Bioscience collaboration which fostered this link, and in particular Prof. McGuckin's work and visits to Texas. The study is published in Cell Proliferation.



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Appendix – Expanded News

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University

Ethics

- A paper by Dartmouth University Professor Ronald M. Green examines the moral questions and the scientific feasibility of deriving hESC lines in ways that avoid destroying living human embryos. The paper considers six current approaches: altered nuclear transfer, parthenogenesis, single-blastomere biopsy, somatic-cell dedifferentiation, the use of "dead" embryos, and the use of abnormal embryos. Green's goal, as stated in the paper, is "to greatly accelerate hESC research that is closer to being universally acceptable." The paper was published in the June 2007 issue of Nature Reviews Genetics. [*](#)
- A paper by Anne Drapkin Lyerly and Ruth R. Faden presents results of a national survey of patients undergoing fertility treatment in the US. The results suggest 60% of patients would be prepared to donate cryopreserved embryos for research leading to stem cell line derivation. Donation for research represented the morally-preferred option in many cases - only 22% of individuals with embryos currently stored indicated that they were likely to donate them to another couple intending pregnancy, comparable in number to those who indicated they were likely to thaw and discard them. The study was published in the July 6 issue of Science. [*](#)

Research

- University of Pittsburgh investigators have engineered artificial blood vessels from muscle-derived stem cells and a biodegradable polymer that exhibit extensive remodelling and remain free of blockages when grafted into rats. The approach could use a patient's own stem cells and could produce blood vessels ready for vascular grafting for heart and kidney disease after a short culture period. The study was presented at the Tissue Engineering and Regenerative Medicine International Society North America Chapter meeting. [*](#)
- Researchers at the University of Buffalo have also tissue-engineered blood vessels, from bone marrow adult stem cells. The blood vessels were tested by transplanting them into the jugular veins of three eight-week-old lambs. They performed well for five weeks and when removed a series of analyses suggested they were operating as normal blood vessels. The work was published in May in Cardiovascular Research. [*](#)
- Researchers at Harvard have successfully transferred nuclei from mouse zygotes (fertilised eggs), two- and eight-celled embryos, ESCs and somatic cells

(donors) to recipient zygotes (not oocytes!) by arresting the cells at mitosis before transfer. Previously, zygotes have been successfully used as recipients of nuclear genetic material only when the donor cells were also zygotes and not from later developmental stages. The results demonstrate that nuclear reprogramming can occur after fertilisation, and indicates that it may be possible to derive genetically tailored hESC lines by transferring somatic cell nuclei to zygotes (instead of oocytes). The researchers were also able to use a zygote containing three sets of chromosomes as the recipient. The finding indicates that zygotes containing supernumerary sets of chromosomes (e.g. where two sperm cells fertilised a single oocyte) can be used to derive ESC lines. An estimated 3 – 5% of fertilised human zygotes fall into this group. Such zygotes are always excluded from clinical use in IVF centres because they cannot develop, and are therefore disposed of – using these would therefore obviate the need for egg donation. The study was published in the June 7 issue of Nature. *

- Research groups at the Whitehead Institute, Cambridge, Massachusetts and at the Harvard Stem Cell Institute in collaboration with scientists at UC Los Angeles reported that they have changed differentiated mouse adult cells into pluripotent stem cells. (A third group from Japan also published these results.) The researchers introduced genes for four transcription factors into mouse skin cells using a viral delivery system. Using cells that had been engineered to express drug-selectable markers under the control of genes crucial for pluripotency allowed for selection of cells that had successfully reverted to a pluripotent state. This technique holds great promise for derivation of patient-specific ESC lines, without having to touch on the controversial issue of using oocytes or blastocysts. However, 20% of the offspring derived in this manner developed tumours, presumably related to the activation of one of the introduced genes, *c-myc*, a well-known cancer gene. The studies were published in July 19 issue of Nature, and in the June 7 issue of Cell Stem Cell. *

- Researchers at the Oregon National Primate Research Center in Portland reported successful somatic cell nuclear transfer using rhesus monkey oocytes. The scientists removed the chromosomes from unfertilized monkey eggs and replaced them with nuclei from the skin cells of an adult rhesus monkey (*Macaca mulatta*). A total of 278 oocytes yielded 21 blastocysts, from which the team eventually derived two embryonic stem-cell lines. The work has not yet been published, but was presented on 18 June at the annual meeting of the International Society for Stem Cell Research. *

- Researchers at Northwestern University's Feinberg School of Medicine in Chicago conducted the first U.S. study to transplant purified adult stem cells into the heart muscle of patients with severe angina. The study provided evidence that the procedure is safe and produced a reduction in angina pain as well as improved functioning in patients' daily lives. This is the first human trial in which patients' own purified stem cells, called CD-34 cells, were injected into their hearts in an effort to spur regrowth of small blood vessels that constitute the

microcirculation of the heart muscle. Researchers believe the loss of these blood vessels contributes to the pain of chronic, severe angina. The double-blind, randomized, placebo-controlled study included 24 patients ages 48 to 84. The new study is published in the June 26 issue of *Circulation*. *

- Researchers from the University of California, San Diego grafted human spinal stem cells into rats paralysed by loss of blood flow to the spine. Three of the nine rats injected with human spinal stem cells (hSSCs) returned to walking at six weeks, and three others had improved mobility in all lower extremity joints. All nine animals grafted with hSSCs achieved significantly better motor scores than those in the control group, and showed a consistent presence of transplanted cells in the spinal area. The lead scientist hopes to move to human clinical trials next year. The study was published in the June 29 issue of *Neuroscience*. *

- Researchers at UC San Francisco published a study showing that adult neural stem cells in the mouse brain are less plastic than previously thought. The authors found that a stem cell's position in the brain determines the type of neuron it generates. The study was published in the July 20 issue of *Science*. *

- Scientists at the University of Wisconsin-Madison have shown in rats that it is possible to rescue the dying neurons characteristic of amyotrophic lateral sclerosis (ALS), a fatal neuromuscular disorder also known as Lou Gehrig's disease. The study showed that stem cells engineered to secrete a key growth factor can protect the motor neurons. However, while the motor neurons within the spinal cord are protected by the growth factor, their ability to maintain connections with the muscles they control was not observed. At present, there are no effective treatments for ALS. The work was published on July 31 in *PloSOne*. *

- Researchers from UCLA and Howard Hughes Medical Institute at the University of Texas Southwestern Medical Center at Dallas reported that they have differentiated hESC cultures into neurons, obtaining a yield of 70-80%. This is much higher than previously achieved. The scientists then went on to isolate the neurons and determine that they had a functional synaptic network. These functional neurons can be used to create a variety of human neurological disease models. The study also compared mature neurons grown from two embryonic stem cell lines approved for research by the National Institute of Health. After differentiation of each cell line into neurons, the resulting mature cells were functionally different. If the conclusions are confirmed in other experiments, it is possible that some cultures of embryonic stem cells will be useful to study some diseases, but not others. The research was published in the online version of *PNAS* on August 6th. *

Company

Click on [*](#) to get back to summary.

Collaborations, Mergers, and Acquisitions

- In May 2007, Advanced Cell Technology of Alameda, California, entered into a letter of intent to acquire Mytogen, Inc. for \$5 million in Advanced Cell stock. Mytogen, a privately held, five-employee company based in Charlestown, Massachusetts, is an autologous adult stem cell company with a therapy for cardiovascular disease that has successfully completed Phase I clinical trials. Upon closing the Mytogen transaction, ACT plans to begin Phase II trials. The technology takes muscle fiber cells known as myoblasts from the patient's thigh. These cells are then expanded in a lab over a two-to-three week period before they are transplanted with a catheter into the damaged scar tissue of the patient's heart. [*](#)

- ThermoGenesis, of Rancho Cordova, California, and the Stem Cell Program at the University of California at Davis entered into a researcher collaboration aimed at developing stem cell therapies based on company's technology. The effort will focus on stem cell treatments for peripheral artery disease, myocardial infarction and dermal wounds. Under the terms of the agreement, ThermoGenesis will supply researchers at UC Davis with technology to collect and process stem cells from patients' own bone marrow or umbilical cord blood. ThermoGenesis will have first option to negotiate a license to the resulting intellectual property. [*](#)

Clinical Trials

- Harvest Technologies Corp. of Plymouth, Massachusetts, announced on 30 May that the Food and Drug Administration (FDA) has granted Investigational Device Exemption approval to commence a 48-patient 'feasibility' clinical trial using the company's BMAC System to treat patients with Critical Limb Ischemia (CLI). The BMAC System is a device for concentrating a patient's own (autologous) bone marrow stem cells in approximately 15 minutes. The study's design provides for injecting these cells into the affected limb to reduce the potential for limb amputation. It is believed that the injection of stem cells will arrest and possibly reverse the effects of CLI, a late-stage form of Peripheral Arterial Disease. Patients who will be enrolled in this study have exhausted all other surgical options and are at extreme risk for major amputation. A European pilot study involving 23 subjects showed promising results. [*](#)

Research

- Geron Corporation of Menlo Park, California, reported on May 17 that its scientists and collaborators at the University of Alberta differentiated hESCs into islet-like clusters (ILCs) that secrete insulin in response to elevated glucose levels. Researchers differentiated hESCs into cell clusters containing the main cellular components of the islets of Langerhans - cells types that express insulin, glucagon and somatostatin, three of the major hormones produced by islet beta,

alpha and delta cells, respectively. The studies demonstrate the feasibility of producing therapeutic cell types from hESCs for the treatment of diabetes. Geron Corporation was granted a U.S. Patent in April 2006 covering the production of insulin-secreting cells from hESCs as well as two U.K. patents covering similar production methods. The study is to be published in the August issue of Stem Cells, and is available now online in Stem Cells Express. *

- Advanced Cell Technology has successfully produced a hESC line without destroying an embryo at its lab in Worcester, Massachusetts. This development was announced at the annual meeting of the International Society for Stem Cell Research (ISSCR) in Cairns, Australia. In August 2006, ACT published a paper in Nature Magazine documenting a technique for removing a single cell from an eight-cell human embryo, and using that cell to generate multiple hESCs without destroying the embryo. The team has now reproduced the work, which may allow circumvention of ethical concerns held by some members of the public. *

- On June 15, Invitrogen Corp., of Carlsbad, California, has launched a new engineered stem cell line that will allow scientists to monitor the pluripotency of hESCs without sacrificing those cells. The line is the first one with this characteristic to be made generally available for sale. A known pluripotency marker was coupled with a green fluorescent protein (GFP) reporter. The engineered line glows green when the cells are in a pluripotent state, but the cells lose their fluorescence as they start to differentiate. This allows scientists to track pluripotency without having to sacrifice the cells as they currently have to do by analysing gene or protein expression. *

- Researchers at Lifeline Cell Technology, Walkersville, Maryland, together with a Russian group, announced that they have created human embryonic stem cells by stimulating unfertilized eggs to begin embryonic development (parthenogenetic cell lines). In this process, embryos are created by activating unfertilised eggs using chemicals, rather than fertilising them with sperm. The resulting cells behaved like normal hESC cells and proliferated for an extended period of at least 10 months. The technique could circumvent the contentious issue of using embryos left over from IVF procedures. It would also allow derivation of stem cells genetically matched to female patients, which could also be a close match for the egg donor's male relatives (this avoids rejection of transplanted cells by the patient's immune system). Previous studies with mouse cells by George Daley's group at the Children's Hospital in Boston showed that parthenogenetic embryonic mouse cells did not provoke an immune reaction in the donor mice. However, this study also revealed that the parthenogenetic cells caused poor tissue growth when incorporated into an embryo of normal cells (chimaera), an issue that has to be investigated for the human cell lines as well. As a first application, Lifeline Cell Technology plans to develop a treatment for macular degeneration using retinal cells produced by the technique. The study was published in June in the journal Cloning Stem Cells. *