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## **Federal Stem Cell Shift Seen Spurring Funding**

By Vita Reed - 3/23/2009

Orange County Business Journal Staff

Next month, stem cell researcher Hans Keirstead plans to apply for a challenge grant with the National Institutes of Health.

It's something he wouldn't have done just three months ago.

Keirstead, a University of California, Irvine, researcher who's something of a stem cell media star, has shied away from federal money in the past because of strings attached by Washington.

The Obama administration's lifting this month of a ban on funding for research involving embryonic stem cells "frees up federal dollars," said Keirstead, who co-directs UC Irvine's Sue and Bill Gross Stem Cell Research Center.

The move "makes a tremendous difference, both for industry confidence in the sector but also for freedom of research," said Keirstead, who also is chairman of the scientific advisory board of Irvine-based California Stem Cell Inc.

Keirstead and other researchers see more than symbolism in the move, which reversed a Bush administration executive order from 2001.

They expect the shift to bring federal research money to Orange County and spur more venture capital investing in stem cell companies.

The move sends a signal that "the feds are in this business again," said Peter Donovan, co-director of UCI's Gross stem cell research center with Keirstead.

"The National Institutes of Health is one of the major, if not the major, funder of biomedical research in the world," Donovan said.

The NIH has allocated \$240 million for embryonic stem cell research and \$928 million for non-embryonic research since 2005, according to Forbes magazine.

The Bush administration restricted funding of embryonic stem cell research to several dozen pre-existing stem cell lines as part of a pro-life policy.

Otherwise, researchers using federal money have had to use stem cells from umbilical cords or adult reproductive organs, which some researchers feel aren't as effective.

Stem cells are being researched to fight ailments such as spinal cord injuries, blindness, diabetes and Parkinson's disease.

California Stem Cell, which was founded in 2005, is working on embryonic stem cell research to treat spinal atrophy, muscular atrophy and amyotrophic lateral sclerosis, or Lou Gehrig's disease. The company received an undisclosed amount of first-round funding from private investors in early 2008.

The lifting of the federal ban should boost investor confidence, Keirstead said.

"That's tremendously important because a great deal of (stem cell) research is done in biotech companies," he said.

Since the ban was lifted, Keirstead said that he's received a lot of calls from venture capitalists and angel investors.

### **Companies**

In January, another company Keirstead works with, Geron Corp. of Menlo Park, received Food and Drug Administration approval for clinical trials of a possible spinal cord injury cure.

Keirstead developed that treatment at UCI. The university gave Geron a worldwide exclusive license for it.

As for California Stem Cell, "I've got a lot of faith in that company," Keirstead said.

"It's in the sweet spot of the stem-cell field. It's the only company I know of that's so close to a clinical trial besides Geron," he said.

Another OC stem cell company, Irvine-based PrimeGen Biotech Corp., uses adult stem cells to regenerate several parts of the body, including heart tissue and kidney and pancreas cells.

Orange County computer entrepreneur Thomas Yuen started PrimeGen in 2002, after one of his daughters had a kidney fail. Yuen also has kidney disease and receives dialysis in his home.

Yuen started PrimeGen shortly before stem cell research became a hot button issue and California voters in 2004 passed Proposition 71, which provided \$3 billion in state funds for stem cell projects and was seen as a repudiation of the Bush administration's ban.

PrimeGen's use of adult cells has kept it clear of ethical questions that have arisen around stem cells.

In an earlier interview, Yuen said the cells that PrimeGen uses don't "require the creation or destruction of an embryo."

There are other benefits of Obama's lifting of the ban, according to researchers.

The executive order should "keep the topic on the front pages as far as awareness of stem cells," said Daniel Segal, chief executive of PacifiCord, a unit of Taiwan-based Health Banks Biotech Co. that just opened a umbilical cord blood banking center in Irvine where stem cells are gathered.

Blood from the umbilical cord contains a type of stem cell called hematopoietic stem cells. These stem cells form all types of blood cells and now are being looked at for their ability to form other kinds of cells and regenerate body parts. Segal described the use of hematopoietic cells as "non-controversial" because they are harvested from waste material and fall into the adult cell category.

The company's research could be of use to biotechnology companies working on stem cell research, including PacifiCord's ability to preserve stem cell lines by cryofreezing them.

For UCI, the lifting of the federal ban will allow researchers there to use the school's laboratory space for embryonic research rather than off-campus labs "that cost a fortune to rent," Donovan said.

"It really simplifies our lives," he said.

#### Drug Company Cortex Cuts Half of Workers

Cortex Pharmaceuticals Inc., a small Irvine drug maker with roots in research from the University of California, Irvine, said last week it cut half its workforce as part of a restructuring.

Cortex, which makes drugs to treat psychiatric and nerve system disorders, said it cut 14 staffers because of the slow economy and "continuing uncertainty in the capital markets."

The company had 27 workers prior to the announcement.

Cortex also said it cut executive salaries and reduced its research efforts in early stage, non-clinical drug programs.

The company said it was going to evaluate options for raising cash, including licensing and seeking partnerships.

Cortex had a recent market value of about \$12 million, which is off by 65% in the past year.

The company was started in the 1990s around work done by Gary Lynch, a neurosciences researcher at UC Irvine.

Early on, Cortex had high hopes for its compounds, called ampakines, to treat memory disorders and other conditions.

The company's main drug candidate, CX717, has faced tough going with regulators.

In 2006, the Food and Drug Administration stopped studies of the drug over concerns raised from animal test data.

After trials were resumed, in 2007 Cortex saw regulators reject plans to run a second-phase clinical trial on CX717 because of toxicity issues.

Cortex had been testing CX717 for treatment of attention deficit hyperactivity disorder.

—Vita Reed