

## **\$50 million raised for stem cell study**

### **Money will help fund adult-cell research by Baltimore company**

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Osiris Therapeutics Inc., a Baltimore company conducting clinical tests of treatments created from adult stem cells, announced yesterday that it had raised \$50 million through a Swiss venture capital firm.

The sum could help Osiris in the quest to commercialize a stem cell product, but some said the money might never have been raised if the company had focused its development on stem cells taken from embryos and fetuses, rather than from adults.

On Capitol Hill and beyond, people are debating the ethics of embryonic stem cell research. The fierce divide is scaring away investors who can't reconcile the science's promise with its potential to become mired in political controversy.

Meanwhile, Osiris, with its focus on adult stem cells taken from willing donors, has forged ahead, unfettered by the contentiousness and backed by wealthy investors.

"You would have a hard time raising \$50 million for embryonic stem cells," said Osiris Chief Executive Officer C. Randal Mills.

His company was hoping to raise \$20 million during this round of financing but pulled in more than twice that through Friedli Corporate Finance Inc., a Zurich, Switzerland, investment company owned by Osiris' chairman of the board.

"Investors invest money because they want a return, and a return on investment only comes when you can commercialize and launch a product," Mills said. "It's not clear whether embryonic stem cells will even be in clinical testing by 2007, and there's very little hope of their being on the market in the next seven or eight years."

Industry analysts were reluctant to speculate on the timeframe, but most agreed that embryonic stem cells are well behind their adult counterparts in clinical testing and that product commercialization for the former is "not imminent," said Morrie Ruffin, vice president of business development for the Biotechnology Industry Organization in Washington.

Osiris said its latest round of capital will keep its three products - all of which regenerate diseased or damaged tissue - on track with the earliest commercialization in 2006, pending U.S. Food and Drug Administration approval.

The agency put Prochymal, which treats a life-threatening disease associated with bone marrow

transplants, on a fast-track development process in January. It is thought to be the first time a stem cell therapy received the fast-track designation.

Embryonic stem cell research and product development have been opposed by people who see it as unethical to harvest cells from fetuses and embryos, including President Bush. In 2001, the president banned federal funding for new embryonic stem cell lines.

The issue gained prominence during the last presidential campaign. Democratic candidate Sen. John Kerry argued for increased embryonic stem cell research to benefit people such as Christopher Reeve. The paralyzed actor, who helped lead the push for expanded research, died shortly before the election.

Last month, the House countered the president's legislation, passing a bill that would allow federal funding for research that used human embryos left from in-vitro fertilization efforts. Bush has vowed to veto it. A hearing on the bill was held yesterday before the Senate.

Stem cells donated from living adults haven't raised the same ethical questions. Osiris harvests its cells from the bone marrow of grown-up volunteers, manufacturing multiple cells from each sample.

Stem cells taken from umbilical cord blood are also considered less contentious than the embryonic cells. Last month, the House also passed a bill that would provide \$79 million in federal funds directed toward creating a national cord-blood bank.

"Clearly, it's a very difficult time for anybody doing research with embryonic stem cells to attract any investment," said C. Rober Eaton, president of MdBio Inc., a private, nonprofit corporation in Frederick dedicated to furthering biotechnology in Maryland. "There's so much uncertainty due to the political baggage of the research."

Linda F. Powers, managing director of Bethesda investment company Toucan Capital Corp., said the ethical debate is not the only thing repelling investors from embryonic stem cell involvement. She's troubled by the science, which is less tested than its adult counterpart.

"The biology concern translates directly into investor concern as much as the ethics controversy," she said.

Powers' company doesn't invest in companies working with embryonic stem cells, though it funds several businesses using adult stem cells, including Baltimore's Theradigm Inc., which is developing treatments for central nervous system disorders.

Stem cells are found naturally in the body and prized for their regenerative abilities. They can renew themselves and some have the ability to develop into different types of cells. Scientists believe they could be used to one day to grow spare body parts as needed.

Embryonic stem cells have generally been promoted as having more potential than their adult counterparts.

"It's a two-edged sword," said Nate Cospers, a consulting manager with Frost & Sullivan, a market research firm in California. Embryonic cells are supposed to have "greater scientific utility," he said, while adult cells have few, if any, ethical concerns. He sees embryonic cells as the better science - and investment.

Such claims make Mills bristle.

"The embryonic stem cell people like to suggest that adult stem cells are less useful," he said. "I'd like to point out that we have three products in clinical trials addressing very serious and life-threatening illnesses."

In addition to Prochymal, Osiris is developing Chondrogen to repair knee tissue and Provacel, which would repair heart-attack damage. The company is also looking to expand the uses of Prochymal to treat Crohn's disease and rheumatoid arthritis and acute organ rejection. Combined, the drugs each have a \$4 billion market opportunity, Mills said.

"If [embryonic stem cell developers] want to come along in 10 years and do something better, that's good," he said. "But I'm dealing with the here and now. I've got patients I can treat right now and patients I can keep from dying, and that's what I'm going to do."

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