

November 11, 2008

Obama election no panacea for stem cell industry

MATTHEW PERRONE

Perhaps no sector has more to gain under the Obama administration than the nation's fledgling stem cell companies, which have long bemoaned a Bush policy that limits funding to embryonic stem cell research.

Barack Obama has pledged to overturn that 2001 policy, which bans government funds for research that involves harvesting new stem cells. President Bush and a minority of Americans say the process is immoral because it destroys human embryos.

But even with the policy overturned, experts say struggling stem cell developers will face a new, equally daunting obstacle: an investment climate devastated by the financial crisis.

"The good news is there will finally be freedom to operate, the bad news is there will be no more venture capital, which is the real freedom," said Stephen Brozak, an analyst with WBB Securities.

Embryonic stem cells are early-stage cells capable of morphing into any of the more than 220 cell types in the human body. The Bush policy does not restrict research funding for stem cell lines created before 2001. However, only about 21 of those lines are available, most created in ways that preclude use in humans.

When scientists isolated the first stem cells from a human embryo in 1998, it was heralded as a breakthrough that eventually could cure diabetes, replace organs and repair spinal injuries. A decade later, the promise of stem cells remains just that — a promise.

No company has sought U.S. approval for a therapy using embryonic stem cells, and the \$150 million "stem cell market" consists entirely of equipment used to study the technology, according to research firm TriMark Publications. Compared with the \$300 billion U.S. drug market, stem cells are barely a blip on most investors' radar.

States and private universities have tried to fill the research funding gap. California, New York and New Jersey have pledged billions for stem cell research, but budget deficits have put much of that money at risk. Last year, New Jersey voters rejected \$450 million for stem cell research grants.

Even at universities, scientists say funding restrictions have created layers of bureaucracy and duplicative spending. For example, Harvard's Stem Cell Institute buys two sets of equipment for scientists: one for federally funded research, and another for all other types of research.

"Most of our faculty here have multiple sources of funding: they have NIH grants and they have private foundation grants," said the institute's director Brock Reeve. "Keeping track of which equipment can be used for various projects is incredibly onerous."

According to Reeve, federal limits have set U.S. researchers back at least two to three years. Other scientists put the figure closer to 10 years. But there is little disagreement on which nation offers the best environment for the burgeoning science.

"Our company is looking very seriously at doing business in China because it is probably the most stem cell friendly place on Earth," said Richard Garr, chief executive of Neuralstem.

With less regulation, some doctors in China have already begun using stem cell injections to treat patients with Parkinson's disease, spinal injuries and other conditions. However rigorous testing and documentation of the treatments is lacking, and some doctors warn that patients are serving as guinea pigs.

Singapore also has become an international hub for stem cell researchers thanks to generous government grants to international scientists.

Rockville, Md.-based Neuralstem has been working for more than 12 years to develop stem cell therapies. The company expects to begin human trials of its first treatment — a spinal injection to treat Lou Gehrig's disease — in the first quarter of 2009.

Like other companies, Neuralstem has focused most of its research on adult stem cell technology, which is not as controversial as embryonic technology because it does not involve the destruction of embryos.

But Garr and other executives say the current policy has dampened Wall Street's interest in all types of stem cell companies. He hopes a reversal will jump-start investment, which has largely dried up since the late 1990s.

"In the commercial world, the impact will be immediate because it will relieve a lot of uncertainty among the investment community that we are going to become an outlaw industry," Garr said.

But even before this fall's financial meltdown, investment in early-stage stem-cell companies was steadily declining. Venture capital investment in biotech startups — which includes stem cell developers — has fallen more than 65 percent to \$443 million in the most recent quarter, from a high of \$1.3 billion in late 1999.

With a deep recession on the horizon and continuing doubts about the commercial viability of stem cell therapies, analysts say startup companies will be hard pressed to get funding. While adult stem cell treatments could be approved in the U.S. within five years, analysts don't expect embryonic stem cell therapies to become available for much longer.

"Even if one of these companies was going to be successful, I doubt you'd have a new embryonic stem cell product on the market in the next 20 years," Leerink Swann analyst Bill Tanner said. "In this kind of capital market, it's just going to be a struggle for them to get funding."

But there may be other investors waiting in the wings: drugmakers.

Roughly \$24 billion worth of drugs are expected to lose patent protection next year, leading to generic competition for a wave of blockbuster products launched in the 1990s. With massive cash reserves, large drugmakers have begun turning to stem-cell technology as a possible way forward.

Pfizer Inc., the world's largest drugmaker, is scheduled to open a new research center this month in the U.K. to research stem cells to treat nervous system disorders. The New York-based company plans to hire 60 scientists for the effort over the next two years.

Earlier this year GlaxoSmithKline PLC, the world's No. 2 drugmaker, entered a \$25 million, five-year agreement with the Harvard Stem Cell Institute aimed at developing therapies for cancer, diabetes and other conditions.

WBB Securities' Brozak said other drugmakers will soon be forced to make similar investments to stay competitive — creating opportunities for small stem cell developers.

"This is survival of the fittest in pharma," Brozak said. "Because if one of their competitors brings out a stem cell product and they don't, they're out of business."