

placenta and umbilical cord blood, Pfizer of New York and Teva Pharmaceuticals of Petach Tikva, Israel, which have already made some investments in stem cell research.

How willing these companies are to take a punt on hESCs in light of Geron's decision and in the current financial climate is another matter. Any potential pay-off on investment appeared to be too distant for Geron. The company would have spent another \$25 million a year to continue the program, and it could take up to another 10 years for GRNOPC1 to satisfy stringent regulatory requirements and reach the clinic. Geron left the stem-cell field, with \$180 million in cash and assets. In contrast, Santa Monica, California-based ACT, the only other firm currently in the US with an hESC product in the clinic—retinal pigment epithelial cells derived from hESCs to treat Stargardt's macular dystrophy and dry age-related macular degeneration—had only \$14 million in cash at the time of Geron's announcement.

ACT's Lanza admits that finding capital has been tough. "This may be one of the hottest

areas in biology, but a venture capitalist who puts in money will want a return on their investment yesterday," says Lanza. "It's cheaper for pharmaceutical companies to sit on the sidelines and wait for [companies] to succeed and just buy them up. We need a different paradigm, it needs to be longer term." West says that he has never seen the industry as crippled as it is for small companies. "There's lots of product opportunities, but limited resources," he says.

According to Carpenter, the big issue is trying to get money for the translational part of clinical development that is expensive and not very publishable. However, the model appears to be evolving in response. "Rather than spinning out companies and trying to raise money to do expensive translational work, I see people being creative in delaying how to spin companies out, and getting into clinical trials and getting proof of concept in humans before going out and trying to raise money."

Carpenter says places like the California Institute for Regenerative Medicine (CIRM) and the National Institutes of Health in the US,

as well as the Center for Commercialization of Regenerative Medicine in Toronto, Canada, are beginning to help through more innovative early funding approaches. "We are already exploring new models to assist companies in this space," says Alan Trounson, president of CIRM. "This includes private-public partnerships, global linkage arrangements and networked clinics, and it is entirely possible that these new models will become dominant as we explore the opportunities for new cell therapies."

Silviu Itescu, CEO of Melbourne, Australia-based adult stem cell-based company Mesoblast applauds the consortia approach proposed by places like CIRM that involve getting together to establish proof of concept for early-stage hESC trials. "No matter what funding mechanism you use to establish proof of concept, though, sooner or later every technology is going to have to come into an organized regulatory environment, and every new product will have to meet the same rigorous testing," Itescu says. "That costs a lot of money, there's no shortcuts around that."

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