CIRM's clinical mindset

By *Tim Fulmer, Senior Writer*

The **California Institute for Regenerative Medicine** (CIRM) didn't waste much time putting the proceeds from an April 22 state bond sale to work. Last week, the institute's 29-member governing board approved \$67.7 million to fund 15 grants focused on early translational stem cell research.

Although CIRM now has awarded \$761 million since the institute was founded following approval by California voters in 2004, the new Early Translational Research grants are the first "specifically designed to move promising basic stem cell research closer to the clinic," said spokesperson Don Gibbons. The grants address two broad areas: the actual design of new stem cell therapies—mostly in neurological indications like Alzheimer's disease (AD), Parkinson's disease (PD) and Huntington's disease (HD)—and the removal of bottlenecks associated with stem cell manufacture, purification and characterization.

According to Gibbons, the predominance of neurological diseases in this wave of grants was happenstance. The grants in the underlying techniques space were more deliberately targeted.

"A key bottleneck in the development of these therapies is ensuring the entire population of undifferentiated stem cells fully differentiates into a

homogeneous population of cells before transplantation into the patient," Gibbons told *SciBX*. "We want to be confident we're indeed putting the cell types into the patient that we think we are, and only those cell types. Transplanting a heterogeneous mixture of differentiated cells could lead to safety and toxicity issues."

A second bottleneck addressed by the grants is the scale-up of production volume that will be required for any stem cell therapy to make it into the clinic.

Two biotechs received funding: **Novocell Inc.**, to develop techniques for removal of residual undifferentiated cells in the manufacturing process, and **BioTime Inc.**, to develop an assay for characterizing stem cell lineages.

In June, CIRM's governing board will vote on whether to award an additional \$30 million from the bond sale to fund 12 more grants in the translational science space. Companies and institutions applying for grants must be located in California.

Although the second round of translational grants will target similar areas to the initial 15, Gibbons said "immunological issues associated with stem cell therapies will also become a focus."

Of the total \$761 million now awarded by CIRM, about \$270 million was allocated to buildings, with the remaining \$489 million put toward research. The latest grants thus amount to about 14% of the research total (see **Table 1, "CIRM-funded translational research"**).

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COMPANIES AND INSTITUTIONS MENTIONED

BioTime Inc. (OTCBB:BTIM), Alameda, Calif.

California Institute for Regenerative Medicine (CIRM), San Francisco, Calif.

Novocell Inc., San Diego, Calif.

Table 1. CIRM-funded translational research.

Institution	Grant (\$M)	Indication
Stem cell therapies		
Burnham Institute for Medical Research	\$3.5	Parkinson's disease (PD)
Salk Institute for Biological Studies	\$6.6	Hematological diseases
The Scripps Research Institute	\$3.1	Osteoarthritis
Scripps	\$5.9	Age-related macular degeneration (AMD)
Stanford University	\$5.7	Wound healing
The Parkinson's Institute	\$3.7	PD
University of California, Davis	\$2.7	Huntington's disease (HD)
University of California, Irvine	\$3.5	Alzheimer's disease (AD)
University of California, Los Angeles	\$5.5	AMD
Stem cell manufacture, purification and characterization		
BioTime Inc. (OTCBB:BTIM)	\$4.7	Assay for characterizing stem cell lineages and removing undesired cell types
Novocell Inc.	\$5.4	Detection and removal of residual undifferentiated stem cells during manufacturing
Scripps	\$6.2	Protocol for quality control of stem cell purification and validation
The J. David Gladstone Institutes	\$1.3	Detection of genetic mutations during stem cell expansion and differentiation
University of California, Davis	\$4.2	Preclinical model to monitor the developmental fate of transplanted cells
University of California, San Diego	\$5.1	Preclinical model of immune response and tolerance during stem cell transplantation