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CIRM funding worth the cost of rules, restrictions?

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In 2004, the voters of California approved Proposition 71, which provided $3 billion dollars over 10 years to support stem cell research not funded by the federal government. Since then, the California Institute for Regenerative Medicine (CIRM) has made two moves affecting businesses: finalizing rules regulating the intellectual property (IP) rights of for-profit grantees of CIRM funds ("rules") in December 2007, and approving an outline of a plan to set aside $500 million in loan funds for companies on Sept. 25. Now that IP rights are clearer and funds are becoming available, how do San Diego stem cell-focused companies make the decision as to whether or not to apply for CIRM funds?

A primary focus of the loans will be to supply funding for companies where other sources of funding do not exist or are difficult to come by. Duane Roth, a board member of CIRM, says that one strategic aim is to "move research into the clinic and get products to patients." Indeed, the loans should help companies through the so-called "valley of death," that key transitional stage during which promising therapeutic research moves from the research bench into the clinic, but where later-stage investors are hard to find until efficacy and safety of the therapeutic is demonstrated.

While CIRM funds could be helpful, even lifesaving, to a company, the funds come with strings attached that affect income streams generated from the company's CIRM-related patents. For example, grantees must pay a fraction of net commercial revenue received from self-commercialized products developed using CIRM funds. The exact amount owed would be negotiated between CIRM and the particular grantee, but is intended to be between 2 percent and 5 percent of net commercial revenue from a patented invention. Additional amounts may be due to the state if a CIRM-funded therapeutic reaches "blockbuster" status. It is still unclear how large CIRM for-profit grants will generally be, though Robert Klein, chairman of CIRM, is in favor of grants of more than $5 million to facilitate clinical trials.

California also expects to benefit from any licensing of patents obtained using CIRM funds. For example, grantees must pay as much as 25 percent of net licensing revenue in excess of $500,000 to California for its General Fund. Revenue from licenses would, however, be pro-rated if other sources of funding — including the grantee's own funds — are used to fund the research leading to the licensed patent. The funding rules also mandate use or licensing of CIRM-funded patented inventions, even if the grantee decides not to commercialize potential resulting products. In such a case, the grantee is required to make commercially reasonable efforts to negotiate non-exclusive licenses to third parties to develop the invention. Otherwise, the state of California, which maintains march-in rights, may be able to force a license to another entity. The criteria by which such march-in rights would be exercised are not currently clear.

The revenue and royalty provisions of the rules are dependent upon commercialization or licensing of "CIRM-funded inventions," that is, patented inventions that resulted wholly or in part from CIRM-funded research. However, it is not clear how, or whether, amounts owed to the state of California would be apportioned if, for example, the company obtains one or more patents covering a stem cell therapeutic prior to receipt of CIRM funds, and subsequently obtains one or more patents, based on CIRM-funded research, that cover aspects of the stem cell therapeutic. This uncertainty, coupled with the revenue and licensing provisions, is sure to raise questions in any potential investors or companies considering partnering with the company.

Grantees must also perform their CIRM-funded research within the state of California. This requirement even extends to services contracted by the grantee, to collaborators the grantee wishes to use in the CIRM-funded project, and likely to the performance of clinical trials.

So given these rules and restrictions, how does a potential grantee decide whether or not to apply for CIRM funds? CIRM appears to be favoring companies that have a research program that has produced a potential stem cell therapy ready for clinical trials. Such companies would have to consider CIRM's requirement that CIRM-funded research be performed in California. The company would also have to balance the mandated royalty and other potential payments with the prospect of finding alternate funding. If alternate funding is not available, then acceptance of CIRM funding may be a good risk. At least one company, **Geron Corp.**, has been cool to the idea of accepting CIRM funding, as it has been successful at alternate routes of financing its stem cell research. However, San Diego-based **DNAmicroarray Inc.**, **RegeneMed Inc.** and Oceanside-based **Raven Biotechnologies** have filed letters of intent to apply for CIRM funds.

Risks and benefits are always assessed within the context of the prevailing economy. The current economy is a particularly bad one, with major market indices having lost more than 30 percent of their value over the last year, and investors flocking to relatively safe investments. Given this, the benefits of applying for and accepting CIRM funds will likely be seen by stem cell companies as far exceeding any future downside.

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