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MEMORANDUM

To: Members, Governing Board, California Institute for Regenerative Medicine

From: James C. Harrison

Date: October 13, 2011

Re: Recommendations of the Intellectual Property and Science Subcommittees Regarding the Strategic Partnership Funding Component of the Opportunity Fund (Our File No.: 2297-0)

At its meeting on June 23, 2011, the Governing Board, by unanimous vote (22-0) approved a motion to allocate \$30 million to the Opportunity Fund, a program designed by staff to implement recommendations made by the External Advisory Panel and to accelerate the development of stem cell therapies.¹ The Board earmarked \$5 million for technology transfer support and referred the three components of the Opportunity Fund (the Bridge Funding Program, the External Innovation Program and the Strategic Partnership Funding Program) to the Intellectual Property and Science Subcommittees for further development, review and recommendation for concept approval to the Governing Board.

On August 24, 2011, the Intellectual Property Subcommittee met to discuss the Strategic Partnership Funding Program. After considerable discussion among members, staff and the public, the Subcommittee directed staff to prepare a motion reflecting the Subcommittee's discussion for consideration at its next meeting. On September 27, 2011, the Intellectual Property Subcommittee met to consider staff's proposed motion. CIRM General

¹ The Opportunity Fund proposal presented by staff is available for review at: http://www.cirm.ca.gov/files/meetings/pdf/2011/06_22_11_Agenda%20Item%202318_for_6_22-3_11_ICOC_Meeting_OppFund.pdf.

Counsel Elona Baum presented the proposal for the Subcommittee's consideration. After discussion among Subcommittee members, staff and the public, the Subcommittee approved a motion by a unanimous vote (6-0) to recommend the Strategic Partnership Funding Program to the Governing Board for concept approval, with an allocation of \$30 million. The detailed concept proposal is attached to this memorandum.

On October 10, 2011, the Science Subcommittee met to discuss the Strategic Partnership Funding Program. After presentations by Co-Chair Os Steward, who is also a member of the Intellectual Property Subcommittee, and Steve Juelsgaard, Co-Chair of the Intellectual Property Subcommittee, and discussion among Subcommittee members, staff and the public, the Science Subcommittee approved a motion by a unanimous vote (11-0) to recommend the Strategic Partnership Funding Program to the Board for concept approval, with an allocation of \$30 million.

Attachment



To: Science Subcommittee
From: Elona Baum, Esq.
Subject: Strategic Partnership Funding Program
Date: September 30, 2011

Background:

The Opportunity Fund concept was developed to address the External Advisory Panel's recommendations that CIRM "attract industry participation through a funding mechanism that is more aligned with industry's financing practices" (Recommendation 7), "...transition to a much more proactive strategy" and adopt a "porous opportunity model rather than an internal pipeline model".

At its June 23, 2011 meeting the Governing Board voted to approve the creation of a \$30 million Opportunity Fund, with \$5 million earmarked for technology transfer support. The Opportunity Fund is comprised of the following three separate funding components, in addition to technology transfer support for recipients of CIRM funding: (i) a Bridge Funding Program, (ii) an External Innovation Funding Program, and (iii) a Strategic Partnership Funding Program. As part of the Board's motion, the three program concepts within the Opportunity Fund were referred to the Science Subcommittee for further development, review and recommendations. In addition, the Strategic Partnership Funding Program was also referred to the Intellectual Property Subcommittee. Following consideration by these Subcommittees the Board directed that the Opportunity Fund concept be brought back to it for final approval

The primary objectives of the Strategic Partnership Funding Program are to create incentives and processes that will: (i) enhance the likelihood that CIRM funded projects will obtain funding for Phase III clinical trials (e.g. follow-on financing), (ii) provide a potential source of co-funding in the earlier stages of clinical development, and (iii) provide CIRM funded projects with access to pharma and large biotech partners that can provide valuable expertise in the areas of regulatory, clinical trial design and manufacturing process development.

The Intellectual Property Subcommittee has recommended changes to the concept plan for the Strategic Partnership Funding Program. The primary changes are to: (i) allocate the full \$30M to the Strategic Partnership Funding Program, with CIRM staff to recommend additional allocations for the other Opportunity Fund program concepts and technology and patent support (ii) expand eligibility to include early stage projects in addition to translational programs. The motion approved by the Intellectual Property and Industry Subcommittee is set forth below along with a summary describing the implementation process.

Intellectual Property Subcommittee Recommendations:

The concept plan which the Intellectual Property Subcommittee recommended for approval by the Governing Board provides the following:

- i) A Program Announcement will be posted announcing the funding program
- ii) Applications will be accepted on a rolling basis and reviewed by the Grants Working Group approximately two times per year
- iii) Eligible projects will be:
 - a. Both existing projects in good standing and new projects (meeting the requirements of Proposition 71)
 - b. Projects at any stage of research and development that fall between basic research through and including Phase II clinical proof of concept studies.
 - c. Only those projects which have third party commercial validation will be considered. Forms of such validation may include (i) a term sheet or a letter of intent to enter into a future collaboration agreement , (provided a binding agreement is entered into prior to the disbursement of CIRM funds), or an existing collaboration agreement with a pharmaceutical or large biotechnology company and/or significant investment from venture capital, (ii) disease foundation funding or (iii) other sources of third party government funding including SBIR funding.
- iv) The Strategic Partner Funding Program shall receive \$30 million in funding which shall be dedicated solely to projects funded under this particular program. Per project awards shall be a maximum of \$10million, excluding funding for technology transfer /patenting support. The per project funding amount may be increased at the discretion of the IP Subcommittee;
- v) The term of awards made under this program is a maximum of four years (unless extended at the discretion of the IP Subcommittee)
- vi) Request that staff advise the Board regarding the amount of funding that would be required for the other two components of the Opportunity Fund and at a minimum approve \$35 million for the Opportunity Fund with \$5 million being dedicated to patent and technology transfer support.

The Funding Process: If approved, the process for awarding funding under this program is as follows:

- Step 1:** Program Announcement Posted (Rolling Submission)
- Step 2:** Application submitted which includes a description of the research and evidence demonstrating commercial validation such as a term sheet describing key rights and obligations of the Grantee and pharma/biotech/venture company including any up-front payments, milestone payments, royalties and go/no-go decisions
- Step 3:** Grants Working Group review
- Step 4:** IP Subcommittee review of proposed term sheet including proposed CIRM commitments for funding and terms of VC/industry commitments
- Step 5:** Governing Board review