



MEMORANDUM

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

From: Elona Baum

Date: August 24, 2012

Re: Proposed Amendment to Concept Approval of the Strategic Partnership Funding Component of the Opportunity Fund

On October 26, 2011, the Board approved the concept plan for the Strategic Partnership Funding program which is a component of CIRM's Opportunity Fund. In proceeding with implementation, it has become apparent to CIRM management that the program will best be served by amending the concept as provided below. A copy of the approved concept showing proposed changes is attached to this memorandum as Exhibit A.

The proposed amendments are essentially three-fold. The first proposed change provides that rather than proceeding with a rolling submission using a Program Announcement, CIRM will implement the program using a standard Request for Application process that has a defined submission period. The rationale for doing so is related in part to the second proposed change. With respect to the second proposed change, we are recommending that each RFA define the scope of funded research and that such definition may be more narrow than the currently approved concept scope which encompasses a broad range of research from basic to phase II clinical studies. This is needed to ensure that CIRM is able to assemble the appropriate experts to review applications. It is recognized that if additional funding is granted by the Board, future RFAs could target different scopes and thereby the overall funding of the program could be as broad as the approved concept scope.

Finally, we are proposing to eliminate the steps relating to IP and Industry Subcommittee review and leave these matters for the Board directly. The concept currently provides that the IP and Industry Subcommittee review evidence of commercial validation such as term sheets and funding commitments which the applicants provide. However, the concept is silent on the Subcommittee's mandate with respect to such review. In addition, the Subcommittee is required to consider if greater than \$10 million and/or a term greater than 4 years should be granted; yet ultimately the Board has to make this funding decision. By having

the Board directly address these issues, we streamline the process, while ensuring ample opportunity for all Board members to consider these issues.

EXHIBIT A



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) ~~i)~~ Approximately twice a year CIRM will post an RFA for the Strategic Partnership Funding program
- ~~ii)~~ Program Announcement will be posted announcing the funding program ii) Applications will be accepted within the time period provided for in the RFA on a rolling basis and reviewed by the Grants Working Group approximately two times per year
~~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, with the specific scope determined within each RFA.
 - 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 Governing Board ~~IP Subcommittee~~;
- ~~v)~~ The term of awards made under this program is a maximum of four years (unless extended at the discretion of the Governing Board ~~IP Subcommittee~~)

- | ~~iv)~~ 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.

~~v)~~
vi)

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

Step 1: ~~RFA will be posted approximately two times per year~~
~~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: CIRM staff confirm satisfaction of commercial validation eligibility requirement~~

Step ~~4~~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