



M E M O R A N D U M

To: Intellectual Property Subcommittee

From: Elona Baum, Esq.

Subject: Opportunity Fund – Strategic Partnership Program

Date: August 12, 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”. The proposed 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 Program.

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, but referred the three program concepts to the Science Subcommittee and in addition required review of the Strategic Partnership Program by the Intellectual Property Subcommittee (IP Subcommittee) for further development, review and recommendation to the Governing Board. Following consideration of these concept plans by the Subcommittees, the Board directed that the Opportunity Fund concept be brought back to the Governing Board for final approval.

Strategic Partnership Program

There are three primary objectives of the Strategic Partnership Program. These are to create the 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 Strategic Partnership Program concept presented to the Board in June, which will be further considered by this Subcommittee, is designed to better align CIRM's funding processes with industry's planning cycles and common partnership models. The proposed concept plan and a proposed process for review and approval of awards are outlined below. **It should be emphasized that as proposed, any project receiving funding under the Strategic Partnership Program would be subject to a Grants Working Group review and Governing Board approval, as more fully described below.**

a.) Concept Plan:

- The Strategic Partnership Program will be comprised of a Program Announcement with rolling submissions and Grants Working Group reviews approximately two times a year.
- A Program Announcement would seek:
 - Projects having a California-based principal investigator partnered with a non-profit, a biotech company or a biopharmaceutical company that is willing to commit to in-kind support (which could include access to proprietary assays, regulatory and manufacturing process development expertise, etc.) as well as funding or co-funding of the development activities; *and/or*
 - Projects having a California-based principal investigator who is funded primarily by venture capital, or has significant funding through foundation support or other sources.
- Core elements of the program include the following:
 - A submission process that is rolling so that the Governing Board can be as agile as possible in responding to select opportunities.
 - A process that allows the Governing Board to commit to future funding today on the condition that certain future milestones and conditions are met so that the strategic partner has the certainty it needs to invest early on (rather than taking a wait-and-see approach).
 - Incentives for grantees and partners that include an accelerated review and future funding commitments (if conditions are satisfied).
 - Intellectual property terms and key terms of a collaboration/co-development agreement between CIRM and partners to be approved by the Intellectual Property Subcommittee.

- Awards under the Strategic Partnership Program will be up to four years, provided that milestones set forth as part of a co-development and collaboration agreement are satisfied. However, to better align with industry practices, the IP Property Subcommittee may approve a term longer than four years.
- The maximum per-project award (not including technology transfer and patent funding assistance) is \$15M, unless the Finance Subcommittee recommends a greater amount.

b.) The Review and Approval Process:

One of the most important means for aligning our funding processes with the partnership models used by pharma and biotech is to provide a certain level of funding commitment through Phase II clinical trials in the event that agreed to milestones and conditions are met. The Opportunity Fund concept provided for a four-year program. However, with respect to awards provided under the Strategic Partnership Program the concept presented in June and being considered by the Intellectual Property Subcommittee provides that the IP Subcommittee may approve a term longer than four years. This flexibility may well be critical to the success of this program. Moreover, to incentivize industry to invest resources and agree to certain up-front and milestone payments, industry may desire that CIRM also be a party to any agreements between a CIRM Grantee and industry partner. To accommodate this, we are proposing that the IP Subcommittee approve terms of any agreements to which CIRM is a party as a precondition to the release of any CIRM funds.

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 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

cc: Melissa King, Executive Director, ICOC Board Relations