Loan Program Overview

Introduction

The following concepts are intended to solicit discussion from the ICOC, the public, and other stakeholders. If the ICOC provides its initial approval of these concepts, the Finance Subcommittee will consider further public comment at a meeting to be scheduled within the next 60 days and then bring the concepts to the ICOC for final approval at its December 2008 meeting.

Rationale for Loan Program

The use of loans provides an advantage to CIRM because loan proceeds can be recycled by CIRM to provide additional loans or grants, thereby expanding the scientific depth of CIRM's funding. In the next six to seven years, some of the loan funds could be recovered and recycled into new grants or loans, whereas grants are one time disbursements. CIRM's loan program will require the recipients of loans to repay CIRM the principal of the loan plus interest. Loan recipients may also be required to provide CIRM with warrant coverage, the scope of which will vary depending upon whether the loan is made on a nonrecourse (e.g., 100% warrant coverage) or recourse (e.g., 10% warrant coverage) basis.[1]

1. Size of Loan Portfolio:

- Given the general lack of funding for early stage translational product development, CIRM intends to support the funding of stem cell-based products by establishing a loan program. Funding for this program will be targeted at $500 million to be distributed over the next six or seven years. Because the ICOC will approve the amount of funds available for loans when it approves the concept plan for each specific RFA, this target can be achieved incrementally and could be revised if the ICOC determined it was desirable to do so.

- The ICOC will also consider whether to ensure the highest quality and the earliest translation of stem cell discoveries to our communities, it would be better to fund a broader portfolio early with the hopes of having a greater number of successful awards that can move forward into clinical trials, or whether it would be better to initially fund more narrowly and await more developments in the field.. .

[1] The California Constitution prohibits the State from holding stock. (Cal. Const., art. XVI, § 6.) Consistent with this prohibition, CIRM does not intend to exercise the warrants but rather would transfer them in exchange for cash. CIRM is in the process of obtaining the Attorney General's concurrence on this proposal.

2. Loans Versus Grants:

- In order to provide an incentive for applicants considering applying for the same Request for Applications (RFA) to apply for loans rather than grants, the maximum amount per loan award should be greater than the maximum amount per grant award. The total amount awarded by the ICOC for grants and loans will turn on the scientific merit of the grant and loan applications.

3. CIRM Milestones and Disbursement of Funds

- Applicants for loans should be required to provide a budget, including a cash flow plan, to demonstrate the funds required to reach their goal. Successful applicants should receive the proceeds of CIRM's loan incrementally by demonstrating that they have met pre-determined scientific and financial milestones and are on track to achieve their goals.

- The following hypothetical illustrates the application of this concept: CIRM issues a translational RFA for programs up to and including Phase 2A, and as part of that RFA offers loan applicants up to $10 million per loan. The use of these funds is restricted to the costs of employees working directly on the program and related out-of-pocket expenses; the funds could not be used for indirect support. Pursuant to this concept proposal, applicants would be required to include a budget setting forth the total anticipated costs (both direct and indirect) required to reach various milestones (e.g., IND, Phase 1, Phase 2B). CIRM would disburse the loan proceeds incrementally based on the applicant's achievement of these milestones and its demonstration of sufficient capital to reach its goal.

4. Delegated Underwriters and Interest Rates

- The ICOC should consider using delegated underwriters to conduct a financial and business review of those loan applicants whom the Grants Working Group recommends for funding or recommends for funding if funds are available. Similarly, delegated underwriters could also be employed to administer the loans. An outline of this proposal is set forth in Addendum A ("CIRM Loan Program: External Financial/Business Review").

- The delegated underwriter, among other tasks, would assess the non-scientific risk of the application and the applicant's financing in recommending to the Finance Committee any deviation from the interest rate guidelines for a particular application. As a general principle, the interest rate should be set higher to the extent that the applicant risk is higher or the applicant's financing is less certain. It is expected that the delegated underwriters would recommend an adjustment of the interest rate within a range that is 2% above or below the average for early stage loans. The Finance Committee would approve the interest rate to the extent that it varies from the guidelines. This is not intended to extend the time for the receipt of funds.

5. Application of Policy Concepts to Specific Factual Circumstances

- Addendum B describes the potential application of these concepts under particular factual circumstances.