



TO: Members, Governing Board

FROM: James C. Harrison, General Counsel

DATE: May 19, 2015

RE: Loan Election Option for Clinical Stage Program Awards

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#### **INTRODUCTION**

The Intellectual Property and Industry Subcommittee met on May 18, 2015, to consider a proposal to permit Clinical Stage Program awardees to elect to treat their award as a loan within the earlier of the submission of an application for marketing approval to the Food and Drug Administration or seven years from the effective date of the award. This loan election option would replace the Loan Administration Policy for Clinical Stage Program awardees. The Subcommittee unanimously recommended Board approval of the proposed policy, which would be included in the Interim Grants Administration Policy for Clinical Stage Projects, and requested that the Board delegate authority to the Subcommittee to set the rate of return for awardees electing the loan option.

#### **BACKGROUND**

CIRM established a loan program in 2009. The original aims of the program included recycling research funds through the repayment of loans and the exercise of warrants issued to CIRM as a condition of the loan. At the time the Governing Board approved the loan program, CIRM anticipated that it would issue approximately \$70 million worth of loans per year and that the agency would ultimately have a \$500 million portfolio of loans. Since CIRM established the loan program, it has made five loans, two of which are still outstanding.<sup>1</sup> The Board has modified the

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<sup>1</sup> CIRM forgave two of the loans because the projects did not achieve their aims and one loan recipient repaid its loan when it decided to terminate its project for business

program on multiple occasions in an effort to make the program more appealing to industry, but notwithstanding these efforts, the program has not met its original expectations.

As a result, consistent with the goals of CIRM 2.0, we have closely reviewed the loan program to evaluate whether it should be maintained. Based on this review, we have concluded that the program should be modified in an effort to serve three important aims. First, it should encourage industry involvement, which is essential to delivering stem cell therapies to patients, by providing an alternative to our grant terms for applicants (and their co-funding industry partners) who may be unwilling to take CIRM funds because of the uncertainty associated with their potential liability for revenue sharing. Second, it should create an incentive for awardees to repay CIRM while the agency continues to make research awards so that the proceeds of the loans can be recycled to make additional research awards. Finally, the program should increase efficiency by reducing the complexity and administrative burden of the existing program. We therefore propose that the Subcommittee consider an alternative approach to the existing loan program for Clinical Stage Program awards.

Under this proposal, recipients of CIRM's Clinical Stage Program awards (PA 15-01, 15-02 and 15-03) would have the option to treat their awards as loans within the earlier of the submission of an application for marketing approval by the Food and Drug Administration or seven years from the effective date of the award. Unless the parties agreed to different terms, the awardee would be required to repay the loan balance within ten days of making the loan election at a rate that would escalate based on the date of repayment. The loan election would become final only after the awardee has satisfied the terms of the election.<sup>2</sup> If an awardee does not make this election, its award would be treated as a grant.

This program would advance CIRM's mission to accelerate the delivery of stem cell therapies to patients with unmet medical needs in three ways. First, it is designed to encourage industry involvement in the commercialization of CIRM-funded inventions by offering an alternative to the traditional grant and loan options. Second, it would create an incentive for awardees to repay CIRM early, so that the agency could use the proceeds to make new research awards. Finally, it would increase efficiency by eliminating the complexity of the loan program and reducing the administrative burden

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reasons. The two outstanding loans are to Capricor and ViaCyte. The existing Loan Administration Policy would continue to apply to these awards.

<sup>2</sup> Under existing CIRM regulations, loan recipients are subject to the access, pricing, and march-in rights established by CIRM's intellectual property regulations. (Cal. Code Regs., tit. 17, § 100801.) These provisions would continue to apply to an awardee that elects to treat its award as a loan.

of negotiating a loan agreement with each loan recipient and maintaining and enforcing a separate administrative policy to cover loans.<sup>3</sup>

We are in the process of gathering additional information in order to determine the appropriate rate of return. We therefore request that the Board delegate the authority to set the rate on an interim basis to the Intellectual Property and Industry Subcommittee. Assuming the Board approves the loan election policy, it will be incorporated into the Interim Grants Administration Policy for Clinical Stage Projects and the Board will have an opportunity to consider further amendments before the policy is finalized.

### **RECOMMENDATION**

Recommend Board approval of the loan election policy for Clinical Stage Program awardees, as described in the attachment to this memorandum, and request that the Board delegate responsibility to the Intellectual Property and Industry Subcommittee to set the rate of return on an interim basis, pending final approval by the Board of the Interim Grants Administration Policy for Clinical Stage Program Awards.

Attachment

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<sup>3</sup> Even though CIRM has used a loan template agreement, each loan has required individual negotiations to complete.

**INTERIM LOAN ELECTION POLICY FOR CLINICAL STAGE PROGRAM AWARDS**

(1) An Awardee may elect to treat its Award as a Loan within the earlier of seven (7) years of the Effective Date of the Award, or the date the Awardee submits an application for marketing authorization from the Food and Drug Administration for the CIRM-Funded Invention or CIRM-Funded Technology, by sending CIRM written notice of its election. Unless CIRM and the Awardee agree to a different repayment period and terms, an Awardee that elects to treat its Award as a Loan shall repay CIRM at the rate specified in paragraph (2) within ten (10) days of making the election.

(2) (a) if the Awardee repays CIRM within three (3) years of the Effective Date of the Award, the Awardee shall repay CIRM [\_\_\_\_\_ percent (\_\_\_%)] of the amount of the Award;

(b) if the Awardee repays CIRM during the fourth year after the Effective Date of the Award, the Awardee shall repay CIRM [\_\_\_\_\_ percent (\_\_\_%)] of the amount of the Award;

(c) if the Awardee repays CIRM during the fifth year after the Effective Date of the Award, the Awardee shall repay CIRM [\_\_\_\_\_ percent (\_\_\_%)] of the amount of the Award;

(d) if the Awardee repays CIRM during the sixth year after the Effective Date of the Award, the Awardee shall repay CIRM [\_\_\_\_\_ percent (\_\_\_%)] of the amount of the Award; and

(e) if the Awardee repays CIRM during the seventh year after the Effective Date of the Award, the Awardee shall repay CIRM [\_\_\_\_\_ percent (\_\_\_%)] of the amount of the Award.

(3) An Award shall be considered to be a Loan only upon the Awardee's satisfaction of all of the terms specified in this Section, including any terms negotiated by the parties pursuant to Paragraph (1).

(4) An Awardee that elects to treat its Award as a Loan shall be subject to CIRM regulation 100801 (Cal. Code Regs. tit. 17, § 100801).

(5) If an Awardee does not make the election specified in Paragraph (1), its Award shall be considered a Grant.

(6) CIRM reserves the right to modify this Section, but the modifications shall apply prospectively to Awards made after the modification takes effect and shall have no application to Awards made before the effective date of the modification.