



TO: Members, Intellectual Property and Industry Subcommittee

FROM: James C. Harrison, General Counsel

DATE: May 11, 2015

RE: Loan Option for Clinical Stage Program Awards

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#### INTRODUCTION

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 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

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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 reasons. The two outstanding loans are to Capricor and ViaCyte.

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.

Under this proposal, recipients of CIRM's clinical stage project awards (PA 15-01, 15-02 and 15-03) would have the option to elect to convert their award from a grant to a loan within the earlier of 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 election to convert from a grant to a loan at a rate that would escalate based on the date of repayment. Conversion from a grant to a loan would become final only after the awardee has satisfied the terms of the conversion.<sup>2</sup>

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 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 Subcommittee ask the Board to delegate the authority to set the rate on an interim basis to the Subcommittee. Assuming the Subcommittee recommends, and the Board approves, the loan option policy, it will be incorporated into the Interim Grants Administration Policy for Clinical Stage Programs and the Board will have an opportunity to consider further amendments before the policy is finalized.

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<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 an awardee that converted its award from a grant to a loan.

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

**RECOMMENDATION**

Recommend Board approval of a modified loan program 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 Grants Administration Policy for Clinical Stage Program Awards.

Attachment

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

(1) An Awardee may elect to convert its Award from a Grant to a Loan within the earlier of seven (7) years of the Effective Date of the Grant, or the date the Awardee receives 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 convert a Grant to 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) A Grant shall be considered to have been converted into 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) 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.

(5) An Awardee that converts its award from a Grant to a Loan shall be subject to CIRM regulation 100801 (Cal. Code Regs. tit. 17, § 100801).