CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

# INTELLECTUAL PROPERTY, REVENUE SHARING, LOAN CONVERSION, MARCH-IN RIGHTS, PRICING PRIMER

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**Intellectual Property:**

Any intellectual property developed over the course of a CIRM funded project is owned by the awardee.

Development and commercialization of CIRM-funded technology or CIRM-funded invention may trigger CIRM's revenue sharing requirements. CIRM's revenue sharing requirements are similarly applied to non-profit and for-profit awardees. General information regarding revenue sharing is included below but prospective applicants are advised to review CIRM's IP FAQ for a detailed overview.

Awardees (and any successor entities) are required to annually report on patent prosecution, licensing events of any intellectual property, including but not limited to CIRM-funded technology, and any revenue.

**Revenue Sharing Requirements (Applicable to grants made after September 4, 2018):**

Prior to commercialization, the awardee (whether non-profit or for-profit) shall not have any revenue-sharing obligations on any licensing revenue received.

Once the Commercializing Entity (whether the awardee or a third party) begins selling the product/services, it will have to share with the State a royalty on commercial revenue as follows: 0.1% per $1 Million in award funds, for the earlier of ten (10) years or 9x the award amount. Thus, for an $8 million award, the Commercializing Entity will owe less than one percent royalty (.8%) on all commercial revenue for ten years (unless payments reach $72 million earlier).

In addition, a Blockbuster Provision of a 1% royalty on net commercial revenues in excess of $500 million per year will also apply only if all the following conditions are met: (1) the 9x award amount or 10 year time limit of the standard revenue sharing requirement has been met (2) CIRM funding of the project exceeds $5M in awards, and (3) a CIRM-funded invention contributed toward the commercialization of the Drug. The Blockbuster Provision applies until the last-to-expire patent covering a CIRM-funded Invention.

The revenue sharing terms have the force of state law and are non-negotiable for CIRM.

**Loan Conversion Option (Extinguishes Revenue Sharing Requirements**):

Note: Loan Conversion option applies only to TRAN1, PDEV and CLIN awards.

The awardee may choose to convert an award into a loan after the Award is completed, but not later than 10 years of the Award's start date. Such a conversion would extinguish the revenue sharing requirements above and instead require loan repayment based on circumstances described in the table below. The rate of repayment varies depending upon award type, stage of research, stage of development at election point and therapeutic class. The term "election point" refers to a point in time before the first read-out of data, including any interim analyses. The loan conversion terms are also non-negotiable.

| Conversion Circumstance | | | Percent of Loan to be Repaid | |
|---|---|---|---|---|
| **Award Type** | **Stage** | **Election Point** | **Non-Cell Therapy** | **Cell Therapy** |
| TRAN1/CLIN1/PDEV | Preclinical | Phase 1 | 80% | 60% |
| TRAN1/CLIN1/PDEV | Preclinical | Phase 2 | 100% | 80% |
| TRAN1/CLIN1/PDEV | Preclinical | Phase 3 | 100% + 15% APR+LIBOR | 100% |
| TRAN1/CLIN1/PDEV | Preclinical | Registration | 100%+20% APR+LIBOR | 100%+7% APR+LIBOR |
| CLIN2 | Phase 1 | Phase 2 | 100% | 80% |
| CLIN2 | Phase 1 | Phase 3 | 100%+15% APR+LIBOR | 100% |
| CLIN2 | Phase 1 | Registration | 100%+25% APR+LIBOR | 100%+10% APR+LIBOR |
| CLIN2 | Phase 2 | Phase 3 | 100%+20% APR+LIBOR | 100% |
| CLIN2 | Phase 2 | Registration | 100%+30% APR+LIBOR | 100%+10% APR+LIBOR |
| CLIN2 | Phase 3 | Registration | N/A | 100% + 25% APR + LIBOR |

**March-in Rights:**

The CIRM march-in rights parallel federal march-in rights under 1980 Bayh-Dole Act (Bayh-Dole), which apply to discoveries arising from NIH funding and which are intended to prevent a useful discovery from being shelved. CIRM's march-in rights were drafted to be similar in concept to the federal march-in rights established under Bayh-Dole where the US government may require a license where "action is necessary to alleviate health or safety needs which are not reasonably satisfied," or where the benefits of the [government-funded] invention are not being made "available to the public on reasonable terms."

**Like federal march-in rights, CIRM's march-in rights are designed to be used rarely.** Under Bayh-Dole there have been five petitions to exercise the march-in rights and the NIH has denied all the petitions.

**Pricing:**

Participation in Statewide Prescription Drug Discount Program: A Commercializing Entity is required to abide by any statewide prescription Drug discount program, which sets benchmark pricing for any purchases by California government entities. As of the date of this writing, there is **NO** statewide prescription Drug discount program in effect.

**Access:**

The Commercializing Entity must submit a plan to afford uninsured Californians access to a Drug that is developed in whole or in part with CIRM funds. CIRM envisions that such a plan will be similar to "patient assistance plans" already prevalent in the pharmaceutical industry. The plan must be provided within 10 business days following final approval of the Drug by the Food and Drug Administration, unless, within that timeframe, the Commercializing Entity seeks an extension from CIRM. The plan shall be "consistent with industry standards" at the time of commercialization. Plans may account for the size of the market and the resources of the Commercializing Entity. In addition, the Commercializing Entity is not

responsible for any costs of administering the Drug, any associated costs of medical procedures or protocols for the Drug therapy, or for any costs for attendant care.