

Shyam Patel, Ph.D. Senior Director of Business Development & Alliance Management CIRM IP & Industry Subcommittee Meeting Presentation 11/08/23







#### **OUR MISSION**

Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world



## CIRM Existing Co-Funding Requirement



What was the intent of the existing co-funding requirements?

- For-Profits: Demonstrate commitment to the proposed project
- Non-Profits: To have an industry partner for phase 2 and later clinical trials

Program	Minimum Co-Funding		
	Non-Profit	For-Profit	
TRAN	N/A	20%	
CLIN1	N/A	20%	
CLIN2	N/A	30%	
	40%	40%	

#### Why are changes being proposed to the existing co-funding requirement?

- For-Profits are operating in a challenging economic environment, and are at a relative disadvantage to non-profits for CIRM award levels.
- Currently, if a non-profit applicant has a for-profit partner, the partner is not required to co-fund the CIRM award.
- Currently, clinical progress of unpartnered academic programs has stalled after first in human studies if the program is unable to raise the 40% required co-funding.

# CIRMO Proposed TRAN/CLIN Co-Funding Requirements



Warrant-based co-funding as an alternative commitment option to cash for the co-funding requirement.

• CIRM had previously required awardees to issue warrants as part of prior Loan Program (community fund exercised and liquidated shares).

Program	Minimum Co-Funding		
	Non-Profit (Unpartnered)	For-Profit OR Non-Profit (Partnered*)	
TRAN	N/A	Cash (20%) or Warrants	
CLIN1	N/A	Cash (20%) or Warrants	
CLIN2 (FIH)	N/A	Cash (30%) or Warrants	
CLIN2 (Post-FIH)	N/A	Cash (40%) or Warrants	

\*Partner - an organization that in exchange for the right to the opportunity for a future financial return has entered into an agreement with the applicant organization relating to the commercialization of the proposed project.





- 40% co-funding requirement is not an incentive for industry partners and is slowing clinical progress.
  - If already partnered, co-funding requirement applies.
- Revenue sharing requirement would provide return to the state if program is successfully commercialized.
  - \$15M CLIN2 award results in 1.5% royalty on revenue up to \$135M/10 years.
- Loan Conversion would, at a minimum, return principal to CIRM.





- For-Profit awardee commits warrants instead of capital.
- Awardee retains capital for operational needs and value creation.
- CIRM commits a higher award amount (up to award cap) to maintain overall financial support of the CIRM-funded project.

Cash-Based Co-Funding (Current) Total Project		Warrant-Based Co-Funding			
Cost	CIRM Award	Awardee Co-Funding Commitment	CIRM Award	Awardee Cash Co- Funding	Awardee Warrant Coverage
\$4.0M TRAN1	\$3.2M (\$4M direct limit)	\$0.8M	\$4.0M (\$4M direct limit)	\$0	\$0.8M
\$8.0M CLIN2	\$5.6M (\$8M limit)	\$2.4M	\$8.0M (\$8M limit)	\$0	\$2.4M

#### CIRCO Prior Subcommittee Feedback on Warrant-based Co-Funding Proposal



- Ensure that the warrant-based co-funding commitment measures up to cash-based co-funding commitment.
- Determine if there is necessity to allow awardee to "buy back" warrants.
- Define company eligibility criteria for election of warrant-based co-funding requirement.





- Applicant elects warrant-based co-funding option at time of application.
  - CIRM term sheet, FAQ and other reference materials will be posted with PAs
  - Applicant may combine warrant-based and cash-based co-funding
- Warrants must be issued at award start.
- There will be no mechanism for "buying back" warrants during or after award period.

Applicant type	Private Company (has not issued preferred shares)	Private Company (has issued preferred shares)	Public Company
Security Type	Common Stock	Preferred Stock	Common Stock
Number of Shares	1 share / \$1 CIRM Co- Funding	[CIRM Co-Funding] / [Preferred Share Price*]	[CIRM Co-Funding] / [Average closing price**]
Warrant Term	10 years	10 years	10 years
CIRM Option	Conversion to preferred stock warrant at next preferred share financing	N/A	N/A

\*The price per share in the most recent equity financing as of the Issue Date.

\*\*Average of closing bid and asked prices of the common stock for the 10-trading day period ending 5 trading days prior to the date of exercise.





# Current proposal values CIRM's additional capital commitment in the CIRM-funded project similarly to investor capital in the company.

Hypothetical Scenario Demonstrating Pre-Funded Warrant Rationale

Co-Funding Coverage: \$1M; Preferred Share Price: \$1; Number of Shares: 1M	Pre-Funded Warrants Exercise Price = \$0.01	CIRM Loan Program Terms Exercise Price = \$1
Cost to Exercise Warrants	\$10,000	\$1,000,000
Co-Funded Award Amount + Exercise Cost	\$1,010,000	\$2,000,000
Shares (Cashless Exercise, \$5 share price)	998,000	800,000





## **Current Solvency & Co-Funding Requirements**

- Application eligibility requirements. At time of application:
  - 180 days of solvency from date of submission
    - Cash-on-hand, committed funding
  - Commit co-funding and contingency funding
    - Cash-on-hand, committed funding, planned fundraising
- Award reporting requirements:
  - Indicate amount spent on co-funding
  - Evidence of ability to co-fund next milestone

### Warrant-Based Co-Funding: Application Eligibility and Award Requirements



Application and Award Requirements for companies selecting warrant-based co-funding option.

• This table only describes additional requirements for selecting warrant-based co-funding option. All other standard application, application eligibility and award requirements apply.

Applicant Type	Private Company (has not issued preferred shares)	Private Company (has issued preferred shares)	Public Company
Application Eligibility	Fundraising Plan	<ul> <li>Fundraising History</li> <li>Lead investor letter of support for CIRM project</li> </ul>	N/A
Award Start	Issue Common Stock Warrant to CIRM	Issue Preferred Stock Warrant to CIRM	Issue Common Stock Warrant to CIRM
Award Period	<ul> <li>Awardee notifies CIRM of preferred share issuance.</li> <li>CIRM BD Team will utilize Industry Alliance Program to assist company's fundraising.</li> </ul>	N/A	N/A





- Negotiation & Issuance of Warrant Managed by CIRM Team with support from outside counsel
- Ongoing Compliance Monitoring Managed by outside counsel
- Exercise of Warrant, Liquidation of Shares & Transfer of Proceeds to CIRM CIRM Fund managed by a California community foundation





- November 2023 IP/Industry Subcommittee Review Warrant-based co-funding and revised co-funding model review
- November 2023 Science Subcommittee Review TRAN, CLIN1 and CLIN2 concept plan changes (Warrant term sheet provided as reference)
- **December 2023 ICOC Review** TRAN, CLIN1 and CLIN2 concept plan changes (Warrant term sheet provided as reference)