Agenda Item #14
8/12-13/08 ICOC Meeting

REPORT OF THE LOAN TASK FORCE SUBCOMMITTEE OF THE

INDEPENDENT CITIZENS OVERSIGHT COMMITTEE

DRAFT POLICY COMPONENTS OF THE ICOC LOAN PROGRAM

AUGUST 12 AND 13, 2008
STANFORD, CALIFORNIA

I. Background

Public-private partnerships involving research and development activities among industry, government, and universities can play an instrumental role in introducing key new technologies and valuable products to the commercial marketplace. Experience shows that partnerships involving government participation in research and development activities with industry, universities, and government laboratories can greatly facilitate the translation of basic research discoveries to products with societal benefits.

The mission of the CIRM is to foster and promote stem cell research with the aim of improving human health. A secondary goal is to strengthen California's biotechnology industry and create collateral economic benefits such as high-paying jobs and increased tax revenues. CIRM believes that the funding of commercial research organizations focused on stem cell-related projects is a key component to achieving the overall mission of the Institute. Increased interest by the commercial research sector in stem cell-related research projects and the successful translation of basic research discoveries into commercial products for public use are primary success indicators (among others) that can be used by CIRM to track benefits of commercial sector funding.

To achieve the goal of commercializing stem cell research-related products, CIRM will fund non-profit and for-profit (commercial) research institutions in California via options that include grants and loans. As required by law, all CIRM-funded research activities must be conducted in the State of California. The goal of a loan program is to fund the translation of research into research tools, medical diagnostics and devices, and therapeutic products. These loans will be targeted at the funding gaps in product development that will serve to leverage participation by follow-on investors, such as venture capital and other capital markets, and result in more products that enter the market. For the State and CIRM, the advantage of a loan program versus a grant is the ability to recycle CIRM research funds, potentially enlarging the return for each CIRM research dollar expended. In addition to loan principal and interest, loans may also feature warrant coverage, depending on the type of loan, which will constitute additional interest-based return on the investment in light of risk posed.

Early stage companies and pre-commercialization entities would be the prime targets for a loan program in light of the lack of funding available in what is known as the "valley of death" for translational development of products. Established companies indicate a loan program would be valuable because there are more research and product development projects worthy of pursuit than can be funded with existing funds available to the companies.

II. Terms of Debt

The task force held several stakeholder meetings throughout the state to gather input from potential loan applicants, banks and other venture capital funders, and members of the Legislature. Also, the task force commissioned a series of reports from PriceWaterhouseCoopers ("PwC") that surveyed the landscape in other states, countries, and disease associations that have loan programs. As a result of this input, the task force worked with PwC to create a draft term sheet and conduct interviews to obtain feedback.

The feedback was then incorporated into a final draft and used to facilitate the development of a model by PwC to project the results of a hypothetical loan program containing the variables listed below. It should be noted that certain terms used in the model are not included in this document, including the loan amounts and interest rates. These items will be specified in each RFA that includes a loan option. Similarly, while the total amount of funds committed to the CIRM Loan Program will be set by CIRM, the Loan Task Force instructed PwC to assume a distribution of roughly $70 million per year in loans that would range between $1-5 million comprising approximately 20 loans per year for a period of eight to ten years.

The following terms were also incorporated into the model.

CIRM LOAN POLICY – TERM SHEET

Disbursement: Milestone driven. [*Prior to funding, applicants will describe pertinent milestones for the overall program to be funded by CIRM. CIRM disbursements will be pegged to successful attainment of pre-approved milestones. This comports with responsible stewardship of CIRM resources and is a common feature in programs from other funding entities*.]

Term of Loan: Six or ten years. [*The term of the loan program must be nuanced to address sometimes competing needs of CIRM and loan recipient - for CIRM the earlier the loan is repaid, the better the chance that loan proceeds can be recycled into additional loans that further the search for cures and therapies. For companies, however, longer terms may increase the ability for a company to* *attract follow-on financing. Successful programs will likely entail incentives to early payback – increasing costs (interest rates, for instance) as loan maturity lengthens*.]

Recourse: May be recourse to the company or non-recourse. [*Recourse refers to the choice of a loan recipient to guarantee repayment. Where a loan is a "recourse" loan, the company commits to repay the loan regardless of the success or failure of the project funded by CIRM. Because a recourse loan usually entails less risk of default than a non-recourse loan, the terms (such as interest rate or warrant coverage) reflect the risk differential.*]

Warrants: Warrant coverage of 10% of the CIRM loan for recourse loans, 100% of the CIRM loan for non-recourse loans, with cap on CIRM ownership of 20% on fully-diluted basis. [*Warrants represent interest yield and premium for risk. The terms will depend on whether the loan is a non-recourse product loan, or whether the loan is a recourse loan which the company promises to repay regardless of the success or failure of the product. The warrants will be exercisable regardless of whether or not the loan ultimately is paid back*.]

Warrant Strike Price: Set at previous round of equity financing prior to CIRM loan approval; if no previous round, then floated until the next round.

Payment Acceleration Triggers:

6-Year Loan: 1) Change of control, including a merger with public or private company if combined enterprise value exceeds $100 million
2) IPO in excess of $20 million. [*Minimum values reflect accommodation of smaller ventures where small companies merge in order to pursue the aim of the funded research, which may be undercapitalized, as opposed to larger mergers that result from market integration of successful CIRM-funded projects.*]

10 Years: 1) Change of control, including a merger with a public or private company if combined enterprise value exceeds $100 million
2) IPO in excess of $20 million
3) Twenty-fold financing (i.e. loan becomes due when the company secures 20 times the original loan amount of follow-on financing)
4) Within 90 Days of FDA submission of an Investigation Device Exemption application (for devices and diagnostics)
5) Within 6 months of beginning a pivotal trial or, within six months of the filing of an IND application (for therapeutics)

Prepayment: At any time. [*While other states' programs sometimes penalize early repayment because is siphons resources from research, prepayment is encouraged in this program insofar as it reflects the generation of follow-on and leveraged financing and enables the CIRM program to recycle loan resources.*]

Loan subordination: Subordinate to other debt financing. [*Debt provided by CIRM may be subordinated to further follow-on funding. Feedback suggests that failure to do so makes CIRM funding "toxic" to additional financing rounds. However, subordination to "equity" rounds of financing is uncommon.*]

Matching funds: Indirect requirement; company will need to raise more funds in order to reach milestones for additional CIRM funding. [*PwC analysis supports this as a similar component in other state loan programs; also when tested with interested community there was general acceptance.*]

Default: In the event the loan recipient is unable to repay the loan and the entity or its intellectual property is not the subject of a repayment-triggering change of control event, Recipient shall not abandon or otherwise further compromise the value of the IP developed with loan proceeds without first making a good faith effort, in consultation with CIRM, to identify other entities which are a) potentially interested in acquiring the IP and b) are willing to undertake the loan obligations. Once identified, Recipient will cooperate in transferring IP to those entities pursuant to a process approved by CIRM. Recipient will give adequate advance notice to CIRM of intent to abandon IP developed with loan funds.

III. Covenants

A loan contract will contain the following elements, derived from CIRM's Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations:

- Access for Californians to CIRM-Funded Stem Cell Therapies: CIRM requires loan recipients to provide drugs and therapies at benchmark prices described in the California Discount Prescription Drug Program (CalRx) (or its equivalent) for:

    1. Individual Californians Participating in CalRx; and
    2. California Entities Purchasing Drugs and Therapies with Public Funds

- Access Plan at Market Launch for Uninsured Californians: Must provide an industry standard plan of access for uninsured Californians not otherwise covered by existing government programs (such as Medicare, Medical, CalRx, Veterans Administration, Health Families Program, AIDS Drug Assistance Program, Genetically Handicapped Persons' Program, California Children's Services Program, et cetera) or private insurance.

- Publication-Related Biomedical Materials Sharing: Requires sharing of materials for research purposes in California at cost where the organization publishes the discovery in a scientific paper, and where sharing the material does not conflict with the business model or otherwise create an onerous financial hardship, until such time as the material is broadly commercially available.

- Press-Release Requirements: Requires notification of CIRM in advance of press-releases referring to CIRM-funded research.

- Funding for California Operations: Terms of the loan require that borrowed funds be expended for use in the State of California.