



JOHN CHIANG
California State Controller

June 30, 2012

To the People of California:

I am pleased to present the seventh annual report of the Citizens Financial Accountability Oversight Committee (CFAOC) to the California Institute for Regenerative Medicine (CIRM).

Proposition 71, passed by voters in November 2004, created CIRM to implement a \$3 billion stem cell research program. It is this committee's responsibility to ensure that those public funds are spent efficiently and effectively on lifesaving medical research. The CFAOC was created by Proposition 71 to provide financial oversight and recommendations to CIRM. The CFAOC must meet annually to review the finances of CIRM and issue an annual report.

Eight years ago, Californians showed their overwhelming support for stem cell research when they approved Proposition 71. Not only did California voters support stem cell research, they also said they were willing to pay for it – and committed more than \$3 billion in public funds, which will be closer to \$6 billion with bond financing, to pursue this promising research. I, too, believe stem cell research holds the key to cures for chronic and life-threatening diseases that affect millions of Americans. The members of this committee not only have the opportunity, but the obligation, to provide expert fiscal review and guidance to the Institute for Regenerative Medicine. We must ensure CIRM's fiscal practices are sound and that we fiercely protect the investment of public funds as we continue to make inroads into this revolutionary field of science and medicine.

Sincerely,

JOHN CHIANG
California State Controller

Contents

COMMITTEE OVERVIEW

History of the Citizens Financial Accountability Oversight Committee	3
Scope	3
Board Members.....	3
Oversight of the California Institute for Regenerative Medicine	6

SEVENTH ANNUAL MEETING

Meeting Details	7
Financial Presentations	7
Committee Discussion	10
Committee Action	15
Public Comments	15

POST-MEETING UPDATES

Committee Overview

History of the Citizens Financial Accountability Oversight Committee

The Citizens Financial Accountability Oversight Committee (CFAOC) was created by Proposition 71, which was approved by voters in November 2004. Proposition 71 charged the CFAOC with reviewing the financial practices and performance of the California Institute for Regenerative Medicine (CIRM) and advising CIRM on its financial practices.

Scope

The CFAOC's six-member board, chaired by the California State Controller, must annually review the financial practices and performance of CIRM. As a part of its evaluation, CFAOC members review CIRM's annual financial audit, the State Controller's evaluation of that audit and the financial practices of CIRM.

Committee Members

The Honorable John Chiang, Chair
California State Controller

Controller John Chiang was elected in November 2006 to serve as California's Chief Fiscal Officer.

The Controller is the chair of the Franchise Tax Board and, during even-numbered years, the State Lands Commission. He serves on 78 boards and commissions including CalPERS and CalSTRS, the nation's first- and second-largest public pension funds.

As Controller, Chiang has moved swiftly to ensure California is on the road to prosperity while meeting its obligations to workers and retirees. Upon assuming office, Chiang immediately hired an independent actuary to determine, ahead of schedule, the costs of post-employment benefits as the first step in crafting California's long-term plan to meet the State's accounting and healthcare commitments.

The Controller brings extensive experience and fiscal leadership to the State Controller's Office. Chiang was first elected to the Board of Equalization in 1998 where he served two terms, including three years as chair. He began his career as a tax law specialist with the Internal Revenue Service and previously served as an attorney in the State Controller's Office.

Chiang is the son of immigrant parents, and graduated with honors from the University of South Florida with a degree in Finance. He received his law degree from the Georgetown University Law Center. Chiang and his wife, Terry Chi, live in Torrance, California.

Daniel Brunner

Retired, Appointed by the State Treasurer

Daniel Brunner has more than 30 years experience in health care law, policy and corporate management in both the public and private sectors. Mr. Brunner co-founded Affordable Health Care Concepts in 1983. The Sacramento-based firm, which developed highly customized PPO networks on the West Coast, was the first to introduce the concept of competitive bidding among hospitals for patient services. It was acquired by First Health in 1987. Through January of 2005, he served as Executive Vice President of First Health and as a member of its Board of Directors.

Mr. Brunner served as General Counsel for the California Governor's Office of Special Health Care Negotiations and was the Director of the Legislative Office at the Western Center on Law and Poverty, General Counsel and Deputy Director of Legal Affairs in the State Department of Benefit Payments and was on the faculty at UCLA and USC law schools.

Mr. Brunner earned a bachelor's degree in accounting at UCLA. He obtained his law degree from California Western University and is a member of the California Bar. In addition, he served on the boards of directors of the Sacramento Theatre Company and Capitol Public Radio. He also serves on the board of visitors of the University of California, Davis, School of Medicine.

Dr. James Kovach *CEO and President of Athleticcode Inc., appointed by the ICOC Chair*

Dr. James Kovach is currently the CEO and founder of Athleticcode, a fitness company using genetic testing and performance data that athletes can use to develop personalized training programs that reduce injury. He serves as the Principal Investigator of the NFL Concussion Study, in which more than 100 former National Football League players have undergone confidential genetic testing of APOE, a gene associated with late-life cognition issues in individuals who have suffered multiple concussions.

Dr. Kovach also serves as Manager of Healthcare System and Physician Outreach for SKS Investments, LLC, where he helps identify hospital and healthcare systems to partner with in developing medical office and life sciences research space.

He served as President and Chief Operating Officer of the Buck Institute for Age Research in Novato, California, in 2005-2010. In 1998-2005, Dr. Kovach was Executive Vice President and Chief Operating Officer of Athersys, Inc., a publicly-traded biotechnology company located in Cleveland, Ohio. He has also directed the Office of Technology Management at the Case Western Reserve University School of Medicine in Cleveland.

Dr. Kovach spent seven years as a middle linebacker in the NFL, playing for the New Orleans Saints and the San Francisco Forty-Niners and attending medical school in consecutive off-seasons. He received his Bachelor of Science degree in biology from the University of Kentucky in 1978, where he graduated cum laude. He received his Doctor of Medicine Degree from the University of Kentucky in 1984. He obtained his law degree from Stanford University in 1990, and practiced as a corporate attorney.

Dr. Loren G. Lipson

Retired, appointed by the State Controller

Dr. Loren G. Lipson is a Professor Emeritus of Medicine at the Keck School of Medicine at the University of Southern California. A resident of Pasadena, Dr. Lipson has been a recognized leader in the field of medicine for 40 years. He has been appointed to academic posts at some of the country's most prestigious universities, including the Harvard Medical School and the USC School of Medicine, where he served as Chief of the Division of Geriatric Medicine, Department of Medicine, from 1984-2004.

Dr. Lipson currently serves as a Geriatric Medicine and Long Term Care consultant to the U.S. Department of Justice, Civil Division; U.S. Department of Health and Human Services, Office of the Inspector General; California Department of Justice's Bureau of Medi-Cal Fraud and Elder Abuse; California Department of Social Services; and the New Mexico Department of Justice, Medicaid Fraud Control Unit.

He was director of two USC Teaching-Nursing Home Programs, the Hollenbeck Home in Los Angeles and the Atherton Baptist Home in Alhambra.

A graduate of Johns Hopkins University School of Medicine, Dr. Lipson received his undergraduate degree in Chemistry from the University of California, Los Angeles.

Jim Lott

Executive Vice President, Hospital Association of Southern California, appointed by the Senate President Pro Tem

Jim Lott is the Executive Vice President of the Hospital Association of Southern California where he is responsible for health care policy development, advocacy, and communications for hospitals serving Los Angeles, Orange, San Bernardino, Riverside, Santa Barbara and Ventura counties.

Prior to his move to Los Angeles, he served for five years as the President and Chief Executive Officer of the Hospital Council for San Diego and Imperial counties.

Mr. Lott served for ten years as Staff Director and Chief Consultant to the Senate Committee on Health and Human Services of the California Legislature. In that capacity, he was one of the principal architects of the health care finance reforms adopted by the California Legislature in 1982. Later, he worked on President Clinton's Health Care Reform Task Force.

Mr. Lott received his undergraduate degree from Cal State L.A., his MBA degree from the University of Redlands, and has achieved candidate status for his doctorate in Education-Organizational Leadership at Pepperdine University. He serves on the boards of the Claremont Universities Consortium, the Los Angeles Economic Development Corporation, and L.A. Care Health Plan, for which he serves as chairperson.

Dr. Gurbinder Sadana

Physician, Appointed by the Assembly Speaker

Dr. Gurbinder Sadana is a long-time private practice physician and specialty consultant with offices in Pomona.

He has been in private practice in Pomona since 1983, and is a specialty consultant and advisor on asthma and related disease. He is also Medical Director of Critical Care Services at the Pomona Valley Hospital Medical Center in Pomona.

Dr. Sadana is a fellow of the American College of Chest Physicians and a member of the Society of Critical Care Medicine. He serves on the Board of Directors of the Pomona Valley Hospital Medical Center Foundation.

His Board Certifications include American Board of Internal Medicine, American Board of Internal Medicine/Critical Care Medicine, and American Board of Internal Medicine/ Pulmonary Medicine.

Dr. Sadana graduated from Gauhati Medical College in Gauhati, Assam, India in 1969, and he has completed extensive post-graduate education including earning a Diploma in Chest Diseases from the University of Delhi, New Delhi, India.

**Oversight of the
California Institute
for Regenerative
Medicine**

When Proposition 71 created CIRM, it also established two structures for providing oversight of the Institute and the taxpayer bond money. The Independent Citizens Oversight Committee (ICOC) consists of 29 members who are appointed by statewide elected officials and Legislative leaders. The ICOC is the board that governs CIRM. ICOC members include scientists, physicians, business people, university administrators and patient advocates. Proposition 71 provided that the Chair and the Vice Chairperson of ICOC shall be full- or part-time employees of the Institute.

The Citizens Financial Accountability Oversight Committee (CFAOC) is chaired by the State Controller and is responsible for reviewing CIRM's annual financial audit, the Controller's review of that audit and the financial practices of CIRM.

Seventh Annual Meeting

Meeting Details

The seventh annual meeting of the Citizens Financial Accountability Oversight Committee was held on January 27, 2012, at the SCAG Board Room, 818 W. 7th Street, 12th Floor, in Los Angeles. All six members were in attendance.

Financial Presentations

On January 27, 2012 the Committee heard presentations regarding the independent audit of CIRM; audit response by CIRM; the State Controller's Office's review of that audit; a status update of CIRM's financial performance, current budget, update of grants awarded, and the grants process.

Independent Audit

Russell Robertson from Macias, Gini & O'Connell (MGO) presented the audit findings for year ending June 30, 2011. MGO did not identify any deficiencies in internal controls over financial reporting. Expenses for FY 2010-2011 were \$206,872,660, a \$62.2 million increase from FY 2009-10: \$13.2 million was on operations, an increase of \$2.6 million from 2009-10, and \$193,653,000 for research grants, an increase of \$61.7 million. CIRM ended the fiscal year with a fund balance of \$252,754,790, the funds major source of funding is bond revenue and investment earnings. This year, CIRM was no longer obliged, per Prop. 71, to pay interest as it is now covered by the General Fund. (Prop. 71 permitted interest payment for first five years to come from the bonds, thereafter, it is to be appropriated from the general fund. The STO estimated that the interest and principal for 2010-11 from the general fund would be \$53,425,000).

CIRM's net assets at the end of June 30, 2011 were \$267,715. In FY 2010-11 CIRM received \$47.1 million in GO bonds. From the 2011 October bonds sales CIRM received an additional \$50.8 million. CIRM has received \$1.3 billion in bonds to date. (Prop. 71 authorizes issuance of not more than \$350 million in bonds annually over a 10-year period for a total of \$3 billion.) Because of the limited revenue from the bond sale in October, the STO also agreed to provide up to \$75 million through the use of commercial paper. If the state sells more bonds in the first part of 2012, CIRM will receive an additional allotment. If no sales occur, the STO will provide an additional \$150 million via commercial

paper over a six-month period. To date, CIRM has awarded \$1.3 billion and allocated an additional \$578 million so have about \$900 million left in new funding to be distributed. CIRM anticipates awarding funds for another four to five years and running out of bond funding by 2020.

The audit offered a clean opinion, meaning the financial statements present fairly the financial position of the governmental activities and the major fund of CIRM as of June 30, 2011. The audit did not identify any deficiencies in internal controls on financial reporting.

(1/27/12 minutes, p. 82-87)

The MGO audit report for FY 2010-2011 can be found online at <http://www.sco.ca.gov/Files-EO/CFAOC/Item 5 - CIRM 2010-11 Audit.pdf>

State Controller's Office Review

Caroline Baez, Manager, Financial Audits Bureau, with the State Controller's Office (SCO) reported on their review of the MGO audit, emphasizing that the objective of the review was to determine whether the audit was performed in accordance with generally accepted auditing standards, government auditing standards, and the California Business and Professions code. The SCO found that the audit was performed in accordance with audit standards and requirements, and did not identify any exceptions. However, they did issue a letter of comment identifying some opportunities for improvement in the firm's audit process and working papers.

(1/27/12 minutes, p. 87-88)

The SCO report can be found online at <http://www.sco.ca.gov/Files-EO/CFAOC/Item 5 - Internet MGO Report Jan 2012.pdf>

Status Update of CIRM

Dr. Matthew Plunkett, CFO of CIRM, presented the status update of CIRM's financial performance, update of grants awarded and the grants process. Dr. Plunkett first commented that as he is new to the financial team he had reviewed prior transcripts and was aware of the issues that have been identified in the past. He believes budgeting and financial reporting should be very closely tied and as such the next year's budget will have additional cost centers and allow anyone to understand where the money is going and what achievements are associated with those costs. Dr. Plunkett further noted that he had taken a fresh look at the Grants Management IT contracting project and has directed the group to move the project along to a maintenance mode by the end of 2012.

Budget

Dr. Plunkett reported that CIRM had budgeted \$8.85 million for salaries and benefits, but had spent \$8.04 million, mostly due to unfilled positions. Chairman Chiang asked for more information on the merit increases and the functions of the positions added, if any of those services were provided by external contracts. Dr. Plunkett replied that the

merit increases averaged 3.5 percent across all of CIRM for the prior fiscal year, and that several of the open positions would replace external work, e.g. the Senior Director of Public Relations, while other new positions would be doing new work such as more science officers to help monitor the programs.

There was a discussion regarding the director's salary increase which had gone from \$137,000 to \$400,000, and the fact that \$250,000 of the salary is paid for with donated funds. Member Lipson asked where the donation was coming from because there could be a conflict of interest and Dr. Plunkett reported that the money was donated in 2006 from a private individual.

For all other expenses, \$7.17 million was budgeted with \$6.95 million spent, for total expenditures of \$14.99 million for the year, \$1.03 million under budget. Dr. Plunkett reported that CIRM had significantly underspent on the ICOC science and working group meetings, \$1.2 million collectively, which was \$671,000 under budget.

In response to Chairman Chiang's inquiry about the "Other" category, Dr. Plunkett reported \$45,000 for electronic journal access, \$50,000 for science office conferences and professional development, \$115,000 for non-capital equipment and office supplies, \$19,000 for photocopy maintenance, \$60,000 for public education events, \$102,000 for employees' professional memberships, the annual report expense and a number of other things. Dr. Plunkett added that in the future, they would be more explicit and avoid using an "Other" category.

A total of \$3.04 million was spent on outside contracts, which included \$1.1 million on the Grants Management IT Project, \$900,000 on legal services, and other contracts.

Regarding the current year budget, there was some discussion on the current cost centers and adding additional cost centers to provide more clarity on what each cost center is for.

Dr. Plunkett reported the year-to-date operating expenses from July through November at \$4.85 million, as compared to the prior year period of \$4.34 million; grant disbursements are at \$88.8 million, which is net of a repayment from a company named Geron to whom CIRM had awarded a loan earlier in the year, but had it returned the money when the company decided to no longer pursue its spinal cord injury program. The available bond cash as of November 30, 2011 was at \$203.2 million, also net of the Geron repayment.

Dr. Plunkett continued with comparing the budget for the current fiscal year to the year which ended June 2011, flagging some of the key variances: salaries and benefits are \$1.5 million higher for the current fiscal year due to adding four employees and issuing merit increases; external contracts, which was over budget last year, should decrease in the current year as positions are moved from contract to in-house. Dr.

Plunkett reported that the total proposed budget for 2011-12 was \$18.50 million.

Committee Discussion

Grants Management IT Project

In a discussion about the Grants Management IT Project, Plunkett reported that the IT budget went significantly over, primarily due to more expenses for the IT project than were anticipated, including changes to the CIRM website.

Chairman Chiang asked for a status of the Grants Management IT Project. Dr. Plunkett reported that CIRM has added a number of significant pieces of functionality to the project over the last 12 months, notably they can now automatically generate lists of potential conflicts for grant applicants, and the process of producing new RFAs has been automated. Projects that are still on the list to complete include automated reporting on the CIRM applicants.

Chairman Chiang asked for a complete list of remaining IT projects, a time frame for completion and the expected costs, and a total for the grants management expenditures.

Dr. Plunkett reported that there was no such list, as they needed to get 90 to 95 percent of the functionality complete and he had directed the group to develop a plan by year end. The remaining expenditures for the Grants Management IT Project is \$1.3 million and the total grants management expenditures would be approximately \$4 million.

Contracts

Member Lipson commented that the external contracts for half a million dollars for lawyer fees or retainers seemed high when CIRM also has internal lawyers. Dr. Plunkett asked ICOC Chairman Jonathan Thomas to comment.

Chairman Thomas reported that there are many issues on which the board relies very heavily on James Harrison from the Remcho law firm; Member Lipson questioned if some of that could be brought in-house. Chairman Thomas replied they had not talked about bringing Mr. Harrison in-house but that they would be happy to review with the board the issues he has previously advised them on.

Member Lott questioned Chairman Thomas about the contract for community outreach, what is being done in-house and what the outside contract was for. Chairman Thomas explained that the contract was for patient advocacy outreach through a series of events around the state but they expect the contract will end when they bring in a director of public communications.

Member Lott asked for the total being spent on advocacy, both public and patient. Dr. Plunkett reported it was \$1.3 million, with half for employee compensation and half for outside contracts. Chairman Thomas offered to provide an itemized list for that expenditure.

Dr. Plunkett stated that according to the terms of Proposition 71, CIRM is under a very rigorous cap on expenses, which states that 3 percent of the \$3 billion may be used for grants administration and an additional 3 percent may be used for general and administrative purposes. CIRM will be focusing on building more conservative budget assumptions so that in 2021, when the last grant awards are made, CIRM will come in under those budget expense caps.

Loan Policy

Member Lipson asked what happens to the loan money that was returned from Geron, and Dr. Plunkett stated that it's available to be re-awarded as part of the \$3 billion.

Chairman Chiang asked if the loan program has changed from the original number of \$500 million. Dr. Trounson responded that CIRM is taking a close look at the loan program in-house, there have only been a small number of loans awarded and they need to see whether it's really achieving what CIRM had set out to do, which led to a more in-depth discussion of the loan program.

Conflicts of Interest

In response to questions related to CIRM's gift policy, Mr. James Harrison, CIRM contract attorney with the Remcho law firm, stated that CIRM is prohibited from accepting gifts from individuals and institutions that either have applied for CIRM funding or that intend to apply, and that donors must sign a letter of commitment attesting that they have not applied for CIRM funding and do not intend to apply for CIRM funding in the future. Chairman Chiang commented that the policy was vague and didn't include a time certain designation for the future. Mr. Harrison replied that he felt the letter of commitment imposes no time limit whatsoever, so presumably if a donor tried to apply for funding, CIRM would identify that as a violation of their letter of commitment. There was further discussion on the CIRM gift policy, funding applications, conflicts of interest policies, and how CIRM differentiates between an individual affiliated with a company or organization and the company/organization itself.

Member Brunner asked if there had been any actual allegations of a conflict or allegations of conflicts, and if so what was the result. Mr. Harrison replied that there was a complaint filed against a board member regarding a telephone call he made after the board had approved an award to his institution. The board member acknowledged that he had made a mistake and the matter was referred to the Fair Political Practices Commission, which sent a warning letter and the matter was concluded. There was another instance where because of a mistake in a communication by staff, members of the board had signed letters of institutional commitment as part of a submitted application package. When this was found out, the applications were disqualified. There was also a technical conflict on the grants working group which was addressed according to procedure and reported to the legislature.

CIRM's Funding Trajectory

Dr. Trounson gave a presentation on the CIRM's funding trajectory showing \$38 million awarded in 2006, \$260 million in 2007, \$640 million in 2008, \$1.02 billion in 2009, \$1.15 billion in 2010 and \$1.35 billion through September of 2011. Of that funding, \$343 million was for facilities and core infrastructure; \$310 million was for intellectual infrastructure; \$299 million was for foundational research and \$397 million was for translational research.

Major milestones include 453 research and facilities grants awarded to 59 California entities; 12 international collaborative funding agreements; and agreements with four U.S. states and foundations, including the National Institutes of Health, with \$138 million allocated, pending or committed. More than 1,000 major scientific papers have been published, 30 percent in high impact journals. CIRM has 45 translational projects moving toward the clinic, and three clinical trials already achieved, two in phase II and one in Phase III; 14 preclinical disease teams have been awarded up to \$20 million.

Dr. Trounson stated that CIRM has basically met the 10 goals of its five year strategic plan:

- CIRM grantees will have six therapies based on stem cell research in pre-clinical development;
- CIRM grantees will have developed new methods for making stem cell lines;
- CIRM grantees will have successfully created disease-specific stem cell lines for four diseases;
- CIRM grantees will have developed methods for growing stem cells in defined media;
- CIRM will have enabled establishment of a stem cell bank;
- CIRM-funded investigators will have demonstrated methods for inducing immune tolerance in animal models;
- CIRM will have increased the workforce of stem cell researchers in California;
- CIRM grantees will have established tools for toxicity testing based on stem cell research;
- CIRM will have enabled effective partnerships in stem cell research between scientific teams in non-profit and commercial sectors; and

- CIRM will have established national and international collaborations in stem cell research to leverage the comparative advantage of California and CIRM collaborators to advance toward therapies.

Dr. Trounson also reported that CIRM would be pushing to embed stem cells with genomics in a new major research platform. The human genome is returning somewhere between \$600 to \$1400 for every one dollar invested and CIRM is looking to establish strategic partnerships with academic and medicine. Major pharmaceutical and biotech companies will want to partner and co-fund the clinical end and take on projects when they pass through phase II. CIRM is looking to accelerate clinical trial effectiveness and competitiveness and Dr. Trounson reported he is pushing CIRM to increase resources for additional staff to manage those clinical trials. CIRM wants to demonstrate the economic benefits to bond investors in this new medicine.

In response to Member Lipson's inquiry about CIRM's long-term goals, Dr. Trounson reported that CIRM will see a multiple number of studies through Phase II, but CIRM does not have the funds to move them through Phase III and Phase IV, which would need to be done by the pharmaceutical industry or some other process.

Transition Plan

Chairman Thomas discussed CIRM's transition plan, noting that CIRM anticipates having funding from the current bond allocation to award through 2016-17, and with multi-year awards the \$3 billion would run out in 2020-21, assuming there is no further funding.

The legislature had asked for an interim transition plan report by January 31, 2012, delivered to the Governor, Controller and legislature within 30 days of completion. Chairman Thomas focused on the sustainability of the *mission*, not of CIRM. Funding through bonds allowed the costs to be spread over the future generations that would benefit from the therapies and cures, which is why CIRM can issue 30-year bonds to cover the debt service for the research, raising nearly \$900 million.

CIRM's 43 major funded projects have addressed 26 incurable diseases and conditions such as heart issues, neurological diseases, vision, and diabetes, and CIRM funds all stem cell types, including embryonic, adult, induced pluripotent stem cells, direct reprogramming and transdifferentiation. California is the leader in the world in funding stem cell research, courtesy of Prop 71 with a vibrant worldwide research effort well under way, facilitated to a large degree by CIRM and its funding efforts.

Dr. Thomas stated that future state funding is a possibility, but it would be premature to consider another bond measure at this time. Instead, CIRM is focusing its effort on sustainability of its mission and enabling others to carry on CIRM'S work. CIRM intends to keep staff until the depletion of the awards, circa 2021. In the future, CIRM will develop

detailed plans to enable transitions for people and the transfer of obligation tracking currently done by CIRM. The current summary of the transition plan includes:

- Establish a platform to enable grantees, industry, other government agencies, disease foundations, venture capitalists and others to continue to pursue CIRM's mission upon the expiration of CIRM's bond funding;
- CIRM will explore and facilitate the creation of Alpha Stem Cell Clinics for the delivery of stem cell based therapies to patients and will work with its collaborative funding partners to replicate the model nationally and internationally;
- CIRM will continue to pursue and strengthen its joint funding efforts with state and international partners, the NIH, disease foundations, industry and venture capitalists in order to build relationships and promote follow-on funding for CIRM's research projects;
- CIRM will work to bring new biotechnology companies to California and create stem cell clusters to promote collaborations with California researchers and to provide a vehicle to translate stem cell discoveries into clinical applications;
- CIRM will explore the creation of a nonprofit venture philanthropy fund to provide funding for stem cell research projects, from IND-enabling research through Phase 2 trials;
- CIRM will fund the creation of an iPSC bank as a resource for California researchers and companies interested in disease modeling and drug discovery;
- CIRM will provide regulatory and product development guidance to its grantees to ensure that they have the tools necessary to take their discoveries from the bench to the bedside; and
- CIRM will support efforts by its grantees to protect CIRM-funded intellectual property in order to safeguard the state's investment and promote the commercialization of CIRM-funded therapies.

Dr. Thomas reviewed some of the lasting accomplishments of CIRM, notably funding \$332 million in new research space in more than a dozen leading academic institutions; awards to facilities have garnered more than \$800 million in matching funds; CIRM has created 13,000 job years of employment in California and will continue to provide a home for thousands of stem cell research scientists for decades to come.

Dr. Trounson added that CIRM has also recently approved the creation of a banking facility for induced pluripotent stem cells which would manage those samples and enable them to be used by researchers. He noted banking companies are interested in this endeavor and that commercial companies are possible, but CIRM would get proposals from non-profits as well. Member Lipson inquired about the conflict of dealing with commercial companies, and Dr. Trounson replied that CIRM would work to ensure any potential conflicts are dealt with, perhaps by retaining ownership of the cells, so they would still make money from owning the samples, which would ensure that California owns this material so the benefits can translate to California and not to the companies.

There was some discussion on the cost to bring a drug through all phases of clinical trials, with Member Lipson reporting the amount at \$200 million and Dr. Trounson saying it was closer to \$4 billion, and therefore CIRM needed to connect with companies that have enough money to bring a drug all the way through FDA testing. He added that California should establish stem cell clinics in California that provide clinical trials as well as treatment. Member Lipson reported they would be selected under an RFA, and would likely be a major medical health group, such as City of Hope, Cedarsr-Sinai or UCLA.

Chairman Thomas reported on the financial concerns of the transition, saying that CIRM needs to evaluate and enable the future creation of a CIRM-like funding agency to continue CIRM's mission. CIRM has been working with a national organization called the Alliance for Regenerative Medicine on plans for a nonprofit venture philanthropy fund, which would be open to projects from all over the country. Regarding the feasibility of an additional bond measure, any sort of discussion of a potential second bond measure is premature and CIRM has made no decisions about in that respect.

CIRM will continue to pursue and strengthen joint funding efforts with state and international partners, the NIH, and disease foundations, and build relationships with industry and venture capitalists in order to promote follow-on funding for CIRM's research programs. CIRM is seeing a developing trend that hopefully will position companies down the road in the event CIRM is no longer around.

(1/27/12 minutes, p. 6-82)

Committee Actions

The committee adopted the transcript of the January 28, 2011 CFAOC meeting.

(1/27/12 minutes, p. 5)

Public Comments

No public comment was made at the meeting on January 27, 2012.

**Citizens Financial Accountability Oversight Committee
to the
California Institute for Regenerative Medicine**

**c/o State Controller's Office
Post Office Box 942850
Sacramento, California 94250-5874
<http://www.cfaoc.ca.gov>**