



Final Transcript

STATE OF CA – CONTROLLERS OFFICE: CFAOC Meeting

December 18, 2024/4:00 p.m. CST

SPEAKERS

Controller Malia M. Cohen
Ms. Baylock
Dr. John Maa
Alfred Rowlett
Dr. Gurbinder Sadana
Craig Harner
Kimberly Tarvin
Jonathan Thomas
Maria Bonneville
Jen Lewis
Rafael Aguirre-Sacasa

PRESENTATION

Moderator Okay, you can begin.

Controller Cohen Thank you very much. All right. This meeting is being called to order. We are gathered here at the California State Controller's Office for the Citizens Financial Accountability Oversight Committee. Please note that this meeting is being recorded. If you are able and willing, please rise, place your right hand over your heart, and join me in saying the Pledge of Allegiance.

All [Pledge of Allegiance].

STATE OF CA – CONTROLLERS OFFICE

Host: Malia Cohen

December 18, 2024/4:00 p.m. CST

Page 2

Controller Cohen Great. Thank you very much. This meeting is now officially called to order. Ms. Baylock [ph], thank you very much. Please call the roll.

Ms. Baylock I will now call the roll for CFAOC members. When your name is announced, please indicate your presence for the record. I have chair and state controller, Malia M. Cohen.

Controller Cohen Here.

Ms. Baylock I have Dr. John Maa.

Dr. Maa Here.

Ms. Baylock Alfred Rowlett.

Alfred Here.

Ms. Baylock Dr. Gurbinder Sadana.

Dr. Sadana Present.

Ms. Baylock Thank you. Controller Cohen, I will turn the meeting back over to you.

Controller Cohen Alright. Thank you very much, Ms. Baylock. First of all, thank you, everyone, for traveling to get here. It's very good to see you as we wrap up 2024. We are in person. We have a quorum, and again, I want to just express my thankfulness that we're all here gathered.

So, as I said in the opening remarks, my name is Malia Cohen. I am the state controller. I have some pleasure to convene today's meeting as the chair of the Citizens Financial Accountability Oversight Committee. For me, the role the state controller is centered on ensuring that every taxpayer dollar is spent wisely, efficiently, and in a way that uplifts our communities.

The controller's office is the financial steward of the fourth largest economy in the world. We oversee the books, the budgets, and the audits, all of it, the whole kit and caboodle. As such, we conduct this annual Citizens Financial Accountability Oversight Committee meeting, and this work is very important, incredibly serious to ensure that all public dollars are spent appropriately.

Just for historical purposes, for those that are new to this body, it's important to acknowledge that the CFAOC was created by passage of Prop 71, the Stem Cell Research and Cures Initiative in 2004 and continued with the passage of Prop 14 in 2020. This annual meeting fulfills the duties assigned to my office as the CFAOC is charged with discussing the annual expenditure of the available bond funding from Prop 14 and the results of annual financial audit of the California Institute for Regenerative Medicine, also known as CIRM.

So, before we discuss the audit reviews and CIRM activities, I want to take a moment to introduce the CFAOC committee members. So, please, if you don't mind, for the members of the public that are tuning in and may not be familiar with you, please just briefly describe yourself.

I'm going to start with on my left, I have Dr. John Maa. Just a quick, brief introduction.

Dr. Maa Thank you, Controller Cohen. I'm a general surgeon in San Francisco. I practice at Marine Health Medical Center. I was the 2018 president of the San Francisco-Marin Medical Society and then in leadership with the California Medical Association and also the governor [audio drops].

Controller Cohen That is an overachiever. All right, next we're going to hear from Alfred Rowlett.

Alfred Thank you, Controller Cohen, and everyone here. Welcome. I am Al Rowlett. Sometimes my parents call me Alfred, so I can be responsive to that. I'm the chief executive officer for a behavioral health organization serving individuals in underserved and fully served communities throughout Central and Northern California who are experiencing a myriad of behavioral health-related issues. Additionally, as a chief executive officer, I have the unique privilege of being a patient advocate in a variety of different settings and looking forward to our discussion.

Controller Cohen Thank you. We're happy to have you, Al. Next, we're going to hear from Dr. Gurbinder Sadana.

Dr. Sadana Thank you, Madam Controller. I've been on this committee since inception of it, and I am a physician in Southern California. I've been involved earlier also in the prescription changes in the state [indiscernible]. I was part of the health syndicate on that. I'm also an

educator and have programs which I run for [audio drops] University of Southern California.

Controller Cohen So, we have another—we have a room full of overachievers. Okay, well, thank you. Thanks for making the trip. It's really good to see you.

Welcome, everyone. I just want to acknowledge a statement of gratitude for your service. Thank you very much for serving and your important contributions to these oversight efforts.

Now, while we will hear from certain leadership later, I also want to acknowledge the following agency representatives Jonathan Thomas is the president and CEO of CRIM. There he is. How are you Mr. President? Jennifer Lewis, vice president of operations. Rafael Aguirre-Sacasa, general counsel. Vito Imbasciani, chair. Thank you.

Maria Bonneville is the ICOC vice-chair, and Scott Tucer [ph]—

W He was unable to come.

Controller Cohen Okay. How about Michelle Lewis? Was she able to be here? Great. Nice to see you, Michelle. Michelle is the director of finance.

All right, so before we move into the details of the meeting, I want to reiterate how honored I am to serve as the chair of the committee and to provide oversight as I strive to empower California with the knowledge to foster a culture of openness and trust. This type of stewardship is personal and important to me. It's important as Prop 14 continues to hold California's trust in helping to support strategy for solving rare and complicated diseases.

So, today, it is about the numbers. I'm excited, and it's also equally important about ensuring that funds are distributed in a way that serves all communities.

We are going to move now to item 4. First, let me check with my colleagues. Are there any opening remarks from anyone? I don't have to be the only one speaking. Okay, all right. You guys have polite laughter.

Okay, so we're going to call item 4.

STATE OF CA – CONTROLLERS OFFICE

Host: Malia Cohen

December 18, 2024/4:00 p.m. CST

Page 5

Ms. Baylock Okay, I will now call roll vote on the motion to approve the minutes from May 29, 2024 meeting. When your name is announced, please indicate your vote for the record. Chair Cohen.

Controller Cohen Okay, before we get to the vote, I just want to summarize item 4 for everyone. So, item 4 is the adoption of the minutes for the May 29, 2024 meeting. Has everyone had a chance to review? Are there any questions or discrepancies or anything that we need to correct? All right, seeing none, let's go ahead and we'll pivot to the AT&T operator to see if there's any public comment on this item.

Moderator [Operator instructions]. Currently no comments in queue.

Controller Cohen Okay. Well, thank you very much. So, may I have a motion to accept the minutes?

M Motion.

Controller Cohen Alright. Thank you, Mr. [indiscernible]. Is there a second?

Dr. Sadana Second.

Controller Cohen Alright, thank you, Dr. Sadana. So, a motion has been made. The motion was then seconded. Please call the roll.

Ms. Baylock Chair Cohen is aye. Dr. Maa.

Dr. Maa Aye.

Ms. Baylock Alfred Rowlett.

Alfred Aye.

Ms. Baylock Dr. Sadana.

Dr. Sadana Aye.

Controller Cohen Alright. Thank you. That motion passed unanimously. Item number 5 is a presentation of a 2022-2023 independent financial audit by Macias Gini & O'Connell. Our next order of business is just to review the independent financial audit. We have Craig Harner joining us here today to present the

financial audit report and also the findings in the report. Mr. Harner, thank you for being here and the floor is yours

Craig Alright. Well, thanks very much, Madam Controller, and thank you, everyone, for the opportunity to present for results of our audit.

Controller Cohen One thing. If you wouldn't mind jumping over to the screen just so if there's anyone recording or online—

Craig Sure. All right. Well, thank you, again, everyone. I'm Craig Harner. I'm an insurance partner with Macias Gini & O'Connell or MGO. I've been working with CIRM since 2015 when I started as an audit manager on the engagement and moved my way up to now serving as the engagement partner responsible for the overall delivery of our services. So, today we're going to go over the results of our audit that performed for CIRM, financial statements from the year ended June 30, 2023, but the first thing I'll go over is really the financial statements themselves.

So, in tab 5, if you want to follow along, page 9 is where the financial statements really begin. The scope of our work is the audit. Pages 9, 10 which is CIRM's financial statements, and you'll see it's broken out by different funds. We have the three—for the first stem cell fund from Prop 71, the second one from Prop 14, and then the licensing and loyalty fund that also came about from Prop 14.

So, this first statement is your balance. You would have your assets, all your cash, investments, receivables, and any accounts payable detailed at the end of the year, and also the remaining fund balances while the next statement provides the information on the revenues and expenditures during the year, so the fund proceeds that came in tracked by each of the different funding sources and all the expenditures that went out either in the form of grant payments or paid operations or administrative expenses.

Our auditor's report also covers budgetary statements that are included in here that show budgeted numbers versus their actual amounts on pages 11, 12, and 13 for each of the main CIRM funds as well as the notes to the financial status.

What our audit opinion does not cover is what's called the MD&A, or management discussion and analysis, and those are on pages 4 to 8. What this is, is management's opportunity to provide kind of a recap or summary of what happened during the year. So, it's a comparison of

current year to prior year balances with high-level explanations of the changes that are significant after the year. We don't audit the MD&A that's provided by management. We do, however, go through and review all the numbers to make sure that they do agree back to the actual statements so that they are based off of the numbers, and then we also look at the explanations and make sure they seem reasonable. So, if something increased, we make sure that [indiscernible] increase, and then what's the reason why, and then make sure that that's reasonable as well.

Now, if we go back to page—so, I'll start off on page 1 again, I'm kind of jumping around here, but page 1 is our independent auditor's report. It lists out management responsibilities and auditor's responsibilities. I'll kind of just go over those real quick just as a reminder for everybody, but so these are management's financial statements. Our report is only the first three pages in here. All the numbers are the responsibility of management.

Management is responsible for the fair presentation of the financial statements in accordance with US GAAP, and they're also responsible for making sure that the financial statements are free of material misstatements whether through the errors or fraud. Management is also responsible for the internal controls relating to the design, implementation, and maintenance of internal bank reporting as it relates, again, to the financial statements, and then also analyzing for the period not to exceed 12 months if there's any going concern issues. So, as of the balancing date, are there any concerns that would stop CIRM from being able to function, and there was none of those this year, as I mentioned.

As the independent auditor, our responsibility is to plan and perform an audit to obtain a high level of assurance, what we call reasonable assurance, but it's not 100%. It's not absolutely assuring over the financial statement based on our audit. We perform what we call a risk based audit approach where we go through we assess in the financial statements, where a higher likelihood of risk and material misstatement is likely to occur and then design procedures that are appropriate, and CIRM addresses the risk. We also evaluate all of the audit entities that we collect and make conclusions on the balances of the numbers that we see in the financial statement.

So, with our audit, we issue three audit reports. Two of them are contained in the packet today. They're the first three pages which is our independent auditor's report, and then the last two pages, pages 32 and 33 in the packet are independent auditor's report on internal control and compliance. This

is an additional report we have to issue when we do an audit, and of course, called government auditing standards. We'll go over that a little bit.

The third report I want to touch on it really quickly. We don't present it to the CFAOC. We do present it to the Independent Citizens Oversight Committee as those charges govern. That contains what we call our required communication. So, it's a summary of all the audit findings, how the audit went, did we have any disagreements with management, any significant issues like that, and we presented that to them last week.

Now, I'll go through the audit results. We are happy to say that we were able to obtain enough audit evidence to render an unmodified opinion, which is a clean opinion or the highest level that we can give an entity as it relates to their financial reporting. We issued our report on March 18 of this year, 2024, and we also issued what we call in relation to opinion on the supplementary information. That's the grant schedule, and what that means is that we don't provide full assurance on it. It's limited assurance that we can reconcile the numbers to the financial statements, so report to the underlying accounting records.

The second report that I mentioned issued is on pages 32 and 33 of our report. Sorry, page 28. When we perform our audit in accordance with the government auditing standards, we have to do some additional procedures and considerations as it relates to internal controls over financial reporting and then on compliance of laws and regulations. So, we spend a lot of time on this audit with compliance of laws and regulations, and the grant expenditures are from each of the propositions, 71 and 14. It lays out what those moneys can be used on. So, we spent a lot of time looking over that, doing a lot of testing there, and we happy to say we didn't have any non-compliance with those laws or regulations as a part of our audit.

We also didn't have any deficiencies in the internal controls that would rise to levels of what we call a material weakness or significant deficiency that would be required to be reported, so another year, another clean audit.

With that, I will take any questions.

Controller Cohen

Thank you. Are there any questions? None? Okay, well [speaker drops]. Dr. Sadena? Okay, I'm going to go first, at least one question. Thank you very much for your presentation. I definitely appreciate it.

To begin, I actually have three questions, but I want to begin with note 7 in your audit report because what it does is it clearly discloses related parties, and there appears to be no issue there. Can you explain the nature of related parties' transactions to maybe someone that is new to this—

Craig Sure. So, related party transaction is transactions that are not within an arm's length. It's kind of like dealing with someone that if you're going to give someone a loan for less than market interest rates, or you sell them some property for a very low amount that doesn't represent the fair value.

Controller Cohen Like a sweetheart deal?

Craig Sweetheart deal, exactly, so stuff like that. It's looking for potential, maybe receivables or payables from related parties that haven't been adequate and disclosed and presented in the financial statements or some additional, as you can see here, you have the related parties that are other State of California agencies. Most of these transactions are on what we call an arm's length transaction. There's reasons for them. There's good business rationale. With related parties sometimes we do not have that.

Controller Cohen Is that the equivalent of my father giving me a short-term loan?

Craig Exactly, written on a napkin or something.

Controller Cohen How common are there related party transactions?

Craig In the government arena, not as common. Well, they're common I'll say in this instance if you look at who the related parties are. A lot of state agencies and departments are dealing with each other. Most of them use the Department of Technology for IT services or use Department of General Services. As we see here, it's the largest one for contracting procurement. I know CIRM uses it for outsource county services, so in the government arena, they're not as prevalent as maybe like a private enterprise or trade companies as far as the risk goes because a lot of times, if they are, it's just with your other departments within the same entity, if you will.

Controller Cohen I have another question. So, we know that auditors are required to communicate with those charged with governance. In this particular case, we're talking about the ICOC. As you're doing right now, can you expand on what that communication relationship has been like throughout your

audit? For example, is it friendly? Is it hostile, cooperative, apprehensive, misleading?

Craig It's been very friendly, open communications with us. We meet with the chair every year during this part of our audit when we are planning, so we have interviews with them about fraud, other business risks, and stuff that we use as part of our information gathering to help our audits along. Then, over the years, too, we haven't really had any significant issues in dealing with them or hostilities, if you will.

Controller Cohen Did you have a question?

M Thank you, Madam Cohen. What I discern, what I appreciate is the perspective from is that CIRM's budgeted expenditures were in excess of \$350 million, I think, and their expenditures were significantly less than that. In a typical profit-loss sort of environment, that's a great thing, but CIRM has a specific charge associated with those dollars, and I was wondering if that raised any concern or questions for you in terms of your perspective.

Craig As far as our perspective, it does to the extent that we want to look to see what's going on, but we understand, too, the model that CIRM uses for their grant expenditures where they're going by—I don't know the words. Do they go by, not a task phase, but a—

Controller Cohen Milestone—

Craig Milestone, thank you. So, sometimes, if the milestones aren't coming in as quickly as anticipated, then the payments can't go out to the grantees. So, sometimes they might be a little slower.

M So, what I appreciate is that that delta might be attributed to the grantees not achieving milestones associated with that.

Craig Yes.

M Okay, thank you.

Controller Cohen Okay, perfect.

STATE OF CA – CONTROLLERS OFFICE

Host: Malia Cohen

December 18, 2024/4:00 p.m. CST

Page 11

- M The reports look very good. I'm curious about the variance on pages 11, 12, and 13, the [speaker drops] on page 13, the licensing, revenues, and royalties.
- Craig Yes, so that's one we actually—our understanding is it hadn't spent any money really from that fund. So, if you look at—if you go back to page 10, there's no expenditures in that licensing revenues and royalties fund, and that is something we're understanding is starting to ramp up, and that, and we're actually working on our audit of 2024 right now. We're trying to finalize that. We have a very similar question, but when is there going to be some activity going out of this fund? Our understanding is that the kind of change in strategic planning going forward, there was some realization they're going to put a little more structure around this and get something in place for CIRM to start spending money on this.
- W Can I add? So, the licensing and revenue fund we went through across the BC budget change proposal process with the legislature to have that appropriate assistance so that's going to support our clinical trial programs in California residents that participate in travel and hotel and lodging and food associated with participating in clinical trial. The other piece of this is we issued a grant to operate the program separate from this fund. That grant did not get approved by our board until '23-'24, and so that's why you haven't seen any expenditures yet because the program is just getting up and running. We're in the pilot mode, so during this [speaker drops].
- Controller Cohen Alright, any other questions? If not, we're going to move on to public comment. All right. Mr. AT&T Operator, could you check to see if there's any public comment?
- Moderator [Operator instructions]. Fiving it a minute here, no comments in queue at this time.
- Controller Cohen Okay, all right. Thank you very much. All right, this is not an action item, so we're going to go to part B, which is the state controller's audit review report. Thank you, Mr. Harner, and so coming up is Kimberly Tarvin who is within my office. She is the audit division chief. Thank you, again, for being here. On behalf of the Controller's Office, Ms. Tarvin is going to provide a presentation on the quality control review of the presentation that you just heard. So, this is an interesting structure, but please share with us your findings.

Kimberly

Absolutely. Thank you, Madam Controller. Pleasure to be here to share these results with everybody here, and so as stated, I am Kim Tarvin. I am the chief over the Division of Audits here at State Controller's Office, and I will be sharing the results on the report that's up on the screen. It was issued October 14, 2024, and it's a quality control review, and what we do is after the financial audit is complete, we conducted a quality control review of the work of MGO and review all of their working papers, support their completion of the report.

So, the first question is, why we do that. That relates to your question. The first reason is that health and safety codes, for the record, is 125290. [indiscernible], if anyone's interested. That is the code that requires CIRM to commission a financial statement audit by an independent CPA, and that same code, it requires a report to be submitted to the controller, and then that same code requires us to do a quality control review.

So, we do the review, of course in accordance with that, but the real reason and the important reason behind why that matters and why it's good for all of you and the public is because it provides an additional level of assurance. So, MGO provides a level of assurance by an independent CPA, and then we look at their work to ensure that they're meeting all of the required professional auditing standards and the Business and Professions Code, the California Business and Professions Code, which provides some more assurance that you can rely on the work that is in that. So, that's really important so those that are using the report for decision making or information or understanding what's happening within CIRM can rely on that work. So, that's why it's really important.

The first thing I'm going to share is the results because I'm sure everyone is most interested in. Right? So, we did conclude that MGO did conduct the work, the CIRM auditor year is June 30, 2023, in accordance with the required professional auditing standards and also the California Business and Profession Code. So, what are those auditing standards for CIRM? We did reference a couple of those codes, but I'm going to spend just a little bit.

So, the first set of standards is the Generally Accepted Auditing Standards in the United States. Those standards are issued by the America Institute of Certified Public Accountants. So, that's one set of standards which has a lot of work and a lot of requirements all within those, and then as Mr. Harner mentioned, on top of that is government auditing standards with even more requirements for the audit chain to follow and make sure that

they document things within all those standards in accordance with all the steps and procedures that are required, and then there's a few other requirement in the Business and Professions Code that relates to CPAs.

So, what we do when we do our work is we look at everything that they conduct. There is a set of working papers which document everything from the beginning planning stages, risk assessment, internal controls, review and auditing of the various accounts and records, all the way to the end, their evaluation of their evidence to get to their conclusions, and ultimately the report. So, we go through all of those things, and we compare what all the auditing standard requirements are, and [speaker drops]. So, it is a pretty big undertaking, and again, they [indiscernible] them.

Controller Cohen It would be a little awkward to criticize [overlapping voice]. That was like the most polite exchange I've ever seen. You're saying that it passed the standard, it looks good. The report is bound.

Kimberly Yes, our review report confirms that they upheld the requirements of both of those standards and—

Controller Cohen [Speaker drops]. I have a couple questions, and then I'll turn to my colleagues. First, what is an ideal window for your team of auditors to perform an annual review of the independent auditor's work so that a report can be provided and presented to the ICOC in a timely manner?

Kimberly Yes, so this year, we put our report in October. In the last several years it's been in the fall, in that time period. Our work is predicated on CIRM closing their books and finalizing their financial statements because the independent audit can't begin until that independent audit happens. Once that report is issued, there's a 60-day window for the CPA firm to finalize all of their documentation and close those out those records. So, once that happens, that's when we can begin our preview.

So, if we were to all move our timelines up a little bit—

Controller Cohen It's in general still fall, but—

Kimberly Yes, so potentially books close by end of September, audit is done and completed. That window closes by March. Then that would give us an opportunity to issue it late April, early May, or if there's shifts—and in addition to that, we also have additional engagements that are going on at

the same time. What all of that would do is you can coordinate and schedule that in so that it can occur on that timeline.

Controller Cohen Okay, if there was a desire for the report to be issued earlier—Mr. Harner is nodding his head.

Craig Yes, trough '24 we're trying to issue [speaker drops].

[Overlapping voices].

Controller Cohen That's good to know. I do have a second question.

Craig The transcriber has asked that if someone makes a comment that's not sitting at the screen if they could announce their name for the transcription record.

Controller Cohen Yes, going forward, we will, and that was the voice of Craig Harner.

Craig Thank you.

Controller Cohen No problem. Thank you. My second question to you is, are there any areas that can be enhanced to improve the quality of the review?

Kimberly That's a really great question, and as I mentioned, the review is very detailed and covers everything from the beginning to the end of the audit, and not just because Mr. Harner is here, but it truly is a comprehensive review. It's comparable to every three years every firm is required to have what's called a peer review, and it's very similar to that process, and that's required by the Board of Accountancy.

So, it's very similar, except that a peer review is of the entire firm and a sample of engagement where our work is engagement specific, but we are working towards getting the report out quicker so it's available and that information is available, and secondly, we are working on enhancing the presentation and format of the report itself, so that is little bit more modernized. We're working on those couple of areas, but the work itself is, like I said, it's very, very comprehensive.

Controller Cohen Sounds like it. Thank you very much for your expertise. I'm going to open it up and see if my colleagues have any questions. If not, we will go to you, Mr. Brad.

STATE OF CA – CONTROLLERS OFFICE

Host: Malia Cohen

December 18, 2024/4:00 p.m. CST

Page 15

Moderator [Operator instructions]. No questions or comments in queue at this time.

Controller Cohen Alright, thank you very much. Okay, this is just an informational item. Is that correct? This report, I'm reading it. No action is taken on this. So, we are going to move on to item 6 which is an action item. Is there a motion to adopt the 2022-2023 independent financial audit? I need a motion and a second.

Alfred So moved.

Controller Cohen Alright. Motion made by Al, and a second by?

Dr. Sadana Second.

Controller Cohen By Dr. Sadana. Could you please call the roll?

Ms. Baylock For the motion to approve the adoption of the 2022-2023 independent financial audit by Macias Gini & O'Connell, when your name is announced, please indicate your vote for the record. Chair Cohen.

Controller Cohen Aye.

Ms. Baylock Dr. Maa.

Dr. Maa Aye.

Ms. Baylock Alfred Rowlett.

Alfred Aye.

Ms. Baylock Dr. Sadana.

Dr. Sadana Aye.

Controller Cohen Alright, thank you. This motion passes unanimously. We're going to be moving on. At this rate, we are going to have to pull the time in on the other end of this agenda.

I'm going to call Item number 7. It's an update on the California Institute for Regenerative Medicine Strategic Plan programs. Next, we'll hear from CIRM's team to share an update on the agency's work which is an important background for CFAOC's oversight function.

Now, just as a little bit of background, we have completed the necessary oversight functions where—the necessary oversight functions were completed for this calendar year, but we wanted to invite CIRM to come, their leadership to come, and report back to the committee on the progress of the strategic plan, any programmatic changes you may have. Curious to hear about clinical trials, grants, awards, and things of that nature, and I also would love to hear your efforts around the DEI efforts that you guys are undertaking. So, good afternoon.

Jonathan

Madam Chair, members of the committee, members of the public. Jonathan Thomas. Keeping with Al's comment earlier, the only person who ever called me Jonathan was my mother. I go by JT. I've had the privilege of being CIRM's board chair for 12 years, and this year made the switch over to be the president and CEO. I've had a wonderful experience with this most interesting job, most incredible team that anybody could ask to work toward.

Along those lines, I want to start by giving a shout out to Jen for the 2024 audit. That's a big deal, and she works tirelessly, not only on our financial issues, but oversees our IT and just general operations as well. We have something called Grants Management which is the entity that once grants are awarded oversees all of that, which is we're talking about milestones and all that sort of thing, that's part and parcel of the very complex system that has been set up to handle all the 1,400-plus grants that we've made since inception, and that's under Jen's purview as well. So, shout out to Jen.

Michelle joined us a couple of weeks ago as our new director of finance having had a great deal of experience in many different agencies at the state level, brings tremendous expertise to that position. Rafael, whom you will hear from after me, is our general counsel and will be presenting today on the performance audit. Great job on that as well as all the other legal issues of the day that come not infrequently to any state agency.

So, these are people you will hear from, and as you did, Madam Cohen, introduced Vito and Maria who run the board expertly which is not an easy task with a 35-member board, and we're very fortunate to have them at the helm. Together, the board and the team are a great team writ large, and I think doing a great job of capably stewarding the taxpayer dollars in this most interesting area.

That is a bit of an opening statement. I wanted to present to you on these particular topics that you referenced in your introduction, Madam Chair, and so let's see, am I controlling this or—

M

Yes.

Jonathan

Okay, so we start any presentation with a mission that sort of guides what we do day-to-day, accelerating world-class science to deliver transformative, regenerative medicine treatments in an equitable manner to a diverse California and world.

Next slide please. So CIRM, as was duly noted, is the product of two propositions, 71 and 14, one which both established the agency and authorized the initial tranche of \$3 billion in state general obligation fund dollars to go to grants and loans. Played out over time, it's almost exclusively been grants with some limited exception to originally academic institutions, research institutions, and biotech companies in California and originally also the stem cell space, which in 2004, was in fledgling form. The first human embryonic stem cell was not even isolated in 1998, so it was very early days when Prop 71 was passed.

Since that time, we had a Prop 14 in 2020. We, believe it or not, ran through our \$3 billion initial amount, and an independent entity called Americans for Cures, which was behind Prop 71, ran a campaign to get Prop 14 on the ballot in 2020. It passed as well, authorized an additional \$5.5 billion, and so together, CIRM, now is an \$8.5 billion agency; 6% of that is set aside for administrative cost. The balance goes to all the various CIRM fund programs which we will touch on here momentarily.

On this slide, as you can see, since inception, we put out \$3.8 billion. That's as of June 30th, added a bit to that since then, but we have a number of different pillars, three of which are basic, translational, and clinical trial. Those three are sort of the continuum of research that we fund. We add to that what we call the infrastructure pillar, and lastly, a very important education program which I'll speak about in some detail in a minute.

Prop 14 notably added gene therapy to stem cell science because the gene therapy field had advanced far enough along, but it is now becoming more mainstream. So, we now fund stem cell and gene therapy related products and programs.

Next slide, please. Briefly on our impact, you can see we cover the gamut of diseases from the ultra-rare to the prevalent, 85-plus at last count. The clinical trial part of our program is affected largely through what we call an Alpha Clinics network across the state, which is at a number of our academic institutions, nine of our academic institutions, that conduct soup-to-nuts clinical trials for both CIRM funded programs as well as qualifying programs that are not CIRM funded, and so that's a very important component of what we do.

On our education front, we've had over 4,300 students from high school on up to post docs that have gone through which we're extremely proud of with a most unique program. More on that later.

We've had over 50 businesses spin out of academia, from programs that we have helped, in part enable, and have generated an economic impact statement which we will need to be updating sometime relatively soon, over 56,000 FTEs across the state of California in this most important subset of bio tech that is stem cell gene therapy.

Next slide, please. So, we have five-year strategic plans, and this was the basic tenet of our most recent which was in 2022, and you can see it there. It has three separate pillars: to advance world-class science, to deliver real-world solutions, and to provide opportunity for all. As you can see, there are subsets below each of these that if we take in the aggregate, all of our programs impact at least one of these three particular tenets. So, it's a very comprehensive program that has many different aspects to it, all towards driving through these three goals. I have something else to say about that towards the tail end of this which is sort of a major deal that's happening this year that impacts the strategic plan.

Next, please. Okay, Madam Chair, on the subject of DEI, basically DEI permeates everything we do. We are very, very committed to it at various levels whether it's the details of the clinical trial program or its internal DEI policies, or it's the representation from underserved communities in our education programs, or whatever. It is something that we take extremely seriously, and I think that we like to sort of think of ourselves as a model for how to go about integrating DEI into every aspect of what we do.

You can see here on this page, the whole idea of patient outreach, which is making sure that the therapies and cures that we will ultimately enable our scientists, at least in part help enable, will be available to all citizens of

California with the heavy emphasis on serving the underserved communities.

Vice Chair Bonneville leads what was created by Prop 14, which we call Accessibility and Affordability Working Group, which is all about this topic, and has such importance in the terms of the proposition that it has its own separate budget, so separate FTE cap. So, that is area of Accessibility and Affordability is key when you're in development of new medical treatments that are pricy, let's face it, and how you make that accessible when it involves working with payors as well as patients and the medical teams themselves, companies themselves. So, it's a big deal.

Again, on education, which is all about creating the workforce of tomorrow, we're very devoted to making sure we have full representation across all demographics.

This third thing, which is something you might not be familiar with the term IPSC repository, we deal with acronyms, as Dr. Maa and Dr. Sadan can speak to. Al, having had many years of experience in this. IPSC stands for Induced Pluripotent Stem Cells which are a new form of stem cell. It was created in the late 2010s by Dr. Shinya Yamanaka from Japan, who came up with a very unusual question. He said, "Gee, I wonder if you can take an adult cell from your blood or your skin or whatever, and subject it to some sort of cocktail of proteins and reverse engineer it back to embryonic stage."

Now, how he'd even think to ask that question is one thing. The fact even more amazing is he figured out how to do it, and he came up with a four-protein cocktail that when embryonic is said to be pluripotent, which means can become anything in the body, and he made it happen. So, they call these newly created stem cells Induced Pluripotent Stem Cells. For that, within five years, he was awarded the Nobel Prize which is amazing because normally you wait 40 years for that, if not posthumously, to get these, and it was of such note and importance that he had a short period of time.

Just as an aside, you may say, well, this is really interesting. What's the big deal with these things? The big deal is that they are extremely valuable for certain types of diseases that you can't just take drugs and test against, most notably in the neurological sector. So, for example, if you come up with Alzheimer's drugs or whatever, you can't just start feeding patients in trials drugs because the FDA won't allow that.

So, what you do instead is you take somebody who has, let's say Parkinson's disease, and you take a skin cell, and you reverse engineer it, and then you reprogram it with yet other proteins to become neurons in a dish, and those neurons are the patient's neurons. You now have Parkinson's disease in the dish, and at that point, you can do what they call high throughput drug screening against these neurons to see if whatever it is you're testing has a material impact on slowing down the development of the disease in the dish. If you can do that, and you get that data, then you qualify to file the FDA for clinical trials, and you can test the drug there having tested against those neurons. That's one example of sort of very cool nature of this.

So, we have a repository of 2,800 cell lines which are pointedly involving the neurons or the cells that we create neurons out of every part of the population demographic, so you want to make sure you have diverse representation in there as well.

A rather long winded discussion of this bullet point, I thought it was interesting. I'm going to hear about this from Maria later on. She did say we needed to expand on these.

Then, we have with the community outreach efforts, which I described. Very capable efforts.

Next slide, please.

Controller Cohen We have a question on this end.

Jonathan Certainly.

Dave Dave Oppenheim, deputy controller senior financial advisor. I sit on behalf of the controller, about 16 boards or so, and a lot [speaker drops] investment opportunities, and DEI is something that is core to launch some of our philosophy here at CO. So, I just want to take it back to your impact page real quick, a few slides back, talking about the varied statistics.

So, as DEI as a core value, are you measuring if some of these quantifiable impacts that you have on the screen, some results of DEI where diverse populations, diverse businesses, diverse jobs that are accounted at 56,000?

How are we really following through to ensure that principle is showing up in some of our impacts, and is that something that's being measured?

Jonathan

Sure? So, I think the answer to that is it's measured in different ways. So, for example, when a researcher applies for a clinical trial, in the application, they have to break down how they are going to have representation in patient group, for example, of whatever it is that they're proposing to be working on, and that actually is such an important component of it that with our clinical trials, we have monthly peer review sessions of those grants that came in that month. We have a patient advocate member of the board as part of the peer reviewers, and that patient advocate actually evaluates the DEI component of the clinical trial applications and scores it, not just comments on it but scores it. So, we have a very good handle on these trials going into it, what their goals are going to be, and we do our best absolutely to monitor that.

Just to give you an example of how important DEI is in this regard, from these peer reviewers evaluating the science, they'll typically recommend either we call a tier-one recommendation, which is we recommend you fund [speaker drops], or a tier-two or tier-three. The tier-one is the only one that says we recommend funding.

So, a few years ago, we had a tier-one recommendation come in on a project, and it had a DEI score on a scale of one to ten, a five. I said, and Al will remember this, I said at the time, "It's great we have science evaluated this first-class, but this DEI score is not acceptable," and we sent it back. They did not fund that. We had them reapply and then go over the part of the application which talked about a much better integration of DEI concepts into what they were doing. They came back and turned up. They had like an eight and an even better scientific analysis, and so that was a, I think, a bellwether moment which shows the seriousness at which we take DEI at CIRM.

So, with education programs, workforce creation, we have statistics, some of which you'll see here later in the presentation, which readily acknowledge the understanding of the applicants for these education programs, how important DEI is and how important it is to have diversity amongst students, etc. So, if you sort of go through different elements of what we do, we absolutely have metrics that we follow and make sure that we're adhering. It is very, very important for sure.

Dave I appreciate that answer and the rigor that you clearly have into the commitment, and that was sort of what I was looking for in terms of making this value a real business proposition and quantifiable in the work that you do. I appreciate the detail about that response.

Jonathan Thank you for asking.

Controller Cohen May I ask a couple questions about DEI?

Jonathan Sure.

Controller Cohen You know, it's a hot topic, and politically we've seen a lot of corporations backing off of their DEI initiatives, allocations to their budget, slashing programs, succumbing to consumer pressure. There's been lawsuits, you name it. Have you felt or has CIRM felt any of that pressure?

[Speaker off mic].

Jonathan We haven't seen—I mean, we're full-speed ahead.

Controller Cohen Okay, Mr. Rowlett has a question.

Alfred My comment is in line with what JT has said. Controller Cohen, over my experience with the organization, the agency, in eight years, I experienced an appreciation of DEI and the perspective of patient advocates and people of lived experience, as well as those that advocate for people in underserved and underrepresented communities.

Again, I gently say this, as you can appreciate from JT's presentation, the science can be at times a bit intimidating, and initially, my experience with the organization was just that. However, there were those of us who wanted DEI to be appreciated and wanted underserved communities, as you said in your opening remarks, to be represented in clinical trials. I'll say more about that later, and so the voice of the advocate, there were certainly opportunities, not just in the scoring, but in the understanding from scientists that DEI matters and all the components of DEI, and that included making sure that underrepresented cell lives were included in trials. So, absolutely.

Jonathan I'd like to just commend Al, who is a tremendous champion of DEI on the board, as well as an enormously valuable board members across many aspects of what we do. So, thank you, Al.

Alfred Thank you.

Controller Cohen Alright, now you make a change.

Jonathan Okay, so just to quickly go through the overview, the funding programs, research, which they say is really esoteric yet very interesting to all of us. So, next slide, please.

I indicated we have these five pillars, which you can see broken down into the scientific pillars plus the education and infrastructure. By infrastructure, we mean things like the Alpha Clinics, whether it was actual bricks and mortar or equipment that goes along with that. We're interestingly adding, per Prop 14, a process of evaluating grants for what we call Community Care Centers of Excellence which are going to be little satellite Alpha Clinics that are in areas that don't have stem cell clinical trial apparatus that are all going to be paired up with existing Alpha Clinics throughout the state.

So, the whole point of this is to get this trial network and care out to as many people as possible. You can see the numbers there. I do want to highlight one thing, which is very important, which is a lot of times people focus on just the clinical work and how things are doing. How far along are the programs? How much have you gotten that's close to commercialization, etc.?

Certainly, something to focus on, but just as important is establishing the pipeline of the research, and that all starts with basic research dollars. You'll note down there that today, we've spent over \$1.3 billion on discovery, which is basic research, and that gets these things going into the pipeline. We've had many awardees who've been starters in the basic research arena, and then we funded them up through the ranks as the projects continue. So, very important.

You can see that we really spread these dollars across all five pillars. I want to note the number for education. You think about this, but here, with this agency funded by taxpayers, has now been able to put out \$650 million for education programs to generate interest starting, again, in the high schools and all the way up through post doctorate work and truly setting the stage for a highly educated workforce in the field as the field continues to develop.

Yes, Madam Controller.

Controller Cohen I'm curious. Are we targeting in the State of California, there are small Latino campuses, Latino colleges across the United States if I'm not mistaken. I know there are HBCUs, are we targeting folks of color for this particular workforce?

Jonathan So, again, starting at the high school level, these are high schools from all over the states in all different communities, and so—

Controller Cohen Public schools.

Jonathan Yes, absolutely, and I know this is not an easy thing to do, but if you want to get a real kick out of something, sometimes, the high school program, which has now been in place for many years, has an annual event where they come together and they give talks, and these kids who go into this program maybe having heard sort of the basics of what a stem cell is, come out eight weeks later, and they sound like PhDs.

It's unbelievable. There are kids from all over the state, and it is, like I say all the time, possibly my single favorite thing that we do because what it does is now we talk to these kids, and now they're hooked. They are going into biology. They're going into all the fields, bioengineering, whatever it might be, which is so critical because we have this industry that's developing in the state. We want to make sure these kids are there, but that's a wonderful event.

We also have the older students now are coming together in a unified program. We just had it at USC a couple months ago, by the way a very cool dinner at the National History Museum the night before. That's a particularly favorite part of this, but anyway—

Controller Cohen My invitation must have gotten lost. I don't know who was in charge of that. We'll have to correct that.

Jonathan Well, we're going to expect you to be there.

Controller Cohen No problem. I do have a question. Is this information on your website, these programs where people can apply?

Jonathan Well, so these programs, the high school programs are not actually at the high schools. They're at institutions, like say, USC and UCSF or

whatever, and the programs are there, but there's a great deal of now well-established line of communication between people who run the programs and all the different schools who have kids who want to apply. So, it's a very well known—

Controller Cohen Great. We'll help you promote that, too.

Jonathan That would be great. We'd love to have you come. It's an unforgettable experience. You sort of sit there, and you almost laugh. You're kidding me. Where do these kids get this expertise so quickly?

Controller Cohen Mr. Rowlett has a question for you.

Jonathan Yes, sir, Al.

Alfred Okay. Thank you, JT. The controller identified DEI as a very common issue today. In the State of California, I experienced that even with the passage of Prop 1, forgive my preamble, that the other very common issue is mental health. I note that in the neural space, you identify in this page, \$275 million invested in the neural space, and again, I equate neural with mental health and with tools associated with what I would describe as persistent psychiatric illness. Again, I know we're a long way from there, but we're trying to get there, and so if you could speak to that because from my perspective, it is the issue that is talked about today everywhere.

Jonahtan Thank you for asking that question. So, this \$275 million line is a bit misleading, because historically throughout the deploying the Prop 71 \$3 billion, roughly 30% of that went to neurological disorders. Now, interestingly, Prop 14 specifically calls out of the \$5.5 billion, \$1.5 billion has to go towards neurological disorders, which is not all that dissimilar from what we've done historically. So, the \$275 million that you see there is on top of the 30% of the \$3 billion we already put out. So, just a sort of a general context sort of statement.

Now, with respect to mental health, under the board's guidance, we have had a new program we put in place, which we call ReMIND which is an acronym, and it was designed to fund neurological research. We started out with an opening—how much, Jen, \$110 million?

Jen Yes, \$110 million.

Jonathan Yes, \$110 million in the first round went entirely to neuropsychiatric disorders. We've had some grants over the years which have been in that field. This was the first specific instance where we targeted that area specifically, and that resulted in a number of grants that are mostly basic research because the neurological field folks probably know is sort of the, if you will, the toughest nut to crack in the field. So, a great deal of the research going on is in the basic research arena where what you're really looking for in that is to identify targets that you can then develop treatments against those targets, what they call biomarkers.

So, this first ReMIND batch all going to neuropsychiatric disorders is all about biomarkers, targets, and it's all basic research, but that's very important, and to the extent you identify targets for a disease that there's never been anything identified that you could go after. That's big. That's going to set the table down the road for actual treatments being developed to go against those targets.

So, that is the first album specifically against that area. We'll be putting more out into that, as we will in the other two areas of neurological disorders, which are loosely called neurodegenerative which would be Alzheimer's, Parkinson's, Huntington's that sort of thing, or third would be neuro injury, traumatic brain injury, spinal cord injury, that sort of thing. So, \$1.5 billion of that, at least, maybe more, we're required to put out \$1.5 billion, and we will. Does that help?

Alfred That's ReMIND?

Jonathan R, small e, and all caps MIND. Anybody know what that stands for? [Overlapping voices]. It's pretty clever. It's like, you know it's like the M is the beginning of one word, the I is in the middle—

Controller Cohen Research using multi-disciplinary innovative approaches in neuro.

Jonathan Very good. Okay, next slide, please.

Okay, so here this is our, again, the basic research. This is the R&D portfolio. I won't go into too much detail here, other than you can sort of crack from the percentages that were spread through all sorts of different things, across many different disease types, and this includes cell and gene therapies. As I said, biologics, which is, you'll remember, monoclonal antibodies and that sort of thing, and then they call small molecules, which

nobody knows what that means, all it means is it's a drug. It's like pills you take, or small molecule, just blend it, just call them something else. I don't know. They call them small molecules.

Anyway, next slide please. Okay, this is the pie chart here of what we're doing, which areas you have clinical trials going on. Again, you can see that there's a hefty chunk of that is for neurological. Again, it covers many different kinds of diseases, all sorts of different what we call modalities which are approaches that you're using to study diseases. So, we were very, very lucky because since California is now undisputedly the largest funder of stem cell and gene therapy research in the world, we have a lot of A-plus science talent here, and they do look to us for funding.

So, we get to see all the cutting-edge stuff which is really fascinating. It's in all these different areas, many, many subsets of each areas. We're at 111 clinical trials which we are very proud of. About 50 or so, give or take, are active at the moment. This is historically over time.

Okay, next slide, please. So this, I don't really need to go through this. I just discussed it, but again, Al, getting to your question, this highlights the seriousness in neuro, generally in neuropsychiatric specifically.

Next slide, please. Okay, here's our section here on the education programs.

Next slide. Again, this sort of speaks for itself. Over 4,300 participants in our various programs over the years.

Next slide, please. Okay, so this SPARK program is our high school program that I was telling you about, 11 such programs. Fantastic group of kids. The level of enthusiasm with which these kids participate and the pride, the only way of describing it, that they have in telling you about what they did that ends of the summer conference. You can see in this particular slide, they do posters which, at every level of medical research, there are posters describing the work, and so these kids just revel in having you stop by their poster and explaining what it is they do. It's wonderful.

The next highest level is an undergraduate program, which is actually a COMPASS program, another acronym, and it's set up to provide mentoring for undergraduate kids, and it's another example of a curriculum development specifically to what we do. It's been in place now for a couple of years. Another huge success.

Next slide please. The Bridges program, which I believe is our first if I'm not mistaken, it started in maybe 2009. It has students from Cal State campuses and community colleges who go for the year or for programs at participating universities that have stem cell curricula programs. They, too, would at the end of their stint, are brimming with information and enthusiasm.

Then finally, the CIRM scholars, which is the highest academic program which you can see, pre doc, post doc, clinical fellows, etc. The latter three programs are the ones that just came together at USC. The SPARK program has its own, sort of high school. It's particularly special.

Next slide, please. Okay, so here are some stats. Madam Chair, you were asking about the different demographics served by the various programs, and you can see here that there's great emphasis on spreading out the demographics amongst different communities. Again, there's this active, almost recruitment process, to make sure that kids from underserved areas get access to these programs.

Next slide please. Here is information on the gender identity and the percentage of students in our different programs that are first generation, which is pretty remarkable statistics. Their programs take great deal of pride in having this very large component of first generation, and again, all of these programs at every level it gets these students more and more hooked and prepared to enthusiastically go out into the real world in the field.

Next slide, please. Okay, on the subject of commercialization of cell of gene therapy.

Next slide, please. As I mentioned, we have this nine Alpha Clinics network. You can see the institutions that house these. They're all leading medical centers spread throughout the state. We have over 250 trials, both that we funded and others have funded, and over 2,000 patients which is a number that's growing monthly as we approve more and more clinical trials.

Then, we have this last statistic which is we have a number of industry contracts affiliated with this, whether it's outside cell manufacturers or whatever, some major component of these programs. I would invite you, all of you, if you get a chance to tour the UC Davis stem cell program and

facilities. As with all of these, it's remarkable what they're doing there. I'm sure that Jan Nolte, who runs that program, would be delighted to host you, and it gives you a real feel for what this is all about. It's highly representative of all of our programs.

Next slide, please. So, this idea of manufacturing is sort of a weird idea. When you think of manufacturing, you think of like making T-shirts and that sort of thing. It's actually a very vibrant cell manufacturing community where you actually reproduce biological products, and these cells need to be very consistent because you want to make sure you're testing treatments against cells that are all safe in any particular instance.

So, that is captured by the term good manufacturing, or GMP practice, so UC Davis, for example, has a GMP facility at which they manufacture cells for different clinical trials. Because this is such an important component of the whole business, we've now established a network of nine members, again, you see on the right there, which are devoted to sharing information about best practices in manufacturing, and they share results and give insights into how they get around bottlenecks and that sort of thing.

It's a network that's unlike any other, as far as we know in the country, as is the Alpha funding network, which we don't know any that are like it anywhere else which, by the way, it sort of captures the essence of CIRM. There is no other CIRM in the country. The next biggest state program is \$100 million and requires appropriation by state legislatures.

Controller Cohen

What state is it?

Jonathan

So, New York, which may not even be in business anymore. Connecticut has a smaller one. Maryland has smaller one. Very few states have anything, and they're all, if not state legislatures, their philanthropically based. So, we're very lucky voters get the insight to give us this very significant—

Controller Cohen

I have a question. Who introduced that legislation? How did it get on the ballot? Through initiative?

Jonathan

It was an initiative. Yes, so it was our first board chair before he was board chair, had type 1 diabetes back in the early 2000s. President Bush had just issued a ban on funding for NIH to develop new embryonic stem cell lines, which sort of brought the field to the screeching halt—

Controller Cohen I remember that.

Jonathan —two or three years after he got started, and so Bob Klein, a gentleman who does a lot of work with housing bonds, came up with the idea of creating an agency to fund research using state funds. He wrote, along with then long-time counsel, James Harrison of Remcho firm, wrote an initiative that required a million-plus signatures to get on the ballot. He got it, and he raised a significant amount of money to fund the campaign. It was a big campaign. It wasn't that much, but statewide—

Controller Cohen Statewide.

Jonathan Yes, and it needed 50% plus 1%, and it got 59% which is a huge win and something that is of importance to patients. It cannot be overstated, obviously, and falls in California into the lead in the field sort of recapturing the frontier spirit that Silicon Valley and the tech space, now California bio tech space in this arena.

So, then, once the measure passed, Bob became the first chair the board. I succeeded him in 2011. Then, when we ran out of funds in 2020, Bob came back, again, outside of CIRM because we can't get involved in anything directly, and he wrote an amended initiative, which was Prop 14, got hit on the ballot. Interestingly, he needed a million-plus signatures again, and as you folks know, the way to do this is you sort of camp outside the Walmarts and Costcos.

It got to be March of 2020, and he had just hit what he needed, and had he gone like another three weeks, he wouldn't—the world shut down. He would not have had enough signatures. He barely made it, and he got it on the ballot, and this time it was a 51% pass rate. So, we were, again, the happiest you are for patients because this has enabled so much more work to be done and teed us up for many years.

Yes.

Controller Cohen I want to call on Dr. Sadana.

Dr. Sadana This question may not be any [indiscernible], but I'd like to know. So, the proposition was passed with regenerative stem cells introducing into it, I mean, it's great. It's wonderful, gene therapy. Does the legislature give us any problems on that introduced gene therapy?

Jonathan The California legislature? No, we haven't had any critiques of that added element at all, and I think the reason why it was included was the field took a while to get to where it sort of ironed out a number of issues that you saw early on in gene therapy, as you know, and so that was included because a lot of work, particularly now in rare disease, is gene therapy related work where you identify many of these diseases have single mutations in their genes. Now, at the advent of very sophisticated gene editing technology, something that Jennifer Doudna is the co-creator of at UC Berkeley, and she too got a Nobel Prize for that, we're able to go in and excise out mutated amino acid base pairs and put in the correct base pairs, and that's revolutionized the treatment of rare disease. So, no. The short answer is we're not receiving any issues on that.

Dr. Sadana So, I'm on the next slide, and I'll influence your presentation maybe a little bit, but recognizing that the auditor said the board recently approved an administrator for the Patient Assistance Fund. There have been no expenditures in that area, or nominal expenditures, in that area, how confident are you on a scale of one to ten and why, that you'll be very aggressive and successful at getting those funds out. I ask the question because patient participation is often, not often is, predicated upon those funds being available to patients and their families.

Jonathan So, the answer is very confident, but it's a bit more nuanced than that. As was noted, the revenues that are generated now from funded projects go into what Jen labeled the Patient Assistance Fund. The first amount of money that came into that was \$15.6 million that arose out of something we funded, research done at Stanford. It's set up to do what Jen described, which is to facilitate all of the things that patients need to be able to participate in trials.

So, there's the money that goes to the patients, and then there's the money that goes out to the contractors who are going to be helping to make that program work. As she said, we just recently finalized a contract with a group of EVERSANA that's going to oversee the administration of that fund for patients.

The reason why this is nuanced is it's going to depend on funding coming in revenues generated by programs that we fund into that Patient Assistance Fund itself, and so that's going to play out over time as the field matures and you start generating more revenues either in the form of royalties that we get if something generates revenues or it's in the form of

something else like this one-time lump sum that came about because of an acquisition of a company that spun out of Stanford that we helped fund, as you recall.

So, very confident that we're getting going on this, but the extent to which that fund grows is something that's going to depend on revenues generated over time, how large that is and when it comes in, and all that sort of thing, but certainly the intent is to get it going. We're doing exactly that now with that initial \$15.6 million, which I guess, Jen, what is the number now with interest?

Jen It's over \$16 million.

Jonathan Over \$16 million.

Dr. Sadana So, I think that it would be interesting in a next audit to hear the qualitative data associated with patient perspective around the fund, and then specifically, and I know the idea was to target underrepresented groups and citizens who typically don't have the kind of access or resources to participate in trials, and how to impactful that's bene and have that represented in some kind of qualitative way would be very useful.

Jonathan Thank you. Great suggestion. Thanks.

Next slide, please. Okay, so this is what we just described. Again, the underlying key component of this is promoting equal access to our startup chronic clinical trials. Very important.

Next slide, please. We touched on this already, Community Care Centers of Excellence specifically designed to serve and treat communities that are underrepresented so that they get just as much access as people who live in Palo Alto, etc., and we're going to be having our first award coming up in January of the first program under this, so stay tuned. Next year, we'll have a lot more on this to report.

I will tell you that we went out, Maria can speak about this in great detail; in designing this program, we went out to areas that don't have academic centers to—do you want to speak a bit about that, the meetings that we had?

- Maria I'd love to. Maria Bonneville. Prior to the proposal going out, our team went out to Inland Empire, Central Valley, past Davis, and around there and had a big meeting here that brought a lot of communities together to ask what services and programs they would need from the Community Care Center around specifically cell and gene therapy. What came back to us was patient navigators, [indiscernible], people who could go out into the community and talk about what cell and gene therapy was and how it could bring resources to the communities.
- It was very informative. It was really great to go out into the communities and really have just a bi-directional conversation that we can understand what the communities were needing. We can make assumptions about what we think, but that's not fair, and so we went out and really garnered great feedback, and that was incorporated into the program and [speaker drops].
- Dr. Sadana Thank you.
- Maria Thank you.
- Jonathan Next slide, please. So, from time to time, engage in partnerships with other leads with respect to particular programs. Here are a couple that are specifically targeting sickle cell disease. One of the NIH institutes, the NHLBI and CIRM joined forces in putting together a co-funded program for sickle cell projects.
- You can see there four trials in the state lead, or three in the state, one in Boston there has an element of California attached to it, which is required. These are in process right now, but of course in the sickle cell arena, you followed a number of months ago, a couple of companies now have come out with products that are in the marketplace now which are very interesting. Gene editing, as I mentioned before, is a key feature in these, but CIRM going forward will always want to partner with other entities that have common interests so that we can leverage our dollars to more efficiently serve research in particular areas.
- Next slide, please. Okay, this is the last slide. I get a kick out of this slide because it's one page, and it represents nine months' worth of work. The team, at the end of last year, we got an enormous increase in the amount of grants that we had coming to us, largely driven by the difficulties in capital markets and biotech. We quickly realized that increased demand, among other things, we needed to take a real look at the remaining\$ 3.8

billion that we have and how we're going to deploy it strategically over the life of the Prop 14 era, however long that lasts, because we want to make sure we get the best thing for targeting diseases and conditions that are most important to the citizens of the State of California, etc.

So, we set upon a reprioritization effort if you will. We call it the strategic allocation framework which is extremely data driven in terms of what the diseases are of greatest moments to the State of California, and we came up with a series of impacts to affect this reprioritized approach, which you see listed there.

The first one is in basic research. The second one is in tools and technologies like gene editing or different vectors that are used, or whatever. The third is in rare disease. BLA is the acronym for the last stage of research where you get granted your BLA. You're through the entire clinical trial continuum. You want to get four to seven rare disease projects through that stage. Then, we have the fourth is to dealing with more prevalent conditions, 15 to 20 therapies, getting them at least to late stage trials. The fifth deals with accessibility, affordability, and last, deals with workforce development.

Each of these six goals has a number of specific recommendations, which we didn't list here because that would take a bit too long to go through, but this is a very well thought out effort, a huge lift by the entire team which literally involved everybody in CIRM working on top of enormous day jobs itself.

The board was extremely involved throughout, probably had 20-plus different meetings and sub-committees and working groups and the full board, etc., and adopted the [indiscernible] in toto in September at our board meeting. So, now it's all about implementing, and that takes the form of developing what we call concept plans, which embody the goals and recommendations, and to have those concept plans, once adopted by the board which will take place over the course of the next year, to then move on to what we call program announcements, which announces to the universe we're going to be having these new programs, embody the concept plans, and then the RFAs go out to solicit grant applications.

That's going to take up bulk of next year implementing all these different things, a huge body of work, again, neatly summarized in the very few words of this page. This is really nothing short of a material amendment to our strategic plan, and this is meant to sort of serve throughout balance of

the Prop 14 funding. There will be strategic plans along the way which embody it, etc. So, that's, that's where we are.

I believe that's last slide if I'm correct. Yes, thank you.

Controller Cohen Thank you.

Jonathan Thank you, and we greatly appreciate your interest in all of this and all the great work you do overseeing what we do. We hope you find this to be a most worthwhile, if not highly unusual, use of taxpayer dollars for the benefit not just Californians but the nation and the world.

Controller Cohen Once again, California is leading.

Jonathan Correct.

Controller Cohen So, this is great. Many of us [speaker drops] with questions. I could hardly wait to the end, but I think Dave had one and Dr. Maa. Does anyone else have any other questions? Okay, go ahead.

Dave It dovetails perfectly to your last comment. A question first. What percentage of the CIRM funds stay here in California for research grants and education? Is that a high percentage, or what's that number?

Jonathan Well, we're basically required to spend it in California because it's taxpayer funded, right, and so the answer to your question is, Jen, you want to give—

Jen So, it's only California organizations can apply for CIRM funding except for the clinical trial space. Typically, because as we know, clinical trial sites could be across the country, and so we will fund the California portion. We will fund the Alpha Clinic site at UC Davis and the site at UCSF, so we'll fund that portion. For example, sickle cell, that's allowable.

Dave That just sort of goes to my observation that just like in many other industries, California has become the leader, or we are a green space, qualification space, the blue space, now the AI space, and the AI space propelled us from the fifth largest economy to the fourth largest economy because of the gravity that we had in that industry. Do you see that California sort of being the center of gravity in the nation or even in the world now in terms of regenerative research and the continuation of

bringing in talent to sort of just continue to exponentially make us that leader?

Jonathan Absolutely, no question about it, and as we do, we go to conferences, and we all have friends who are in the field in other states who are extremely envious not just of the funding, but at the fact the point you just alluded to. Funding begets talent, and scientists come and bring their post docs, they bring their people, their labs. So, there is no question, zero, that we are the leader in the field and in the world in terms of having this ecosystem in the state pursuing this, and we're fortunate to be able to help play a non-trivial role in this.

Dave A follow-up question. I mentioned AI as an industry. Sitting here in California it's become dominant, but AI is taking on so many different, very beneficial potentials for the state, for the workforce. How is AI starting to move into your area in terms of accelerating research and discoveries and opportunity? What I see of what used to take five years accelerates to months, if not weeks, for the analysis, a lot of the data that AI can turn on now.

Jonathan That's right. So, specifically in terms of data analysis, it's going to have a dramatic impact, and what that does is it not only helps analyze whatever it is you're doing at the time the data is referring to, but it's going to dramatically have an impact across the board, on what scientists do because you can be able to derive from that what works, what doesn't work, what works faster, what doesn't work, what the targets are that are specifically shaped to be able to be something that a drug or a cellular therapy, whatever can apply to all of that stuff.

I think you're going to see there are large AI departments springing up across biopharma worldwide that expect to use it as a way to accelerate, and when you accelerate, you reduce time. Time is money, and logically you need more and more, and it gets your results quicker, and so it is no question about it's going to play a major role.

We had a very interesting chat. If any of you want, I can send you a contact for a guy at Cedars who gave a talk on AI in the field at a conference we were just at for our for Alpha Clinics a month or so ago that's fascinating. I'd be happy to put you in touch with him so you can see that presentation and get a real handle.

Dave Yes, the Department of Finance at the Stanford AI research team present to a number of top state executives, and the level of acceleration and potential is just amazing, and really as a financial advisor to the controller's the reason for my questions is not only it looks bright for California's economic future through all of these centers of gravity and industries. I often say, we don't create businesses in California. We create industries in California, but what goes with that are all the quality jobs that attach and attract to those industries.

So, it's so wonderful to be part of a presentation like that just looking at the opportunity for California, our economy and the type of jobs that we can have here in California.

Jonathan Yes, I couldn't agree more. Thank you for making that point.

Controller Cohen Great. We'll keep moving forward. Thank you, Dr. Thomas. That was a very comprehensive review, thank you.

All right, we are down to informational item. Let me just do a check. Do we need a bio break, anyone? Not to embarrass anyone. Let me rephrase that. Do we need a ten-minute stretch? No? Okay, we'll keep pushing through.

All right, let's go ahead and call item number 8. Now, while some of this information maybe have been captured in item 7, this is an opportunity for CIRM staff to provide any additional information on CIRM's performance audit. We'll now hear from Rafael Aguirre-Sacasa to provide details on the CIRM performance audit process.

Rafael Thank you very much. Again, do I have time, or are we stopping at 4:00? I can do relatively quick—

Controller Cohen I would appreciate relatively quick.

Rafael Okay, all right. What I'll do is I'll do a thematic overview because most of the slides are kind of grouped together with the themes, but if there are any specific questions, please let me know in advance. The difference is the updates from the last time I presented to the Controller's Office in February are the green fonts. You will see that there's been, in my opinion, a fair amount of progress on all of these.

I want to start off with a couple things. As a general counsel for CIRM, I'd like to state the pleasure to serve for CIRM at the request of the citizens of California, but also it's a pleasure to work with people like Vito, JT, and Maria because compliance is something that I firmly believe starts with the cone at the top, and they make my job easier. That's not very common for us. That's always a challenge for general counselors to whether they have strong compliance support, and for me, that's one thing that I can honestly say that not only with the leaders, but throughout the whole organization, we have a very strong, I would say, integrity culture, and so that makes my job easier. Everyone understands how important it is as stewards to the taxpayers of California to do this.

So, we're going over the '22 and '23 performance audit and management's response, and we're going to close out some issues from 2019 and 2020.

Controller Cohen Before we get into your presentation, I forgot to take public comment on the previous item, item number 7. Just going to briefly go back, open up public comment, and ask the operator to see if there's anyone online that would like to comment on Dr. Thomas's presentation.

Moderator [Operator instructions]. Currently no comments in queue.

Controller Cohen Alright. Thank you very much. All right, now we can continue.

Rafael Okay, so why don't we start on the next slide, please? Thank you. Again, I think this is an important one, so I'll spend a minute on this one. This was with respect to the CEO reporting structure. As part of the reorganization of CIRM, the CEO has created the position of VP of Operations, Jennifer Lewis here, the chief science officer and executive strategy officer with a focus on rare diseases, and the associate vice president of pre-clinical development. Mr. Thomas has also streamlined the decision making structure by creating a five-member executive team, I think it was down from nine, and the number of correct reports has been reduced from twelve to eight. So, I think that's an important one that emphasizes how we're trying to be streamlined and efficient.

Next slide, please. Again, another important one. This one talks about board engagement, making sure that in a hybrid world, we are making sure that there is plenty of board engagement with a 35-member board. Real quickly, extra effort is being made to do in-person meetings four to five times a year. The Board Governance team also conducted a survey of the

board members to get input as well as ideas to improve things, and then one thing that I participate in is the Board Governance and CIRM teams for the individual sort of subject matter areas developing sort of small group primers to discuss what we do on a daily basis to educate our board members. For example, IP regulations that we do that for our board members and stuff like that so they understands what that impact entails.

Skip two slides please, if you don't mind. One more, please. Thank you.

This is an important one because it deals with the intellectual property and revenue sharing requirements. Last time we had mentioned that we had some members who had failed to respond to us, whether it's their IP saving reports or otherwise. We have followed up with the non-responders, which are 22%. The important thing is that any non-responder will be ineligible for any future CIRM funding until any deficiencies are remedied, and we are constantly, quarterly, if you will, following up with them to make sure that they fulfill their obligations. That's an important one, obviously, because that's what leads to revenue which obviously flows to the patients.

M [Speaker off mic]. We're very well aligned on that one, so thank you.

Rafael Perfect. Great. Okay, two slides, please.

This one is an important one because it deals with our research data. As far as the restructuring program, we're developing a comprehensive data infrastructure framework that's going to sort of help us analyze all of our research status. It includes the deployment of the dashboard, and it's currently in our staging environment. We're also expanding our data sharing and management plans to include translational clinical research. The clinical trials information dashboard for the Alpha Clinics network and other CIRM funded trials is in development with an RFP that has been issued and proposals due in January to enhance the accessibility and transparency.

Existing DSMPs discovery awards and 172 additional data sets for older grants have been digitized with the potential for further data expansion as funding allows. In other words, you're trying to take advantage of the technology to make this assets information much more accessible. I imagine somewhere down the road we will look at some AI tools to see what we can use internally, because again, we want to make sure that this is in a closed environment if we do bring that in, but again, this is

important, because again, we're trying to get better understanding of our data.

Thank you. The next two or three slides deal with HR recommendations. I'd like to call out our new director of HR, Denise Daniel, who has come back to CIRM, and she has implemented a lot of process improvements dealing with our onboarding process, making it a much more streamlined and efficient, user-friendly process, obviously, for our new employees. Also improving the quality of memorializing our policies and procedures for HR. That's really important. We want to make sure that everything is clear and transparent for employees.

Then, the other one is one of the comments was on improving our change management processes. The HR team has created a standard organizational change management process. This is to improve transparency and accountability for our employees and how and how they manage upcoming changes in the life, and the HR team has also held meetings with any affected employees with respect to any change to discuss the changes and scopes on how that would affect their day-to-day jobs and stuff like that. So, this is a much more hands-on, much more integrated HR team, in my opinion.

three slides forward, please.

Controller Cohen

Before we—

Rafael

Yes, ma'am.

Controller Cohen

Mr. Oppenheim has a question.

Dave

Yes, just a few comments on some of the observations that you made. I'm really happy to see you tightened up your sole source contact process. I think that's very important in the business that we're all in. On your comprehensive database, of all the research and everything, my comment, and this isn't criticism, more of an observation. I would think in this type of work that we're in that would have been a foundational piece of something that we would have wanted to have very strong to start because part of the opportunities in this program is the sharing and transparency of all this information. So, I'm really glad that you're continuing to make progress, and that's something I continue to be interested in your progress as well.

Then the last point, on the HR issue in terms of bringing people onboard and whatnot, you mentioned four to six months, I think, and you're bringing that down through some change of processes and whatnot. I would have to think, in this very competitive field, you're basically missing out on a lot of best talent that will not sit there for four to six months waiting for an offer into any capacity.

Rafael That was previously. Now it's been cut down quite a bit. That's what we were spending for. I think it's down one to two months on average for our recruitment. So, we understood that that was an opportunity to improve on that.

Dave [Speaker drops].

Jonathan Our jobs are in high demand. Whenever we advertise for something, we get a very quick and large response, and that allows for us to accelerate even further once we have that good talent pool coming in. We're in good shape.

Rafael That's great. A couple slides down, please, if you don't mind. There you go. It's with respect to the compensation policy. The ICOC, Independent Citizens Oversight Committee, reviewed and approved the compensation plan and updated positional salary levels in our board meeting. So, again, this is something that we hadn't done in a couple years—

Controller Cohen This is for the executive staff or for the entire organization?

Rafael For the entire organization. We continue to look at that—

Controller Cohen I have a question. I know you're trying to go fast. Do you guys bring in consultants to assist you with the government structure but also compensation packages?

Rafael I'll speak to compensation which is what I know. Previously we engaged an outfit called Morgan HR that helped. Because of the way our positions are defined, it isn't really easy to find a one-to-one correspondence with the job market and to see what the appropriate salary levels of compensation are. So, we did a gig with Morgan HR who helped us create that a couple of years ago. We will do this again in the next year or two. We'll do an analysis of where we are. We believe that we now have the internal skills and capabilities do that in-house with our new HR team.

Controller Cohen: Also part of figuring the compensation package that you're offering, you do some kind of an assessment in the marketplace. Because they're so unique, who are you comparing yourself to?

Rafael: Well, we have the University of California, the medical school. So, that's proposition driven, so that's our general guidepost, if you will, but then again, we do take into consideration private industry as well to make sure.

Controller Cohen: Because you're competing.

Rafael: Yes, of course.

Controller Cohen: You're able to compete against private industry? You're so closely connected to the—

Rafael: Well, remember, as JT noted, it's that people want to work for us. I mean, I'll speak for myself, it's a great job. People are motivated—

Controller Cohen: I agree. If things don't work out for me here. Maybe it was my [overlapping voices]. I at least know the strategic plan.

Rafael: There you go. Again, we do think that there are some benefits. I think moving to the 2019-2020, performance audit, a couple slides down. Yes, thank you very much.

Most of these, again, have been moved towards what I would consider almost a complete stage. Again, they're not going to be closed until the next performance audit is performed I think in a couple of years, but we think that most of these are very close to being done. This one closed. Let me see which one I would like to speak about.

The next one, the next slide is an IP side. We already talked about the IP exposures.

This one, one more slide, please. Okay, this one goes to—

Controller Cohen: This is finding which one?

Rafael: Finding number 7, page 48, and it's with respect to EIA. This is one of the reasons I wanted to touch upon this one. It's two parts.

The first part was the recommendation that we engage with EIA consultants to encourage to help our help train our GWG for both diversity, perspectives, backgrounds ,and expertise. We did that at the beginning of last year, if I'm not mistaken, or at the end of 2023 December. We had a DIE consultant come out, meet with our GWG team and provided training and some feedback from board members to improve our processes for recruiting GWG members with the goal of increasing our expertise and our skill level, if you will.

Additionally, do that's with respect to our GWG, which is a board function. Internally, we, CIRM, are preparing an RFP for additional consulting services with a goal of returning a DEI advisor to help us assess our internal protocols and processes to make sure that you know we're approaching it properly from a DEI perspective and see how we can increase our efforts there. So, one is external to the board, and one is internal for us, and that will be again launched in the first quarter of 2025.

Controller Cohen

Okay.

Rafael

Alright. Next two slides down. I'll talk about this one because the beginning of sort of the IT world and continuing to manage our data. One of the recommendations was that we implement a new document system. I'm happy to report that as of September 30th, the IT department had fully migrated to Microsoft Office 365 and SharePoint for document management purposes. I'm still learning, but we're going to get there. They're very keen on that. It's very good.

There were a couple of other slides moving forward. They talked about customer relation management systems to collect and better analyze our scientific data as well as publication from our from our grantees.

The software development team has selected Salesforce as a CRM vendor, and they're currently working on the implementation, so that will address a couple of these findings as well. We should be, again, able to close those.

Also, potentially one of the recommendations was to enhance our cybersecurity program. The executive team of CIRM reviewed and approved the new cybersecurity policy, and the IT team is currently formulating a plan to implement and align that policy with [audio drops].

I'm sorry that that was a very high level and fast review of everything. I'd be happy to go into more specifics.

Controller Cohen Thank you very much to you and also to Dr. Thomas. Are there any questions going to staff? All right, we'll go to public comment. Mr. Brad, can you check the line to see if anyone would like to speak?

Moderator [Operator instructions]. We have no lines in queue.

Controller Cohen Okay, thank you. We're going to go on to item number 9, which is public comment, which is an important section on our agenda. Before we hear and receive public comments, I want to physically invite any CIRM leadership team members that are not here, maybe that are online and want to speak or acknowledge or those that are here can also speak. CIRM leadership or any team member who is not on today's agenda, you now have an opportunity to comment on anything, please. Come up to the chair.

Alright, Mr. AT&T operator, please check the lines.

Moderator [Operator instructions]. We still have no lines in queue.

Controller Cohen Okay. Thank you. We're going to keep moving forward. Item 10 is just board member comments, commonly closing remarks. Last few thoughts. Dr. Sadana.

Dr. Sadana It's an honor to be [speaker drops]. Congratulations to CIRM. Great job, wonderful, and it's been progressing. Thank you.

Jonathan Thank you. It's been a pleasure to be able to work with you for many years. We got to see the evolution of programs. Appreciate that comment very much.

Controller Cohen Dr. Maa.

Dr. Maa Great meeting, wonderful information. I just wanted to share [speaker drops]. Unfortunately, a number of state agencies, universities that are funded by the FDA, in particular, notified that they're funding [speaker drops] administration beginning with support for training. So, I just want to make everyone aware that the landscape probably start to see some of the changes, but again, we're [speaker drops].

Controller Cohen Great, thank you.

Jonathan We're very attuned to that monitoring very carefully.

Controller Cohen Mr. Rowlett

Alfred [Speaker off mic]. No other remarks at the moment, and I always want to take a moment to applaud CIRM on a successful audit and what the future holds for you. Especially interested in the AI question and how that will impact CIRM [speaker drops].

Controller Cohen Okay. Can we take public comment on the board comments?

M Are you looking at me? [Overlapping voices]. It can't hurt. Might as well ask. It can't hurt.

Controller Cohen Okay. All right, let's go ahead. Operator, can you open it up to public comment, public comment on the board comments? Okay, sounds like there is none. We'll keep moving.

Item 11 is the consideration for the draft agenda for next meeting. I just wanted to see if any of my colleagues had any suggestions on items that they'd like to see on the agenda. Yes, Dr. Maa.

Dr. Maa [Speaker off mic] a comment by being at my medical school at George Daley, and I'm very interested in the comment earlier. Dave requested partnerships with other states. It's encouraging to hear that in Massachusetts, he had not identified, but I was wondering a little bit of more information about what's going on in other states and ways to amplify that partnering.

Jonathan We'll be happy to do that. In the interest of time, I could do it now, but I think we'll save it until next time. We're very close to any of the [indiscernible] professionals all over the country. Be happy to reported on that next time.

Dave I'd be interested in a little more information on loans versus grants. I understand grants, but loans are very powerful as well as it kind of gives people an impetus to be more, I think, accountable, affordable, and leveraging that financing structure that's part of CIRM. Maybe a little more strategically, if you find that would add value and to report back on how you're looking at loans versus grants.

STATE OF CA – CONTROLLERS OFFICE

Host: Malia Cohen

December 18, 2024/4:00 p.m. CST

Page 46

Jonathan Great.

Controller Cohen Great. Any other comments? Seeing none, we are on Item 12, which is our adjournment, and I'm asking for continuing for this meeting to have the CIRM leadership report back to the committee on the progress of the CIRM strategic plan, programmatic changes, clinical trials, grants awarded, and of course, CIRM's overall future.

Now that all the business is concluded today, we will meet next year. The meeting notice with the date and time will be posted ten days prior to the meeting, and again, thank you very much for your hard work. This meeting is adjourned. Thank you.

All Thank you.