BEFORE THE

INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION:	SANFORD CONSORTIUM 2880 TORREY PINES SCENIC ROAD LA JOLLA, CALIFORNIA
DATE:	THURSDAY, SEPTEMBER 23, 2015 10 A.M.
REPORTER:	BETH C. DRAIN, CSR CSR. NO. 7152
BRS FILE NO.:	97938

I N D E X

I N D E X (CONT'D.)

DISCUSSION ITEMS

SAN DIEGO, CALIFORNIA; THURSDAY, SEPTEMBER 24, 2015

10 A.M.

CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY. THIS IS J.T. FROM CIRM HEADQUARTERS IN SAN FRANCISCO. WELCOME TO THE SEPTEMBER ICOC BOARD MEETING. MARIA IS GOING TO LEAD US HERE AND A NUMBER OF FOLKS GATHERED TOGETHER HERE IN SAN FRANCISCO. MANY OF YOU ARE ON VIA PHONE. WOULD LIKE TO NOTE THAT RANDY IS DOWN IN SAN DIEGO AT THE CONSORTIUM WITH A NUMBER OF OUR BOARD MEMBERS AND A NUMBER OF MEMBERS OF THE PUBLIC. WITHOUT FURTHER ADO, MARIA, WILL YOU LEAD US HERE IN THE PLEDGE OF ALLEGIANCE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN THOMAS: THANK YOU VERY MUCH, EVERYBODY. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: PRESENT.

MS. BONNEVILLE: SUE BRYANT. KEN BURTIS.

DR. BURTIS: PRESENT.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: PRESENT.

MS. BONNEVILLE: ANNE-MARIE DULIEGE. ELIZABETH FINI.

DR. FINI: PRESENT.

MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY GASSON. DAVID HIGGINS.

MR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: PRESENT.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE. BERT LUBIN. SHLOMO MELMED.

DR. MELMED: PRESENT.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: HERE.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: PRESENT.

MS. BONNEVILLE: JOE PANETTA. ROBERT PRICE. FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: PRESENT.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: PRESENT.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: PRESENT.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES. KRISTINA

VUORI.

DR. VUORI: HERE.

MS. BONNEVILLE: DONNA WESTON.

DR. WESTON: HERE.

MS. BONNEVILLE: DIANE WINOKUR. BRUCE WINTRAUB.

MR. WINTRAUB: PRESENT.

DR. PRICE: MARIA, ROBERT PRICE. I'M HERE.

MS. BONNEVILLE: THANK YOU.

CHAIRMAN THOMAS: THANK YOU, EVERYBODY. WE'RE GOING TO PROCEED TO THE PROPOSED CONSENT CALENDAR, ITEMS 6 TO 9. ANYBODY, SINCE YOU HAVE THE MATERIALS, HAVE ANY COMMENTS OR QUESTIONS ON ANY OF THE CONSENT ITEMS? HEARING NONE, JAMES.

MR. HARRISON: WE DON'T HAVE A QUORUM YET. SO IF YOU WOULD LIKE, YOU CAN ASK FOR A MOTION TO APPROVE AND SECOND AND THEN TAKE A VOTE ONCE WE OBTAIN A QUORUM.

CHAIRMAN THOMAS: OKAY.

DR. GASSON: JAMES, THIS IS JUDY GASSON. I'M ON NOW.

MS. BONNEVILLE: THANK YOU.

CHAIRMAN THOMAS: THANK YOU. SO WE HAVE A MOTION, AS JAMES JUST SUGGESTED, TO APPROVE THE

CONSENT ITEMS.

DR. JUELSGAARD: THIS IS STEVE JUELSGAARD. I SO MOVE.

CHAIRMAN THOMAS: THANK YOU, MR. JUELSGAARD. IS THERE A SECOND?

DR. GASSON: SECOND.

CHAIRMAN THOMAS: THANK YOU. OKAY. WE'RE GOING TO HOLD THAT. WE'VE GOT THE MOTION AND THE SECOND.

I WOULD LIKE TO, BEFORE WE HEAD INTO THE NEXT PORTION OF THE AGENDA, WHICH IS GOING TO BE ACTION ITEMS, SINCE WE ARE SPREAD OUT IN A NUMBER OF SITES, IF THOSE OF YOU WHO HAVE MEMBERS OF THE PUBLIC WITH YOU, COULD LET US KNOW AT THIS POINT.

MS. CHEUNG: WE HAVE MEMBERS IN SAN DIEGO.

DR. GASSON: I HAVE ANDREW WITH ME.

CHAIRMAN THOMAS: THANK YOU, JUDY.

DR. FINI: HELLO, J.T. THIS IS ELIZABETH FINI. I'M AT USC AND I HAVE DR. ARLENE CHIU WITH ME.

CHAIRMAN THOMAS: THANK YOU. OTHERS WITH MEMBERS OF THE PUBLIC?

MS. CHEUNG: THIS IS SAN DIEGO. WE HAVE MEMBERS HERE.

CHAIRMAN THOMAS: OKAY. WE'RE GOING TO

PROCEED --

MS. BONNEVILLE: I'D LIKE TO CONFIRM THAT KRISTINA VUORI IS ON THE LINE.

MS. CHEUNG: YES. SHE'S HERE.

MS. BONNEVILLE: I'M TOLD THAT KRISTINA, DAVID, AND JACK ARE AT THE CONSORTIUM, BUT I CAN'T HEAR, SO I DON'T KNOW IF YOU'RE ON MUTE.

CHAIRMAN THOMAS: WE SEEM TO BE HAVING A BIT OF TECHNICAL DIFFICULTY.

(PAUSE IN PROCEEDINGS.)

MS. CHEUNG: WE DO HAVE MEMBERS OF THE PUBLIC HERE IN SAN DIEGO AND ALL THE BOARD MEMBERS ARE HERE.

MS. BONNEVILLE: LET ME JUST GET THAT ON RECORD. KRISTINA VUORI.

DR. VUORI: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

MR. HIGGINS: HERE.

MS. BONNEVILLE: AND JACK DIXON.

DR. DIXON: HERE.

MS. BONNEVILLE: THANK YOU.

CHAIRMAN THOMAS: OKAY. THANK YOU, EVERYBODY. SO WE HAVE A MOTION AND SECOND ON THE CONSENT ITEMS. DO WE HAVE TO POLL EVERYBODY ON THIS, JAMES? SO, MARIA, WILL YOU PLEASE CALL THE

ROLL.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: SUE BRYANT. KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE. ELIZABETH FINI.

DR. FINI: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

MR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE. BERT LUBIN. SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA. ROBERT

PRICE.

DR. PRICE: YES.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: AYE.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES. KRISTINA VUORI.

DR. VUORI: YES.

MS. BONNEVILLE: DONNA WESTON.

DR. WESTON: YES.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: BRUCE WINTRAUB.

DR. WINTRAUB: YES.

CHAIRMAN THOMAS: OKAY. THANK YOU. MOTION PASSES. WE'LL PROCEED NOW TO OUR ACTION ITEMS. AS YOU KNOW, IT IS OUR PRACTICE TO HAVE

ACTION ITEMS, THERE'S AN OPPORTUNITY FOR THE PUBLIC TO COMMENT AT THE END OF THE PRESENTATION AND DISCUSSION BY THE BOARD. AND FOR THOSE MEMBERS OF THE PUBLIC WHO DO WISH TO COMMENT ON THE PARTICULAR ITEMS AT ISSUE, THAT IS THE TIME TO DO SO. THERE'S A WRAP-UP PUBLIC COMMENT SESSION THAT IS MEANT TO BE ON OTHER ITEMS AT THE END OF THE BOARD MEETING. AND AGAIN, MEMBERS OF THE PUBLIC, IF YOU ARE GOING TO GIVE PUBLIC COMMENT, PLEASE REMEMBER THAT YOU HAVE THREE MINUTES TO DO SO.

ITEM NO. 7, OUR FIRST ACTION ITEM, CONSIDERATION OF AMENDMENTS TO THE CONCEPT PLANS FOR THE TRANSLATIONAL AND CLINICAL PROGRAMS REGARDING LOANS AND TO THE TRANSLATION AND DISCOVERY PROGRAMS REGARDING SCHEDULES. WE'RE GOING TO HAVE A PRESENTATION HERE BY DR. OLSON.

DR. OLSON: THANK YOU, CHAIRMAN THOMAS. MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, AND MEMBERS OF CIRM TEAM, WHAT I'D LIKE TO DO TODAY IS JUST PRESENT TO YOU THE PROPOSED UPDATE TO THE DISCOVERY AND TRANSLATION CONCEPT PLANS THAT WERE PRESENTED AND APPROVED BY YOU, THE BOARD, AT THE JULY 23D MEETING AND ALSO AN UPDATE TO THE CLINICAL CONCEPT PLAN THAT YOU APPROVED LATE LAST YEAR.

SO THERE ARE TWO CHANGES. THE FIRST ONE I

WANT TO DISCUSS IS THE CHANGE IN THE LOAN ELECTION OPTION. UNDER THE APPROVED CONCEPT PLANS, SUCCESSFUL APPLICANTS WHO RECEIVED A TRANSLATION STAGE AWARD FOR EARLY DEVELOPMENT OF A THERAPEUTIC, A DIAGNOSTIC TEST, OR A MEDICAL DEVICE, OR SUCCESSFUL APPLICANTS WHO RECEIVED A CLINICAL STAGE AWARD FOR A THERAPEUTIC OR A MEDICAL DEVICE COULD ELECT TO TREAT THE AWARD AS A LOAN AT ANY TIME WITHIN THE EARLIER OF A PERIOD SPECIFIED OR A REGULATORY SUBMISSION FOR MARKETING.

SINCE THE CONCEPT PLAN APPROVAL, CIRM HAS BEEN CONTINUING TO REFINE THE LOAN ELECTION POLICY IN ORDER TO ESTABLISH AN APPROPRIATE RATE OF RETURN FOR AWARDEES WHO ACTUALLY ELECT THE LOAN OPTION. BASED ON THIS ANALYSIS, WE ARE NOW PROPOSING TO OFFER THE LOAN OPTION ONLY TO THERAPEUTIC DEVELOPMENT AWARDEES IN ORDER TO AVOID THE COMPLEXITY ASSOCIATED WITH ESTABLISHING REPAYMENT TERMS FOR DIAGNOSTICS AND DEVICES WHICH HAVE VARIABLE REGULATORY PATHWAYS.

THE LOAN ELECTION TERMS FOR THERAPEUTICS WILL BE SPECIFIED IN THE CLINICAL AND IN THE DISCOVERY AND TRANSLATION PROGRAM GRANTS ADMINISTRATION POLICY WHICH WILL BE PRESENTED TO THE BOARD FOR CONSIDERATION LATER THIS FALL.

AS NOTED BY THE SCIENCE SUBCOMMITTEE AT A MEETING EARLIER THIS MONTH, THE LOAN ELECTION OPTION WAS INTENDED TO ENCOURAGE INDUSTRY PARTICIPATION. SO WE WILL CONTINUE TO MONITOR THIS PROGRAM IN ORDER TO DETERMINE WHETHER THE ABSENCE OF A LOAN OPTION FOR DIAGNOSTICS AND FOR MEDICAL DEVICES IS ACTUALLY A BARRIER TO APPLICATION SUBMISSION. IF SO, WE WILL RETURN TO THE BOARD WITH A REQUEST FOR MODIFICATION.

SO ARE THERE ANY QUESTIONS REGARDING THIS PARTICULAR PROPOSED CHANGE? IF NOT, I'LL PROCEED TO THE SECOND ITEM, WHICH IS A REQUEST TO ELIMINATE THE SPECIFICITY IN THE DISCOVERY AND TRANSLATION CONCEPT PLANS REGARDING APPLICATION SUBMISSION DEADLINES.

THE DISCOVERY AND TRANSLATION CONCEPT PLANS THAT WE PROPOSED IN JULY AND WERE APPROVED BY THE BOARD INCLUDED DETAILS ON THE TIMING AND ORDER OF SUBMISSION OF APPLICATIONS IN RESPONSE TO PROGRAM ANNOUNCEMENTS THAT FALL UNDER THE D AND T PROGRAMS. CIRM, IN ORDER TO OPERATE EFFICIENTLY AND TO RESPOND TO CHANGING CIRCUMSTANCES, NEEDS TO BE NIMBLE AND FLEXIBLE. THEREFORE, TO ENSURE THAT CIRM CAN REMAIN FLEXIBLE TO MEET THESE NEEDS, WE PROPOSE TO ELIMINATE THE SPECIFICITY IN THE TIMING OF APPLICATION SUBMISSION AS OUTLINED IN THE DISCOVERY AND TRANSLATION CONCEPT PLANS. AGAIN, THIS WAS

PRESENTED TO THE SCIENCE SUBCOMMITTEE EARLIER THIS MONTH AND, YOU KNOW, ESSENTIALLY THEY APPROVED IT.

THE TIMING OF APPLICATION SUBMISSION WILL BE DEFINED IN THE PROGRAM ANNOUNCEMENTS WHEN THEY APPEAR. SO THE CIRM TEAM WOULD LIKE TO RECOMMEND THAT THE BOARD APPROVE PROPOSED AMENDMENTS TO THE TRANSLATION AND DISCOVERY PROGRAM AND CLINICAL PROGRAM OFFERING THE LOAN OPTION ONLY TO THERAPEUTIC DEVELOPMENT AWARDEES UNDER THE CLINICAL AND TRANSLATION PROGRAMS TO TREAT THEIR AWARD AS A LOAN UNDER TERMS TO BE PRESENTED TO THE BOARD AS PART OF THE CLINICAL AND DISCOVERY AND TRANSLATION PROGRAM GRANTS ADMINISTRATION POLICY.

AND SECOND, WE WOULD REQUEST, WE WOULD RECOMMEND THAT THE BOARD ELIMINATE THE SPECIFICITY DETAILED IN THE DISCOVERY AND TRANSLATION CONCEPT PLANS REGARDLESS OF SCHEDULE FOR SUBMISSION OF APPLICATION IN RESPONSE TO PROGRAM ANNOUNCEMENTS THAT ARE ISSUED UNDER THESE PLANS. THANK YOU.

DR. MILLS: IF I MAY JUST MAKE A FEW CLARIFYING COMMENTS ABOUT THE PROPOSAL THAT PAT HAS JUST LAID OUT SO PEOPLE UNDERSTAND SPECIFICALLY WHAT WE'RE TRYING TO DO.

THE REQUEST, THE SECOND REQUEST IN THE PROPOSAL, I THINK, IS AN IMPORTANT ONE. AT THE LAST

MEETING THERE WERE -- AT THE LAST BOARD MEETING, THERE WERE SEVERAL REQUESTS THAT CENTERED AROUND CHANGING THE SEQUENCE IN WHICH THE DISCOVERY AND THE TRANSLATIONAL PROGRAMS WERE STARTED, RECOGNIZING THAT BOTH OF THOSE PROGRAMS WOULD CONTINUE ON INDEFINITELY THROUGH CIRM'S LIFE ALTERNATING EVERY THREE MONTHS TO, INSTEAD OF STARTING WITH THE DISCOVERY PROGRAMS AND THEN THREE MONTHS LATER SWITCHING TO THE LAUNCH OF THE TRANSLATIONAL PROGRAMS, TO INSTEAD START WITH TRANSLATIONAL PROGRAM AND THEN MOVE INTO THE DISCOVERY PROGRAM. BECAUSE OF THE SPECIFICITY THAT WE PUT IN THE CONCEPT PLAN, WE WERE UNABLE TO JUST MAKE THAT CHANGE UNILATERALLY.

SO SPECIFICALLY WE'RE ASKING FOR THAT SEQUENCING SPECIFICITY TO BE REMOVED FROM THE CONCEPT PLAN. THE NET EFFECT OF THAT WILL BE, IF THAT IS DONE, THEN WE WILL LAUNCH THE TRANSLATIONAL PROGRAM AND ACCEPT APPLICATIONS WITHIN THE NEXT SEVEN DAYS. SO THAT'S THE EFFECT OF WHAT WE'RE DOING.

(APPLAUSE.)

CHAIRMAN THOMAS: OKAY. THANK YOU VERY MUCH, RANDY. DO WE HAVE A MOTION FROM A MEMBER OF THE BOARD ON THIS ITEM?

MS. WINOKUR: I SO MOVE.

CHAIRMAN THOMAS: THANK YOU. WAS THAT DIANE?

MS. WINOKUR: UH-HUH.

CHAIRMAN THOMAS: THANK YOU, DIANE. IS THERE A SECOND?

MR. HIGGINS: I SECOND.

MS. CHEUNG: DAVID SECONDS FROM UCSD.

CHAIRMAN THOMAS: OKAY. DR. HIGGINS SECOND. DISCUSSION BY MEMBERS OF THE BOARD? HEARING NONE, DO WE HAVE PUBLIC COMMENT?

DR. MILLS: WE DO HERE. HOLD ON JUST ONE SECOND.

MR. RODUNSKY: MY NAME IS MICHAEL RODUNSKY, AND I AM ONE OF THE PATIENTS WITH PARKINSON'S THAT WILL BE INVOLVED IN JEANNE LORING AND MELISSA HOUSER'S STUDY SUPPORTED BY SHERRIE GOULD. AND WE ARE VERY, VERY APPRECIATIVE OF THIS PROPOSED CHANGE, AND WE HOPE THAT IT PASSES. WE ARE IN GREAT NEED TO MAKE THIS HAPPEN FOR US, AND I JUST WANT TO SAY THANK YOU VERY, VERY MUCH, KEVIN, RANDY, THE WHOLE TEAM, DAVID, THANK YOU VERY MUCH.

CHAIRMAN THOMAS: THANK YOU.

MS. ROBB: HI. I'M JENNIFER ROBB. I'M GIDDY. THANK YOU VERY MUCH FOR THIS. JENNIFER

ROBB, AND I'M ABSOLUTELY GIDDY. THANK YOU ALL FOR THE SPECIAL CONSIDERATION FOR SUMMIT4STEMCELL AND ALL TRANSLATIONAL PROGRAMS. I APPLAUD THAT AND I HOPE IT PASSES.

MS. GOULD: THIS IS SHERRIE GOULD. AND I CAN'T THANK CIRM ENOUGH AND ALL OF YOU FOR GIVING US THE OPPORTUNITY, AND THAT IS REALLY WHAT WE WANTED IS JUST AN OPPORTUNITY TO APPLY FOR A GRANT, FOR MONEY FOR SOMETHING THAT'S APPROPRIATE FOR OUR PROJECT. AND THIS IS REALLY OUR FIRST OPPORTUNITY TO DO SO, AND THE GRATITUDE CANNOT BE EXPRESSED DEEPLY ENOUGH. THANK YOU SO VERY MUCH.

CHAIRMAN THOMAS: THANK YOU.

DR. HOUSER: HELLO. I'M MELISSA HOUSER. I'M A CLINICAL NEUROLOGIST SPECIALIZING IN PARKINSON'S DISEASE, WORKING WITH JEANNE LORING ON OUR PARTICULAR PROJECT. BUT I JUST SPEAK ON BEHALF OF ALL THE PEOPLE IN THIS ROOM IN SAN DIEGO BECAUSE YOU CAN'T SEE US HERE, BUT WHEN RANDY ANNOUNCED THAT, THERE WAS AN AUDIBLE GASP FROM THE PUBLIC, AND WE APPRECIATE THIS MOVEMENT SO MUCH FOR TRANSLATIONAL WORK. THANK YOU.

CHAIRMAN THOMAS: THANK YOU.

MR. FITZPATRICK: MY NAME IS ED FITZPATRICK. I'M ONE OF THE EIGHT INVOLVED IN THIS

PROGRAM, AND I CAN'T THANK YOU ENOUGH. AND IT IS CLEAR TO ME THAT THE LAST ROUGHLY 11 YEARS SINCE THIS PROGRAM STARTED, GREAT THINGS HAVE BEEN BEGINNING TO HAPPEN, AND NEXT NOVEMBER 2016, I THINK YOU'RE GOING FOR ANOTHER GRANT OF $5 BILLION. I THINK THIS IS A STEP THAT'S GOING TO GET YOU THAT MONEY. THANK YOU VERY MUCH.

CHAIRMAN THOMAS: THANK YOU.

DR. LORING: THIS IS JEANNE LORING. I JUST WANT TO POINT OUT THAT ONE OF THE MEMBERS OF THE GROUP THAT WE HAVE FOR THE PILOT PROJECT FOR PARKINSON'S DISEASE WOULD SPEAK EXCEPT FOR SHE'S IN TEARS. SHE'S SO HAPPY.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU. SO WE GO NOW TO THE VOTE. MARIA, WILL YOU CALL THE ROLL.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: SUE BRYANT. KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE. ELIZABETH FINI.

DR. FINI: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

MR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE. BERT LUBIN. SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA. ROBERT PRICE.

DR. PRICE: YES.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES. KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: DONNA WESTON.
DR. WESTON: YES.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: BRUCE WINTRAUB.
DR. WINTRAUB: YES.
MR. HARRISON: MOTION CARRIES 20 TO ZERO.
CHAIRMAN THOMAS: THANK YOU, MR. HARRISON. ON TO ITEM NO. 8.
(APPLAUSE.)
CHAIRMAN THOMAS: NO. 8, CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO PROGRAM ANNOUNCEMENT 15-02, PARTNERING OPPORTUNITIES FOR CLINICAL TRIAL STAGE PROJECTS. I'M GOING TO BE TURNING THIS OVER AT THIS POINT TO MR. SHEEHY.
MR. SHEEHY: THANK YOU, CHAIRMAN THOMAS. IS SOMEONE FROM THE CIRM TEAM, PERHAPS DR. SAMBRANO, GOING TO PRESENT ON THIS APPLICATION?
DR. SAMBRANO: YES. I'M PREPARED TO

PRESENT.

MR. SHEEHY: GREAT. GREAT. AND I JUST, AGAIN, I CAN'T SAY THIS TOO OFTEN. I REALLY WANT TO COMMEND THE CIRM TEAM FOR THE EFFICIENCY AND THE SPEED AND THE QUALITY OF THE APPLICATIONS AND THE PROCESSING OF THE APPLICATIONS. THIS HAS REALLY BEEN AMAZING. WHAT ROUND ARE WE ON, DR. SAMBRANO, OF THIS INITIATIVE SINCE WE STARTED?

DR. SAMBRANO: SO OUR INITIAL REVIEW ROUND BEGAN IN MARCH, AND SO WE'RE NOW IN SEPTEMBER, SO WE'RE ABOUT SEVEN OR EIGHT.

MR. SHEEHY: THAT'S GREAT. IT'S JUST A MACHINE.

ANYWAY, DR. SAMBRANO, IF YOU WOULD LIKE TO TAKE US THROUGH THIS APPLICATION.

DR. SAMBRANO: THANK YOU, MR. SHEEHY. WE'RE BRINGING FOR YOUR CONSIDERATION AN APPLICATION THAT WAS SUBMITTED AND REVIEWED UNDER THE CLINICAL PROGRAM 15-02 AS WAS INDICATED. AND 15-02 SUPPORTS SPECIFICALLY CLINICAL TRIAL PROJECTS.

ON SLIDE 3 ON THE DECK THAT I PROVIDED YOU, THERE'S JUST A BRIEF REMINDER OF THE SCORING SYSTEM THAT IS UTILIZED BY THE GRANTS WORKING GROUP. VERY SIMPLE, 1, 2, OR A 3. A SCORE OF 1 MEANING THE APPLICATION IS OF EXCEPTIONAL MERIT AND WARRANTS

FUNDING. A SCORE OF 2 MEANS IT IS A PROMISING PROPOSAL, BUT DOES NOT WARRANT FUNDING AT THIS TIME, BUT COULD BE RESUBMITTED TO ADDRESS AREAS FOR IMPROVEMENT. A SCORE OF 3 MEANS THAT IT'S SUFFICIENTLY FLAWED SUCH THAT IT SHOULD NOT BE FUNDED.

ON SLIDE 4 I HAVE A SUMMARY OF THE SPECIFIC PROPOSAL CTS1-08280. THIS IS A PHASE III CLINICAL TRIAL FOR GLIOBLASTOMA. THE THERAPY IS AN AUTOLOGOUS ONE THAT UTILIZES DENDRITIC CELLS THAT ARE PULSED WITH SPECIFIC PEPTIDES THAT ARE DERIVED FROM THE TUMORS FROM THE PATIENT AND THEN REINTRODUCED AS A CELL THERAPY BACK TO THE PATIENT TO INCITE THE IMMUNE SYSTEM TO ATTACK THE TUMOR.

THE INDICATION IS FOR NEWLY DIAGNOSED GLIOBLASTOMA PATIENTS.

AND THE GOAL OF THIS STUDY IS TO COMPLETE A PHASE III CLINICAL TRIAL UNDER AN SPA TO DEMONSTRATE BOTH SAFETY AND EFFICACY OF THE THERAPY FOR THESE PATIENTS.

THE MAJOR PROPOSED ACTIVITIES INCLUDE CLINICAL SITE INITIATION AND PATIENT ENROLLMENT AT MULTIPLE SITES, THE MANUFACTURE OF THE AUTOLOGOUS THERAPEUTIC PRODUCT FOR EACH PATIENT IN THE TRIAL, AND TO CONDUCT ALL THE ACTIVITIES RELATED TO THE

MULTICENTER TRIAL, AND PERFORM THE FINAL DATA ANALYSES.

THEY REQUEST 19.9 MILLION FROM CIRM. THE APPLICANT IS PROVIDING 35.4 MILLION IN CO-FUNDING.

ON THE FINAL SLIDE IS A SUMMARY OF THE GWG REVIEW AND ALSO OUR INTERNAL BUDGET REVIEW. WE CONDUCT A THOROUGH BUDGET REVIEW BEFORE AN APPLICATION GOES TO THE GWG, AND THIS APPLICATION PASSED. SO THE BUDGET IS GOOD. THE GWG GAVE IT A SCORE OF 1, AND THIS IS AN EXAMPLE OF AN APPLICATION THAT WENT THROUGH THE GWG TWICE. SO ORIGINALLY IT RECEIVED A SCORE OF 2, AND SO THE APPLICANT HAD THE OPPORTUNITY TO ADDRESS CONCERNS. AND WHAT WE SPECIFICALLY DO IS PROVIDE THE APPLICANT A SUMMARY OF KEY CONCERNS AS WELL AS RECOMMENDATIONS TO ADDRESS THOSE CONCERNS. IN THIS PARTICULAR CASE THE APPLICANT SUBMITTED A NEW REVISED APPLICATION WITHIN TWO WEEKS. SO BASICALLY WITHIN THE FOLLOWING MONTH WE WERE ABLE TO REVIEW THE RESUBMITTED APPLICATION. THE APPLICANT VERY WELL ADDRESSED THE CONCERNS OF REVIEWERS, AND THEY OVERWHELMINGLY GAVE THIS APPLICATION A SCORE OF 1.

FOLLOWING THAT MEETING, CIRM TEAM OFTEN WILL FOLLOW WITH ITS OWN RECOMMENDATION, AND IN THIS CASE WE CONCUR WITH THE GRANTS WORKING GROUP

RECOMMENDATION FOR AN AWARD AMOUNT OF 19.9 MILLION.

SO ARE THERE ANY QUESTIONS?

MR. SHEEHY: SO DO WE HAVE NO QUESTIONS FROM BOARD MEMBERS?

CHAIRMAN THOMAS: JEFF, IT'S J.T. THIS ISN'T A QUESTION, JUST A COMMENT THAT BUILDS OFF OF WHAT YOU SAID A FEW MINUTES AGO, WHICH IS THIS IS A GREAT EXAMPLE OF THE BEAUTY OF THE 2.0 PROCESS THAT RANDY AND THE TEAM HAVE INSTITUTED WITH RESPECT TO OUR PROJECTS. IT ALLOWED FOR TAKING A PROJECT THAT WAS GOOD, BUT NOT QUITE AT THE RECOMMENDED FOR FUNDING LEVEL, AND ALLOWED FOR INPUT AND REVISION AND REAL-TIME TURNAROUND REAPPLICATION WHICH LED TO THIS REVISED SCORE AND HIGH DEGREE OF ENTHUSIASM FROM THE GRANTS WORKING GROUP. THIS IS EXACTLY A TEXTBOOK EXAMPLE OF HOW CIRM'S PROCESSES HAVE BEEN IMPROVED THROUGH 2.0 TO ALLOW FOR THIS SORT OF THING. SO I JUST WANT TO ECHO WHAT JEFF SAID AND CONGRATULATE RANDY AND THE TEAM FOR PUTTING IN PLACE NOW A REAL IMPROVED PROCESS THAT WILL ONLY MAKE THE QUALITY OF OUR PROJECTS BETTER. MR. SHEEHY.

MR. SHEEHY: THANK YOU, CHAIRMAN THOMAS. I THINK THE NEXT STEP IS A MOTION AND A SECOND FROM A MEMBER OF THE COMMITTEE. I JUST WANT TO NOTE TOO THAT THERE'S REAL NEED IN THESE PROJECTS THAT WE'RE

APPROVING. THIS PARTICULAR DISEASE HAS A MEDIAN SURVIVAL RATE OF JUST OVER A YEAR. SO IF WE DO GET SUCCESS WITH SOME OF THESE PROJECTS, WE WILL MAKE AN IMMENSE DIFFERENCE IN PATIENT'S LIVES.

SO DO I HAVE A MOTION TO APPROVE?

MS. LAPORTE: SO MOVED.

MR. SHEEHY: OKAY. AND CAN I GET A SECOND?

MR. ROWLETT: SECOND.

MR. SHEEHY: GREAT. THANKS, AL. AND THEN AT ANY OF THE SITES IS THERE PUBLIC COMMENT? MAYBE WE'LL START IN SAN DIEGO.

MS. CHEUNG: NO PUBLIC COMMENT HERE.

MR. SHEEHY: AND I THINK THE OTHER SITES WE HAVE ARE AT UCLA.

DR. GASSON: YES. WE HAVE PUBLIC COMMENT.

MR. SHEEHY: OH, GREAT.

DR. GENGOS: THANK YOU FOR THIS OPPORTUNITY TO COMMENT. I'LL READ MY COMMENTS SO AS TO STAY BRIEF. MY NAME IS ANDREW GENGOS. I'M THE PRESIDENT AND CEO OF IMMUNOCELLULAR THERAPEUTICS, WHICH IS THE COMPANY DEVELOPING THE TREATMENT CONTEMPLATED IN THIS GRANT APPLICATION.

I'D LIKE TO GIVE YOU A SENSE FOR HOW IMPORTANT THIS POTENTIAL FUNDING IS TO BRING CANCER

PATIENTS WHO REALLY DON'T HAVE MANY TREATMENT OPTIONS AND HAVEN'T SEEN MUCH INNOVATION IN OVER A DECADE. IMMUNOCELLULAR IS A SMALL CALIFORNIA-BASED BIOTECHNOLOGY COMPANY. WE CURRENTLY HAVE SIX FULL-TIME EMPLOYEES IN OUR PUBLICLY LISTED COMPANY.

FOR SOME TIME NOW I'VE BEEN MEETING WITH INVESTOR GROUPS THAT FOCUS AT LEAST SOME OF THEIR CAPITAL ON PUBLIC BIOTECHNOLOGY COMPANIES. TO BE CLEAR, BIOTECHNOLOGY TREATMENT DEVELOPMENT PROGRAMS ARE RISKY, AND WE ALL KNOW THAT THERE'S A LARGE FAILURE RATE IN THE CLINICAL TRIAL PROCESS LEADING TO FDA REGISTRATION.

IN GLIOBLASTOMA ANY PHASE III REGISTRATIONAL TRIAL IS GOING TO TAKE A LONG TIME TO EXECUTE BECAUSE THE FDA REQUIRES OVERALL SURVIVAL AS THE REGISTRATIONAL ENDPOINT. WE PROJECT OUR PHASE III PROGRAM WILL REQUIRE FIVE YEARS TO EXECUTE. FRANKLY, THIS TIME PERIOD IS OUTSIDE THE INTEREST OF MOST PUBLIC MARKET INVESTORS IN TERMS OF THEIR INVESTMENT HORIZON AND, THEREFORE, IN THEIR EYES, HANDICAPS OUR PROJECT COMPARED TO OTHER PROJECTS THAT CAN EXECUTE IN A SHORTER TIME FRAME. THE RESULT IS THAT INVESTMENT CAPITAL IS HARD TO COME BY FOR THESE TYPES OF PROMISING AND HIGHLY INNOVATIVE THERAPIES ESPECIALLY WHEN THE INVESTMENT HORIZON IS

LONG AND A SMALL COMPANY WITHOUT PRODUCT REVENUES IS AT THE HELM.

WE, THEREFORE, ALSO CONSIDERED OTHER POTENTIAL SOURCES OF CAPITAL, INCLUDING GOVERNMENT AND PHILANTHROPIC ENTITIES.

CIRM'S INTEREST IN ICT 107, OUR DENDRITIC CELL IMMUNOTHERAPY THAT TARGETS CANCER STEM CELLS IN GLIOBLASTOMA, IS CRUCIAL FOR MANY REASONS. LET ME ELABORATE ON ONLY TWO. FIRST, THEIR INDEPENDENT SCIENTIFIC REVIEW AND ENDORSEMENT OF OUR PROGRAM REPRESENTS AN OBJECTIVE VALIDATION OF OUR DENDRITIC CELL IMMUNOTHERAPY TECHNOLOGY. THIS IS A SIGNAL TO THE SCIENTIFIC AND FINANCIAL COMMUNITIES THAT THE PROGRAM HAS GENUINE POTENTIAL.

SECOND, THEIR POTENTIAL FINANCIAL SUPPORT OF THIS PROGRAM TRULY ENABLES US TO EXECUTE THIS PHASE III PROGRAM AND DELIVER ON OUR PROMISE TO BRAIN CANCER PATIENTS TO PUSH THIS PROMISING TECHNOLOGY FORWARD.

I DON'T THINK IT'S AN OVERSTATEMENT TO SAY THAT WITHOUT CIRM SUPPORT, THIS PROGRAM WOULD NOT GO FORWARD. CALIFORNIA'S INNOVATIVE BIOTECHNOLOGY COMMUNITY NEEDS INSTITUTIONS LIKE CIRM. CLEARLY WE NEED CIRM, AND BRAIN CANCER PATIENTS NEED CIRM.

SO, IN CONCLUSION, AND ON BEHALF OF MY

COLLEAGUES AT IMMUNOCELLULAR, I'D JUST LIKE TO THANK CIRM FOR THEIR CONSIDERATION OF THIS WORTHWHILE PROJECT. WE'RE DEEPLY AND HUMBLY IN YOUR DEBT FOR THE POTENTIAL SUPPORT YOU WILL PROVIDE US AND HOW IT WILL ENABLE US TO DELIVER FOR THESE PATIENTS. THANK YOU AGAIN FOR THE OPPORTUNITY TO COMMENT.

CHAIRMAN THOMAS: THANK YOU, DOCTOR.

MR. SHEEHY: YES, THANK YOU FOR YOUR COMMENTS. THE OTHER ITEM WHERE WE HAVE PUBLIC, I THINK, IS AT USC. ARE THERE ANY COMMENTS THERE, FURTHER COMMENT.

DR. FINI: NO, WE HAVE NO COMMENT AT THIS SITE.

MR. SHEEHY: GREAT. SO I THINK WE'RE READY TO CALL THE ROLL. WE COVERED ALL OUR PUBLIC COMMENT SITES. SO, MS. BONNEVILLE.

MS. BONNEVILLE: THANK YOU.

ANNE-MARIE DULIEGE. DAVID HIGGINS.

MR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA. FRANCISCO PRIETO. ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES. DIANE WINOKUR.
MS. WINOKUR: YES.
MR. HARRISON: MOTION CARRIES.
MR. SHEEHY: GREAT. WELL, I THINK THAT CONCLUDES THE BUSINESS OF THE APPLICATION REVIEW SUBCOMMITTEE. IT'S BACK TO YOU, CHAIRMAN THOMAS. THANK YOU.
CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY. ON TO ITEM NO. 9, CONSIDERATION OF AMENDMENTS TO THE LOAN ADMINISTRATION POLICY TO PERMIT EXISTING LOAN

RECIPIENTS WHOSE LOAN HAS BEEN FORGIVEN TO CONVERT THE AWARD TO A GRANT. WE'RE GOING TO HAVE A PRESENTATION BY MR. TOCHER.

MR. TOCHER: THANK YOU, J.T. GOOD MORNING, CHAIRMAN AND MEMBERS OF THE GOVERNING BOARD.

AS YOU ARE AWARE, THE AGENCY IS CURRENTLY REVIEWING ALL ITS POLICIES TO FIND EFFICIENCIES AND ASSURE THAT THESE POLICIES CONTINUE TO SERVE OUR MISSION AND OUR STAKEHOLDERS. TO THAT END, EARLIER THIS MONTH THE IP AND INDUSTRY SUBCOMMITTEE UNANIMOUSLY APPROVED A PROPOSAL TO AMEND OUR LOAN ADMINISTRATION POLICY TO PERMIT A LOAN RECIPIENT WHOSE LOAN HAS BEEN FORGIVEN TO CONVERT THAT LOAN TO A GRANT.

SO BY WAY OF BACKGROUND, THERE ARE TWO WAYS THAT THE LOAN OBLIGATION REPAYMENT WORKS. A LOAN RECIPIENT CAN CHOOSE BETWEEN EITHER A COMPANY-BACKED LOAN, IN WHICH CASE THE LOAN IS REPAID REGARDLESS OF THE SUCCESS OF THE PROJECT, OR A PRODUCT-BACKED LOAN WHICH IS ONLY REPAID IF THE PRODUCT IS SUCCESSFUL.

IN THAT LATTER SCENARIO, IF NOT SUCCESSFUL, THE LOAN IS AUTOMATICALLY FORGIVEN ASSUMING VARIOUS CONDITIONS ARE MET. HOWEVER, THE

LOAN IS THEN REINSTATED AUTOMATICALLY IF REVENUE IN THE FUTURE IS GENERATED. AS A RESULT, WE'VE LEARNED FROM A STAKEHOLDER THAT THIS LOAN MUST BE CARRIED ON THE COMPANY'S BOOKS INDEFINITELY DUE TO THIS SPRINGING OBLIGATION TO REPAY THE LOAN.

THE PROPOSAL AS WE'VE MADE IS TO AMEND THE LOAN ADMINISTRATION POLICY IN THE CONTEXT OF A PRODUCT-BACKED LOAN TO ALLOW THE COMPANY TO CONVERT THAT LOAN ONCE IT'S FORGIVEN INTO A GRANT. AS SUCH, GOVERNED BY THE RULES GOVERNING A TYPICAL GRANT, THE LOAN RECIPIENT WOULD THEN UNDERTAKE THE REVENUE SHARING OBLIGATIONS THAT ARE PRESENT UNDER OUR IP POLICY.

BECAUSE THIS PROPOSAL IS TO AMEND OUR LOAN ADMINISTRATION POLICY IN THE FORM OF A REGULATION, WE'RE BEFORE YOU TODAY TO ASK FOR YOUR APPROVAL TO INITIATE THE RULEMAKING PROCESS TO SOLICIT FURTHER PUBLIC INPUT FROM STAKEHOLDERS AND MEMBERS OF THIS BOARD AND THE PUBLIC AND TO THEN, AS A RESULT OF THAT INPUT, BRING BACK A FINAL PROPOSAL ON AN AMENDMENT TO THE BOARD BEFORE FINAL ADOPTION. AND IF THERE ARE ANY QUESTIONS, I'D BE HAPPY TO TAKE THEM.

CHAIRMAN THOMAS: OKAY. HEARING NO QUESTIONS, I NEED A MOTION TO APPROVE.

MS. WINOKUR: I SO MOVE.

CHAIRMAN THOMAS: THANK YOU, DIANE. SECOND?

DR. JUELSGAARD: I SECOND.

CHAIRMAN THOMAS: THANK YOU, MR. JUELSGAARD. IT'S BEEN MOVED AND SECONDED. ANY FURTHER DISCUSSION BY MEMBERS OF THE PUBLIC? ANY COMMENTS BY MEMBERS OF THE PUBLIC? HEARING NONE, MARIA, WILL YOU CALL THE ROLL.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: SUE BRYANT. KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE. ELIZABETH FINI.

DR. FINI: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

MR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA. ROBERT PRICE.

DR. PRICE: YES.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES. KRISTINA

VUORI.

DR. VUORI: YES.

MS. BONNEVILLE: DONNA WESTON.

DR. WESTON: YES.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: BRUCE WINTRAUB.

DR. WINTRAUB: YES.

MS. BONNEVILLE: THANK YOU.

MR. HARRISON: MOTION PASSES 21 TO ZERO.

CHAIRMAN THOMAS: THANK YOU, MR. HARRISON. THAT CONCLUDES THE ACTION ITEMS. WE'RE NOW GOING TO PROCEED TO THE DISCUSSION ITEMS. I'LL TAKE THEM A BIT OUT OF ORDER. WE'RE GOING TO START WITH THE UPDATE ON OUR STRATEGIC PLAN. I'LL TURN IT OVER HERE TO DR. MILLS.

DR. MILLS: THANK YOU VERY MUCH, CHAIRMAN THOMAS AND THE BOARD AND ALL STAKEHOLDERS IN ATTENDANCE TODAY. I WANT TO PROVIDE AN UPDATE ON THE STRATEGIC PLAN AND THE STRATEGIC PLAN PROCESS THAT'S BEEN UNDER WAY FOR SOME TIME NOW AT CIRM AND GIVE ALSO SOME CLARITY ON THE PROCESS MOVING FORWARD.

SO TODAY I'M GOING TO GO THROUGH I WOULDN'T SAY IN VERY HIGH LEVEL, BUT JUST IN SORT OF

MEDIUM LEVEL DETAIL THE STRATEGIC PLAN AS IT EXISTS CURRENTLY. AND THEN WE ARE GOING TO LISTEN AND RECEIVE FEEDBACK ON THIS PLAN, MAKE EDITS TO THE ACTUAL PLAN DOCUMENT ITSELF, WHICH WE WILL HAVE IN FRONT OF THE SCIENCE SUBCOMMITTEE LATER, I BELIEVE, IN NOVEMBER IN DRAFT FORM. WE'LL THEN TAKE COMMENTS FROM THE SCIENCE SUBCOMMITTEE, INCORPORATE THOSE INTO WHAT WE BELIEVE THEN WOULD BE FINAL EDITS, AS WELL AS COMMENTS FROM ANY OTHER STAKEHOLDERS WHO COMMENT, TURN THOSE INTO FINAL EDITS. AND THEN THE GOAL IS TO BRING THIS PLAN TO THE BOARD FOR FULL APPROVAL IN THE DECEMBER MEETING COMING UP.

SO I'M GOING TO TAKE YOU THROUGH, AND I'M GOING TO TRY AND DO IT QUICKLY FOR THE SAKE OF TIME, BUT THERE ARE A LOT OF IMPORTANT PARTS. AND SO IT'S NOT GOING TO BE SUPER QUICK, SO I'LL APOLOGIZE FOR THAT IN ADVANCE.

THE FIRST THING I TALK ABOUT WITH THE STRATEGIC PLAN IS THE STRATEGIC PLANNING PROCESS THAT WE'VE HAD ONGOING AT CIRM SINCE ACTUALLY A LITTLE AFTER I ARRIVED AT THE AGENCY. THE POINT OF THIS PROCESS IS NOT TO COME UP WITH A VISION OF GOOD OR OKAY OR MEDIOCRE OR ACHIEVABLE, BUT TO ACTUALLY COME UP WITH A VISION OF SOMETHING THAT WOULD BE GREAT, SOMETHING THAT WOULD REALLY BE FANTASTIC

THAT, IF WE WERE SUCCESSFUL, WOULD MAKE AN ENORMOUS IMPACT IN THE LIVES OF THE PATIENTS THAT WE CARE FOR. SO THAT'S WHERE THE STRATEGIC PLANNING PROCESS CAME UP.

THE STRATEGIC PLANNING PROCESS HAS INVOLVED ALMOST EVERY STAKEHOLDER THAT'S EXPRESSED ANY INTEREST IN THE STATE OF CALIFORNIA AND BEYOND. MATTER OF FACT, NOT VERY LONG AGO, I WAS IN THIS VERY ROOM MEETING WITH MANY OF THE SAME PATIENT ADVOCATES AND PATIENTS WHO ARE HERE TODAY. THAT WAS PART OF THE STRATEGIC PLANNING PROCESS. AND COMMENTS FROM THAT ARE INCORPORATED INTO THIS PLAN. WE MET WITH EVERY MAJOR RESEARCH INSTITUTION IN THE STATE OF CALIFORNIA IN PREPARATION FOR THIS. WE MET WITH INDUSTRY STAKEHOLDERS, WE HAD CONVERSATIONS OBVIOUSLY WITH THE BOARD, AND THEN THE INTERNAL CIRM TEAM HAS BEEN INTIMATELY INVOLVED WITH THIS. SO THIS PROCESS IS ONE THAT'S EVOLVED OVER A PERIOD OF TIME AND HAS TAKEN INPUT FROM REALLY EVERY SOURCE THAT WAS INTERESTED IN PARTICIPATING.

SO REALLY QUICKLY ABOUT THE STRATEGIC PLANNING PROCESS. I'VE TALKED ABOUT THIS A COUPLE OF TIMES. THERE'S A LOT OF WAYS TO DO THIS THAT ARE REALLY COMPLEX AND SOMETIMES OVERLY COMPLEX AND BURDENSOME. TO HAVE A SUCCESSFUL PLAN, YOU REALLY

ONLY NEED THREE THINGS. THE FIRST THING YOU NEED TO DO IS ESTABLISH WHERE YOU ARE NOW. THAT REQUIRES AN HONEST ASSESSMENT OF THE ENVIRONMENT THAT YOU'RE ACTUALLY IN, HOW THAT ENVIRONMENT'S CHANGED. YOU HAVE TO CONFRONT FACTS, SOMETIMES BRUTAL FACTS. YOU HAVE TO BE VERY HONEST ABOUT THAT. THAT PROCESS ENDS WITH REALLY UNDERSTANDING THE MISSION OF THE AGENCY AND MAKING SURE THAT WE'RE ALL ALIGNED AROUND THAT.

SO ONCE YOU KNOW WHERE YOU ARE, THEN YOU GET INTO WHERE YOU WANT TO GO. AND THIS IS WHERE YOU COME UP WITH A VISION OF WHAT GREAT LOOKS LIKE. AND THERE'S DIFFERENT WAYS OF DOING THAT IN BRAINSTORMING AND BENCHMARKING AND A LOT OF DIFFERENT THINGS, BUT COME UP WITH A MISSION THAT DESCRIBES WHERE YOU WANT TO GO.

AND THEN THE LAST PART IS SIMPLY FIGURING OUT THE BEST WAY TO GET THERE. ONCE YOU KNOW WHERE YOU ARE AND YOU KNOW WHERE YOU WANT TO GO, THAT'S WHERE THE STRATEGY PART OF STRATEGIC PLANNING COMES IN. AND SO I'LL BE GOING THROUGH THESE THREE THINGS TODAY WITH REGARDS TO CIRM'S STRATEGIC PLAN.

THE FIRST THING WE'LL START WITH, WE'LL START WITH THIS CONCEPT OF WHERE ARE WE. A REALLY IMPORTANT ASPECT TO UNDERSTAND FOR CIRM IS ITS

FINANCIAL LIFE AND ITS FUNDING RUNWAY. SO THE AMOUNT OF AWARDS THAT CIRM HAS TO GIVE OVER ITS ENTIRE LIFE WAS ABOUT 2.75 BILLION. WE HAVE AWARDED ABOUT 2 BILLION OF THAT ALREADY. WE HAVE 775 MILLION THAT'S NOT COMMITTED. WE HAVE A PLAN THAT WILL CALL FOR ABOUT 190 TO $200 MILLION IN NEW AWARDS EVERY SINGLE YEAR FOR THE NEXT FIVE YEARS.

AS PART OF THAT, WE ESTIMATE THAT SOMETIMES WHEN WE ISSUE AN AWARD, THE PROJECT DOESN'T WORK OUT, AND WE GET SOME OF THAT MONEY BACK. AND THAT HAPPENS AT A RATE OF ABOUT 10 TO 15 PERCENT OF EVERY DOLLAR THAT WE AWARD COMES BACK TO CIRM IN AN AWARD REDUCTION OR MODIFICATION. SO, THEREFORE, OUR NET SPENDING WOULD BE ABOUT 170 MILLION. AND SO THAT'S HOW YOU GET TO $775 MILLION IN UNCOMMITTED FUNDS THAT WILL LAST FIVE YEARS WHEN ALLOCATED AT THE RATE OF 190 TO 200 MILLION A YEAR. SO FIVE YEARS IS OUR REALISTIC TIMELINE. REALISTIC, FOUR AND A HALF YEARS IS OUR REALISTIC AWARD TIME HORIZON, AND SO THIS PLAN TAKES A LOOK AT HOW CIRM CAN DO THE BEST IT POSSIBLY CAN AND ACHIEVE THE MOST IT CAN ACHIEVE IN THAT TIME PERIOD.

TODAY WE HAVE SPENT OR AWARDED $1.3 BILLION ON DISEASE-SPECIFIC RESEARCH. THIS ACROSS ALL KINDS OF FUNDING, FROM THE EARLIER STAGE

RESEARCH, TRANSLATIONAL RESEARCH TO CLINICAL STAGE RESEARCH. THAT HAS GIVEN US NOW 15 TRIALS, 15 CLINICAL TRIALS, AND YOU CAN SEE THE CLINICAL TRIALS LISTED. AND YOU CAN ALSO SEE THE MAKEUP OF OUR DISEASE-SPECIFIC FUNDING. SO NEURO IS BY FAR THE LARGEST FOLLOWED BY CANCER AND CARDIOVASCULAR, AND YOU CAN SEE THE REMAINING AREAS.

WE HAVE BEEN -- TO DATE WE HAVE BEEN OVERWHELMINGLY FUNDING ACADEMIC VERSUS INDUSTRY TO THE TUNE OF 91 PERCENT TO 9 PERCENT. I'LL SAY IF YOU LOOK AT THIS WITHOUT ANY CONTEXT, THAT MIGHT SEEM A LITTLE OVERWHELMING. IT'S NOT QUITE -- IT'S NOT QUITE THAT OVERWHELMING GIVEN THAT A LOT OF OUR PROGRAMS THAT WE'VE FUNDED, PARTICULARLY EARLY ON, MAJOR FACILITIES AND THE LIKE, ONLY HAD AN OPPORTUNITY TO GO TO ACADEMIA. WITH THAT SAID, ABOUT 20 PERCENT OF OUR CLINICAL PROGRAMS RIGHT NOW ARE THROUGH INDUSTRY, 80 PERCENT ARE STILL IN ACADEMIA. THE REASON THIS IS IMPORTANT IS BECAUSE AS CIRM MOVES FURTHER AND FURTHER ALONG IN DEVELOPING THESE STEM CELL THERAPIES, IT WILL ULTIMATELY BE INDUSTRY THAT WE WILL NEED TO BE PARTNERED WITH TO BE ABLE TO DELIVER THEM TO PATIENTS. SO ACADEMIA IS IN THE EARLY TRANSLATIONAL, EVEN EARLY CLINICAL STAGES; BUT

COMPANIES COMMERCIALIZE THINGS, AND THAT ENABLED US TO GO FROM TREATING INDIVIDUALS TO ENTIRE POPULATIONS OF PATIENTS. AND IT'S BEEN VERY CLEAR UP UNTIL NOW THAT THERE'S BEEN AN INDUSTRY BIAS AGAINST GETTING INVOLVED IN STEM CELL THERAPY.

SO MOVING ON TO WHERE WE ARE TODAY, SO WE'VE SPENT A TOTAL OF $2 BILLION, AS I SAID, AND WE'VE SPENT THEM ON SORT OF FIVE PILLARS, OR FIVE MAJOR INITIATIVES. SO WE HAVE INFRASTRUCTURE PROGRAMS LIKE THE ALPHA CLINICS, THE GENOMICS CENTER, THE IPS CELL BANK. WE HAVE EDUCATIONAL PROGRAMS, SPENT $370 MILLION ON EDUCATIONAL ACTIVITIES, AND THEN WE HAVE OUR DISCOVERY, TRANSLATIONAL, AND CLINICAL PIECES THAT YOU CAN SEE UP THERE. THE POINT OF THIS, AND THIS IS A REALLY, REALLY IMPORTANT POINT AND A MAJOR SHIFT THAT'S GOING TO BE GOING ON AT CIRM, IS WE HAVE CREATED WITH THESE $2 BILLION VERY BEAUTIFUL PIECES, BUT THEY EXISTED AS PIECES, NOT AS AN INTEGRATED MACHINE. AND SO THAT'S ONE OF THE THINGS THAT WE'RE GOING TO BE CHANGING.

SO YOU CAN JUST TAKE A LOOK BACK THROUGH OUR HISTORY. CIRM HAS EXISTED AS AN INITIATIVE-BASED AGENCY. AND WHAT I MEAN BY THAT IS THAT EARLIER ON IN CIRM'S LIFE SPAN, WHEN CIRM

STARTED AND IT WAS STARTING TO GET GOING, THERE WASN'T TREMENDOUS DEMAND FOR DISCOVERY, TRANSLATIONAL, AND CLINICAL STAGE RESEARCH. ACTUALLY THERE WASN'T THAT MUCH DEMAND FOR ANY STEM CELL RESEARCH. THE FIELD WAS STILL VERY YOUNG. AND SO WHAT THE AGENCY WOULD DO, IN ORDER TO BE AS RESPONSIVE AS IT POSSIBLY COULD, WOULD BE ONCE THERE WAS CRITICAL MASS AROUND A PARTICULAR AREA, IT WOULD OFFER AN INITIATIVE. AN INITIATIVE WOULD ESSENTIALLY POP UP, AND THEN YOU COULD APPLY FOR THAT INITIATIVE. THE PROBLEM WITH THAT, THOUGH, IS YOU WOULDN'T KNOW WHEN THAT INITIATIVE WOULD POP; BACK UP AGAIN, IF EVER. AND SO WE ENDED UP WITH THIS INITIATIVE-BASED SYSTEM.

NOW, THE GREAT NEWS IS THE WORLD HAS CHANGED BETWEEN 2004 AND 2015, AND FOR STEM CELLS IT'S CHANGED IN A VERY GREAT WAY BECAUSE WE NOW HAVE DEMAND TO HAVE THESE PROGRAMS RUN, NOT AS INITIATIVES, BUT AS A MACHINE, AS A PROCESS THAT RUNS OVER AND OVER AND OVER AGAIN. AND THAT IS THIS BIG SHIFT THAT CIRM IS IN THE PROCESS OF PIVOTING TO. WE HAVE GONE FROM AN INITIATIVE-BASED APPROACH TO A SYSTEMS-BASED APPROACH WHERE EVERY YEAR MULTIPLE TIMES A YEAR ALL OF THESE PROGRAMS WILL BE OFFERED OVER AND OVER AND OVER AGAIN, AND YOU WILL

KNOW WHEN THEY'RE AVAILABLE. THEY WILL BE LINKED UP IN A WAY THAT MAKES SENSE SO THAT WHEN YOU'RE DONE WITH ONE STAGE OF RESEARCH, THE NEXT STAGE OF RESEARCH IS THERE WAITING TO TAKE YOU FORWARD. AND SO YOU CAN SEE DISCOVERY OFFERED TWICE A YEAR, TRANSLATIONAL TWICE A YEAR, CLINICAL 12 TIMES A YEAR. ALL OF THESE PIECES ARE WORKING TOGETHER. SO WE'VE TAKEN AN INITIATIVE-BASED AGENCY THAT WAS LESS PREDICTABLE, BUT HIGHLY RESPONSIVE, AND WE'RE NOW TURNING IT INTO A SYSTEMS-BASED AGENCY. AND THE THING THAT'S ENABLED US TO MAKE THIS SWITCH TO A SYSTEMS-BASED AGENCY IS THE DEMAND THAT WE NOW HAVE FOR THESE KINDS OF TECHNOLOGIES.

SO THE FIRST PART OF CIRM WAS VERY SUCCESSFUL CREATING THE DEMAND. NOW OUR JOB AT CIRM IS HOW DO WE TAKE THIS DEMAND AND ASSEMBLE THESE PARTS INTO A MACHINE WHERE EVERY SINGLE THING WE HAVE, EVERY SINGLE INITIATIVE WE HAVE AT CIRM IS NOW ASSEMBLED INTO THIS GIANT ENGINE THAT WILL ACCELERATE THINGS FROM THE EARLIEST STAGES OF RESEARCH ALL THE WAY THROUGH GETTING THESE THERAPIES TO THE PATIENTS THAT DESPERATELY NEED THEM AS QUICKLY AS POSSIBLE AND IN A WAY THAT EXISTS NOWHERE ELSE IN THE WORLD.

SO THIS IS WHAT WE'RE DOING SORT OF IN A

BIG PICTURE. WE ARE CREATING A GIANT, COORDINATED, INTEGRATED STEM CELL MACHINE AT CIRM. AND I THINK THIS IS A VERY, VERY EXCITING OPPORTUNITY THAT WE HAVE TO DO THIS. WE'VE SEEN THIS ALREADY WITH THE CLINICAL PROGRAM WHICH LAUNCHED IN JANUARY WITH THE DISCOVERY AND TRANSLATIONAL PROGRAMS. ALL OF THOSE PIECES LINE UP AND CONNECT AND LINK TO ONE ANOTHER, NOT AS SEPARATE PARTS, BUT AS AN INTEGRATED MACHINE.

OTHER THINGS THAT WE'VE LEARNED HERE, MOVING ALONG. WE HAVE VARIOUS STAKEHOLDER MEETINGS. AS I SAID, WE HAD ONE IN THE VERY ROOM THAT I'M IN TODAY, AND ONE OF THE THINGS THAT I HEARD IN THIS SPECIFIC ROOM, I THOUGHT IT WAS VERY INSIGHTFUL. I WENT UP TO KEVIN AFTER, I SAID, "WE'VE GOT TO PUT THAT IN THE PLAN." AND IT WAS SIMPLY A QUESTION THAT WAS ASKED FROM ONE OF THE PATIENTS HERE, AND THAT QUESTION WAS THIS ALL SOUNDS GREAT, BUT WHAT CAN WE DO? WE'RE HERE AND WE WANT TO HELP. WHAT CAN WE DO? WE THOUGHT ABOUT THAT, AND THAT'S A REALLY IMPORTANT PART. SO IT'S VERY CLEAR THAT OUR PATIENTS AND OUR PATIENT ADVOCATES DON'T WANT TO BE SPECTATORS IN THIS. THEY WANT TO BE ACTIVE PARTICIPANTS, AND WE'VE GOT TO DO THAT, AND WE HAVE A PLAN FOR THAT.

WE ALSO TALKED TO OBVIOUSLY INVESTIGATORS

FROM VARIOUS INSTITUTIONS, ALL THE INSTITUTIONS. AND ONE OF THE THINGS THAT WE FOUND WAS THAT THEY DON'T LIKE DOING BORING TRANSLATIONAL RESEARCH. THEY LIKE DOING THE FUN AND EXCITING TRANSLATIONAL RESEARCH. SO THINGS LIKE DOING MECHANISM OF ACTION STUDIES AND ACTUALLY SHOWING THAT THEIR CELL THERAPIES MAKE A DIFFERENCE. WE DIDN'T FIND A SINGLE INVESTIGATOR THAT REALLY WANTED TO DO A STABILITY STUDY OR A PRECLINICAL TOX STUDY WHOSE ONLY PURPOSE WAS TO SATISFY THE FOOD AND DRUG ADMINISTRATION. AND SO WE NEED TO WORK ON WAYS OF HELPING THEM OUT THERE.

EVERY SINGLE ACADEMIC INSTITUTION THAT WE TALKED TO, WITHOUT EXCEPTION, REQUESTED HELP IN LINKING RESEARCHERS TOGETHER AT VARIOUS STAGES. SO A DISCOVERY STAGE RESEARCHER THAT HAS AN INTEREST IN TECHNOLOGY THAT WANTS TO MOVE IT INTO TRANSLATION WANTS HELP IDENTIFYING GOOD TRANSLATIONAL RESEARCHERS, TRANSLATIONAL TO CLINIC, AND ALL OF THESE TO INDUSTRY. AND SO WE NEED TO WORK ON THAT.

AND THEN LASTLY, CIRM NEEDS TO BE A BIGGER DEAL TO PEOPLE OUTSIDE OF THE OTHERWISE CIRM COMMUNITY. CIRM IS STILL UNDERAPPRECIATED AND UNDERREPRESENTED IN THE GENERAL FIELD OF REGENERATIVE MEDICINE, AND THAT'S SOMETHING WE NEED

TO FIX. WE NEED TO DRAMATICALLY INCREASE AWARENESS FOR THIS AGENCY AND WHAT THIS AGENCY IS GOING TO BE DOING.

WE DID SURVEYS. WE DID SURVEYS OF THE BOARD, AND WE DID SURVEYS OF THE GENERAL PUBLIC. AND THERE WERE SOME INTERESTING FINDINGS. WE HAD A TOTAL OF 217 RESPONSES FROM THE GENERAL PUBLIC, AND THERE WERE SOME INTERESTING FINDINGS. FIRST IS RISK TOLERANCE AMONG ALL STAKEHOLDER GROUPS IS HIGH. SO 64 PERCENT RESPONDED WITH A FOUR OR FIVE WITH A FIVE BEING THE MOST -- THE LEAST RISK AVERSE.

ONCE OF THE QUESTIONS WE ASKED WAS WHAT IS SORT OF THE SINGLE MOST IMPORTANT THING THAT CIRM COULD DO AS A METRIC OF SUCCESS. AND THIS ONE WAS ALSO, I THINK, VERY INSIGHTFUL. THAT IS, DEMONSTRATING PROOF OF CONCEPT IN HUMANS, 70 PERCENT OF RESPONDENTS SAID THAT WOULD BE THE SINGLE MOST IMPORTANT THING CIRM CAN DO. IT WAS VERY INSIGHTFUL, AND WE ACTUALLY NEED TO LISTEN TO THIS AND FIGURE OUT HOW WE CAN MAKE THE AGENCY MORE RESPONSIVE TO THAT.

SIXTY-TWO PERCENT OF RESPONDENTS SAID CIRM SHOULD ONLY FUND PROJECTS WHERE OUR INVOLVEMENT IN THEM IS AN ACCELERATING ACTIVITY. I ACTUALLY AM VERY GLAD TO HEAR THAT THIS WAS AN OVERWHELMING

RESPONSE BECAUSE CIRM SHOULD BE AN ACCELERATING AGENCY. OUR MISSION IS TO ACCELERATE STEM CELL THERAPIES TO PATIENTS WITH UNMET MEDICAL NEEDS. SO IF OUR FUNDING ISN'T ACCELERATING SOMETHING, WE'VE KIND OF LOST OUR WAY THERE.

AND THEN LASTLY, AND THIS ONE REALLY JUMPED OFF THE PAGE, 70 PERCENT OF RESPONDENTS IDENTIFIED THE FOOD AND DRUG ADMINISTRATION AS THE SINGLE BIGGEST IMPEDIMENT TO DEVELOPING A STEM CELL THERAPY TODAY. AND SO THAT'S A MESSAGE THAT WE ALSO HEARD FROM PEOPLE THAT DIDN'T PARTICIPATE IN THE SURVEY AS WELL, AND SO WE NEED TO LOOK AT HOW WE CAN HELP THAT.

SO SORT OF IN SUMMARY ON THE WHERE WE ARE TODAY PIECE OF THIS, HISTORICALLY CIRM EXISTED AS AN INITIATIVE-BASED AGENCY. WE ARE BECOMING A SYSTEM-BASED AGENCY. IT WILL TAKE A LITTLE WHILE TO ASSEMBLE AND FULLY START THAT ENGINE, BUT I THINK ONCE THAT ENGINE GETS STARTED, IT'S GOING TO PAY A VERY BIG DIVIDEND.

SECONDLY, WITH VERY FEW EXCEPTIONS, AND THERE ARE SOME, MOST OF OUR PRIORITIES ARE ALIGNED AMONGST OUR STAKEHOLDERS, WHICH WAS NICE TO SEE.

I THINK THE TRANSLATIONAL STAGE OF DEVELOPMENT REPRESENTS ENORMOUS OPPORTUNITY FOR US

TO SPEED THINGS UP. SO THE AVERAGE TIME IN TRANSLATIONAL RESEARCH FOR A SMALL MOLECULE THAT GETS APPROVED IS 3.2 YEARS. THE AVERAGE TIME A CELL THERAPY SPENDS -- A STEM CELL THERAPY SPENDS IN TRANSLATION IS EIGHT YEARS FOR THE SAME ACTIVITIES. WE HAVE GOT TO GET THAT EIGHT-YEAR PERIOD DOWN TO THREE YEARS SO WE CAN START GETTING THESE THINGS EVALUATED MORE QUICKLY IN PATIENTS.

IT IS CLEAR THAT STEM CELL THERAPIES CONTINUE TO BE A DISADVANTAGED CLASS OVER OTHER KINDS OF MEDICINES. THAT'S BOTH FROM A REGULATORY STANDPOINT AND FROM A COMMERCIAL STANDPOINT.

AND THEN LASTLY, THE REGULATORY ENVIRONMENT IS CLEARLY SEEN AS AN IMPEDIMENT TO DEVELOPING THESE THERAPIES.

SO LET'S GET INTO -- NOW THAT WE KNOW WHERE WE ARE, LET'S GET INTO WHERE WE'RE GOING AND HOW WE'RE GOING TO GET THERE AS PART OF THE PLAN. SO THERE'S A STATUS BAR SO YOU GUYS WILL KNOW WHERE WE ARE AND, MORE IMPORTANTLY, HOW CLOSE WE ARE TO THE END. YOU WILL BE ABLE TO SEE THIS STATUS BAR MOVE ACROSS THE SCREEN ON THE BOTTOM.

SO THE FIRST THING WE HAD TO DO WAS WE HAD TO EVALUATE OUR MISSION AND CONFIRM OUR MISSION. SO 96 PERCENT OF RESPONDENTS, OF STAKEHOLDERS AGREED

THAT OUR MISSION WAS PROPERLY STATED AS TO ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. FURTHERMORE, 100 PERCENT OF OUR BOARD RESPONDING TO THIS QUESTION ALSO ANSWERED THAT THIS WAS OUR MISSION. SO HAVING A GOOD, CONCISE, CRISP MISSION IS A GREAT PLACE FOR US TO START BECAUSE WE WILL ALWAYS ORIENT TOWARDS THAT. ALMOST EVERYTHING ELSE IS UP FOR DEBATE OR DISCUSSION ABOUT HOW WE'RE GOING TO GET THERE, BUT OUR MISSION CAN'T BE. THIS HAS TO BE OUR GUIDING STAR, THE THING THAT DOESN'T MOVE, THAT WE NEVER EVER, EVER STOP MOVING TOWARDS. SO THE FACT THAT WE HAVE THIS KIND OF CONSENSUS, AND I WOULD JUST SAY AT 96 PERCENT, THIS ISN'T CONSENSUS, THIS IS CONVICTION. THIS IS WHAT CONVICTION LOOKS LIKE AROUND THIS MISSION. NOW WE KNOW EXACTLY WHERE WE WANT TO GO.

SO HOW ARE WE GOING TO DO THAT? WHAT ARE WE GOING TO DO? WELL, IT CENTERS AROUND CREATING THIS GIANT ENGINE THAT I TALKED ABOUT. BUT CLEARLY IF WE LISTEN TO OUR STAKEHOLDERS, THERE'S MORE TO THAT THAN JUST BUILDING THIS ENGINE. SO THE IDEA HERE IS WE'RE GOING TO EXPONENTIALLY -- AND THESE WORDS ARE USED INTENTIONALLY, MEANING WE'RE NOT GOING TO LINEARLY CLIMB OUT -- WE ARE GOING TO

EXPONENTIALLY CLIMB OUT, ADVANCE CIRM'S MISSION BY LEADING A COORDINATED CAMPAIGN THAT HOLISTICALLY ATTACKS THE OBSTACLES, MEANINGFULLY AFFECTING THE SPEED, PROBABILITY, AND SUSTAINABILITY OF STEM CELL TREATMENTS TO HELP PATIENTS IN NEED. SO IT OVERLAYS NICELY WITH OUR MISSION.

OBVIOUSLY THERE'S A LOT OF OUR MISSION IN THERE. BUT THERE ARE SOME KEY THINGS IN HERE. ONE IS LEAD. I'VE GONE OUT AND I'VE TALKED WITH A LOT OF PEOPLE, A LOT OF OTHER REGENERATIVE MEDICINE INSTITUTES IN OTHER STATES AND OTHER COUNTRIES, AND THEY ALL LOOK TO US. AND THEY SAY CIRM SHOULD BE LEADING MORE. WE ARE BY FAR THE LARGEST REGENERATIVE MEDICINE INSTITUTE IN THE WORLD. IT'S TIME THAT WE START LEADING LIKE WE WERE; AND BY THE WAY, EVERYONE WANTS US TO. SO WE'RE GOING TO GET INTO THE LEADERSHIP BUSINESS A LITTLE BIT MORE.

THIS COORDINATED CAMPAIGN, THAT MEANS MAKING ALL OF OUR PIECES NOT JUST FIT TOGETHER, BUT WORK TOGETHER AND PULL IN THE SAME DIRECTION. HOLISTICALLY ATTACKS ALL THE OBSTACLES. EVERYTHING THAT'S IN OUR WAY, THAT IS IN THE WAY OF A STEM CELL THERAPY REACHING A PATIENT, IS GOING TO BE FAIR GAME FOR CIRM TO GO AFTER. AND THEN OBVIOUSLY THE WHOLE THING IS ABOUT GETTING THESE TREATMENTS TO HELP

PATIENTS IN NEED.

SO I'M GOING TO USE ANOTHER ANALOGY HERE. I OBVIOUSLY USE A LOT OF ANALOGIES, BUT I LIKE TO DO THEM BECAUSE I THINK THEY CAN MAKE SORT OF SOMETIMES WHAT WOULD SEEM LIKE COMPLEX THOUGHTS MORE CLEAR AND MORE EASILY UNDERSTANDABLE. AND SO HERE WE HAVE THE WAY CIRM HAS EXISTED. AND THAT IS WE'RE GOING TO USE THE ANALOGY OF CIRM IS TRYING TO PUSH A GIANT BOULDER OVER A HILL, AND THAT GIANT BOULDER REPRESENTS STEM CELL TREATMENTS. AND ON THE OTHER SIDE IS THE VALLEY OF HAPPINESS IS OUR PATIENTS WHO DESPERATELY NEED THIS BOULDER TO BE EFFECTIVELY MOVED OVER THIS HILL AND DELIVERED TO THEM. I DON'T KNOW WHY WE WOULD WANT A BOULDER DELIVERED TO YOU, BUT JUST GO WITH THE ANALOGY FOR A SECOND.

AND WHAT CIRM HAS BEEN DOING IN THE PAST IS A VERY HONORABLE JOB OF PUSHING THIS BOULDER. AND THERE'S A LOT RIGHT ABOUT PUSHING THIS BOULDER OVER THE HILL. SO THE FIRST THING WE'RE GOING TO DO IS, FIRST, WE HAVE THESE STRATEGIC THEMES WITH SPECIFIC ACTIONS. THE FIRST THING WE'RE GOING TO DO IS WE'RE GOING TO PUSH HARDER AND BETTER. WE'RE GOING TO TAKE ALL OF OUR PROGRAMS AND WE'RE GOING TO LINE THEM UP, AND WE ARE GOING TO COORDINATE THEM ALL, AND WE ARE GOING TO GET GOOD AT THEM. WE'RE

GOING TO GET GREAT AT THEM. THAT IS, WE'RE GOING TO FULLY OPERATIONALIZE CIRM 2.0, CLINICAL, TRANSLATIONAL, AND DISCOVERY, ALL WORKING TOGETHER IN A COORDINATED FASHION. WE ARE GOING TO OPEN TRANSLATIONAL AND ACCELERATING CENTERS THAT WORK TOGETHER, THAT TAKE THAT EIGHT-YEAR DEVELOPMENT TIME AND SQUEEZE IT DOWN AND AT LEAST CUT IT IN HALF, AND WE'RE GOING TO FOCUS OUR PROGRAMS. AND SO WE'RE GOING TO BE LOOKING AT THINGS WHERE CIRM SHOULD BE FUNDING, THE SWEET SPOT FOR CIRM.

DEMONSTRATING PROOF OF CONCEPT IN HUMAN CLINICAL TRIALS, MEANING WE HAVE TO LOOK AT THE KINDS OF ENDPOINTS WE'RE HAVING IN OUR HUMAN CLINICAL TRIALS, AND WE NEED TO LOOK AT THE TYPES OF HUMAN CLINICAL TRIALS THAT WE ARE PARTNERING WITH.

SO THE FIRST PART OF THE STRATEGY IS PUSH, BUT NOT PUSH AS AN INDIVIDUAL OR AS AN INITIATIVE, BUT PUSH AS A GIANT, COORDINATED MACHINE THAT CAN REALLY GET THAT BOULDER MOVING.

SECOND PART OF OUR STRATEGY IS IF YOU LOOK, THERE IS NOTHING ON THE OTHER SIDE OF THAT HILL HELPING US HERE. AND THAT JUST IS FLAT OUT THERE IS NOT ENOUGH DOWNSTREAM DEMAND THAT'S CURRENTLY ENGAGED IN THE WORK THAT WE'RE TRYING TO DO. IF I HAD TODAY A SMALL MOLECULE AND A STEM CELL

THERAPY THAT HAD EXACTLY THE SAME AMOUNT OF DATA, THAT WERE AT EXACTLY THE SAME STAGE OF DEVELOPMENT, INDUSTRY WOULD PARTNER THAT SMALL MOLECULE AT 50 TO 1 OVER THE STEM CELL THERAPY. WE NEED THEM INVOLVED, BUT WE ALSO NEED OTHER PIECES INVOLVED.

IT WAS REALLY TELLING TO HEAR THAT A RESEARCHER THAT ENGAGED IN BASIC OR DISCOVERY RESEARCH DIDN'T KNOW HOW TO GET AHOLD OF AND IN CONTACT WITH A TRANSLATIONAL RESEARCHER THAT COULD HELP TAKE THAT PROGRAM FORWARD. SO WE'RE GOING TO BE LAUNCHING SOMETHING CALLED A CIRM EXCHANGE. INTERNALLY WE KIND OF JUMP AROUND. IT'S LIKE THE MATCH.COM. IT'S HOW DO WE HAVE PEOPLE DOWNSTREAM THAT ARE INTERESTED IN THIS KIND OF WORK PULL FORWARD THE GREAT WORK FROM EARLIER STAGE RESEARCHERS THAT HAVE BEEN FUNDED BY CIRM?

WE'RE ALSO GOING TO BE LOOKING -- SO CIRM HAS LIKE 300 DIFFERENT PROGRAMS. THE VAST MAJORITY OF THOSE HAVE NO PARTNERSHIP. SO WE'VE HAD A TEAM AT CIRM THAT'S GONE AROUND TALKING TO TECH TRANSFER OFFICES AT ALL OF THE DIFFERENT MAJOR UNIVERSITIES, AND THEY ARE DESPERATE FOR HELP. HOW CAN YOU HELP GET OUR STEM CELL PROGRAMS PARTNERED UP WITH INDUSTRY? WELL, ONE OF THE THINGS WE CAN DO IS WE CAN TAKE A MORE AFFIRMATIVE ROLE IN THIS AND SAY WE

HAVE A HUGE NUMBER OF THESE PROGRAMS. CAN WE AGGREGATE LIKE PROGRAMS TOGETHER? AND I DON'T EXACTLY KNOW WHAT LIKE WOULD BE. IT WOULD BE SORT OF DEPENDENT ON THE PERSON INTERESTED IN DOING IT. BUT LET'S SAY ALL THE CARDIAC PROGRAMS OR ALL THE OCULAR PROGRAMS OR ALL THE ORPHAN PROGRAMS AND CAN WE BUNDLE ALL OF THESE THINGS UP THAT HAVE SYNERGISTIC OPPORTUNITIES INTO A PACKAGE AND GET THAT PACKAGE LAUNCHED AS A COMPANY IN THE STATE OF CALIFORNIA THAT WILL ALSO BE PULLING THESE TECHNOLOGIES FORWARD AND CREATING JOBS AND COMMERCIALIZING LIFE-SAVING THERAPY.

SO BOTTOM LINE IS WE ARE NOT GOING TO BE ALONE IN THE PUSHING BUSINESS. WE ARE GOING TO AFFIRMATIVELY GET OTHER RESOURCES INVOLVED TO HELP PULL SO WE CAN MOVE THIS BOULDER AS QUICKLY AS WE CAN FROM LEFT TO RIGHT.

AND THE LAST SIDE OF THIS COMES DOWN TO THAT HILL IS JUST TOO DAMN BIG RIGHT NOW. AND A LOT OF THAT HILL CENTERS AROUND THE REGULATION THAT IT TAKES. IT SHOULDN'T TAKE EIGHT YEARS FOR A STEM CELL THERAPY TO BE ABLE TO GO FROM CONCEPT TO IND, AND THERE SHOULDN'T BE THE BARRIERS THAT THERE ARE AGAINST DEVELOPING TREATMENTS FOR ORPHAN CONDITIONS THAT CURRENTLY EXIST TODAY.

SO WHAT WE'RE GOING TO DO IS WE'RE GOING TO ORGANIZE AN ARMY OF STAKEHOLDERS, PATIENTS. THE ACADEMIC COMMUNITY HAS SPOKEN LOUDLY ABOUT THIS. THE OTHER REGENERATIVE MEDICINE INSTITUTES HAVE SPOKEN LOUDLY ABOUT THIS. AND WE'RE GOING TO, AND I MEAN THIS, WE'RE GOING TO WORK WITH THE FDA TO FIGURE OUT WHATEVER COVER OR WHATEVER HELP THEY NEED IN ORDER TO COME UP WITH A REGULATORY PARADIGM THAT IS UNIQUE AND SPECIFIC AND, MOST IMPORTANTLY, RESPONSIVE TO CELL THERAPY SO WE CAN LEVEL THIS PLAYING FIELD SO IT'S NOT THIS 50 TO 1 SMALL MOLECULE VERSUS CELL THERAPY, BUT THAT THESE THERAPIES ARE GIVEN THE OPPORTUNITY THEY NEED IN ORDER TO ADVANCE.

SO THE LAST PART OF THE STRATEGY IS LEVEL. LEVEL THIS PLAYING FIELD A LITTLE BIT MORE SO THIS BOULDER CAN PROGRESS FROM WHERE IT IS TODAY TO THE PATIENTS THAT NEED IT. AND SO THAT'S WHAT WE MEAN BY THIS HOLISTIC APPROACH. THAT'S WHAT WE MEAN WHEN WE SAY WE'RE GOING TO ATTACK EVERY OBSTACLE THAT IS IN OUR WAY. ANYTHING WE CAN THINK TO DO IN ORDER TO MAKE PROGRESS WE'RE GOING TO GO AFTER IT AT CIRM, AND WE'RE GOING TO DO IT WITH A TREMENDOUS AMOUNT OF URGENCY BECAUSE WE DON'T HAVE A LOT OF TIME LEFT.

SO THE STRATEGY IS VERY SIMPLE. WHEN YOU

LOOK AT IT THIS WAY, IT IS PUSH, PULL, AND LEVEL, AND IT IS ALL FOR PROGRESSING THESE STEM CELL THERAPIES FORWARD IN A COORDINATED WAY.

THE QUESTION YOU MIGHT HAVE IS CAN WE AFFORD THAT? YES. WE HAVE ABOUT A BILLION DOLLARS IN ROUND NUMBERS TO DEPLOY. AND I SAY A BILLION BECAUSE IF YOU DO THE MATH ON HAVING AWARDS WE CAN MAKE OUT, WE CAN DO ABOUT 890, ALMOST 900 MILLION. WE ALSO HAVE ALL ADMINISTRATIVE WORK WHICH IS INVOLVED IN PUSHING THIS BOULDER, ALL THE ADMINISTRATIVE FUNDS. BUT THE BOTTOM LINE IS WHEN YOU COST THESE PROGRAMS OUT OVER TIME, THEY'RE DOABLE. THEY FIT WITH THIS BUDGET. SO IT'S GOING TO REQUIRE, OBVIOUSLY, A LOT OF EFFORT AND A LOT OF COORDINATION, BUT THIS IS A PROGRAM THAT FINANCIALLY WE'RE ABLE TO DO AND WE'RE ABLE TO GET DONE AND SO WE WILL.

THE NEXT THING WE HAVE TO LOOK AT IS WHAT ARE WE GOING TO GET FOR THAT. SHOULDN'T SAY FINANCIAL OUTLOOK ON THERE. SO THIS IS THE INTENDED OUTCOMES FOR THIS EFFORT. WE ARE GOING TO HAVE 50 NEW CLINICAL TRIALS STARTED. SO WE HAVE 15. IN THE FIRST 11 YEARS WE HAD 15 CLINICAL TRIALS STARTED. OVER THE NEXT FIVE YEARS, WE'RE GOING TO HAVE 50 NEW CLINICAL TRIALS THAT GET STARTED THAT COVER AT LEAST

20 UNIQUE DISEASES. WE WILL HAVE INDICATIONS FOR CHILDREN, AT LEAST FIVE PEDIATRIC, AT LEAST 10 OR 15 INDICATIONS. WE'RE GOING TO INCREASE PROGRESSION OF THAT. THIS IS A VERY IMPORTANT THING THAT'S UNIQUE TO CIRM, BUT A PROGRESSION EVENT FOR US IS SOMETHING FOR MOVING DISCOVERY TO TRANSLATION, OR TRANSLATION TO CLINICAL, CLINICAL TO COMMERCIAL. THAT WOULD BE A GREAT PROGRESSION EVENT. THOSE ARE PROGRESSION EVENTS. WE'RE GOING TO INCREASE PROGRESSION EVENTS SO THAT ACROSS THE BOARD AT LEAST ONE OUT OF OUR THREE PROGRAMS MOVES FORWARD. RIGHT NOW THAT NUMBER SITS AT AROUND 7 PERCENT. SO BY LINKING THESE THINGS TOGETHER, WE THINK WE'RE GOING TO HAVE A DRAMATIC UPTAKE IN HOW FAST AND HOW EFFICIENTLY THESE PROGRAMS MOVE FROM LEFT TO RIGHT.

AS I TALKED ABOUT BEFORE, AN EIGHT-YEAR PRECLINICAL TIME IS WAY TOO LONG. WE'RE GOING TO CUT IT BY AT LEAST IN HALF SO WE CAN GET TREATMENTS INTO PATIENTS MORE QUICKLY. WE'RE GOING TO WORK WITH THE FDA TO COME UP WITH A SYSTEM THAT MAKES SENSE. LAST WEEK I WAS IN JAPAN. I MET WITH THE HEAD OF THE CENTER FOR BIOLOGICS IN JAPAN. JUST TO GIVE YOU AN IDEA OF THIS STUFF IS POSSIBLE, JAPAN ENACTED THIS LAST YEAR. THEY DIDN'T START THINKING ABOUT IT LAST YEAR. THEY ENACTED IT LAST YEAR.

IT'S ACTUALLY BEEN UP AND RUNNING FOR ABOUT A FULL YEAR. LAST WEEK THEY APPROVED THEIR FIRST STEM CELL THERAPY IN THAT COUNTRY'S HISTORY. SO THIS IS POSSIBLE. IT WORKS. OTHER COUNTRIES AROUND THE WORLD ARE DOING IT. UNITED STATES FDA ALSO NEEDS TO DO IT, AND WE NEED TO EXIST AS AN AGENCY THAT CAN HELP THEM GET THAT DONE HOWEVER THAT IS.

AND THEN LASTLY, WE'VE GOT TO, AS PART OF THIS PULL, WE'VE GOT TO MAKE SURE THAT OUR UNPARTNERED PRODUCTS GET PARTNERED. SO WE WANT TO HAVE AT LEAST A HALF OF EVERYTHING THAT COMES INTO OUR CLINICAL PROGRAM UNPARTNERED BE PARTNERED BY THE TIME THAT IT LEAVES CIRM.

SO THESE ARE THE SPECIFIC OUTCOMES THAT WE'RE LOOKING TO DO. I'M NOT GETTING INTO PROGRESS MILESTONES, WHICH ARE BETWEEN WHERE WE ARE NOW AND THIS, BECAUSE IT WOULD TAKE TOO LONG AND THERE ARE TOO MANY OF THEM. THERE ARE PROGRESS MILESTONES, BUT THESE ARE THE INTENDED OUTCOMES THAT WE'RE LOOKING TO HAVE.

NOW, GETTING CLOSE TO FINISHING, MERCIFULLY, BUT IT IS IMPORTANT TO KNOW THIS IS NOT AN EASY-TO-ACHIEVE PLAN. THIS IS REALLY HARD. IF WE DO THIS, WE WILL HAVE SUCCESSFULLY CHANGED REGENERATIVE MEDICINE, NOT JUST IN CALIFORNIA, NOT

JUST IN THE UNITED STATES, BUT IN THE WORLD. AND THAT'S WHAT I WANT. I WANT A PROGRAM THAT IS REALLY HARD, BUT REALLY IMPACTFUL IF WE'RE SUCCESSFUL. THE DOWNSIDE OF THAT IS THERE ARE VERY REAL RISKS ASSOCIATED WITH THIS PLAN. YOU NEED TO KNOW THAT BECAUSE WE CAN'T BE THE AGENCY THAT OVERHYPES. WE'RE GOING TO TRY TO DO SOMETHING MONUMENTAL, AND OUR EYES ARE WIDE OPEN THAT THERE ARE VERY REAL OBSTACLES THAT STAND BETWEEN US AND SUCCESS. SO LET'S GO OVER WHAT SOME OF THESE ARE.

FIRST, WE MIGHT NOT HAVE A SUFFICIENT NUMBER OF GOOD PROJECTS, MERITORIOUS, SCIENTIFICALLY MERITORIOUS PROJECTS IN ORDER FOR US TO REACH OUR GOALS. WE ARE SETTING UP THIS ENGINE THAT CAN HANDLE MOVING 50 CLINICAL TRIALS -- INITIATING 50 CLINICAL TRIALS OVER THE NEXT FIVE YEARS, THE 250 NEW DISCOVERY PROGRAMS. WE HAVE AN ENGINE THAT CAN HANDLE THIS. WHAT WE'RE GOING TO NEED TO MAKE SURE IS WE HAVE SUFFICIENT NUMBER OF QUALITY PROJECTS TO GO THROUGH THIS. AND THAT'S A RISK.

WE MAY NOT HAVE SUFFICIENT INTEREST FOR QUALIFIED APPLICANTS FOR SOME OF OUR KEY COMPONENTS. WE TALKED ABOUT BEING AN ACCELERATING CENTER, WHICH IS A REALLY HIGH-END CRO SPECIFICALLY DESIGNED FOR CALIFORNIA STEM CELL PROJECTS AND A TRANSLATING

CENTER NECESSARY TO DO THE TRANSLATING WORK, THE COMMERCIALIZATION ENTITIES TO PARTNER UP OUR UNPARTNERED PROGRAMS. THERE MAY NOT BE SUFFICIENT INTEREST EXTERNALLY. WE HAVE TO BE AWARE OF THAT. WE HAVE TO TRY TO FIGURE OUT HOW WE CAN GET THAT INTEREST.

THIS IS A REAL CONCERN WE HAVE INTERNALLY AT CIRM. WE HAVE A LIMITED LIFE SPAN AHEAD OF US AS AN AGENCY. WE ARE OBVIOUSLY RUNNING OUT OF MONEY. AT THE END OF THIS PROGRAM, CIRM WILL BE OUT OF MONEY, AND WE HAVE TO WORRY INTERNALLY ABOUT THE ABILITY TO ATTRACT AND RETAIN THE OUTSTANDING TEAM THAT WE CURRENTLY HAVE AT CIRM. AND I CANNOT SAY ENOUGH GREAT THINGS ABOUT THE GROUP OF PROFESSIONALS WE HAVE RIGHT NOW INSIDE THE AGENCY ALL PULLING IN THE SAME DIRECTION AND REALLY JUST DOING A PHENOMENAL JOB. AND I WORRY ABOUT THEM AND I WORRY ABOUT HOW WE'RE GOING TO KEEP THAT TEAM TOGETHER MOVING FORWARD. IT'S A REAL RISK.

WE MAY NOT BE ABLE TO ATTRACT SUFFICIENT INVESTORS TO COME AND HELP LAUNCH SOME OF THESE THINGS. AND AT THE END OF THE DAY, WE MIGHT GO AND TRY TO PUSH THE MOUNTAIN, THAT'S THE FDA, AND THAT MOUNTAIN MAY NOT MOVE. NOW, WE'RE GOING TO WORK REALLY HARD ON THAT, BUT IT MAY NOT HAPPEN. AND SO

WE JUST NEED TO BE AWARE OF THESE RISKS AND WORK REALLY HARD TO MITIGATE AND WORK AROUND THEM.

SO I WILL STOP NOW AND TAKE QUESTIONS, BUT LEAVE YOU WITH THIS CONCEPT THAT WE NOW HAVE THIS INTEGRATED APPROACH AT CIRM. WE'RE BECOMING NOT JUST CIRM 2.0, BUT WE'RE REALLY TRYING TO PUSH CIRM 2.0 BEYOND THAT TO WHERE WE ATTACK ALL OF THE OBSTACLES THAT STAND IN OUR WAY, AND WE'RE GOING TO PUSH THAT BOULDER UP THAT HILL, WE ARE GOING TO ENGAGE INDUSTRY AND OTHER KEY STAKEHOLDERS THAT ARE DOWNSTREAM TO GET INTO THE GAME AND START PULLING, AND WE'RE GOING WORK WITH THE FDA TO LEVEL THE PLAYING FIELD ON THIS. SO PUSH, PULL, LEVEL IS A SIMPLISTIC WAY OF TALKING ABOUT OUR STRATEGIC PLAN GOING FORWARD.

IF YOU HAVE ANY COMMENTS OR QUESTIONS ABOUT THIS, DO NOT CALL ME, CALL KEVIN. NO, I'M JOKING. YOU CAN CALL ME TOO. BUT HERE'S KEVIN'S CONTACT INFORMATION. AND, J.T., I AM SORRY FOR RAMBLING ON, AND I TURN IT BACK TO YOU, SIR.

CHAIRMAN THOMAS: THANK YOU, DR. MILLS. AS YOU CAN TELL, EVERYBODY ON THE PHONE, RANDY AND TEAM AND ALL OF US HAVE PUT AN ENORMOUS AMOUNT OF WORK INTO DEVELOPING THIS STRATEGIC PLAN GOING FORWARD. AND I WOULD VERY MUCH LIKE TO CONGRATULATE

ALL MEMBERS OF THE TEAM FOR A TERRIFIC EFFORT AND WOULD JUST SAY I THINK RESULTED IN A HIGHLY SUBSTANTIVE AND VERY EXCITING PLAN.

ARE THERE COMMENTS BY MEMBERS OF THE BOARD ON DR. MILLS' PRESENTATION?

DR. JUELSGAARD: I HAVE A QUESTION. SO, RANDY, SLIDE 27, WHICH IS TERMED "FINANCIAL OUTLOOK," BUT WHICH HAS A LIST OF INTENDED OUTCOMES, RESEMBLES A FIVE-YEAR LONG-RANGE PLAN IN MY EXPERIENCE. AND WHAT'S NEEDED, THEN, IS A SERIES OF GOALS YEAR BY YEAR THAT ARE AIMED AT ACHIEVING THAT FIVE-YEAR PLAN. AND YOU TALKED ABOUT MILESTONES BEFORE, SO I ASSUME THE NEXT TIME WE TALK ABOUT THIS THAT YOU'RE GOING TO HAVE SOME CLOSER-IN GOALS THAT ARE IN LINE WITH THESE INTENDED OUTCOMES THAT TAKE US THROUGH HOW WE'RE GOING TO GET THERE ON A YEAR-BY-YEAR BASIS.

DR. MILLS: YEAH. THAT'S CORRECT, STEVE. THAT WAS A COMMENT THAT I MADE WHEN ON THAT SLIDE IS I HAD SPECIFIC ACTIONS AND WE HAD INTENDED OUTCOMES, AND OBVIOUSLY PROGRESS MILESTONES ARE A VERY IMPORTANT PART OF THE STRATEGIC PLAN AND MAKING SURE THAT WE STAY ON TRACK TO ACHIEVING THESE GOALS. FOR BREVITY, OBVIOUSLY WE COULDN'T PUT EVERYTHING INTO THIS PLAN, BUT THE ACTUAL WRITTEN DOCUMENT WILL

CONTAIN THE SPECIFIC PROGRESS MILESTONES FOR THE SPECIFIC ACTIONS THAT WILL, IF ACHIEVED, GIVE US A HIGH LIKELIHOOD OR HIGH CONFIDENCE THAT THE OUTCOMES THAT I DID LIST IN THIS PLAN WILL BE ACHIEVED.

DR. JUELSGAARD: PERFECT. THAT'S GREAT. THANK YOU.

CHAIRMAN THOMAS: OTHER COMMENTS FROM MEMBERS OF THE BOARD?

MR. ROWLETT: I HAVE A QUESTION, CHAIRMAN THOMAS.

CHAIRMAN THOMAS: YES, MR. ROWLETT.

MR. ROWLETT: THERE'S A BULLET THAT SAYS PATIENT ADVOCATES WANT A MORE ACTIVE ROLE, AND I WON'T READ THE REST OF IT. AND CERTAINLY THAT RESONATES WITH ME, AND I'M LOOKING FORWARD TO, RANDY, HAVING YOU ENGAGE THE PATIENT ADVOCATES CERTAINLY IN A MORE ROBUST WAY.

AND ALSO TO COMMENT THAT AS A MEMBER OF THE GRANTS WORKING GROUP, BEING GIVEN THE OPPORTUNITY TO ENGAGE IN THE EVALUATION PROVIDED MY UNDERSTANDING OF ALL THE SCIENCE, I'M NOT A SCIENTIST, BUT CERTAINLY I'M AN ADVOCATE FOR PATIENTS AND MAKING SURE THAT WE REPRESENT A DIVERSITY OF CALIFORNIA AS WE COME UP WITH REMEDIES FOR DISEASES THAT AFFECT ALL OF OUR CONSTITUENTS.

IN SHORT, THAT'S PART OF THE ROLE OF A PATIENT ADVOCATE FROM MY PERSPECTIVE. AND SO MORE OF THAT KIND OF ENGAGEMENT IS INVIGORATING FOR ME. THE FIRST BULLET THERE MEANS A LOT TO ME.

CHAIRMAN THOMAS: THANK YOU, MR. ROWLETT. OTHER COMMENTS FROM MEMBERS OF THE BOARD?

MR. SHEEHY: IF I CAN MAKE A COUPLE. SO I HAD REALLY TWO QUESTIONS OR COMMENTS, QUESTIONS. SO ON THIS FDA ISSUE, I ASSUME THERE WILL BE MORE DETAIL WHEN THIS COMES FORWARD, BUT THIS SEEMS LIKE THAT TO REALLY DO THAT RIGHT IS PROBABLY GOING TO INVOLVE EITHER ADDITIONAL PERSONNEL OR ADDITIONAL FUNDING BECAUSE THIS IS OBVIOUSLY A WASHINGTON-BASED EFFORT. AND I THINK MOST OF OUR WORK, AT LEAST IN GOVERNMENT RELATIONS, THAT INVOLVED THE STATE. SO FIRST OF ALL, WHERE WILL THAT FUNDING COME FROM? I'M GUESSING IT COMES OUT OF THE OPERATIONS BUDGET THAT WE HAVE AS OPPOSED TO THE GRANT FUNDING BUDGET. AND REALLY WHAT'S THE THINKING THERE BECAUSE IT SEEMS LIKE THAT'S A MASSIVE EFFORT COORDINATING RESEARCHERS, INDUSTRY, AND, VERY IMPORTANTLY, PATIENTS AND PATIENT ADVOCATES BECAUSE I THINK IT WAS VERY COMPELLING TO HAVE PATIENTS. AND YOU'VE ALLUDED TO THAT, AND I'M SURE THERE WILL BE MORE DETAIL, BUT I'M JUST WONDERING HOW YOU VISUALIZE

BECAUSE I DO THINK THERE'S A BIG BUDGET IMPACT HERE IF THIS IS TO BE DONE SUCCESSFULLY.

DR. MILLS: JEFF, SO ONE OF THE THINGS THAT CIRM CAN DO THAT PLAYS A ROLE IN HERE CENTERS AROUND COORDINATING THE VARIOUS GROUPS THAT EXIST RIGHT NOW THAT ARE TRYING TO DO THIS PIECEMEAL AND ONE OFF. AND THAT'S AS I'VE GOTTEN DEEP INTO THIS TOPIC, THAT'S THE ONE PIECE THAT HAS BECOME CLEAR. THERE ARE PROBABLY TEN ORGANIZATIONS TRYING TO DO THIS ALL BY THEMSELVES ALL IN AN UNCOORDINATED WAY.

WITH REGARDS TO THE SPECIFIC FUNDING AND COORDINATION OF IT, YES, IT WILL TAKE ADMINISTRATIVE FUNDS TO DO IT. I THINK THERE'S ALSO AN OPPORTUNITY AROUND THE COORDINATING FOR US TO ALSO USE SOME OF THE CONFERENCE FUNDS AS WELL. BUT THAT IS SOMETHING WE'RE AWARE OF, AND WE'RE MAKING THE SPACE IN THE BUDGET TO DO IT. YES, THERE WILL BE MORE DETAIL IN THE PLAN.

MR. SHEEHY: I HAVE TWO QUESTIONS AND WANTED TO JUST FINISH IF THAT'S OKAY.

CHAIRMAN THOMAS: SURE.

MR. SHEEHY: SO JUST A PART TWO TO THAT. ARE YOU LOOKING AT LEGISLATION IN WASHINGTON OR ADMINISTRATIVE CHANGES AT THE FDA? JUST TRYING TO FIGURE OUT WHAT THE NATURE -- HOW YOU'RE GOING TO

ATTACK IT.

DR. MILLS: IT WILL DEPEND. RIGHT NOW THERE ARE A COUPLE OF INITIATIVES UNDER WAY. AND SO WE'RE GOING TO HAVE TO SEE HOW IT ROLLS OUT, JEFF. AND SO I THINK RIGHT NOW IT WOULD BE -- WE DON'T HAVE THAT BALL YET PULLED TOGETHER BECAUSE THERE ARE A COUPLE OF PIECES THAT ARE STILL MOVING.

MR. SHEEHY: AND THEN MY OTHER QUESTION. SO JUST A GENERAL COMMENT. I THINK THERE IS LIKE A BIG GAP HERE IN THAT I THINK WE SHOULD EITHER -- TO ME IT SEEMS LIKE WE SHOULD ADDRESS THE FUTURE OF CIRM GIVEN THAT THIS IS LIKELY TO BE THE LAST STRATEGIC PLAN UNDER CIRM 1.0 FUNDING. SO EITHER MAYBE THIS INVOLVES THE LEADERSHIP OF THE BOARD, BUT REALLY AT LEAST SOME SCENARIOS OR OPTIONS OR NOT, JUST THE ASSUMPTION THAT WE'RE GOING TO CEASE WHEN THIS FIRST TRANCHE OF MONEY RUNS OUT, THAT'S THE END OF CIRM, SOMETHING ABOUT THAT BECAUSE IT SEEMS TO ME THAT WITHOUT HAVING SOME SORT OF EITHER OPTIONS OR DEFAULT TO JUST ENDING WHEN WE END. BUT THERE'S A LACK OF CLARITY ON THAT, AND I THINK THAT WOULD BE HELPFUL TO HAVE THAT AS PART OF WHAT I BELIEVE WILL LIKELY BE THE LAST STRATEGIC PLAN FOR CIRM'S FIRST -- FOR THE PROP 71 FUNDING. NO?

DR. MILLS: I MEAN I THINK -- SO OBVIOUSLY

WE HAVE VARIOUS ROLES. OPERATIONALLY AT CIRM OURS IS TO DO THE MOST WE CAN WITH WHAT WE HAVE. I THINK YOU'RE CORRECT IN SAYING IT'S A TOPIC THAT THE BOARD, I THINK, NEEDS TO TAKE UP AND HAVE A DISCUSSION AROUND. OUR VIEW OF THIS IS WE NEED -- THE WAY WE MAKE THE BEST CASE FOR CIRM IS BY DOING THE MOST WE CAN WITH WHAT WE'VE BEEN GIVEN. AND SO THAT'S WHAT THIS PLAN CONTEMPLATES.

CHAIRMAN THOMAS: I THINK, JEFF, THE POINT IS VERY WELL TAKEN. WE SHOULD KEEP PART OF THE DISCUSSION AVAILABLE IN DECEMBER FOR THAT PARTICULAR TOPIC.

MR. SHEEHY: OH, GREAT. THANK YOU.

DR. MELMED: I'D ALSO ECHO THE CONGRATULATIONS TO THE CIRM FOR A REALLY ENTHUSIASTIC AND PASSIONATE PRESENTATION WHICH GOES A LONG WAY TO ACHIEVING OUR GOALS. I'D JUST LIKE TO EMBELLISH THE CONCERNS THAT WERE EXPRESSED ABOUT THE POSSIBILITY THAT WE WON'T HAVE SUFFICIENT APPLICATIONS AND THERE WILL BE NOT BE SUFFICIENT QUALITY PROJECTS TO FUND. SOMEHOW I HOPE THAT IN OUR PLAN WE'RE NOT NEGLECTING THE INITIATION OF TRANSLATIONAL PROJECTS TO DEVELOP THE FARM OF HIGH QUALITY SCHOLARLY WORK IN TRANSLATIONAL STEM CELL PROGRAMS. IF WE DON'T DEVELOP PI'S AND WE DON'T

DEVELOP STEM CELL LABS, NO ONE ELSE IS GOING TO DO IT. SO I THINK THAT THE CAUTION THAT WAS EXPRESSED ABOUT THE POSSIBILITY OF NOT HAVING SUFFICIENT PROJECTS TO FUND IS A VERY REAL CAUTION. AND I WOULD HOPE THAT STAFF HAS A MECHANISM TO ADDRESS THE CONCERN OF ENRICHING THE FARM BACK HOME WHO ARE GOING TO DEVELOP THESE PROJECTS FROM THEIR LABS.

DR. MILLS: YEAH. THAT'S WHAT WE HAVE REALLY TRIED TO DO BY THE ENORMOUS, I WOULD SAY, INVESTMENTS THAT WE HAVE PROPOSED IN THE EARLIER STAGES OF RESEARCH, THE DISCOVERY AND THE TRANSLATIONAL RESEARCH. SO THIS PLAN CONTEMPLATES SPENDING $180 MILLION IN DISCOVERY AND $175 MILLION IN TRANSLATIONAL STAGE RESEARCH OVER THE NEXT FIVE YEARS.

JUST TO GIVE YOU A COMPARISON OF THE WAY THIS USED TO WORK, THESE TWO PROGRAMS HISTORICALLY AT CIRM HAVE BEEN OFFERED ABOUT EVERY 24 MONTHS. UNDER THIS PROPOSED PROGRAM, AND ACTUALLY UNDER JUST THE CIRM 2.0 THAT WAS APPROVED AT THE LAST BOARD MEETING FOR DISCOVERY AND TRANSLATIONAL, THAT WILL GO FROM EVERY 24 MONTHS TO EVERY SIX MONTHS. AND SO WE'RE BASICALLY GOING TO QUADRUPLE THE OFFERING THAT'S BEEN TAKING PLACE HISTORICALLY, AND THAT IS IN HOPES, OBVIOUSLY, OF BEING ABLE TO HAVE ENOUGH

PROGRAMS COME IN AND HAVE THOSE PROGRAMS BE SUCCESSFUL AND THAT OBVIOUSLY MOVE DOWNSTREAM.

BUT WHEN I TALKED ABOUT THE SUFFICIENT NUMBER OF MERITORIOUS PROJECTS TO MEET OUR OBJECTIVES, THIS IS AN IMPORTANT THING. WE ARE NOT TRYING TO ACHIEVE A SUCCESS. WE'RE TRYING TO CREATE A MACHINE THAT, UNLIKE ANYWHERE ELSE IN THE WORLD, ACCELERATES STEM CELL THERAPIES FOR WHEREVER THEY ARE. IF THEY ARE IN THE EARLIEST STAGE RESEARCH, WE WANT THEM TO MOVE TO TRANSLATIONAL, THINGS IN TRANSLATIONAL INTO THE CLINIC, AND THE THING IN THE CLINIC HOPEFULLY TO PATIENTS. AND SO IT'S ABOUT CREATING THAT ENTIRE CONTINUUM, NOT ANY ONE PARTICULAR PIECE.

DR. MELMED: OKAY, THANK YOU. BUT THEN AS LONG AS WE DON'T GET UNDUE EXPECTATIONS BY THE PUBLIC THAT WE WILL HAVE 50 TRIALS. WE MAY NOT.

DR. MILLS: WE MAY NOT. THAT IS CORRECT.

CHAIRMAN THOMAS: OTHER COMMENTS BY MEMBERS OF THE BOARD? OKAY. HEARING NONE, THANK YOU VERY MUCH, DR. MILLS. ARE THERE ANY MEMBERS OF THE PUBLIC WHO WOULD LIKE TO COMMENT ON THIS PRESENTATION?

DR. MILLS: WE HAVE SOME HERE.

DR. LORING: SO THAT WAS A TERRIFIC

PRESENTATION, BY THE WAY.

(APPLAUSE.)

DR. LORING: AND YOU CAN TELL THAT THE PUBLIC HERE IN SAN DIEGO REALLY DID ENJOY IT. SO I HAVE -- I ALSO AM VERY GRATEFUL FOR THE OPPORTUNITY TO BE ABLE TO APPLY FOR A TRANSLATIONAL AWARD FOR OUR PARKINSON'S DISEASE PROGRAM BECAUSE THAT IS THE STAGE AT WHICH OUR PROGRAM IS NOW.

I JUST HAVE ONE QUESTION, AND IT GOES BACK TO SLIDE 8. YOU DON'T HAVE TO GO BACK TO SLIDE 8. THAT WAS THE TIMING OF WHEN THE APPLICATIONS CAN COME THROUGH. AND THERE'S A DIFFERENCE BETWEEN 2X FOR THE DISCOVERY AND TRANSLATIONAL AND 12X FOR THE CLINICAL. AND I WAS WONDERING IF THERE'S ANY FLEXIBILITY IN THE TRANSLATIONAL PROGRAM TO MAKE IT A BIT MORE FREQUENT SO IT FITS IN BETWEEN THOSE TWO. AND THE REASON I ASK IS THAT YOU HAVE THIS TERRIFIC, VERY FAST FEEDBACK FOR THE CLINICAL PROJECTS IN WHICH IT WENT FROM A TWO TO A ONE BECAUSE OF THE FEEDBACK FROM THE GRANT REVIEWERS.

SO I WOULD LIKE TO HAVE IN THE TRANSLATIONAL PROGRAM THAT OPPORTUNITY AS WELL SO THAT IF WE GOT TWO ON OUR FIRST APPLICATION, WE WOULDN'T HAVE TO WAIT FOR A REALLY LONG TIME TO BE ABLE TO USE THE FEEDBACK THAT WE GET AND REAPPLY.

SO THAT'S MY QUESTION. IS THERE ANY FLEXIBILITY IN THE NUMBER OF TIMES THAT THE TRANSLATIONAL GRANTS CAN BE APPLIED FOR?

CHAIRMAN THOMAS: DR. MILLS.

DR. MILLS: OKAY. GOOD NEWS. YES. ACTUALLY ONE OF THE FEATURES, AND I THINK WE PROBABLY UNDERPUBLICIZED THIS WHEN WE TALKED ABOUT DISCOVERY AND TRANSLATION, BUT WHAT WE SAW IN THE CLINICAL PROGRAM TODAY WAS A GREAT THING. WE SAW A PHASE III CLINICAL PROGRAM COME IN AND HAVE THE OVERWHELMING NUMBER OF GWG MEMBERS RECOMMEND IT, THAT IT WAS A GOOD PROGRAM, BUT THAT IT NEEDED TO GET BETTER IF IT WAS GOING TO GET FUNDING. AND THEN IN A RELATIVELY SHORT PERIOD OF TIME, IN A 30-DAY TIME PERIOD, THAT PROGRAM WENT FROM RECEIVING A SPLIT VOTE, WHICH ENDED UP AS A TWO, TO A UNANIMOUS VOTE AS A THREE. AND THIS WAS ONLY SOMETHING THAT WE HOPED WOULD HAPPEN WITH CIRM 2.0 WAS THAT WE WOULDN'T JUST LAUNCH PROGRAMS FASTER, BUT WE WOULD LAUNCH PROGRAMS BETTER, THAT THE 70 THAT ALWAYS USED TO SORT OF CONFRONT AND CHALLENGE THE BOARD WOULD BE SOMETHING THE BOARD WOULDN'T HAVE TO DEAL WITH MAKING A TOUGH DECISION ON. WE COULD HAVE THAT COME BACK AND GET LAUNCHED AS A 95 AND THEN EVERYONE WOULD WIN. IF WE COULD DO THAT IN A REASONABLE

PERIOD OF TIME.

AND THAT'S A FEATURE THAT WE BUILT INTO DISCOVERY AND TRANSLATION TOO. WE HAVEN'T TALKED ABOUT IT AS MUCH. WE CAN'T RUN THOSE REVIEW CYCLES ANY MORE FREQUENTLY THAN THAT. WE JUST DON'T HAVE THE BANDWIDTH TO DO IT. BUT THE GREAT THING ABOUT OUR REVIEW CYCLES, AND ALSO CONTRAST THIS TO THE WAY IT USED TO BE WHERE THESE THINGS ONLY HAPPENED EVERY 24 MONTHS ON AVERAGE, A TRANSLATIONAL PROGRAM, FOR EXAMPLE, ONLY HAPPENED EVERY 24 MONTHS. SO WHEN YOU GOT YOUR FEEDBACK THAT SAID THAT DIDN'T GO WELL, IT WAS A REAL PROBLEM BECAUSE YOU HAD TO NOW WAIT 24 MONTHS FOR THAT OPPORTUNITY. WELL, NOW YOU'LL GET YOUR FEEDBACK. LET'S SAY YOU APPLY IN JANUARY. YOU'LL GET YOUR FEEDBACK IN MAY ON HOW IT WENT. AND IF IT IS A TWO OR A SCORE THAT'S NOT IN THE RANGE OF FUNDING, YOU WILL HAVE YOUR COMMENTS AND CAN IMMEDIATELY APPLY AGAIN FOR THE JULY FUNDING.

SO THE REVIEW PROCESSES ARE INTENDED TO WORK FOR TRANSLATIONAL AND DISCOVERY EXACTLY LIKE THEY WORK FOR CLINICAL SO THAT YOU DON'T HAVE TO WAIT TWO YEARS, YOU DON'T EVEN HAVE TO WAIT A YEAR. YOU HAVE TO WAIT -- YOU GET YOUR FEEDBACK, YOU MODIFY YOUR APPLICATION, AND YOU'RE APPLYING AGAIN FOR THIS SAME PROGRAM IN SIX WEEKS.

SO I'M ACTUALLY GLAD YOU ASKED THE QUESTION BECAUSE IT'S A FEATURE I WANTED TO MAKE SURE THAT EVERYONE UNDERSTOOD AND APPRECIATED ABOUT THE DISCOVERY AND TRANSLATIONAL PROGRAMS.

MS. GOULD: MY NAME IS SHERRIE GOULD, AND I AM REPRESENTING THE SUMMIT4STEMCELL GROUP. AND I WOULD SAY ON BEHALF OF MYSELF AND THE HUNDREDS OF PEOPLE THAT ARE INVOLVED IN THIS PROJECT THAT WE WOULD BE HAPPY TO COMPLEMENT CIRM AND STAND BEHIND CIRM AS FAR AS THE POWER OF PATIENT ADVOCACY IN RAISING MONEY AND SUPPORTING THESE TYPE OF RESEARCH PROJECTS. SO I JUST WANTED TO COMMEND YOU AND CERTAINLY OFFER WHATEVER SUPPORT WE CAN GIVE IN TERMS OF GETTING OTHER PATIENT GROUPS INVOLVED.

DR. MILLS: THANK YOU.

CHAIRMAN THOMAS: THANK YOU. ANY OTHER COMMENTS IN SAN DIEGO? ANY OTHER COMMENTS EITHER AT UCLA OR USC? OKAY. I THINK THAT THEN CONCLUDES THAT AGENDA ITEM.

WE DID HAVE A HARD STOP AT 11:30. WE HAVE ONE MORE AGENDA ITEM THAT IS, I BELIEVE, ALEX, ABOUT A TEN-MINUTE ITEM MAX. IF WE COULD INDULGE THOSE ON THE PHONE, UPDATE ON THE MOSS-ADAMS AUDIT AND HOW WE ARE BEING RESPONSIVE TO IT. SO IF YOU DON'T MIND, WE MIGHT EXTEND A FEW MORE MINUTES AND I'LL TURN IT

OVER HERE TO ALEX.

DR. CAMPE: THANK YOU, CHAIRMAN THOMAS, MEMBERS OF THE BOARD, PRESIDENT MILLS, AND CIRM. I'D LIKE TO UPDATE EVERYONE ON OUR PERFORMANCE AUDIT REPORT. AS YOU ALL KNOW, MOSS-ADAMS, MARK STERANKA, PRESENTED IN MAY OF 2015, A FEW MONTHS AGO, ON THEIR FINAL REPORT TO US. THIS IS THE SECOND PERFORMANCE AUDIT WE RECEIVED. IT WAS FOR THE '13-'14 FISCAL YEAR. AND AMONG OTHER THINGS, HE DID COMMEND US ON STRENGTHENING OUR GRANTS MANAGEMENT SYSTEM, THE GRANTS REVIEW PROCESSES, AND OUR OVERALL ORGANIZATIONAL CULTURE.

WITH THE '13-'14 AUDIT WE SEE 12 RECOMMENDATIONS, AND WE ARE ALL FOCUSING VERY MUCH ON THOSE 12 RECOMMENDATIONS SO THAT WE CAN ACHIEVE FURTHER EFFICIENCIES AND EFFECTIVENESS WITHIN THE ORGANIZATION.

I'D LIKE TO QUICKLY RUN THROUGH THE 12 RECOMMENDATIONS. IF ANYONE HAS ANY QUESTIONS, FEEL FREE NOW OR AT THE END TO ASK ME.

WE DID GET A RECOMMENDATION TO ADDRESS GRANTS MANAGEMENT SYSTEM ISSUES IN THE NO. 1 ISSUE REGARDING FINANCIAL INTEREST DISCLOSURE FORMS, AND WE WILL CONTINUE TO USE THE GMS SYSTEM TO CAPTURE THIS INFORMATION.

THE NO. 2, WE'RE ADDRESSING FINANCIAL INTEREST DISCLOSURE FORM REVIEW AND REPORTING PROCESSES. WE WILL IMPLEMENT GMS MODULES, A MODULE TO DOCUMENT ALL ACTIONS NECESSARY TO ENSURE THAT WE HAVE ACCOUNTABILITY IN THOSE AREAS.

THE THIRD ITEM, WE ARE ADDRESSING IMPLEMENTING POLICIES AND PROCEDURES AND RESOURCES TO ACHIEVE MORE TIMELY REVIEW OF PROGRESS REPORTS. THIS IS AN ITEM THAT DID COME UP A FEW YEARS AGO, AND WE ARE CONTINUING TO ADDRESS THIS. OUR TARGET WITHIN THE ORGANIZATION IS 30 CALENDAR DAYS FOR PROGRESS REPORT REVIEW IN ORDER TO PRIORITIZE THIS WORK ACROSS THE ENTIRE ORGANIZATION.

THE FOURTH ITEM IS IMPLEMENTING PROCEDURES TO ENSURE ADHERENCE TO THE GRANTS ADMINISTRATION POLICY, AND WE ARE WORKING ON THAT TO IMPLEMENT NEW BUSINESS RULES AND SOP'S TO ENSURE FINAL PROGRESS REPORTS ARE SUBMITTED AND CONTINUE TO USE THE PAYMENT MODULE IN THE GRANTS MANAGEMENT SYSTEM TO ADDRESS ANY LATE ANNUAL PROGRESS REPORTS.

THE FIFTH ITEM, ADDRESSING IMPLEMENTING ENHANCEMENTS TO THE GRANTS MANAGEMENT SYSTEM TO SUPPORT INCREASED ACCOUNTABILITY AND ENFORCEMENT OF ANNUAL UTILIZATION REPORT REQUIREMENTS, WE ARE PROVIDING ADDITIONAL NOTIFICATION TO GRANTEES AND

IMPLEMENTING POLICIES TO ADDRESS MORE TIMELY SUBMITTAL OF THE REPORTS.

THE SIXTH ITEM IS CIRM-FUNDED IP DEVELOPMENTS. WE ARE ADDING THREE FIELDS IN THE IP MODULE OF THE GRANTS MANAGEMENT SYSTEM TO REFLECT THE FOLLOWING THREE COMMERCIAL EVENTS THAT WE WANT TO ENSURE WE GATHER THE APPROPRIATE DATA ON. ONE, INITIATION OF CLINICAL TESTING; TWO, THE INITIATION OF PIVOTAL STUDIES; AND, THREE, APPLICATION FOR MARKETING APPROVAL.

THE SEVENTH ITEM IS DEVELOPING AN INTERNAL SLATE OF OPERATIONAL PERFORMANCE MEASURES ALIGNED WITH CIRM'S STRATEGIC PLAN AND REPORTING REGULARLY TO THE ICOC. THIS IS SOMETHING WE'RE DIRECTING AS PART OF THE CORE 2.0 PROCESS WHERE OUR INTERNAL ADMINISTRATIVE AREAS ARE COLLABORATING TO ADDRESS THIS AND REVIEWING ALL OUR POLICIES TO MAKE THEM CONSISTENT WITH OUR OVERALL STRATEGIC PLAN AND ADDRESSING INEFFICIENCIES AND SUCH.

NO. 8 IS CONTINUE TO PROACTIVELY FOCUS ON IMPROVING EMPLOYEE ENGAGEMENT THROUGH ACTIVE EMPLOYEE OUTREACH. THIS IS BEING DONE IN MULTIPLE WAYS INCLUDING, BUT NOT LIMITED TO, HOLDING QUARTERLY MEETINGS, ENGAGING TEAM IN STRATEGIC PLAN, AND MANY OTHER ITEMS.

NO. 9 IS ENSURING THAT THE PERFORMANCE EVALUATION AND MERIT INCREASES OCCUR IN A TIMELY MANNER. I CAN TELL YOU ALL THAT IT WAS IMPLEMENTED IN A TIMELY MANNER ON JULY 1 OF THIS YEAR, AND OUR PLAN IS TO CONTINUE THAT IN THE FUTURE.

NO. 10 IS CONTINUE TO MONITOR CURRENT TRENDS IN WEB APPLICATION DEVELOPMENT. THIS WILL CONTINUE TO BE ADDRESSED AND HAS BEEN. OBVIOUSLY THIS IS DEPENDENT ON THE LIFE SPAN OF CIRM, AND WE'LL CONSIDER NEW WEB APPLICATION DEVELOPMENT PLATFORMS FOR ANY NEW NON-GMS OR GRANTS MANAGEMENT SYSTEM WEB APPLICATION DEVELOPMENT.

NO. 11 IS TO CONTINUE TO IDENTIFY AND PURSUE OPPORTUNITIES TO ENHANCE GRANTS MANAGEMENT SYSTEM CAPABILITIES TO AUTOMATE PROCESSES, REDUCE PAPERWORK, AND, OF COURSE, ENHANCE INFORMATION ACCESS. WE'LL BE WORKING TO -- CONTINUE TO WORK WITH THE STAKEHOLDERS TO DEFINE SUCH AND IMPROVE BUSINESS PROCESSES.

AND THE LAST ONE IS ACTUALLY A FOLLOW-UP FROM THE 2010/2011 PERFORMANCE AUDIT RECOMMENDATIONS. AND THIS IS TO ENSURE THAT ANY REMAINING AUDIT RECOMMENDATIONS FROM THAT PERIOD ARE ADDRESSED GOING FORWARD FOR '13-'14.

SO WE'D THANK YOU FOR HEARING ALL OF THAT.

AS I SAID, WE'RE ALL FOCUSED IN ON THIS, AND WE WILL CONTINUE TO GIVE UPDATES TO THE BOARD ABOUT WHERE WE ARE IN THE PROGRESS IN COMPLETING THESE RECOMMENDATIONS. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, ALEX. ANY COMMENTS OR QUESTIONS? OKAY. WE ARE NOW IN THE GENERAL PUBLIC COMMENT SEGMENT. ANY COMMENTS TO BE MADE BY MEMBERS OF THE PUBLIC ON ANY OTHER TOPICS WE HAVEN'T DISCUSSED?

MS. CHEUNG: WE HAVE A MEMBER OF THE PUBLIC IN SAN DIEGO.

MS. ROBB: IT'S JENNIFER ROBB. I FEEL LIKE A KID AT CHRISTMAS. THANK YOU, EVERYONE, VERY MUCH FOR THIS. I LOVE THE NEW PROGRAM AND THE PRESENTATION, RANDY. IT'S AGGRESSIVE, AMBITIOUS, AND I'M HOPING IT'S VERY SUCCESSFUL, BUT THANK YOU.

CHAIRMAN THOMAS: THANK YOU. ANY OTHER PUBLIC COMMENT? HEARING NONE, I'D LIKE TO AT THIS POINT GIVE MR. JUELSGAARD, MR. ROWLETT, ANYBODY ELSE WHO WOULD CARE TO OFFER ANY REAL-TIME COMMENTARY OR ANALYSES ON THE PENNANT RACE OF THE NATIONAL LEAGUE.

DR. JUELSGAARD: J.T., HOPE SPRINGS ETERNAL.

CHAIRMAN THOMAS: THANK YOU, MR. JUELSGAARD. MR. ROWLETT, DO YOU HAVE ANY COMMENT?

MR. ROWLETT: NOT AT THIS TIME, SIR. HOWEVER, I WILL BE CHATTING WITH YOU SOON.

MS. CHEUNG: J.T., WE ACTUALLY HAVE ONE PERSON WHO WOULD LIKE TO MAKE ADDITIONAL PUBLIC COMMENT HERE.

CHAIRMAN THOMAS: PRESUMABLY THAT'S ON ANOTHER TOPIC, BUT, YES, PLEASE, GO AHEAD.

MR. RODUNSKY: I'M AFRAID I'M NOT MUCH OF A BASEBALL FAN. THIS IS MICHAEL RODUNSKY AGAIN. AGAIN, I WANT TO THANK RANDY AND THE TEAM AT CIRM FOR HELPING US OUT.

I WOULD LIKE TO ASK A KIND OF MECHANISTIC QUESTION BECAUSE AT LEAST TO ME IT WAS A WELCOME SURPRISE THAT YOU CHANGED WHEN WE COULD START APPLYING FOR OUR GRANT. AND IT SOUNDED LIKE THAT WAS IN SEVEN DAYS. CAN YOU PROVIDE MORE DETAIL ON WHEN THIS FUNDING GRANT APPLICATION ACCEPTANCE STARTS IN SEVEN DAYS, WHEN DOES IT CLOSE, WHAT CAN WE EXPECT IN TERMS OF APPROVAL, DENIAL TIMING, ETC.?

CHAIRMAN THOMAS: DR. MILLS.

DR. MILLS: ALL OF THAT INFORMATION WILL BE CONTAINED IN WHAT WE CALL A PROGRAM ANNOUNCEMENT, WHICH DETAILS THE APPLICATION. WE ANTICIPATE HAVING THAT POSTED WITHIN THE NEXT SEVEN DAYS. THAT WILL NOT BE TOMORROW. BUT IT WILL BE -- WE FEEL

CONFIDENT WE'LL HAVE IT UP WITHIN THE NEXT SEVEN DAYS. AND THAT WILL OUTLINE THE REVIEW PERIOD.

WE ANTICIPATE NOT HAVING A VERY LENGTHY OPEN PERIOD FOR THIS ONE BECAUSE WE HAVE TO GET IT STARTED RIGHT AWAY. SO I WOULD ANTICIPATE THE APPLICATION WOULD PROBABLY -- THE APPLICATION WINDOW TO APPLY WOULD PROBABLY CLOSE SOMETIME IN NOVEMBER. AND THEN, AS I SAID, WE WOULD ANTICIPATE HAVING COMMENTS -- HAVING THE REVIEW DONE BY WHAT WE CALL OUR GRANTS WORKING GROUP AND HAVING COMMENTS BACK IN FOUR TO FIVE MONTHS FROM THAT, AND THEN A FUNDING DECISION ABOUT ROUGHLY A HUNDRED -- BY THE ICOC, WHICH IS THE FINAL FUNDING DECISION THAT TAKES PLACE, ABOUT 180 DAYS AFTER IT CLOSES. THOSE ARE ROUGH TIME FRAMES RIGHT NOW THAT WILL BE SPELLED OUT MORE EXPLICITLY IN THE PROGRAM ANNOUNCEMENT THAT POSTS. AND THEN, AGAIN, KEEP IN MIND THAT IS FOR THE FIRST ONE, AND THEN THEY WILL RUN OVER AND OVER AND OVER AGAIN FROM THAT POINT FORWARD.

CHAIRMAN THOMAS: ANY OTHER COMMENTS BY ANYBODY AT THIS POINT ON ANY TOPIC? HEARING NONE, I BELIEVE THAT CONCLUDES OUR AGENDA. THANK YOU VERY MUCH, EVERYBODY.

(THE MEETING WAS THEN CONCLUDED AT 11:45 A.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING ON SEPTEMBER 24, 2015, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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