

**BETH C. DRAIN, CA CSR NO. 7152**

BEFORE THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE AND THE  
APPLICATION REVIEW SUBCOMMITTEE  
TO THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: VIA ZOOM

DATE: FEBRUARY 23, 2023  
9 A.M.

REPORTER: BETH C. DRAIN, CA CSR  
CSR. NO. 7152

FILE NO.: 2023-08

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**I N D E X**

| <b>ITEM DESCRIPTION</b>  | <b>PAGE NO.</b> |
|--|-----------------|
| <b>OPEN SESSION</b>  |                 |
| 1. CALL TO ORDER   | 3               |
| 2. ROLL CALL   | 3               |
| <b>ACTION ITEMS</b>  |                 |
| 3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1 OR 2)   | 5               |
| <b>CLOSED SESSION</b>  |                 |
| NONE   |                 |
| 4. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEM 3 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)). |                 |
| <b>DISCUSSION ITEMS</b>  |                 |
| 5. GENERAL COMMENTS ON ARS PROCESS   | 16              |
| 6. PUBLIC COMMENT  | NONE            |
| 7. ADJOURNMENT   | 20              |

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FEBRUARY 23, 2023; 9 A.M.

CHAIRMAN THOMAS: OKAY. ARE WE RECORDING?  
GOOD MORNING, EVERYBODY. WELCOME TO THE FEBRUARY  
MEETING OF THE APPLICATION REVIEW SUBCOMMITTEE.  
HOPE EVERYBODY IS KEEPING WARM AND DRY.

MARIANNE, WILL YOU PLEASE CALL THE ROLE.

MS. DEQUINA-VILLABLANCA: SURE. DAN  
BERNAL. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MS. DEQUINA-VILLABLANCA: JUDY CHOU.  
LEONDRA CLARK-HARVEY. ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. DEQUINA-VILLABLANCA: YSABEL DURON.

MS. DURON: HERE.

MS. DEQUINA-VILLABLANCA: MARK  
FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. DEQUINA-VILLABLANCA: FRED FISHER.

DR. FISHER: HERE.

MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.  
DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. DEQUINA-VILLABLANCA: STEVE  
JUELSGAARD. RICH LAJARA.

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MR. LAJARA: HERE.

MS. DEQUINA-VILLABLANCA: CHRISTINE  
MIASKOWSKI. LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: HERE.

MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. DEQUINA-VILLABLANCA: JOE PANETTA.

MR. PANETTA: HERE.

MS. DEQUINA-VILLABLANCA: AL ROWLETT.

MR. ROWLETT: HERE.

MS. DEQUINA-VILLABLANCA: MARVIN SOUTHARD.

DR. SOUTHARD: HERE.

MS. DEQUINA-VILLABLANCA: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. DEQUINA-VILLABLANCA: KAROL WATSON.

DR. WATSON: HERE.

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1 MS. DEQUINA-VILLABLANCA: WE HAVE A  
2 QUORUM.

3 CHAIRMAN THOMAS: THANK YOU.

4 MR. TOSHER: JUST BEFORE WE BEGIN, JUST  
5 WANTED A REMINDER TO MEMBERS DURON AND WATSON THAT  
6 THERE ARE CONFLICTS IN THIS. WE'LL BE MONITORING  
7 AND WON'T CALL YOUR NAMES.

8 CHAIRMAN THOMAS: THANK YOU, SCOTT.

9 OKAY. WE HAVE ONE ACTION ITEM TODAY FOR  
10 OUR AGENDA, WHICH IS CONSIDERATION OF APPLICATIONS  
11 SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE  
12 PROJECTS PROGRAM ANNOUNCEMENT CLIN1 OR 2. HAVE A  
13 PRESENTATION BY DR. SAMBRANO. GIL.

14 DR. SAMBRANO: OKAY. THANK YOU, MR.  
15 CHAIRMAN.

16 GOOD MORNING, EVERYONE. I HOPE YOU'RE  
17 HAVING A GOOD START TO YOUR DAY. IT IS COLD OVER  
18 HERE AS WELL. SO WE HAD A LOT OF FROST, BUT NOT TOO  
19 BAD.

20 WE'RE STARTING OUR MEETING, AS WE ALWAYS  
21 DO, WITH OTHER MISSION, WHICH IS TO ACCELERATE  
22 WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE  
23 REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE  
24 MANNER TO A DIVERSE CALIFORNIA AND WORLD. AND AS  
25 YOU KNOW, WE PRESENT THIS MISSION STATEMENT NOT JUST

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1 AT THESE MEETINGS, BUT ALSO AT OUR GRANTS WORKING  
2 GROUP MEETINGS TO MAKE SURE THAT EVERYBODY IS ON THE  
3 SAME PAGE AS TO WHY WE ARE HERE.

4 THIS SLIDE IS A REMINDER AND AN UPDATE TO  
5 OUR OVERALL BUDGET ALLOCATION FOR CLINICAL STAGE  
6 PROGRAMS. SO THE FISCAL YEAR ALLOCATION IS 169  
7 MILLION. THE AMOUNT THAT'S REQUESTED TODAY IS 15.6  
8 MILLION FROM TWO APPLICATIONS. WE HAVE THUS FAR  
9 ABOUT A HUNDRED MILLION THAT'S BEEN APPROVED BY THE  
10 BOARD IN PREVIOUS APPLICATION AWARDS. AND SO IF WE  
11 APPROVE THE 15.6 LATER TODAY, THAT WOULD LEAVE US  
12 WITH ABOUT 54 MILLION IN BALANCE.

13 THE SCIENTIFIC SCORING THAT'S USED UNDER  
14 OUR CLINICAL PROGRAM IS A 1, 2, AND 3 SYSTEM. A  
15 SCORE OF 1 MEANS THAT THE APPLICATION HAS  
16 EXCEPTIONAL MERIT AND WARRANTS FUNDING. A SCORE OF  
17 2 MEANS IT NEEDS IMPROVEMENT. THOSE TYPICALLY GO  
18 BACK TO THE APPLICANT TO ADDRESS ANY CONCERNS OR  
19 CLARIFY ANY ISSUES. A SCORE OF 3 MEANS THAT IT'S  
20 SUFFICIENTLY FLAWED THAT IT DOESN'T WARRANT FUNDING.  
21 AND FOR THOSE APPLICATIONS, WE DON'T ACCEPT THEM  
22 BACK FOR AT LEAST A PERIOD OF SIX MONTHS.

23 THE REVIEW CRITERIA THAT ARE USED BY THE  
24 GRANTS WORKING GROUP TO ASSESS AND SCORE THESE  
25 APPLICATIONS ARE BASED ON THE FOLLOWING FIVE

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1 QUESTIONS. DOES THE PROJECT HAVE THE NECESSARY  
2 SIGNIFICANCE AND POTENTIAL FOR IMPACT? MEANING WHAT  
3 VALUE DOES IT OFFER? IS THIS SOMETHING THAT IS  
4 WORTH DOING? DOES IT HAVE A GOOD RATIONALE? IS IT  
5 WELL-PLANNED AND DESIGNED? IS IT FEASIBLE, MEANING  
6 THEY HAVE AN APPROPRIATE TEAM AND ALL THE  
7 APPROPRIATE RESOURCES THAT THEY NEED TO CARRY OUT  
8 THE ACTIVITIES THAT ARE PROPOSED. AND THEN,  
9 FINALLY, DOES THE PROJECT UPHOLD THE PRINCIPLES OF  
10 DIVERSITY, EQUITY, AND INCLUSION?

11 THE COMPOSITION OF THE GRANTS WORKING  
12 GROUP INCLUDES SCIENTIFIC MEMBERS WHO WE BRING  
13 TOGETHER FROM VARIED AREAS OF EXPERTISE TO EVALUATE  
14 APPLICATIONS FROM THAT SCIENTIFIC PERSPECTIVE. THEY  
15 PROVIDE A SCIENTIFIC SCORE ON ALL APPLICATIONS. WE  
16 ALSO HAVE OUR GRANTS WORKING GROUP BOARD MEMBERS WHO  
17 ARE PATIENT ADVOCATE AND NURSE MEMBERS OF THE ICOC,  
18 WHO PROVIDE THE DEI EVALUATION AND SCORES ON ALL THE  
19 APPLICATIONS. AND THEY ALSO, DURING THE COURSE OF  
20 THE MEETING, PROVIDE US A SUGGESTED SCIENTIFIC  
21 SCORE. THAT'S NOT REFLECTED IN THE FINAL SCORE, BUT  
22 THEY DO SUGGEST A SCORE. WE ALSO BRING IN  
23 SCIENTIFIC SPECIALISTS. THESE ARE NONVOTING  
24 PARTICIPANTS WHO FILL IN GAPS IN KNOWLEDGE THAT WE  
25 MAY HAVE, AND WE BRING THOSE IN AS NEEDED. THEY

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1 PROVIDE AN INITIAL SCORE, BUT NOT A FINAL SCIENTIFIC  
2 SCORE WHEN PARTICIPATING.

3 ALL RIGHT. SO THE FIRST APPLICATION THAT  
4 WE'RE GOING TO CONSIDER TODAY IS CLIN1-14265. THIS  
5 IS JUST A REMINDER OF THE CONFLICTS THAT PERTAIN TO  
6 THIS APPLICATION. SO, AGAIN, TO BE MINDFUL OF  
7 DISCUSSION AND VOTING.

8 THE APPLICATION IS A CLIN2, MEANING IT'S A  
9 CLINICAL TRIAL PHASE APPLICATION. IT'S ENTITLED  
10 "PHASE 1B RANDOMIZED, BLINDED, PLACEBO-CONTROLLED  
11 DOSE RANGING STUDY EVALUATING (THE NAME OF THE  
12 PRODUCT) FOR SAFETY, PHARMACODYNAMICS, AND  
13 BIOMARKERS IN KNEE OSTEOARTHRITIS."

14 SO THIS THERAPY IS A GENE THERAPY. IT IS  
15 FOR OSTEOARTHRITIS OF THE KNEE, AND THEIR GOAL IS TO  
16 COMPLETE A PHASE 1B CLINICAL TRIAL. THE FUNDS  
17 REQUESTED ARE 11.6 MILLION. THEY ARE PROVIDING  
18 CO-FUNDING OF 7.75, WHICH IS THE 40 PERCENT THAT'S  
19 REQUIRED FOR THIS PARTICULAR APPLICANT.

20 SOME BACKGROUND ON OSTEOARTHRITIS. IT  
21 AFFECTS OVER 27 MILLION PEOPLE IN THE U.S., AND IT'S  
22 THE LEADING CAUSE OF DISABILITY. IN PARTICULAR,  
23 KNEE OSTEOARTHRITIS ACCOUNTS FOR MORE THAN 80  
24 PERCENT OF THAT DISEASE BURDEN. SO IT'S CERTAINLY A  
25 SIGNIFICANT PORTION OF OSTEOARTHRITIS ALTOGETHER.



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1 THE DISEASE RESULTS IN BREAKDOWN OF THE  
2 JOINT TISSUE AND INFLAMMATION ACCOMPANIED BY PAIN,  
3 WHICH IS THE PREDOMINANT SYMPTOM OF OSTEOARTHRITIS.

4 THE CURRENT STANDARD OF CARE DOES DEPEND  
5 ON THE SEVERITY AND RANGES FROM LIFESTYLE CHANGES,  
6 TO USE OF PAIN RELIEVING ANTIINFLAMMATORY  
7 MEDICATION, TO SURGICAL PROCEDURES WHICH MAY INCLUDE  
8 JOINT REPLACEMENT IN SEVERE CASES.

9 THE PROPOSED THERAPY UNDER THIS  
10 APPLICATION OFFERS THE POTENTIAL FOR A ONE-TIME  
11 TREATMENT THAT COULD SIGNIFICANTLY REDUCE THE  
12 INFLAMMATORY PROCESS AND BY DOING SO FACILITATE  
13 REPAIR AND REGENERATION OF CARTILAGE TISSUE.

14 THIS PARTICULAR PRODUCT IS A STEM OR GENE  
15 THERAPY. IT IS A GENE THERAPY, AND SO THAT'S WHY IT  
16 QUALIFIES. AND IT TARGETS THE CHONDROCYTES WITHIN  
17 THE ARTICULAR CARTILAGE OF THE KNEE.

18 IN TERMS OF PROJECTS THAT ARE IN OUR  
19 PORTFOLIO, WE DO HAVE ONE OTHER ACTIVE PROJECT THAT  
20 IS AT THE CLIN1 STAGE OR IND-ENABLING STUDY STAGE  
21 FOCUSED ON KNEE OSTEOARTHRITIS. THE CANDIDATE IS  
22 DIFFERENT. THIS ONE IS A CELL THERAPY IN THIS OTHER  
23 CLIN1 PROJECT. SO IT'S A PLURIPOTENT STEM  
24 CELL-DERIVED CHONDROCYTE THAT'S SEATED ON A MATRIX  
25 AND IMPLANTED INTO THE KNEE. WHEREAS, THE CURRENT

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1 PROJECT IS A GENE THERAPY THAT TARGETS CHONDROCYTES.  
2 SO A BIT DIFFERENT IN THEIR APPROACHES.

3 THIS PARTICULAR APPLICANT HAS NOT  
4 PREVIOUSLY RECEIVED A CIRM AWARD. SO THIS WOULD BE  
5 THEIR FIRST.

6 THE SUMMARY OF THE GRANTS WORKING GROUP  
7 RECOMMENDATION IS AS FOLLOWS. WE HAD 14 MEMBERS WHO  
8 GAVE THIS A SCORE OF 1, NONE THAT GAVE A SCORE OF 2,  
9 AND ONE THAT GAVE A SCORE OF 3. SO THE OVERALL  
10 SCORE IS A 1, AND THE DEI SCORE ON A SCALE OF 1 TO  
11 10 IS AN 8. AND THE CIRM TEAM RECOMMENDATION IS TO  
12 FUND IN CONCURRENCE WITH THE GRANTS WORKING GROUP  
13 RECOMMENDATION FOR THE AMOUNT OF 11.6 MILLION. MR.  
14 CHAIRMAN.

15 CHAIRMAN THOMAS: THANK YOU VERY MUCH,  
16 GIL. DO WE HEAR A MOTION TO APPROVE?

17 MR. ROWLETT: SO MOVED.

18 DR. SOUTHARD: SOUTHARD SECONDS.

19 CHAIRMAN THOMAS: MOVED BY AL, SECONDED BY  
20 MARV. DO WE HAVE QUESTIONS OR COMMENTS FROM MEMBERS  
21 OF THE BOARD? HEARING NONE, DO WE HAVE ANY PUBLIC  
22 COMMENT?

23 MS. DEQUINA-VILLABLANCA: I SEE NONE, J.T.

24 CHAIRMAN THOMAS: THANK YOU, MARIANNE.  
25 SCOTT, WILL YOU PLEASE CALL THE ROLL.

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1 MR. TOSHER: MARIA BONNEVILLE.  
2 VICE CHAIR BONNEVILLE: YES.  
3 MR. TOSHER: ANNE-MARIE DULIEGE.  
4 DR. DULIEGE: YES.  
5 MR. TOSHER: MARK FISCHER-COLBRIE.  
6 DR. FISCHER-COLBRIE: YES.  
7 MR. TOSHER: FRED FISHER.  
8 DR. FISHER: YES.  
9 MR. TOSHER: DAVID HIGGINS.  
10 DR. HIGGINS: YES.  
11 MR. TOSHER: RICH LAJARA.  
12 MR. LAJARA: YES.  
13 MR. TOSHER: LAUREN MILLER-ROGEN.  
14 MS. MILLER-ROGEN: YES.  
15 MR. TOSHER: ADRIANA PADILLA.  
16 DR. PADILLA: YES.  
17 MR. TOSHER: JOE PANETTA.  
18 MR. PANETTA: YES.  
19 MR. TOSHER: AL ROWLETT.  
20 MR. ROWLETT: YES.  
21 MR. TOSHER: MARVIN SOUTHARD.  
22 DR. SOUTHARD: YES.  
23 MR. TOSHER: JONATHAN THOMAS.  
24 CHAIRMAN THOMAS: YES.  
25 MR. TOSHER: KAROL WATSON.

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1 DR. WATSON: YES.

2 MR. TOSHER: THANK YOU. THE MOTION  
3 CARRIES, J.T.

4 CHAIRMAN THOMAS: THANK YOU, SCOTT. ON TO  
5 THE NEXT APPLICATION, GIL.

6 DR. SAMBRANO: THANK YOU, MR. CHAIRMAN.

7 THE NEXT APPLICATION IS CLIN1-14299.  
8 HERE'S THE LIST OF CONFLICTS FOR THIS PARTICULAR  
9 APPLICATION.

10 THE TITLE OF THE APPLICATION IS "EX VIVO  
11 ENGINEERING OF AUTOLOGOUS HEMATOPOIETIC STEM CELLS  
12 FOR THE TREATMENT OF HYPOPHOSPHATASIA." THIS IS A  
13 THERAPY THAT IS GENETICALLY MODIFIED HEMATOPOIETIC  
14 OR BLOOD STEM CELLS. THE INDICATION IS FOR THIS  
15 RARE DISEASE OF BONE MINERALIZATION THAT'S CALLED  
16 HYPOPHOSPHATASIA OR HPP.

17 THE GOAL OF THIS STUDY IS TO COMPLETE  
18 PRECLINICAL STUDIES TO FILE AN IND. THE AMOUNT  
19 REQUESTED IS JUST UNDER 4 MILLION, AND THE  
20 CO-FUNDING PROVIDED IS JUST UNDER 1 MILLION TO COVER  
21 THE 20 PERCENT THAT'S REQUIRED.

22 SO BACKGROUND ON THE HYPOPHOSPHATASIA.  
23 THIS IS A RARE SYSTEMIC METABOLIC DISEASE, AFFECTS  
24 ABOUT ONE IN A 100,000 IN NORTH AMERICA, AND IT'S  
25 CAUSED BY A MUTATION IN THE GENE THAT REGULATES BONE

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1 MINERALIZATION. AND SO THE SEVERE FORM OF THIS  
2 DISEASE, WHICH TYPICALLY OCCURS IN THE PRENATAL OR  
3 INFANTILE, IN YOUNG CHILDREN, HAS A VARIETY OF  
4 SYMPTOMS WHICH CAN INCLUDE RESPIRATORY FAILURE,  
5 SEIZURES, BONE DEFORMITIES, AND MOTOR DEVELOPMENT  
6 DELAYS. AND IN ITS MOST SEVERE FORM HAS 58 TO 100  
7 PERCENT MORTALITY IN THE FIRST YEAR OF LIFE.

8 SO FOR THE VALUE PROPOSITION, THE CURRENT  
9 STANDARD OF CARE FOR THIS DISEASE INCLUDES ENZYME  
10 REPLACEMENT THERAPY WHICH REQUIRES WEEKLY INJECTIONS  
11 AND IS ACTUALLY QUITE COSTLY. AND THE PROPOSED  
12 THERAPY WOULD INVOLVE A GENE MODIFIED BLOOD STEM  
13 CELL TRANSPLANT THAT HAS THE POTENTIAL TO DELIVER  
14 THE MISSING ENZYME INDEFINITELY BECAUSE THE  
15 TRANSPLANT WOULD ENGRAFT AND PRODUCE THIS ENZYME ON  
16 A PERMANENT BASIS, AND ULTIMATELY WOULD BECOME A  
17 MORE AFFORDABLE THERAPEUTIC OPTION FOR PATIENTS.

18 THE PRODUCT IS A STEM CELL OR GENE  
19 THERAPY. IT IS BOTH ACTUALLY. IT INVOLVES BLOOD  
20 STEM CELLS THAT ARE GENETICALLY MODIFIED, AND SO  
21 THAT IS WHY IT QUALIFIES FOR CIRM.

22 IN TERMS OF PORTFOLIO PROJECTS, WE DON'T  
23 HAVE ANY ACTIVE PROJECTS THAT ARE ADDRESSING THE  
24 HYPOPHOSPHATASIA IN PARTICULAR, BUT WE DO HAVE SOME  
25 PROJECTS THAT ADDRESS OTHER UNRELATED METABOLIC

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1 DISORDERS, SUCH AS CYSTINOSIS, TYPE 1 DIABETES, AND  
2 MPS TYPE 1.

3 THE APPLICANT TEAM HAS NOT PREVIOUSLY  
4 RECEIVED A CIRM AWARD, SO THIS WOULD ALSO BE A NEW  
5 AWARD TO THIS TEAM.

6 THIS IS A SUMMARY OF THE GRANTS WORKING  
7 GROUP RECOMMENDATION. WE HAD 13 MEMBERS WHO GAVE  
8 THIS A SCORE OF 1. WE HAD ONE MEMBER WHO GAVE IT A  
9 SCORE OF 2, NONE THAT GAVE A SCORE OF 3. SO THIS IS  
10 A RECOMMENDATION TO FUND WITH AN OVERALL SCORE OF 1.  
11 THE DEI SCORE IS A 9 OUT OF 10, AND THE CIRM TEAM  
12 RECOMMENDATION IS TO FUND IN CONCURRENCE WITH THE  
13 GRANTS WORKING GROUP RECOMMENDATION FOR JUST UNDER 4  
14 MILLION. MR. CHAIRMAN.

15 CHAIRMAN THOMAS: THANK YOU, GIL. VERY  
16 HAPPY TO SEE A COUPLE OF PROJECTS WITH EXCEPTIONAL  
17 SCIENTIFIC MERIT AS VOTED ON BY THE GWG, BUT JUST AS  
18 MUCH, TWO VERY HIGH DEI SCORES. SO VERY HAPPY ABOUT  
19 THIS. DO WE HEAR A MOTION TO APPROVE?

20 DR. HIGGINS: SO MOVED.

21 CHAIRMAN THOMAS: MOVED BY DAVID. SECOND?

22 DR. SOUTHARD: MARV SECONDS.

23 CHAIRMAN THOMAS: MARV SECOND. QUESTIONS,  
24 COMMENTS FROM MEMBERS OF THE BOARD? HEARING NONE,  
25 IS THERE ANY PUBLIC COMMENT?

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1 MS. DEQUINA-VILLABLANCA: I SEE NONE, J.T.

2 CHAIRMAN THOMAS: THANK YOU. PLEASE,

3 SCOTT, WILL YOU CALL THE ROLL.

4 MR. TOSHER: MARIA BONNEVILLE.

5 VICE CHAIR BONNEVILLE: YES.

6 MR. TOSHER: ANNE-MARIE DULIEGE.

7 DR. DULIEGE: YES.

8 MR. TOSHER: YSABEL DURON.

9 MS. DURON: YES.

10 MR. TOSHER: MARK FISCHER-COLBRIE.

11 DR. FISCHER-COLBRIE: YES.

12 MR. TOSHER: FRED FISHER.

13 DR. FISHER: YES.

14 MR. TOSHER: DAVID HIGGINS.

15 DR. HIGGINS: YES.

16 MR. TOSHER: RICH LAJARA.

17 MR. LAJARA: YES.

18 MR. TOSHER: LAUREN MILLER-ROGEN.

19 MS. MILLER-ROGEN: YES.

20 MR. TOSHER: ADRIANA PADILLA.

21 DR. PADILLA: YES.

22 MR. TOSHER: JOE PANETTA.

23 MR. PANETTA: YES.

24 MR. TOSHER: AL ROWLETT.

25 MR. ROWLETT: YES.

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1 MR. TOSHER: MARVIN SOUTHARD.

2 DR. SOUTHARD: YES.

3 MR. TOSHER: JONATHAN THOMAS.

4 CHAIRMAN THOMAS: YES.

5 MR. TOSHER: THANK YOU, J.T. THE MOTION  
6 CARRIES.

7 CHAIRMAN THOMAS: THANK YOU, SCOTT.

8 GIL, I BELIEVE THAT CONCLUDES YOUR  
9 PRESENTATION FOR TODAY.

10 DR. SAMBRANO: YES, IT DOES. THANK YOU,  
11 MR. CHAIRMAN.

12 CHAIRMAN THOMAS: THANK YOU. AS ALWAYS,  
13 THANK YOU TO YOU AND THE REVIEW TEAM.

14 WE ARE NOW GOING OUT OF THE ACTION ITEM  
15 PART OF THE AGENDA. WE'RE ON TO DISCUSSION ITEMS  
16 NO. 5, GENERAL COMMENTS BY ANYBODY ON THE  
17 APPLICATION REVIEW SUBCOMMITTEE PROCESS. THIS IS A  
18 RECURRING ITEM.

19 DR. DULIEGE: J.T., I DON'T HAVE  
20 NECESSARILY A COMMENT OR A QUESTION, BUT YOU CAN  
21 MAYBE HELP US BY TELLING US WHERE YOU THINK WE  
22 SHOULD FOCUS? IS THERE ANY CHALLENGE, ANY PROBLEM,  
23 OR CHANGE THAT WE DON'T KNOW ABOUT AND WE SHOULD  
24 KNOW ABOUT?

25 CHAIRMAN THOMAS: NO.



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1 DR. DULIEGE: MORE A RHETORICAL QUESTION  
2 IN SOME WAYS.

3 CHAIRMAN THOMAS: IT'S REALLY A RHETORICAL  
4 QUESTION. JUST IF THERE ARE ELEMENTS OF WHAT WE DO  
5 THAT ANYBODY WOULD LIKE TO COMMENT ON. IT'S NOTHING  
6 MORE SPECIFIC THAN THAT.

7 DR. DULIEGE: THEN JUST ONE THING. WHEN  
8 IT COMES TO CLINICAL TRIALS, AND IT'S GOING BACK TO  
9 THE COMMENT I MADE LAST TIME. I FULLY REALIZE THAT  
10 CIRM IS VERY DILIGENT IN CHECKING IF THE COST OF THE  
11 REQUEST, THE AMOUNT OF THE REQUEST FOR FUNDING IS  
12 JUSTIFIED AND IF THINGS ARE DONE THE RIGHT WAY. ON  
13 THE OTHER HAND, IN RARE CASES I'VE BEEN SURPRISED  
14 ABOUT LITERALLY THE COST OF CLINICAL TRIALS FOR THE  
15 NUMBER OF PATIENTS TREATED. LAST EXAMPLE WAS, I  
16 THINK, ESSENTIALLY A REQUEST FOR \$4 MILLION FOR A  
17 PHASE 1 TRIAL PER PATIENT. AND I WONDER IF THERE'S  
18 SOMETHING THAT SHOULD BE DONE ABOUT THIS OR NOT.

19 CHAIRMAN THOMAS: WELL, GIL, DO YOU WANT  
20 TO RESPOND TO THAT? IT'S OBVIOUSLY A FUNCTION OF  
21 THE RARITY OF THE DISEASE AND THE EXPENSE OF THE  
22 PARTICULAR PHASE THAT WE ARE VOTING ON. BUT, GIL,  
23 DO YOU HAVE ANY COMMENTS ON THAT?

24 DR. SAMBRANO: YES. IT'S A VERY GOOD  
25 QUESTION. AND IT'S SOMETHING THAT, AS MENTIONED, WE

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1 DO MAKE A POINT OF BENCHMARKING OUR APPLICATIONS  
2 BASED ON EVERYTHING THAT WE HAVE EVER RECEIVED AND  
3 THE COSTS. IT DOES BECOME A BIT COMPLICATED IN  
4 TERMS OF THE SPECIFIC REASONS FOR THE COST WITHIN A  
5 SPECIFIC TRIAL. AND SO WHAT WE ARE TRYING TO DO IS  
6 DEVELOP, ONE, A TUTORIAL, IF YOU WILL, OF WHAT WE DO  
7 TO PROVIDE TO YOU SO THAT YOU UNDERSTAND KIND OF  
8 WHAT THE PARAMETERS ARE BEHIND ALL OF THIS, AS WELL  
9 AS ENSURE THAT OUR BENCHMARKING IS GENERALLY ON  
10 TARGET, THAT WE ARE NOT OFF BY ANY SIGNIFICANT  
11 AMOUNT THAT WOULD CAUSE CONCERN. AND THEN, PERHAPS,  
12 WHETHER THERE IS A CUTOFF, A PLACE THAT WOULD BE  
13 REASONABLE FOR US TO SAY THIS IS TOO MUCH, AND WE  
14 DON'T KNOW WHERE THAT IS AT THE MOMENT.

15 SO IT IS SOMETHING THAT WE ARE WORKING ON  
16 TO BETTER DEFINE AND STRUCTURE TO HELP YOU IN YOUR  
17 DECISION-MAKING AS WELL BECAUSE I KNOW THAT IN SOME  
18 CASES, AS YOU ALLUDED TO LAST TIME, IT CAN APPEAR TO  
19 BE EXTREMELY EXPENSIVE FOR SOME TRIALS.

20 DR. DULIEGE: THANK YOU. YOU ALWAYS  
21 PROVIDE VERY GOOD AND COMPLETE RESPONSES.  
22 APPRECIATE IT.

23 CHAIRMAN THOMAS: THANK YOU, GIL.  
24 DAVID.

25 DR. HIGGINS: YES, SIR. J.T., THIS IS A

**BETH C. DRAIN, CA CSR NO. 7152**

1 QUESTION FOR YOU. IS THIS MEETING TODAY YOUR LAST  
2 ARS MEETING, OR ARE YOU GOING TO CHAIR THE ONE IN  
3 MARCH AS WELL?

4 CHAIRMAN THOMAS: I AM CHAIRING THE MARCH  
5 MEETING. WE'LL SWEAR IN DR. IMBASCIANI AT THE END  
6 OF THAT MEETING. AND PART AND PARCEL OF THAT  
7 MEETING WILL BE AN APPLICATION REVIEW SUBCOMMITTEE  
8 COMPONENT WHICH I WILL BE CHAIRING.

9 DR. HIGGINS: GOOD. WE CAN SAVE OUR  
10 ROASTING FOR THEN?

11 CHAIRMAN THOMAS: YES.

12 VICE CHAIR BONNEVILLE: I EXPECT EVERYONE  
13 TO ROAST. SO PLEASE BE PREPARED. FOR ART AS WELL.

14 CHAIRMAN THOMAS: YES. WOULD EXPECT NO  
15 LESS AND BE VERY DISAPPOINTED IF THAT WEREN'T THE  
16 CASE.

17 MR. TOSHER: IT'S GOING TO BE A TWO-DAY  
18 MEETING, J.T.

19 CHAIRMAN THOMAS: I'M ALLOCATING AN HOUR  
20 FOR MARIA ALONE. OKAY.

21 ANY OTHER GENERAL COMMENTS ABOUT THE ARS  
22 PROCESS? OKAY. HEARING NONE, DO WE HAVE ANY PUBLIC  
23 COMMENT ON ANYTHING THAT ANYBODY WANTS TO COMMENT  
24 ON?

25 MS. DEQUINA-VILLABLANCA: NONE, J.T.

**BETH C. DRAIN, CA CSR NO. 7152**

1                   CHAIRMAN THOMAS: OKAY. WELL, I THINK IN  
2                   THAT CASE, THAT CONCLUDES TODAY'S AGENDA. FOR THOSE  
3                   OF YOU IN THE BAY AREA, WE HOPE YOU GET STAFF BACK  
4                   SHORTLY. FOR THOSE OF US IN SOUTHERN CALIFORNIA,  
5                   WE'RE HOPING THAT THE LAKERS GET OUT OF 13TH PLACE  
6                   AND SOMEHOW MAKE IT INTO THE PLAYOFFS. WE'LL KNOW  
7                   BY THE NEXT MEETING.

8                   ON THAT NOTE, THANK YOU, EVERYBODY, FOR  
9                   YOUR ATTENDANCE. AND WE WILL SEE YOU ALL ON MARCH  
10                  28TH. MEETING STANDS ADJOURNED. THANK YOU.

11                  (THE MEETING WAS THEN CONCLUDED AT 9:26 A.M.)

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**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 VIRTUAL PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON FEBRUARY 23, 2023, 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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