**MEMORANDUM**

**Date:** May 21, 2012

**From:** Alan Trounson, PhD
CIRM President

**To:** Independent Citizen's Oversight Committee

**Subject:** Extraordinary Petition for Application TR3-05626 **(LATE)**

Enclosed is a petition letter from Dr. Walter Boyd of the University of California Davis, an applicant for funding under RFA 11-02, CIRM Early Translational III Awards. This letter was received at CIRM on May 19, 2012, which is less than the 5 business days requested by the ICOC for extraordinary petitions. We are forwarding it pursuant to the ICOC Policy Governing Extraordinary Petitions for ICOC Consideration of Applications for Funding.

UNIVERSITY OF CALIFORNIA, DAVIS

BERKELEY $ DAVIS $ IRVINE $ LOS ANGELES $ MERCED $ RIVERSIDE $ SAN DIEGO $ SAN FRANCISCO SANTA BARBARA $ SANTA CRUZ

W. DOUGLAS BOYD, M.D.
PROFESSOR OF CLINICAL SURGERY
DIRECTOR OF ROBOTICS AND BIOSURGERY
CARDIOTHORACIC SURGERY

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May 18, 2012

RE: TR3-05626: Extracellular Matrix Bioscaffold Augmented with Human Stem Cells for Cardiovascular Repair

Dear Members of the ICOC,

We are filing an extraordinary petition requesting, please, further consideration for our RFA 11-02 grant TR3-05626 that recently scored a 67, one point below others recommended for funding.

This letter addresses the extraordinary circumstance that supports further consideration of this proposal. We now have the fully executed Material Transfer Agreement in place, and we continue to have a strong industry partner in Cook Biotech Inc., who will supply us with the matrix material and technical expertise to create a new bioengineered cardiac patch material.

Please find enclosed our strong letter of support and evidence of the fully executed MTA from Dr. Michael Hiles, Ph.D., Vice President for Research and Clinical Affairs and CSO at Cook Biotech Incorporated.

Cook Biotech is strongly supportive of our proposed large animal studies, to be conducted under "Good Laboratory Practices" regulations for IND-enabling studies (CFR Title 21 Part 58). These studies have the potential to rapidly lead to a new tissue engineered product that combines mesenchymal stem cells, known for their pro-angiogenic and anti-scarring and inflammatory properties, with the FDA approved SIS material to be provided by Cook Biotech. If funded, we will work closely with CIRM and Cook to move this product into the clinic at the end of the potential funding period.

Thank you in advance for further considering our application.

Sincerely,

W. Douglas Boyd, MD
Professor of Clinical Surgery
Medical Director of Robotics Surgery
Division of Cardiothoracic Surgery

COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

May 16, 2012

Dear Members of the ICOC,

I would like to provide a letter of strong support for Dr. Walter Boyd's grant, "TR3-05626: Extracellular Matrix Bioscaffold Augmented with Human Stem Cells for Cardiovascular Repair".

I am Chief Scientific Officer for Cook Biotech, Incorporated, the manufacturer of small intestinal submucosa (SIS) graft material. We are based in West Lafayette, Indiana, and were the first to commercialize acellular, non-crosslinked, extracellular-matrix-based surgical grafts back in 1998. To date we have shipped these technologically-advanced grafts to more than 70 countries and augmented more than 2 million patient treatments for soft tissues all over the human body. Further, it makes evolutionary, biological, and medical sense to try to create next-generation therapies combining the scaffolds and signals of an intact ECM with the active nature of living cells.

In December 2011, Cook Biotech completed a fully executed a Material Use Agreement with the University of California, Davis, to permit exploration of such combination therapies—especially in the area of cardiac repair. The work that is proposed by Dr. Boyd (a leading cardiothoracic surgeon who is using our manufactured and FDA-cleared SIS product routinely and in over 300 cardiac surgery patients) is both exciting and well-conceived. The proposed large animal studies, to be conducted under Good Laboratory Practices (GLP) regulations as IND-enabling studies, have the potential to lead to a new tissue engineered product that combines mesenchymal stem cells, known for their pro-angiogenic and anti-scarring and inflammatory properties, with our safe and proven SIS material. It could be the first real regenerative medicine product of its kind.

We will most-definitely support this work with technical support and supplies of SIS material, and we look forward to real progress from this well-qualified group.

Sincerely,

Michael Hiles, Ph.D.
Vice President for Research
Chief Scientific Officer

consent of CBI. This Agreement constitutes the entire agreement between the parties with respect to the Material and Information, supersedes all previous agreements or representation between the parties, and cannot be changed or amended except by written agreement executed by both parties.

17. The effective date of this Agreement shall be the latest date on which it is signed on behalf of a party hereto.

If the foregoing terms and conditions are acceptable to Recipient, please indicate acceptance by having one (1) copy executed by Recipient and returned to the undersigned.

RECIPIENT

AGREED AND ACCEPTED:

By _____

Name David R. McGee

Title Executive Director,
UC Davis Technology Transfer Services

Date 12/9/11

COOK BIOTECH INCORPORATED

AGREED AND ACCEPTED:

By _____

Name Michael Hiles

Title VP Research & CSO

Date 06Dec11