#### THE UNIVERSITY OF MICHIGAN

Approved by the Regents September 17, 2009

REGENTS COMMUNICATION

### ACTION REQUEST

Subject:

Third Amendment to License Agreement between the

University of Michigan and NanoBio Corporation

Action Requested: Approval of Amendment

#### Preamble:

A statutory conflict of interest situation was identified by the Office of Technology Transfer while reviewing the technology transfer agreement. This then triggered a review by the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Board and agreed to by the parties involved.

This proposed third amendment ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professor James R. Baker, Jr. is both an employee of the University of Michigan ("University") and an Owner, Director and Officer of NanoBio Corporation ("Company"). The law permits such an Agreement provided it is disclosed to the executive officers and approved in advance by a 2/3 vote of the Regents of the University of Michigan.

# **Background:**

Dr. James R. Baker, Jr., the Director of the Michigan Nanotechnology Institute for Medicine and Biological Sciences and Professor in the Departments of Internal Medicine and Biomedical Engineering, is an Owner, Director and Officer of a forprofit company called NanoBio Corporation. The University and the Company entered into the original license in August 2000 when the Company was formed to commercialize therapeutic uses of emulsion-based compositions. This license has been twice amended to add additional technologies from the University. The Company now wishes to add the following technologies from the University into the existing license:

UM File No. 4104, entitled: "ITC and Zeta Potential Measurements of Nanoemulsions" (inventors James R. Baker, Jr., Paul E. Makidon, and Nicholas J. Mank)

- File No. 4137, entitled: "Nanoemulsion Activation-Physical and Biochemical Requirements" (inventors James R. Baker, Jr., Paul E. Makidon, Nicholas J. Mank, Anna U. Bielinska)
- File Nos. 4205, 4207, entitled: "IL-6 Signaling and Nanoemulsions"; and "Uric Acid and Nanoemulsions" (inventors James R. Baker, Jr., Paul E. Makidon, Jeffery V. Groom II, Luz Pamela Blanco)
- File No. 4162, entitled: "Topical Nanoemulsion Therapy for Burn Wounds" (inventors James R. Baker, Jr., Mark R. Hemmila, Stewart C. Wang, Tarek Hamouda (NanoBio))
- File No. 4367, entitled: "Respiratory Syncytial Virus Vaccine Induction with Nanoemulsion Immunization" (inventors Nicholas W. Lukacs, Dennis Lindell, James R. Baker, Jr.)
- File No. 4370, entitled: "Streptococcus Adjuvanted with Nanoemulsion" (inventors James R. Baker, Jr., Paul E. Makidon, Nicholas J. Mank, Whitney A. Dunlap, and Jessica A. Knowlton)
- File No. 4470, entitled: "NE-based Burkholderia Vaccine" (inventors James R. Baker, Jr., John J. LiPuma, Jessica Ann Knowlton, Paul E. Makidon, Luz Blanco, Jeffery V. Groom II)

# Parties to the Agreement:

The Regents of the University of Michigan and NanoBio Corporation.

# **Agreement Terms:**

Agreement terms include giving the Company an exclusive license with the right to grant sublicenses. The Company will pay a royalty on sales and reimburse patent costs. The University will retain ownership of the licensed technology and may continue to further develop it and use it internally. No use of University services or facilities, nor any assignment of University employees, is obligated or contemplated under the Agreement. Standard disclaimers of warrantees and indemnification apply, and the Agreement may be amended by consent of the parties. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

## **Pecuniary Interest:**

The pecuniary interest of Dr. Baker arises from his ownership interest in NanoBio Corporation.

# Net Effect:

The Office of Technology Transfer has negotiated and finalized the terms of an amendment to the existing worldwide exclusive license agreement for patents related to UM OTT File Nos. 4104, 4137, 4205, 4207, 4162, 4367, 4370 and 4470 for all fields. The Company will obtain use and commercialization rights to the above listed University technology.

#### Recommendations:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. In light of this disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I <u>recommend</u> that the Board of Regents approve the third Amendment between the University and NanoBio Corporation.

Respectfully Submitted,

Stephen R. Forrest

Vice President for Research

September 2009

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