THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents July 19, 2007

ACTION REQUEST

Subject:

Research Agreement between the University of Michigan

and OtoMedicine, Inc.

Action Requested: Approval of Research Agreement

Preamble:

A statutory conflict of interest situation was identified by the Division of Research Development and Administration while reviewing the proposed research agreement which then triggered a review by the OVPR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflicts of interest was then developed by the Committee and agreed to by the parties involved.

This proposed research agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Dr. Josef Miller is an employee of the University of Michigan ("University") and partial owner and Chair of the Board of Directors of OtoMedicine, Inc. 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. Josef Miller, Professor of Otolaryngology, is a partial owner and Chair of the Board of Directors of a for-profit company called OtoMedicine, Inc. ("OtoMedicine"). OtoMedicine was formed recently to develop pharmaceuticals for the prevention and treatment of hearing disorders and desires to support a research contract related to the inventions made by Dr. Miller. A technology option agreement has been disclosed under separate Regental Action.

Nature of the Agreement:

OtoMedicine has received an option agreement from the University that relates to the subject of the research project. The proposed project involves analysis of data resulting from clinical trials ongoing at other institutions related to a compound for prevention of noise-induced hearing loss.

Agreement Terms:

The terms of the Agreement will conform to University policy. Dr. Roderick Little, Professor, Department of Biostatistics, who has no financial interest in the OtoMedicine, will direct the project over an initial six month period at an estimated cost of \$8,740. The Agreement will include a provision allowing extension and modification of the project upon mutual agreement of the parties.

University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Impact of the Agreement:

This project will provide further information that will assist the University and OtoMedicine in assessing and further developing certain compounds, obtaining regulatory approvals, and commercializing treatments and preventions for noise-induced hearing loss.

Recommendation:

This matter has been reviewed and approved by the OVPR Conflict of Interest Review Committee. In light of the disclosure made in this document and our finding that the Agreement was negotiated in conformance with standard University practices, I <u>recommend</u> that the Board of Regents approve of the University's entering into this Agreement with OtoMedicine, Inc.

Respectfully submitted,

Stephen R. Forrest

Vice President for Research

July 2007