

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and OcuSciences, Inc.

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form which 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 research agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professors Victor Elnor and Howard Petty are both employees of the University of Michigan ("University"), and partial owners and officers of OcuSciences, Inc. The law permits such an Agreement provided it is disclosed to the Board of Regents ("Regents") of the University of Michigan and approved in advance by a 2/3 vote.

Background:

Howard Petty, Ph.D., a Professor of Ophthalmology & Visual Sciences and Microbiology & Immunology, and Victor Elnor, M.D., Ph.D., a Professor of Ophthalmology & Visual Sciences and Pathology, are the partial owners and officers of a for-profit company called OcuSciences, Inc. (the "Company"). The Company wishes to fund a project entitled "Effects of Oral T-3550549 on the Pathological Responses to Retinal Ischemia-Reperfusion Injury" (ORSP# 16-PAF00709) in the Department of Ophthalmology & Visual Sciences under the direction of Drs. David Antonetti and Steven Abcouwer. The purpose of this project is to test the efficacy of Takeda compound T-3550549 (549) in prevention of retinal neurodegeneration, neuroinflammation and vascular permeability following retinal ischemia-reperfusion (IR) injury in pigmented rats.

This proposed research agreement is being undertaken following a prior research agreement and license that have resulted in forgiven debt and a currently outstanding receivable. Under the terms of a master agreement previously approved by the Board of Regents, OcuSciences, Inc. issued an \$858,135 subcontract to the University for a project funded by MacuCLEAR, Inc. Due to a legal dispute between OcuSciences, Inc. and MacuCLEAR, Inc., the subcontract was terminated early and the University was not reimbursed for \$83,981 in project-related expenses. Under the terms of a license agreement with the University, OcuSciences, Inc. is also delinquent on \$72,526 in patent costs. OcuSciences, Inc. has agreed to a payment plan of \$5,000 per quarter beginning the first quarter of 2016, or payment in full upon the completion of a seed round or Series A funding of not less than \$1 million.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately one (1) year. The amount of funding support will not exceed \$105,300. Terms of the Agreement will include up front payment of no less than 75% of the total funding. Since research projects are often amended, this agreement includes a provision for changes in time, amount, and scope. 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

The Agreement will support an effort by Drs. David Antonetti and Steven Abcouwer to use their expertise and University laboratory, as well as other University resources to test the efficacy of Takeda compound T-3550549 (549) in prevention of retinal neurodegeneration, neuroinflammation and vascular permeability. This Agreement will continue to facilitate an important relationship with Takeda and the significant initial payment assures that the Project will be financially sound.

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 recommend that the Board of Regents approve the University's entering into this Agreement with OcuSciences, Inc.

Respectfully submitted,



S. Jack Hu
Interim Vice President for Research

September 2015