UNIVERSITY CONTRACT TO LICENSE TECHNOLOGY TO A COMPANY OWNED BY A SCHOOL OF MEDICINE FACULTY MEMBER

RECOMMENDATION

The Administration recommends that the Board of Governors authorize the President or her designee to enter into a contract with Ripple Biosciences, LLC, a Michigan Limited Liability Corporation for an option for an exclusive license for commercialization of the intellectual property encompassing the development of a diagnostic entitled "Sperm Epigenetic Aging Predicts Reproductive Outcomes." The proprietary technology and associated trade secrets describe an epigenetic clock (*i.e.*, biological aging) for sperm that is associated with time-to-pregnancy (TTP) among couples trying to conceive. The 'clock' is also associated with gestational age, current smoking and phthalate exposure – indoor pollutants – and can assist in directing treatment options.

BACKGROUND

J. Richard Pilsner, Ph.D., MPH, is professor and the Robert J. Sokol, MD Endowed Chair of Molecular Obstetrics and Gynecology in the School of Medicine at Wayne State University. Dr. Pilsner has developed a diagnostic technology for assessment of male infertility and its relationship to the probability of pregnancy. The technology has been disclosed to the University (WSU technology, 23-1705). As described in the disclosure, there is a strong relationship between chronological age and DNA methylation profiles in most somatic tissues and has the estimation of biological age and the calculation of epigenetic 'clock' metrics, such as DNA methylation age and epigenetic age acceleration. This describes the degree in which predicted biological age deviates from chronological age. However, existing clocks in somatic tissue do not work well in germ cells such as sperm. Dr. Pilsner and his team developed an epigenetic clock (*i.e.*, biological aging) for sperm that is associated with time-to-pregnancy (TTP) among couples trying to conceive. The technology is currently protected in the form of trade secrets and work continues towards a patent submission.

Ripple Biosciences, LLC, incorporated in Michigan in 2024, was founded to develop and commercialize this technology as a diagnostic (STTR being submitted 05 Sep 2024). Dr. Pilsner is the founder and owner of Ripple Biosciences, LLC, located at 18530 Mack Ave., Ste. 290, Grosse Pointe Farms, Michigan 48236.

Michigan Conflict of Interest law requires specific sunshine procedures in order for a University employee, or a company owned by a University employee, to contract directly or indirectly with the University:

(A) The employee must disclose any pecuniary interest in the contract to the Board and the disclosure must be made a matter of record in the

BOARD OF GOVERNORS AGENDA SEPTEMBER 13, 2024

Board's proceedings.

- (B) The contract must be approved by a vote of not less than two-thirds of the full membership of the Board in open session.
- (C) The Board's minutes must report:
 - (i) The name of each party involved in the contract.
 - (ii) The terms of the contract, including duration, financial consideration between the parties, facilities or services of the public entity included in the contract, and the nature and degree of assignment of employees of the public entity for fulfillment of the contract.
 - (iii) The nature of any pecuniary interest.

If the Board approves this Recommendation, the minutes will report as follows:

The Board of Governors authorized the President, or her designee, to enter into a contract with Ripple Biosciences, LLC, in which Dr. J. Richard Pilsner holds an equity position.

- (i) The parties involved in the contract are Wayne State University and Ripple Biosciences, LLC.
- (ii) The contract will provide:
 - (a) Scope: An option to acquire an exclusive, worldwide royalty bearing license.
 - (b) Duration: The term of the option shall be for twelve (12) months with the opportunity to extend for a further period of twelve (12) months upon payment of additional consideration.
 - (c) Financial Consideration: An option fee of \$3,000.
 - (d) No University facilities or services of the University are included in the contract; and
 - (e) No University employees are assigned in connection with the contract.
- (iii) Dr. J. Richard Pilsner's pecuniary interest as the sole member of the LLC

BOARD OF GOVERNORS AGENDA SEPTEMBER 13, 2024

consists of a current one hundred percent (100%) ownership of Ripple Biosciences, LLC. Dr. Pilsner will therefore have the potential to financially benefit from the commercial success of the company. Dr. Pilsner has filed a Financial Conflict of Interest with the Office of Research Integrity.