This document is scheduled to be published in the
Federal Register on 11/06/2018 and available online at
https://federalregister.gov/d/2018-24225, and on **govinfo.gov**

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Therapeutics for insulin resistance and Non-Alcoholic Fatty Liver Disease/Non-Alcoholic Steatohepatitis (NASH/NAFLD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization patent license to Ovensa, Inc. headquartered in Ontario, Canada, to practice the inventions embodied in the patent application(s) listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Ovensa: HHS Ref. No. E-103-2013-0, U.S. Provisional Patent Application 61/839,239, “Glucan-Encapsulated siRNA For Treating Type 2 Diabetes Mellitus,”

filed June 25, 2013, International Patent Application PCT/2014/043924 filed June 24, 2014, European Patent Application 14818342.9 filed June 24, 2018, and US Patent 10,077,446 filed June 24, 2014 and issued September 18, 2018. The patent rights in this invention have been assigned to the Government of the United States of America. The prospective license would be granted worldwide and in a field of use not broader than therapeutics for preventing or treating insulin resistance and non-alcoholic fatty liver disease/non-alcoholic steatohepatitis. The scope of any proposed licensed may also be limited to products sold that include therapeutic siRNAs encapsulated in nanoparticles made from either glucan based biopolymers and/or Ovensa's TRIOZAN™ (N,N,N-Trimethyl Chitosan) proprietary biopolymer.

The invention pertains to the use of glucan encapsulated non-immunostimulatory small interfering RNAs (siRNAs) to treat type-2 diabetes. Endocannabinoids (EC) are lipid signaling molecules that act on the same cannabinoid receptors that recognize and mediate the effects of endo- and phytocannabanoids. EC receptor CB1R activation is implicated in the development of obesity and its metabolic consequences, including insulin resistance and type 2 diabetes. Beta-cell loss has been demonstrated in a Zucker diabetic fatty (ZDF) rat model of type-2 diabetes through CB1R-mediated activation of a macrophage-mediated inflammatory response. Conversely, rats treated with a peripheral CB1R antagonist restores normoglycemia and preserves beta-cell function. Similar results are seen following selective in vivo knockdown of macrophage CB1R by daily treatment of ZDF rats with the instant D-glucan-encapsulated CB1R small interfering RNA (siRNA). Knock-down of CB1R using glucan encapsulated siRNA represent new methods of treating type-2 diabetes or preventing the progression of insulin resistance to overt diabetes.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective

exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: October 24, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager,

National Heart, Lung, and Blood Institute,

Office of Technology Transfer and Development.

[FR Doc. 2018-24225 Filed: 11/5/2018 8:45 am; Publication Date: 11/6/2018]