

HISTORY:

None.

[FR Doc. 2020-15380 Filed 7-15-20; 8:45 am]

BILLING CODE 4150-28-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of an Exclusive Patent License: Gene Therapy for Treatment or Prevention of Niemann-Pick Disease Type C1, Subject to Existing Three Non-Exclusive Licenses****AGENCY:** National Institutes of Health, Health and Human Services (HHS).**ACTION:** Notice.

SUMMARY: The National Human Genome Research Institute is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the United States, European and Canadian Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to AveXis, Inc., located in Bannockburn, Illinois, USA.

DATES: Only written comments and/or applications for a license which are received by the National Human Genome Research Institute's Technology Transfer Office on or before July 31, 2020 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Anna Solowiej, Ph.D., J.D., Senior Licensing and Patenting Manager, NHGRI Technology Transfer Office, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20817 (for business mail); Telephone (301) 435-7791; Email: anna.solowiej@nih.gov.

SUPPLEMENTARY INFORMATION:**Intellectual Property**

Group A, HHS Reference No.: E-185-2014-0: "Viral Gene Therapy as Treatment for Cholesterol Storage Disease or Disorder"

I. U.S. Provisional Application 62/144,702, filed April 8, 2015, expired (HHS Reference No.: E-185-2014-0-US-01).

II. PCT Application PCT/US2016/026524, filed April 7, 2016, expired (HHS Reference No.: E-185-2014-0-PCT-02).

III. U.S. Application 15/565,065, filed October 6, 2017 (HHS Reference No.: E-185-2014-0-US-04).

IV. Canadian Application 2,982,129, filed October 6, 2017 (HHS Reference No.: E-185-2014-0-CA-05).

V. European Application 16717228.7 filed November 8, 2017, issued as EP 3280451, validated in Italy, Spain, France, UK, and Germany (HHS Reference No.: E-185-2014-0-EP-06).

Group B, HHS Reference No.: E-100-2017-0: "Codon-Optimized Human NPC1 Genes for the Treatment of Niemann-Pick Type C1 Deficiency and Related Conditions"

I. U.S. Provisional Application U.S. 62/522,677, filed June 20, 2017, expired (HHS Reference No.: E-100-2017-0-US-01).

II. PCT Application PCT/US2018/038584, filed June 20, 2018, expired (HHS Reference No.: E-100-2017-0-PCT-02).

III. U.S. Application U.S. 16/623,863 filed December 19, 2019 (HHS Reference No.: E-100-2017-0-US-05).

IV. Canadian Application 3,068,010, filed December 19, 2019 (E-100-2017-0-CA-03).

V. European Application 18740403.3 filed January 20, 2020 (HHS Reference No.: E-100-2017-0-EP-04).

The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to manufacture and commercialization of pharmaceutical products for the treatment and/or prevention of Niemann Pick disease, Type C1 (NPC1) using gene therapy in humans that incorporate the Licensed Product(s), in combination with AAV9, subject to three existing non-exclusive licenses for this technology.

Above listed patent portfolio cover inventions directed to gene therapy and specifically, expression vectors and therapeutic methods of using such vectors in the treatment of Niemann-Pick Disease Type C1.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Human Genome Research Institute 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.

In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated

confidentially, and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 7, 2020

Claire T. Driscoll,

*Director, Technology Transfer Office,
National Human Genome Research Institute.*

[FR Doc. 2020-15342 Filed 7-15-20; 8:45 am]

BILLING CODE 4140-01-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of an Exclusive Patent License: Gene Therapy for Ocular Disease****AGENCY:** National Institutes of Health, Health and Human Services (HHS).**ACTION:** Notice.

SUMMARY: The National Eye Institute, the National Institute on Deafness and Other Communication Disorders, and the National Heart, Lung, and Blood Institute, institutes of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an exclusive patent license to VegaVect, Inc., a start-up company spun-off from the University of Pittsburgh Medical Center Enterprises and incorporated as a C corporation under the laws of the state of Delaware, to practice the inventions covered by the patent estate listed in the **SUPPLEMENTARY INFORMATION** section of this notice. This is a second notice intended to apprise the public of a change in prospective licensee of the subject intellectual property rights in the stated field of use from a first notice: Prospective Grant of An Exclusive Patent License: Gene Therapy for Ocular Disease, published in the **Federal Register** on November 26, 2019.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center (representing the National Eye Institute and the National Heart, Lung, and Blood Institute (representing the National Institute on Deafness and Other Communication Disorders)) on or before July 31, 2020 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and

comments relating to the contemplated an 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:

INTELLECTUAL PROPERTY

NIH ref No.	Title	Patent application No.	Filing date	Issued patent No.	Issue date
E-284-2012-0-US-01	Methods And Compositions For Treating Genetically Linked Diseases Of The Eye.	61/765,654	February 15, 2013.		
E-284-2012-1-US-01	Methods And Compositions For Treating Genetically Linked Diseases Of The Eye.	61/815,636	April 24, 2013.		
E-284-2012-2-PCT-01	Methods And Compositions For Treating Genetically Linked Diseases Of The Eye.	PCT/US2014/16389 ..	February 14, 2014.		
E-284-2012-2-AU-02	AAV8 retinoschisin expression vector for treating X-linked retinoschisis.	2014216160	February 14, 2014	2014216160	July 13, 2017.
E-284-2012-2-CA-03	AAV8 retinoschisin expression vector for treating X-linked retinoschisis.	2900231	February 14, 2014	2900231	July 30, 2019.
E-284-2012-2-JP-04	Methods And Compositions For Treating Genetically Linked Diseases Of The Eye.	2015-558144	February 14, 2014	6449175	December 14, 2018.
E-284-2012-2-US-05	Methods And Compositions For Treating Genetically Linked Diseases Of The Eye.	14/766,842	February 14, 2014	9,873,893	January 23, 2018.
E-284-2012-2-US-07	Methods And Compositions For Treating Genetically Linked Diseases Of The Eye.	15/876,821	February 14, 2014	10,350,306	July 16, 2019.
E-284-2012-2-EP-06	Methods And Compositions For Treating Genetically Linked Diseases Of The Eye.	14708176.4	February 14, 2014.		
E-284-2012-2-PCT-08	Methods And Compositions For Treating Genetically Linked Diseases Of The Eye.	PCT/US2019/14418 ..	January 21, 2019.		
E-164-2018-0-US-01	Intraocular Delivery Of Gene Therapy Expression Vectors.	62/701,267	July 20, 2018.		
E-164-2018-1-US-01	Intraocular Delivery Of Gene Therapy Expression Vectors.	62/724,480	August 29, 2018.		
E-164-2018-2-US-01	Intraocular Delivery Of Gene Therapy Expression Vectors.	62/768,590	November 16, 2019.		
E-164-2018-3-PCT-01	Intraocular Delivery Of Gene Therapy Expression Vectors.	PCT/US2019/042365	July 18, 2019.		

All U.S. and foreign patents and applications claiming priority to any member of the above.

The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to human therapeutics for (1) X-linked juvenile retinoschisis and (2) schisis cavity associated ocular disease or injury.

The aforementioned patent estates cover inventions directed to gene therapy and specifically, expression vectors and therapeutic methods of using such vectors in the treatment of ocular diseases resulting from failure to produce or the defective production of an ocular protein. This invention is also directed to methods of administering expression vectors capable of modulating a target gene or gene product for the treatment of ocular disease.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Heart, Lung, and Blood Institute 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.

In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 2, 2020.

Michael Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute.

[FR Doc. 2020-15340 Filed 7-15-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; NTU Bench Testing.

Date: August 12, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1078, Bethesda, MD 20892 (Virtual Meeting).