[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, 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 OcQuila Therapeutics Ltd., a C corporation incorporated under the laws of the state of Delaware and a limited company incorporated under the laws of the United Kingdom, to practice the inventions covered by the patent estate listed in the Supplementary Information section of this notice**.**

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 **[INSERT DATE 45 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER]** 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 thirty () 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 USC 552.

Dated: November 21, 2019.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager,

National Heart, Lung, and Blood Institute.

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