- TEKTURNA (aliskiren hemifumarate)
 VIMOVO (naproxen/esomeprazole magnesium)
- 11. VIREAD (tenofovir disoproxil fumarate)
- 12. XOFLUZA (baloxavir marboxil)

Center for Devices and Radiological Health

- CONTEGRA PULMONARY VALVED CONDUIT (Humanitarian Device Exemption (HDE))
- 2. ELANA SURGICAL KIT (HDE)
- 3. ENTERRA THERAPY SYSTEM (HDE)
- 4. LIPOSORBER LA-15 SYSTEM (HDE)
- 5. MEDTRONIC ACTIVA DYSTONIA THERAPY (HDE)
- 6. MINIMALLY INVASIVE DEFORMITY CORRECTION (MID-C) SYSTEM
- 7. PLEXIMMUNE IN-VITRO DIAGNOSTIC TEST (HDE)
- 8. PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE (HDE)
- 9. THE TETHER—VERTEBRAL BODY TETHERING SYSTEM

Dated: August 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-17041 Filed 8-9-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Notice is hereby given of a meeting of the HEAL (Helping to End Addiction Long-Term) Multi-Disciplinary Working Group.

The meeting will be open to the public as indicated below via NIH Videocast. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 program documents and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the program documents, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: HEAL Multi-Disciplinary Working Group (MDWG) Meeting. Date: September 1-2, 2021.

Open: September 01, 2021, 10:30 a.m. to 11:30 a.m.

Closed: September 02, 2021, 11:30 a.m. to 4:30 p.m.

Closed: September 02, 2021, 10:30 a.m. to 3:45 p.m.

Agenda: Provide an update on Helping to End Addiction Long-Term (HEAL) Initiative projects and obtain expertise from MDWG relevant to the NIH HEAL Initiative and to specific HEAL projects.

Videocast: The open portion of the meeting will be live webcast at: https://videocast.nih.gov/.

Place: National Institutes of Health, Building 1, Wilson Hall, 1 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebecca G Baker, Ph.D., Office of the Director, National Institutes of Health, 1 Center Drive, Room 103A, Bethesda, MD 20892, (301) 402–1994, Rebecca.baker@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Office of the Director for the NIH HEAL Initiative website: https://heal.nih.gov/news where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 5, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–17012 Filed 8–9–21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Center for Scientific Review Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

URL for virtual access:—https://videocast.nih.gov/watch=42556

Name of Committee: Center for Scientific Review Advisory Council.

Date: September 27, 2021. Time: 1:00 p.m. to 4:30 p.m.

Agenda: Provide advice to the Director, Center for Scientific Review (CSR), on matters related to planning, execution, conduct, support, review, evaluation, and receipt and referral of grant applications at CSR.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bruce Reed, Ph.D., Deputy Director, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–9159, reedbr@mail.nih.gov.

Information is also available on the Institute's/Center's home page: https://public.csr.nih.gov/AboutCSR/Organization/CSRAdvisoryCouncil, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 5, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-17043 Filed 8-9-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Listing of Members of the National Institutes of Health's Senior Executive Service 2021 Performance Review Board (PRB)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health's Senior Executive Service 2021 Performance Review Board.

FOR FURTHER INFORMATION CONTACT: For further information about the NIH Performance Review Board, contact Mr. Kha Nguyen, Director, Division of Senior and Scientific Executive Management, Office of Human Resources, National Institutes of Health, Building 31, Room 1C31P, Bethesda, Maryland 20892, telephone 301.594.3022 (not a toll-free number), email kha.nguyen@nih.gov.

SUPPLEMENTARY INFORMATION: This action is being taken in accordance with

Title 5, U.S.C., section 4314 (c) (4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the NIH Performance Review Board, which oversees the evaluation of performance appraisals of NIH Senior Executive Service (SES) members: Alfred Johnson, Chair

Amed Joinson, Cha.
Courtney Billet
Michael Gottesman
Darla Hayes
Michael Lauer
Kathleen Stephan
Lawrence Tabak

Dated: August 2, 2021.

Lawrence A. Tabak,

 $\label{lem:principal Deputy Director, National Institutes of Health.} Principal Deputy Director, National Institutes of Health.$

[FR Doc. 2021–17039 Filed 8–9–21; 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: Multi-Domain
Amphipathic Helical Peptide for Use as
A Human Therapeutic in Patients With
Atherosclerotic Cardiovascular
Disease, Including Patients
Undergoing Cardiovascular Surgery
Who Are at risk of Acute Kidney Injury

AGENCY: National Institutes of Health, HHS

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute, an institute of the National Institutes of Health,
Department of Health and Human
Services, is contemplating the grant of an exclusive patent license to Phyxius
Therapeutics, Inc., a start-up company 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 first notice intended to apprise the public of a change in prospective licensee of the subject intellectual property rights in the stated field of use.

DATES: Only written comments and/or applications for a license which are received by the National Heart, Lung, and Blood Institute on or before August 25, 2021 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 Davis, J.D., Ph.D., Senior Technology Transfer Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479, phone number 301–451–9032, or michael.davis4@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

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NIH REF No.	Title	Patent Application No.	Filing Date	Issued Patent No.	Issue Date
E-114-2004-0- US-01.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	60/619,392	10/15/04		
E-114-2004-0- PCT-02.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	PCT/US2005/	10/14/05		
E-114-2004-0- AU-03.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	2005295640	10/14/05	2005295640	11/10/11
E-114-2004-0- CA-04.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	2584048	10/14/05	2584048	08/09/16
E-114-2004-0- EP-05.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0- JP-06.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	2007–536912	10/14/05	5,091,679	09/21/12
E-114-2004-0- US-07.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	11/577,259	04/13/07	7,572,771	08/11/09
E-114-2004-0- US-08.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	12/497,443	07/02/09	8,071,746	12/06/11
E-114-2004-0- US-09.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	12/766,761	04/23/10	8,148,323	04/03/12
E-114-2004-0- CH-11.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0- DE-12.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0- ES-13.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0- FR-14.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0- GB-15.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0- IT-16.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	05815961.7	10/14/05	1812474	05/26/10
E-114-2004-0- US-17.	Multi-Domain Amphipathic Helical Peptides And Methods Of Their Use.	13/407,132	02/28/12	8,835,378	09/16/14

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 use as a human therapeutic in patients with atherosclerotic cardiovascular disease (ASCVD), including patients undergoing cardiovascular surgery who are at risk of acute kidney injury.

The patents listed above cover an invention directed to peptides or