



## Guidance

### 1 SUBMITTING AN APPLICATION

#### 1.1 Instructions

All applications should be submitted by email to [applications@PathwaysResearchAwards.com](mailto:applications@PathwaysResearchAwards.com)

The following items should be included in the submission email:

- Completed Pathways Research Awards Application Form
- Completed Pathways Research Awards Budget Form
- NIH Biosketch of applicant
- Letter (1 page) of mentor support
- Letter (1 page) from Division Chief or Department Head confirming academic appointment (or postdoctoral fellowship)
- Additional supporting documents may be included but are not required. Supporting documents may NOT include part of the Application (for example, figures or references).

Attachments may be sent as individual files or in a zip file.

The [Pathways Research Awards Application Form](#) should be downloaded from the Pathways Research Awards program website.

The [Pathways Research Awards Budget Form](#) should be downloaded from the Pathways Research Awards website.

Please note, you may need to right-click and select “save target as” to download the files.

#### 1.2 Key Dates

##### 1.2.1 Application Deadline

October 30, 2020 (by 11:59 pm Eastern Daylight Time)

##### 1.2.2 Notification of Review Committee Decision

Q1 2021

##### 1.2.3 Public Announcement of Awardees

Q2 2021

#### 1.2.4 Funding

Grants will be funded after execution of **Alkermes Pathways Research Awards**® Terms and Conditions and receipt of all regulatory or institutional approvals (as applicable). The Third Annual Pathways program will provide individual grants amounts of up to \$100,000 each for junior investigators to conduct research in Substance Use Disorders (SUD), Schizophrenia or Bipolar Disorder.

## 2. SCOPE OF AWARD

### 2.1 Scope of Awards

The program is designed to support clinical and basic research in therapeutic areas that are of interest to Alkermes, focusing on central nervous system disorders. In the future, other therapeutic areas may be considered.

The areas of scientific interest are:

- **Substance Use Disorders (SUDs)**
- **Schizophrenia**
- **Bipolar Disorder**

For each area of interest, applications are invited on:

- Preclinical, clinical, translational and epidemiological research
- Research on treatment and patient-centered outcomes
- Clinical and health economic outcomes using real-world data
- Outcomes research supporting continuity of care utilizing telehealth or other technology-based approaches

Please note that therapeutic treatment studies using an Alkermes product will require additional review by Alkermes.

Research projects should yield results that merit submission as abstracts to scientific meetings and, subsequently, publication in peer-reviewed journals.

### 2.2 Eligibility

This grant is for investigators who are in the early stages of their career; specifically, they may be the recipient of a career development (K) award or other mentored research grant, but not a funded R01 grant or equivalent at the time of application.

Researchers with an academic position above assistant professor are not eligible.

Pathway Research Awards will be awarded to applicants who have demonstrated a commitment to SUD, schizophrenia, or bipolar disorder research. Eligible applicants must meet the following criteria:

- Have an MD, PhD, or equivalent
- Affiliated with a medical or research center within the United States at the time of application

- Within 5 years of initial academic appointment (e.g., assistant professor) or current postdoctoral fellow
- Research focuses primarily on furthering our knowledge of SUDs, schizophrenia, or bipolar disorder
- Have a research mentor with extensive experience in the field of SUDs, schizophrenia, or bipolar disorder
- Have not received an NIH R01 grant at the time of award\*.
- Willing and able to accept funding from a for-profit pharmaceutical company
- Able to complete the proposed research within 2 years (the “**Research Project Period**”)
- Citizen or permanent resident of the United States or holder of a temporary non-immigrant visa that is valid for the duration of the 2-year grant period.

Applications should show the commitment and ability to follow local and international requirements as applicable (GCP/ICH), including, but not limited to the following: 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 58, 21 CFR Part 312, ICH-E6.

\*Applicants who are awarded an NIH R01 after submission of the Pathways application should notify [applications@pathwaysresearchawards.com](mailto:applications@pathwaysresearchawards.com) to withdraw their application immediately after R01 notification.

Previously declined applications can be resubmitted for reconsideration one time.

## 2.3 Criteria for Selection

Alkermes fully funds the Pathways Research Awards program. Additionally, Alkermes and its agency partner provide the infrastructure and administrative support required to facilitate the application process and the independent review process, in addition to notifying applicants and distributing Awards. All applications will be formally reviewed by, and only by, an independent Review Committee comprising prominent researchers in the field. The Review Committee has final responsibility for selection of Awardees.

Note: A preliminary review of submissions will be completed by Alkermes to ensure that there are no regulatory/legal restrictions on the Applicant and that there are no concerns with the proposed work from a compliance or patient safety perspective.

When the Review Committee evaluates a proposal, they will consider criteria, including but not limited to:

- **Overall impact**
- Applicant
  - Whether applicant is qualified in terms of education, experience, and background to conduct the proposed research
  - Career development plan/career goals
- Mentor
  - Are the qualifications of the mentor in the area of the proposed research appropriate to the development of independent investigators?

- Does the mentor adequately address the applicant's potential and his/her strengths and areas needing improvement?
- Environment and institutional commitment to the applicant
- Research plan
  - Is the research proposal scientifically sound?
  - The scientific rigor and medical value of the proposed research, including likelihood that it will be completed within 2 years and outcomes will be published or otherwise publicly presented to the scientific and medical communities

## 2.4 Budget

Total budget should not exceed \$100,000, including direct research project-related costs and institutional overhead.

### **Funds may be used for:**

- Personnel necessary to complete the research project.
- Funding for hours of work, which are specified in the research project.
- Supplies and consumables necessary to fulfill the research project's aims.
- Travel to a scientific meeting for presentation of data from the research project may be included. This may be up to \$1,500.
- Overhead costs.
  - Additional documentation is required for overhead costs greater than 30% for clinical projects and greater than 50% for non-clinical projects.

**Funds may not be used for** any expenses unrelated to the research project. Additionally, funds may not be used for equipment, including computers and tablets, office supplies, tuition, fees, dues, and subscriptions.

This is a competitive grant program. Each grant is non-renewable and paid as described below. A competitive grant awarded by the Review Committee cannot later be amended upwards with additional funding. Grants will be paid in USD at these milestones:

- Upon successful execution of the Alkermes Pathways Research Awards® Terms and Conditions and receipt of institutional or ethics approvals (as applicable)
- Upon the receipt of an appropriate progress report at 6 months after initiation of the Research Project Period
- Upon the receipt of an appropriate progress report at 12 months after initiation of the Research Project Period
- Upon completion of the research project and receipt of a final report that may or may not be in the form of a manuscript

Additionally, funding provided through the program may be subject to reporting to the Centers for Medicare and Medicaid Services (CMS) as part of the Sunshine Act. In compliance with the Sunshine Act, Alkermes will report annually on payment and other transfers of value made to covered recipients. A final financial report is due 60 days after the end of the funding period reconciling the proposed budget with the actual expenditure. In the event that unexpended funds remain at the end of the funding period, these funds must be returned to Alkermes program.

**Note:** Grants will be awarded to each grantee's institution. Grants distributed under this program may not have industry funding or duplicate funding from any other source, including government or non-governmental sources. To avoid overlap with a Pathways Research Award, no other government, non-governmental, or industry-sponsored projects may cover the same work scope as that for which funding is requested in the application to the Pathways Research Award program. However, a Pathways Research Awards program grant may be related to other funding from foundations or government agencies, as long as there is no direct overlap. It is the responsibility of the applicant to justify the novelty of the proposal and provide evidence that the application does not overlap with any current or pending funding. Pathways Research Awards program grants cannot be provided to studies that are already in progress.

### **3. RESEARCH ON ALKERMES PRODUCT**

If Alkermes drug is requested and is available, it will be provided at no cost in a sufficient quantity to complete the research project. Alkermes will not provide funding to purchase Alkermes drug. Proposals for research utilizing pharmacotherapy will be considered for a Pathways Research Award regardless of the manufacturer of the agent used. Use of Alkermes product is not required.

### **4. PUBLICATION OF RESULTS**

The Pathways Research Awards program encourages investigators to publish results from supported research projects (journal or congress submissions) with acknowledgement: "Funded by a Pathways Research Award, an independent competitive grants program supported by Alkermes." For publications including an Alkermes product, Alkermes reserves the right to review and possibly comment on the publication before submission.

### **5. FURTHER INFORMATION**

If you require clarification of any information, please contact the Pathways Research Awards Program Manager by the email [info@PathwaysResearchAwards.com](mailto:info@PathwaysResearchAwards.com)