



## Guidance

### 1 SUBMITTING AN APPLICATION

#### 1.1 Instructions

All applications should be submitted through the [Pathways Application Portal](#).

The following items should be included in the submission via the portal:

1. Completed Pathways Research Awards Application Supplement Form
2. Completed Pathways Research Awards Budget Form
3. NIH Biosketch of applicant
4. Letter (1 page) of mentor support
5. 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. Note that supporting documents may NOT include part of the Application (for example, figures or references).

The [Pathways Research Awards Application Supplement 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

November 12, 2021 (by 11:59 pm Eastern Daylight Time)

##### 1.2.2 Notification of Review Committee Decision

Q1 2022

##### 1.2.3 Public Announcement of Awardees

Q2 2022



### 1.2.4 Funding

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

## 2. SCOPE OF AWARD

### 2.1 Scope of Awards

The program is designed to support research in therapeutic areas that are of interest to Alkermes, focusing on AUD, OUD and serious mental illness (SMI). In the future, other therapeutic areas may be considered.

The areas of scientific interest are:

- **Schizophrenia**
- **Bipolar Disorder**
- **AUD**
- **OUD**

For Schizophrenia and Bipolar Disorder, 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
- Research addressing health disparities and advancing health equity

For AUD and OUD, applications are invited on:

- 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
- Research addressing health disparities and advancing health equity

*\*Please note that we are not accepting preclinical applications for the 4<sup>th</sup> annual application cycle for AUD or OUD grants.*

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 DP2 award 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 schizophrenia, bipolar disorder, AUD or OUD research. Eligible applicants must meet the following criteria:

- Have an M.D., Ph.D., 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 schizophrenia, bipolar disorder, AUD or OUD
- Have a research mentor with extensive experience in the field of schizophrenia, bipolar disorder, AUD or OUD
- Have not received a DP2 award or 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 a DP2 award or an NIH R01 after submission of the Pathways application should notify [info@pathwaysresearchawards.com](mailto:info@pathwaysresearchawards.com) to withdraw their application immediately after award 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 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 healthcare 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?
- Research 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. Travel expenses may not exceed \$1,500 over the duration of the project.
- Overhead costs.
  - Please work with your mentor and office of Clinical Research/Grants to ensure that overhead costs are tailored to the scope of the project. Indirect rates, as with all elements of the budget, are a factor in the review.
  - 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 according to the terms of the contract with Alkermes and generally 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 the receipt of an appropriate progress report at 18 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, but the awards are specific to the grantees. 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, provided 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 via the [Pathways Inquiry Submission Form](#).