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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for “\$100,000 for Start a SUD Startup” Challenge

SUMMARY: The National Institute on Drug Abuse (NIDA), one of the components of the National Institutes of Health (NIH), announces the “\$100,000 for Start a SUD Startup” Challenge. The Challenge goal is to support research ideas that would further an understanding of neurobiology as it relates to Substance Use Disorders (SUD) and that are intended to be the basis for the development of a new and potentially successful start-up. NIDA hopes that participation in the contest will enable scientists to test the hypothesis that their research idea can be fostered into a biotech startup, and that eventually any newly created startups will contribute to the pool of innovative small business companies that can successfully compete for NIDA’s Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) funding. Each Challenge winner will receive \$10,000. The Challenge total purse is up to \$100,000.

DATES: The Challenge begins [INSERT THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]

Submission Period: [INSERT THE DATE OF PUBLICATION IN THE FEDERAL REGISTER] to September 16, 2016, 11:59 p.m., ET.

Judging Period: September 19, 2016 to October 21, 2016

Winners Announced: October 24, 2016

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SUPPLEMENTARY INFORMATION:

The Institute's Statutory Authority to Conduct the Challenge. NIDA is conducting this Challenge under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Reauthorization Act of 2010, 15 U.S.C. 3719. The general purpose of NIDA is to conduct and support biomedical and behavioral research, health-services research, research training, and health-information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers. This Challenge is consistent with and advances the mission of NIDA as described in 42 U.S.C. 285o in that it supports new and potential biotech start-ups in the development of research ideas that would further an understanding of neurobiology as it relates to SUD.

Subject of Challenge. NIDA is excited to announce the first competition for biomedical scientists with the goal to support research ideas that would further an understanding of neurobiology as it relates to SUD and that are intended to be the basis for the development of a new and potentially successful start-up. NIDA hopes that participation in the contest will enable scientists to test whether their research ideas can be fostered into a biotech startup. In 2016, NIDA will award up to \$100,000 in prizes to up to 10 winners of the contest, \$10,000 each.

Are you a biomedical scientist who believes that he/she has a research idea for a biotech start-up? This Challenge is unique because NIDA intends to fund the “would be” startup Founders much earlier than most investors, incubators, or traditional modes of research funding (e.g. small business grants).

What does it take to participate in the Challenge? The team or an individual must have a research idea that could further the understanding of SUD and is intended to be the basis of the development of a new and potentially successful startup. The research “idea” is the product that your future startup will offer. Here, the term startup “product” is used in its broadest definition. Product is any source of value for the people who become customers. Services, subscriptions, software as a service (SaaS), physical/tangible products, aggregations, etc. could all provide value and thus be considered startup products. The startup product could be the result of novel scientific discoveries, repurposing an existing technology for a new use, extending a research observation into a different area, devising a new business model or distribution/delivery channel that unlocks value currently concealed, or simply bringing a product or service to previously underserved set of customers. The Founder (the teams or an individual) must demonstrate through the Submission the passion, drive, discipline, ability to work collaboratively and willingness to push forward under conditions of extreme business uncertainty.

The winners of this Challenge are encouraged to use the prize funds to develop a minimum viable proof (MVP) as quickly as possible and to obtain customer feedback to discover if MVP meets the customer needs. If the product prototype is successfully validated, winners are encouraged to create or further advance their biotech startup no later than 6 months after the prize is awarded. Post Challenge, as with all other NIH grant

applicants, NIDA staff will provide dedicated assistance and guidance about the NIH grant submission process, including submissions for the SBIR/STTR grants.

The research idea must be broad enough to address multiple conditions, diseases, or indications consistent with SUD or be specific for prevention and treatments of SUD. For example, if your idea can only work for cancer or diabetes, entering this Challenge is not appropriate. However, if the plan is to test an idea for a research tool that would further an understanding of neurobiology or epigenetics relevant to SUD to progress faster and with greater fidelity, entering this Challenge is appropriate.

Rules for Participating in the Challenge. The Challenge is open to any Founder 18 years of age or older. No prior startup experience is necessary. A Founder may be (i) an entity or (ii) an individual or group of individuals (i.e., a team assembled with the purpose of participating in this Challenge).

- (1) To be eligible to win a prize under this Challenge, an individual or entity:
 - a. Shall have registered to participate in the Challenge under the rules promulgated by NIDA as published in this Notice;
 - b. Shall have complied with all the requirements set forth in this Notice;
 - c. In the case of a private entity, shall be incorporated in and maintain a primary place of business or research activity in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States. However, non-U.S. citizens and non-permanent residents can participate as a member of a team that otherwise satisfies the eligibility criteria. Non-U.S. citizens and

non-permanent residents are not eligible to win a monetary prize (in whole or in part). Their participation as part of a winning team, if applicable, may be otherwise recognized when the results are announced.

- d. May not be a Federal entity;
- e. May not be a Federal employee acting within the scope of the employee's employment and further, in the case of HHS employees, may not work on their submission(s) during assigned duty hours;
- f. May not be an employee of the NIH, a judge of the challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family of such a party (i.e., spouse, parent, step-parent, child, or step-child).
- g. Must be a potential start-up (i.e. not yet formed) or a new start-up (i.e. in the early stage of formation and development).

- (2) Federal grantees may not use Federal funds to develop their Challenge submissions.
- (3) Federal contractors may not use Federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submission.
- (4) Submissions must not infringe upon any copyright or any other rights of any third party.
- (5) By participating in this Challenge, each Founder (whether competing singly or in a group) and entity agrees to assume any and all risks and waive claims against the Federal government and its related entities (as defined in the COMPETES Act), except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from

participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

- (6) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no Founder (whether competing singly or in a group) or entity participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.
- (7) By participating in this Challenge, each Founder (whether competing singly or in a group) and entity agrees to indemnify the Federal government against third party claims for damages arising from or related to Challenge activities.
- (8) A Founder or entity shall not be deemed ineligible because the Founder or entity used Federal facilities or consulted with Federal employees during the Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.
- (9) By participating in this Challenge, each Founder (whether participating singly or in a group) or entity retains title and full ownership in and to their submission and each participant expressly reserves all intellectual property rights (e.g., copyright) in their submission.
- (10) NIDA reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, and/or (b) not award any prizes if no entries are deemed worthy.
- (11) Each Founder (whether participating singly or in a group) or entity agrees to follow all applicable Local, State, and Federal laws and regulations.

(12) Each Founder (whether participating singly or in a group) and entity participating in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each such contestant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.

(13) Scientists working on the projects that are directly applicable or adaptable to benefit the SUD field, NIDA's mission area, are especially encouraged to apply. A team can also include engineers, IT, business or other professionals in the biomedical science/health care field;

(14) Winners are encouraged to submit the minimum viable proof (MVP) report 6 months after the prize payment.

Registration Process for Contestants. To participate in this Challenge visit www.challenge.gov, search for "Start a Startup" Challenge and follow the instructions.

Submission Requirements. Each submission for this Challenge requires a complete "Submission Package." The Submission Package includes a 4-page written proposal describing an idea and 5-min video introducing the team. Both the idea and the Founders will be evaluated.

1) In the proposal:

1. Describe your research idea that would further an understanding of neurobiology as it relates to SUD and that is intended to be the basis for a successful start-up. (1 page)

2. Convince the Challenge reviewers of your technical competence as a biomedical scientist. Be brief, selective and persuasive. Do not use the NIH Bibliographic Sketch format. (0.5 page)
3. Describe, in as many details as possible, what the prototype of your product would look like. Then, walk the Challenge reviewers through the typical use of the product, using simple terms and instructions. (1.5 pages)
4. Explain the methods you will use (how, when, where, whom) to determine whether the product is needed by the target audience and whether that audience would be willing to pay for the product. (1 page)

The proposal must consist of a PDF file with at least 1 inch margins and no more than four (4) pages long. Font size must be no smaller than 11 point Arial. All submissions must be in English. The Contestants must not use HHS's logo or official seal or the logo of NIH or NIDA in the submissions, and must not claim federal government endorsement.

- 2) A brief video (link to YouTube) must be no longer than five (5) minutes. If the Challenge submission is from the team of Founders, the entire team must participate in the submitted video. In the YouTube video:
 - Tell NIDA something, in one minute or less, that can illustrate the drive or the desire of each founder to develop a product that would further an understanding of neurobiology as it relates to SUD and that is intended to be the basis for a successful start-up.

- Tell NIDA something about each founder that shows a high level of scientific and entrepreneurial ability.
- Tell NIDA something about each founder that shows a high level of perseverance and grit.
- Tell NIDA about a time when your great idea was rejected. What was your response?
- Tell NIDA how you design scientific experiments in general.

Amount of the Prize; Award Approving Official. Up to ten monetary prizes will be awarded. The total prize award pool is up to \$100,000. No institutional indirect costs are allowed. The names of the winners and the titles of their submissions will be posted on the NIDA web site. The award approving official for this Challenge is the Director of the National Institute on Drug Abuse.

Payment of the Prize. Prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. The NIH/NIDA will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis upon Which the Winner Will Be Selected. The judging panel will make recommendations to the award approving official based upon the following 5 criteria.

Each criterion will be scored with the maximum of 10 points.

1) **Significance and Unmet Needs** (0-10 points). Are there significant needs for your product or service? Does the project address an important problem or a critical barrier to progress in the field of drug abuse research? If the aims of the project are achieved, how will scientific knowledge, technical capability, service or clinical practice be improved?

2) **Innovation** (0-10 points). Does the submission seek to shift current paradigms by utilizing novel theoretical concepts, approaches, methodologies, instrumentation, service or interventions for drug abuse research? Is your product novel in a broad sense? Is a refinement, improvement or new application of theoretical concepts, approaches or methodologies instrumentation or interventions proposed?

3) **Approach** (0-10 points). Are the overall strategy, methodology, and analyses well-reasoned and appropriate to test the proposed idea? Has feedback from end users been incorporated into the validity of the idea proposed?

4) **Team expertise** (0-10 points). Does the individual or team demonstrate high level of ability, perseverance and grit?

5) **Commercialization** (0-10 points). Is there a clear path for the product/service to reach the market? Are the product users and purchasers clearly identified?

Submissions that are responsive and comply with the entry requirements will be reviewed by a panel of judges consisting of federal employees. The responsive and compliant submissions entries will be scored in accordance with the judging criteria outlined above. Final recommendations will be determined by a vote of the judges based on score. Scores from each criterion will be weighted equally, but failure to meet a

minimum standard for any one criterion might disqualify a submission. The score for each submission will be the sum of the scores from each of the voting judges.

Authority: 15 U.S.C. 3719

Dated: June 7, 2016.

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Director, National Institute on Drug Abuse

National Institutes of Health

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