

Call for Proposals: The School of Medicine Basic Sciences Pilot Innovation Ignition Fund Program

Overview:

The Vanderbilt School of Medicine Basic Sciences (VBS) fosters an environment where curiosity thrives, and scientists are empowered to contribute to the body of fundamental knowledge about human biology, health, and disease. Discoveries can sometimes be leveraged as the basis for early-stage drug discovery and other medical advances. In this spirit, we announce the pilot phase of a new program, the Innovation Ignition Fund. The ignition fund aims to support promising early-stage small molecule therapeutic projects and provide critical guidance and mentoring to nurture such projects to the point where they are ready for major funding, industry partnership, and/or spin-off to sustain momentum toward their potential success.

In its pilot phase, the Innovation Ignition Fund will support one to three proposals up to \$250,000/year for up to two years, focusing on the initial data-gathering experiments required for de-risking projects in the target validation through lead optimization stage range, drawing on drug discovery expertise within the Vanderbilt Institute of Chemical Biology (VICB), Warren Center for Neuroscience Drug Discovery (WCNDD), and the Vanderbilt Center for Cancer Drug Discovery.

Purpose:

The School of Medicine Basic Sciences seeks to identify, kickstart, and mentor innovative small molecule drug discovery projects to accelerate the identification and characterization of a drug discovery candidate for clinical development and potential commercialization. Compelling therapeutic projects from talented faculty and trainees who have not previously delved deeply into drug discovery with the goal of advancing to clinical trials require seed funding and expert guidance to develop a lead compound. The Innovation Ignition Fund aims to support faculty projects with promising early-stage drug discovery potential by helping them to develop their projects to the point where they become attractive for continued funding and development by investors or through an industry partnership. With the success of the pilot phase, the future Innovation Ignition Fund is envisioned to be evergreen, funded in part through future licensing revenues and philanthropic support.

Centralizing a source of strategic feedback and funding from the School of Medicine Basic Sciences and the Office of the Vice Provost for Research and Innovation will significantly improve the focus and throughput of drug discovery and development projects in the school, leading to a more robust culture of shared drug discovery expertise, more extensive interaction of faculty with companies or investors, and/or more licensure or spin-off opportunities in the therapeutic space, ultimately contributing innovation and chemical matter to the therapeutics development pipeline.

Innovation Ignition Fund Eligibility

Faculty with a primary or secondary appointment in a School of Medicine Basic Sciences department can submit proposals as a principal investigator (PI). The PI will be the project's direct contact and can have co-principal investigators (Co-PIs). Eligible proposal projects ranging from target validation to hit identification to lead optimization will be eligible for review and mentorship by drug discovery experts. The focus is on providing funds





for the initial data-gathering experiments that will further de-risk the program from a chemical and/or biological perspective to take the project to the next stage, where it will be attractive for other funding sources.

A critical component of a successful application will be the demonstrated involvement of scientists with a track record of success in drug discovery. To satisfy this condition, applicants must include a supporting letter indicating a commitment to assist with the project from one of the following: Gary Sulikowski, Director of VICB, Craig Lindsley, Director of the Warren Center for Neuroscience Drug Discovery, Stephen Fesik, Professor of Biochemistry, Pharmacology, and Chemistry, or Alex Waterson, Director of the Vanderbilt Center for Cancer Drug Discovery. Alternatively, the applicants may include a supporting letter from another scientist in academia or industry with a proven track record in successful drug discovery.

The Innovation Ignition Fund will fund one to three proposals at up to \$250,000 for the first year to enable faculty with a novel small molecule therapeutic idea to develop an initial proof of concept. The total year-one funds available is \$250,000. Progress toward achieving milestones during the first year will determine whether funding for a second year will continue. The budget for projects receiving an additional year of funding will be up to \$250,000. The total year-two budget for this program is \$250,000. Funds cannot be used to pay more than 10% of the PI's salary and/or more than 5% of a co-PI's salary. They also cannot be used to pay institutional overhead, subcontract fees, or to purchase capital equipment totaling more than \$25,000 (over two years).

Application Process:

To apply, please submit a three-to-four-page proposal that describes the biomolecular target. This description should convey a clear link, such as genetic evidence, to a specific disease or condition's pathophysiology and a clear understanding of the biology of the disease. The proposal should also include information about cell-based assays, established in vitro or in vivo models, and any relevant biomarkers useful in characterizing compounds and/or evaluating efficacy. Provide an initial hypothesis for how modulation of the target would elicit a novel pharmacology to treat the disease and how this project would fill a critical unmet medical need. It is also essential to include a two-year timeline for execution and completion of the proposed research, an assessment of the patient population that would benefit from a successful drug, and whether the drug would be first-in-class or instead compete against existing treatments. The timeline should include a statement describing milestones for the expected progress of the project at the end of one year and at the end of two years, along with the anticipated next steps. In addition to the project proposal, provide a projected budget with justifications. You must include the name and primary department of the PI and a complete list of Co-PIs and their primary department or institution. Applications will be accepted starting February 1, 2024. Proposals should be submitted by email as a single PDF file to the Assistant Dean for Research, Selene Colon (selene.colon@vanderbilt.edu), by April 1, 2024.

Review Criteria:

Reviewers of proposals will use the following criteria.

- Project addresses a critical unmet medical need
- Strength of target validation





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- Availability of tools for pre-clinical development (relevant in vitro screening tools, cell-based assays, animal models of disease, etc.)
- Degree of unmet medical need and feasible path to clinical proof-of-concept and regulatory approval (recognizing this will take much more than two years)
- Potential for pharmaceutical/investor interest if the project advances
- Investigators willing to engage with drug discovery experts on campus in a highly collaborative manner
- Potential to develop a strong IP position
- There must be no other current funding for this project

Review Process:

The proposals will undergo review by a panel including the following members:

- Margaret Read, Ph.D., General Manager Corporate Alliances, CTTC, and Associate Director, Translational Science, VICB
- Mike Villalobos, Ph.D., Life Sciences Licensing Manager, CTTC
- o Chuck Sanders, Ph.D., Vice Dean of Basic Sciences, School of Medicine
- o Selene Colon, Ph.D., Assistant Dean for Research, Basic Sciences
- Asit Parikh, M.D., Ph.D., President and Chief Executive Officer MOMA Therapeutics (Basic Sciences Board of Visitors)
- Mace Rothenberg, M.D., Co-chair, Life Sciences Consortium of the CEO Roundtable on Cancer (Basic Sciences Board of Visitors)
- o Laurent Audoly, Ph.D., Founder, Parthenon Therapeutics (Basic Sciences Board of Visitors)
- William Pao, M.D., Ph.D., Former Chief Development Officer and Executive Vice President, Pfizer (Basic Sciences Board of Visitors)
- o Clayton Knox, M.D., President, Velosity Capital (Basic Sciences Board of Visitors)

Reporting and Accountability:

Funding from the Innovation Ignition Fund for an additional year will be milestone-driven by agreed-upon go/no-go metrics. A review will occur in month 10 of the first year to assess project progress. Recipients will be expected to submit a progress report (deadline: first day of the tenth month of the project) detailing the achievement of project milestones, a financial statement describing how project funds were spent, and any deviations from the proposed scope of work. If recipients don't meet the agreed-upon milestones, they are expected to explain why and provide a plan for achieving them before the end of the project year.

A short final progress report describing the overall achievements of projects funded for a second year is due within three months of the end of the project. These final reports should describe the plan for continuing the project scientifically and regarding funding/collaboration.

For any questions or clarifications regarding this request for applications (RFA) or the application process, please email Dr. Selene Colon (<u>selene.colon@vanderbilt.edu</u>).

