

MSU-Molecular Discovery Group Pilot Grant Application

E-mail complete application as *PDF* to Joseph Nichols DDProgram@list.msu.edu

Application Due Date: **Friday, February 14, 2020 at 5:00 PM**

Title of Project:
PI Name:
MSU Phone number:
E-mail:
Department:
Co-investigators and departments:
Area of application (check all that apply): <input type="checkbox"/> Human Health <input type="checkbox"/> Animal Health <input type="checkbox"/> Plant Sciences/Agriculture <input type="checkbox"/> Other (specify)
Target Product Profile (TPP) (check one, see attached forms) <input type="checkbox"/> Therapeutics (TTP template 1) <input type="checkbox"/> Agricultural (TTP template 2) <input type="checkbox"/> Technology/Diagnostics (TTP template 3) or <input type="checkbox"/> Basic Research
1. Abstract (200-word limit)
2. Scientific background and significance. If the project is successful, describe how the technology will be used and what its impact will be. (Limit 1 page)
3. Target product profile (TPP) - Therapeutics (Template 1), Agricultural (Template 2), or Technology/Diagnostics (Template 3) Fill out appropriate attached form.
<i>If a commercial application is envisioned, mark above which area is considered and fill out appropriate attached form. If not, explain how this work will support extramural funding for this program.</i>

4. Describe key work to be completed including time-line, decision-matrix and feasibility relative to key milestones (i.e. short-term laboratory objectives). Explain potential problems/liabilities and how they can be mitigated? Describe how this study fits into a longer-range commercialization plan. (Limit 2 pages)

5. Plan for future funding or commercialization based on work outcome. Identify next round of funding and what data is required. (Limit 1 page)

6. Key literature and citations

7. Budget for proposed work. Up to 10% of the award can be used for project work outside the core labs.

- No funds may be used to support salary
- Funds must be spent within 12 months of award date. Reviews of progress will be provided at mid-term quarter by the PI and core leaders.
- Proposals **must** include an attached quote directly from the core(s) for the proposed project. Please consult the staff of each core for availability (see below).

Budget Summary

Item	Cost
<i>ADDRC - Services</i>	
<i>ADDRC - Reagents/Supplies</i>	
<i>MCC - Chemist labor</i>	
<i>MCC - Reagents/Supplies</i>	
<i>In vivo Facility - Services</i>	
<i>In vivo Facility - Reagents/Supplies</i>	
<i>PI Lab Reagents/Supplies (10% or less)</i>	
Total	

8. Biosketch of PI and co-PIs (2-page limit) to be sent with grant application as additional files (not required from core personal).

Contacts:

For budget quotations or information on the overall program, please contact the director (or staff) of the core that is most relevant to your project. If you are unsure, please contact Dr. Nichols below.

MSU Drug Discovery Project Manager

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Target Product Profile (TPP)

- Defines the clinical and commercial criteria for discovering and developing a successful drug
- Defines the minimum and optimum criteria for the drug discovery project
- Provides a shared vision for the direction of a project
- Can and should be modified during the lifetime of the project to address changing opportunities
- *Not all items will be known early in the project. Information available will grow with time*
- *Screening programs may not have as much information as advanced programs.*

Template 1 (Therapeutics)

Item	Comments/Data
Market – Therapeutics (human or companion animal)	
Primary Indication (Note if there are secondary indications)	
#Patients and type (human or which animal species)	
Existing Agents for Indication and weaknesses (Key question-Do current therapies meet clinical needs?)	
Anticipated market value if known.	
Biology	
Mechanism of Action (MOA) or phenotype	
Biomarkers (Identified)	
Clinical Do-ability – Can the mechanism be tested clinically? (Yes or No, path forward)	
Risks (selectivity, development of resistance, etc.)	
Safety	
Equivalent or improved safety over existing agents? Yes or No. Explain	
Safety risks vs. benefits considerations	
Other considerations?	
Drug Profile	
If known, candidate series and structure (or series to be pursued) if known. Is it suitable as a drug or probe (physical properties, rule-of-5, etc.)	
Acceptable / Required modes Administration (IV, SubQ, IP, Oral, Topical, Other)	

Intellectual Property	
Patents filed or to be filed, Invention disclosures filed with MSU (if program has advanced to this level)	
Plan to patent filing	

Template 2 (Agricultural)

Item	Comments/Data
Market - Agricultural (Veterinary, Crop and Food Security)	
Primary application (Note if there are secondary uses)	
#Patients (cattle, swine, chickens, hectares of land, etc.)	
% not responding to existing products	
Existing compounds for application and weaknesses. How will this product address weaknesses?	
Required efficacy (% survival, increase in yield, etc.)	
Anticipated market value (MSU Technologies) – Have there been discussions with MSU Technologies?	
Biology	
Mechanism of Action (MOA) or phenotype	
Biomarkers (Identified?)	
Clinical Do-ability – Can the mechanism be tested in the field? (Yes or No, path forward)	
Other features? (development of resistance, etc.)	
Safety	
Need for equivalent or improved safety over existing agents? (User, environmental, etc.) Yes or No. Explain	
Required withdrawal periods (if feed animal)	
Safety risks vs. benefits considerations	
Agent Profile	
Candidate compound and <i>structure</i> (or series to be pursued) if known	
Acceptable / Required modes of use or application.	
Use frequency (Single or multiple application)	
Intellectual Property	
Patents filed or to be filed, Invention disclosures filed with MSU	
Plan to patent filing	

Other	
Commercial Risks (Public perception, potential regulatory changes, etc.)	

Template 3 (Technology)

Item	Comment / Data
Market – Technology	
Primary application (Note if there are secondary uses)	
Market size	
Are there competing technologies? Weaknesses? How can they be addressed with this technology?	
Required increases in efficiency, delivery, etc. (% survival, increase in yield, etc)	
Anticipated market value (MSU Technologies) – Have there been discussions with MSU Technologies?	
Technology	
Description of technology	
Do-ability – How can the technology be applied?	
Safety	
Need for equivalent or improved safety over existing tech. (User, environmental, etc.) Yes or No. Explain	
Safety risks vs. benefits considerations	
Intellectual Property	
Patents filed or to be filed, Invention disclosures filed with MSU	
Plan to patent filing	
Other	
Why would this product would be used over existing tech?	
Commercial Risks (Public perception, potential regulatory changes, etc.)	

Example of completed Target Project Profile

*delete in submitted version

Item	Comment / Data
Market – Therapeutics (human or companion animal)	
Primary Indication (Note if there are secondary indications)	Skin and Soft tissue infections (>\$1 billion). Secondary – Diabetic foot MIC90s (Clinical Pathogens) <ul style="list-style-type: none"> • Indication 1 -S.aureus (<0.25 ug/mL) – primary pathogen of interest
#Patients	80,000 human patients / yr.
Existing Agents for Indication and weaknesses	Zyvox -oxazolidinone (\$ 2 billion in sales but going off patent). New agent will have to compete with a generic. Little development of antimicrobial resistance seen in clinic
Anticipated market value (MSU Technologies)	\$300 million 5 th yr sales
Biology	
Mechanism of Action (MOA) or phenotype	RNA polymerase; Frequency of resistance < 10 ⁻⁸
Biomarkers (Identified)	Reduction of bacterial load (disease)
Clinical Do-ability – Can the mechanism be tested clinically? (Yes or No, path forward)	Yes. A number of antibacterial agents have been tested clinically. Clinical program well-understood.
Other features? (i.e.; development of resistance)	No cross-resistance to any known class of antibacterials.
Safety	
Equivalent or improved safety over existing agents? Yes or No. Explain	Peptides are generally safer than other classes of drugs. No bone marrow toxicity expected as typically seen with Zyvox.
Safety risks vs. benefits considerations	Safety- improved over Zyvox against two or more of the following. No worse for the others. <ul style="list-style-type: none"> • severe diarrhea • fungal infections • thrombocytopenia • myelosuppression • serotonin syndrome • neuropathies • angioedema Regulatory advantage would be antimicrobial activity against pathogens not susceptible to front-line therapy. Although providing regulatory advantage, no marketing value would be realized

	w/o an increase resistance in clinical setting (>20%).
Other considerations?	
Drug Profile	
Candidate compound and <i>structure</i> (or series to be pursued) if known	Cyclopeptides (8-amino acids)
Acceptable / Required modes Administration (IV, SubQ, IP, Oral, Topical, Other)	IV with step-down to oral.
Dosing Frequency (Once-a-day, twice-a-day, etc.)	IV in hospital setting with stepdown therapy to oral (2X / day).
Intellectual Property	
Patents filed (application #) or to be filed, Invention disclosures filed with MSU	Invention disclosure filed May 2017.
Plan to patent filing	Patent to be filed June 2018 (Composition of matter)
Other	
Commercial Risk	<ul style="list-style-type: none"> • Reserved for second line therapy due to concerns over resistance development • Agent doesn't meet superiority requirements for efficacy. May impact potential value.