In 2011, the NIH Blueprint for Neuroscience Research, a consortium of 15 NIH Institutes and Centers that support neuroscience research, launched the Blueprint Neurotherapeutics Network (BPN). The BPN serves as a pipeline between the typical endpoint of NIH-funded research and the beginning of industry drug development. The BPN provides neuroscience researchers with funding and access to a full range of industry-style drug development services and expertise. The program is intended for projects requiring medicinal chemistry optimization and CRO support through phase I clinical testing. Each project is directed by a Lead Development Team composed of the principal investigator, industry consultants hired by NIH, and NIH staff.

**PROGRAM GOALS**

- To de-risk potential therapeutics to the point that industry will invest in them allowing potential new drugs to reach patients efficiently.
- To provide grant funding and necessary resources (contracts, consultants, etc.) that are typically lacking in our research community.

**WHAT WE OFFER**

- BPN provides non-dilutive funding to investigators from academia and industry.
- Investigators retain rights to intellectual property.
- Access to CRO’s under contract to NIH.
- Access to consultants and staff with extensive industry experience covering the major needs:
  - Assay development expertise, pharmacology, medicinal chemistry, pharmacokinetics, toxicology, process research, chemical/formulation development, and Phase I clinical testing.
  - Fast track SBIR U44 grants for small businesses.

**ENTRY CRITERIA**

**Discovery**

- Novel target for the disease
- Strong biological validation
- Feasible path to the clinic
- Robust in-vitro assay for optimization
- Strong conformational assays
- Project must require medicinal chemistry
- Amenable to chemistry
- IP free of obvious roadblocks

**Development**

- Strong data linking target to disease
- Biological & ADMET activity appropriate for intended clinical use
- Efficacy/PD when delivered by clinically intended route
- Fully profiled, defensible ADMET results
- Feasible path to the clinic
- IP free of obvious roadblocks

**MILESTONE PROGRESSION BY STAGE**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Preparatory Phase</th>
<th>Hit to Lead</th>
<th>Lead Optimization</th>
<th>Predevelopment</th>
<th>IND enabling</th>
<th>Phase I trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>UG3 6-12 months</td>
<td>Entry permitted along spectrum</td>
<td>12 months</td>
<td>12 months</td>
<td>6 months</td>
<td>12 months</td>
<td>8 months</td>
</tr>
</tbody>
</table>

- **UGS 6-12 months (entry permitted along spectrum)**
- **UGS 1-4.5 years depending on entry point**

- MS1b-assay
- MS2b-chem
- MS1a-candidate selection
- MS4a-IP-IP established
- MS5a-intermediate
- MS4a-pre-IND
- MS5b-stable form ID
- MS5c-monitoring
- MS5d-clinic
- MS5a Freel: IND
- MS7b-human PK acceptable

**BPN PROJECTS IN THE NEWS**

- **Tetra Discovery Partners**
  - Announces Positive Results from Phase 1 Studies of Cognition-Drug Candidate, BPN14770

- **Forbes**
  - "One Doctor's Hopeful Plan To Eradicate Alzheimer's ...

- **BlackThorn Therapeutics**
  - Receives Up to $8 Million in NIH Blueprint Neurotherapeutics Network Funding to Advance Kappa Opioid Receptor (KOR) Antagonist Program

- **Lin Bioscience**
  - First-in-Class Therapeutic Program to Treat Dry Aged-Related Macular Degeneration from Columbia University in Collaboration with NIH

**INFRASTRUCUTRE, EXPERTISE, & FUNDING**

- **Lead/Product Development Team**
  - Principal Investigator
  - Industry-seasoned consultants
  - NIH staff

- **Bioactivity/ Efficacy Studies**
  - Medicinal Chemistry
  - PK/Tox
  - Manufacturing & Formulation
  - Data Management
  - Clinical Trials

- **NIH Grant**
- **NIH Contracts**
- **Manufacturing & Formulation**
- **Clinical Trials**

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