ONE-ON-ONE WITH THE NIH

BIO & HEALTH

CEO & INVESTOR FORUM

3.22.19
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North Carolina Biotechnology Center

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Sands Capital ventures
Leveraging the NIH for Technology Development and Commercial Success

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MAVA/VABio/NCBIO Life Sciences Forum
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NIH:
Economic Development is Part of Our Mission

- IP appropriately utilized for technology development/commercialization
- Attract new R&D resources
- Obtain return on public investment
- Benefit public health
- Stimulate economic development

NIH: Economic Development is Part of Our Mission

#1 – Global Innovator (government)
Extramural Research vs. Intramural Research

Extramural Research:
- ~ 80% of NIH budget
- Supporting research worldwide
- > 50,000 awards annually (including SBIR)
- Direct funding

Intramural Research:
- ~ 10% of NIH budget
- Supporting research by on-site faculty
- > 2,000 active collaborative research projects
- Indirect funding & cost sharing
NIH Inventions
Common Myths About Working with NIH

• Basic research
  FACT: Translational/clinical assets

• Only drugs
  FACT: Devices/Dx/Biomarkers/Wearables/Tools/Digital Health

• No exclusive licenses
  FACT: Exclusivity can be negotiated

• Cumbersome process
  FACT: We are transaction experts

• Only develop internal ideas
  FACT: Ideas can originate in company partners

https://techtransfer.cancer.gov
What is Technology Transfer?

➢ **Technology** developed by NIH must **transfer** to external partner for commercialization.

➢ **U.S. Federal Technology Transfer Act:**
  • Patents as incentive for commercial development of federal technologies;
  • Allow research collaborations and licensing with external partners.
Tech Transfer Connects Inventors w/External Partners, Turning Ideas into Health Products

- NIH Facilitates technology development by providing:
  - industry and academic collaborations/licenses
  - access to research and clinical materials

- Navigates process of invention reporting, patenting, development and licensing
Whatever Your Technology Area, One of the 27 Institutes/Centers Can Help

The NIH Office of the Director

- National Institute on Aging (NIA)
- National Institute of Minority Health & Health Disparities (NIMHD)
- National Institute of Allergy & Infectious Diseases (NIAID)
- National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)
- National Library of Medicine (NLM)
- National Heart, Lung, & Blood Institute (NHLBI)
- National Human Genome Research Institute (NHGRI)
- Fogarty International Center (FIC)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of Arthritis & Musculoskeletal & Skin Disease (NIAMS)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Mental Health (NIMH)
- National Institute for Advancing Translational Sciences (NCATS)
- National Heart, Lung, & Blood Institute (NHLBI)
- National Institute of Child Health and Human Development (NICHD)
- National Institute of Drug Abuse (NIDA)
- National Institutes of Health Clinical Center (NIHCC)
- National Institute of Neurological Disorders & Stroke (NINDS)
- National Institute of Nursing Research (NINR)
- National Institute of Alcohol Abuse & Alcoholism (NIAAA)
- National Institute of Biomedical Imaging & Bioengineering (NIBIB)
- Technology Transfer Center (TTC)
- National Eye Institute (NEI)
- Center for Information Technology (CIT)

Q: What if you are interested in a technology outside these Institutes/Centers?
A: Any TT office is glad to connect you!
NIH Patent Portfolio

• Assets available for licensing/collaboration:
  o Therapeutics
  o Devices
  o Diagnostics
  o Wearables and digital health
  o Vaccine
  o Software

• Non-patented technologies available as research tools under non-exclusive licenses

• Pre-clinical and clinical stage technologies
NIH Agreements

- Address technology/knowledge gaps
- Enhance pipeline
- We help with a needs assessment
- More complex = more time
- Who pays for what?
  - Negotiated
  - Usually shared costs
  - Indirect support
What are the Advantages for Companies?

- Access to unique reagents and resources
- Access to scientific and regulatory expertise
- Exclusive license option to inventions developed during CRADA
  - No equity
  - NIH cannot spin out a company to compete for the new IP
  - Reasonable milestone payments and royalties
What are the Advantages for NIH?

- Access to cutting-edge innovations
- Access to commercial development expertise
- Funds for research project
- Satisfaction of getting medical solutions to patients
NIH Success Story: Collaborative Development

NIH → Industry

GARDASIL®

- Vaccine against Human Papilloma Virus (HPV)
- Cooperative Research and Development Agreement (CRADA) collaboration between Merck Co. and NCI Center for Cancer Research (CCR)
- No. 2 of the NIH Top 20 Commercially Successful Inventions (based on royalties on product sales) from 2008-2016
  - Merck 2016 U.S. Sales = $542 Million
- Launched in 2007 → No. 4 on NIH Top 20 CSI
  - Merck 2008 Sales = $286 M
NIH Success Story: Somnology, Inc.

NIH Industry

- Developed a wearable sleep monitoring device (the Plex® Sleep Scanner)
- Allows sleep studies in the comfort of own home
- Lowers stress, no stranger watching you sleep in a strange place
- Somnology looking for NIH partner to validate their device in a sleep study

**TIMELINE:**

- CEO and NIH meet at conference
- Series of meetings to learn about technology
- NIH identifies appropriate clinician for collaboration
- Research Collaboration Agreement begins negotiation
- Research Collaboration Agreement executed in 3 months
Who are our Potential Partners?

• **Traditional partners:**
  - Large and mid-size U.S. companies

• **Newer players in the ecosystem:**
  - US or ex-US companies of any size/stage
  - Entrepreneurs
  - Investors (e.g., angels and venture capitalists)
  - Trade associations and economic development entities
  - Technology Scouts
  - Foundations and philanthropies
  - Service providers (e.g., law, accounting & consulting firms)
Pursuing a Partnership with NIH – Our Technology Transfer Center Can Help

- Not a special program
- Not a competitive process
- No application deadlines
- Provide indirect support – not direct grant funding

- Get started via email or phone
  - Reach out with small amount of technical information
  - Know your technology fit
  - Know your “ask”

- We try to identify internal champion (NIH investigator)
# Partnering with NIH

**Offers Significant Commercialization Potential**

## Acquisition

| Kite | Gilead | for US $11B |

## Collaborators and Licensees

<table>
<thead>
<tr>
<th>Organization</th>
<th>Product</th>
<th>2017 Worldwide Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merck</td>
<td>Gardasil</td>
<td>US $2.3B</td>
</tr>
<tr>
<td>Takeda</td>
<td>Velcade</td>
<td>US $1.3B</td>
</tr>
<tr>
<td>Janssen</td>
<td>Prezista</td>
<td>US $1.8B</td>
</tr>
<tr>
<td>Sobi</td>
<td>Synagis, Sporanoxx</td>
<td>US $667M, US $14M</td>
</tr>
</tbody>
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NIH Value Proposition

$5B Product sales from licensed NIH/FDA IP (FY13)

✓ No equity position
✓ 10% overhead rate
✓ Doesn’t take your IP
✓ Validate your technology and/or test in humans
✓ World-renowned researchers and resources
✓ Prestige factor: Collaboration = higher company profile
And So, In Summary …
Contact Us – Let’s Explore Working Together

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• NIH Website: www.ott.nih.gov
• NCI Website: https://techtransfer.cancer.gov/
• Listserv distributions of new opportunities
• Social Media 📞 Twitter
• General information email: NCItechtransfer@mail.nih.gov
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