Bio Start-ups: “Doing Business” With the NIH

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Why Do Business With NIH?

- Annual budget of $39.2 billion (FY19)
- ~10% of funding for intramural research
- 6,000 intramural scientists / 18,000 staff / 2,000 projects
- Basic & clinical research discoveries
- Collaborations with industry & academia
- Partners commercialize into products
Your Six Top NIH Business Tips & Opportunities For Start-Ups

- In-licensing of NIH technology
- Research collaborations with intramural NIH
- Using pre-clinical / clinical NIH services
- Selling products / services to NIH
- Getting grants & contracts from NIH
- Utilizing NIH information sources
Tip #1: NIH Technology Licensing
Characteristics of the NIH Intramural Research Program “Pipeline”

- Novel, fundamental research discoveries
- “Supermarket” for research tools
- Collaborations (CRADAs) for basic or clinical studies
- Selected projects in early clinical trials
- Product sales by licensees: ~$ 6B
Sample Licensee Product Approvals

- Angiotech    Taxus & Zilver (drug stents)
- Genzyme      Thyrogen (rTSH)
- Medimmune    Synagis (RSV mab)
- Millennium   Velcade (myeloma drug)
- Biogen Idec  Zevalin (NHL I\textsubscript{131} mab)
- Amgen        Kepivance (KGF)
- Merck        Gardasil (HPV vaccine)
- Tibotec/J&J  Prezista (HIV protease drug)
Special Developments For Small Companies

- **Start-up Express License Agreements**
  -- Option & Exclusive licenses with low or deferred financial terms

- **SBIR-TT Program**
  -- Bundle of SBIR award & exclusive license to intramural technology
Start-Up Challenge Contests: Licensing to University Start-Ups

Partnerships with Center for Advancing Innovation & private foundations
Tip #2: NIH Basic Research Collaborations
NIH Research Collaborations

- “Internal Use” Research Tool Licenses
- Cooperative Research And Development Agreement (CRADA)
- Clinical Trial Agreement
- Specialized Development Services
- Training Programs
- Informal “official duty” collaborations
Tip #3: NIH Pre-Clinical & Clinical Research Services
Pre-Clinical Research: NCI Developmental Therapeutics Program

- Assay development for screening
- Synthesize small quantities of compounds
- Provide compound libraries & reagents
- Pharmacology and toxicology testing
- Formulation
- Clinical batch production
- Services open to NIH & non-NIH organizations
Clinical Trials At NIH
Clinical Center
Clinical Trials Programs at Cancer Therapy Evaluation Program (CTEP)

IND sponsorship

Drug Supply

Protocols

Adverse Event Reporting

Monitoring

Patents

Publications

Data Rights

CTEP

NCI
Clinical and Translational Science Activities

- Clinical and Translational Science Awards

Rare Diseases Research and Therapeutics

- Therapeutics for Rare and Neglected Diseases
- Office of Rare Diseases Research
- Bridging Interventional Development Gaps

Re-engineering Translational Sciences

- NIH Chemical Genomics Center
- Toxicology in the 21st Century
Tip #4: Selling Products To NIH
Selling Products To NIH

- Largest US consumer of bioscience reagents & instruments
- Blanket purchase agreements (BPA)
- NIH Central Storeroom
- NIH Research Festival (Bethesda & Ft. Detrick Maryland campuses)
- Biodefense & translational research initiatives
Tip #5: Getting NIH Grants & Contracts
NIH Grant & Contract Opportunities

- Over 80% of NIH budget as grants & contracts
- Applicants for most programs can be for-profit or non-profit
- SBIR / STTR must be at least 51% US owned
- Venture-backed firms now eligible for SBIR
- Non-dilutive funding
- Many R&D contracting opportunities

See: https://grants.nih.gov/funding/contracts.htm
Small Business R&D Funding

**SET ASIDE**

**SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

- 3.0% (FY16)
- 3.2% (FY17)

**SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**
Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

- .45% (FY16)
- .45% (FY17)
SBIR / STTR: 3 Phase Program

**Discovery**

- **Phase I Feasibility Study**
  - Budget Guide: $150K for SBIR and STTR
  - Project Period: 6 months (SBIR); 1 year (STTR)

**Development**

- **Phase II Full Research/R&D**
  - $1M for SBIR and STTR, over two years

- **Phase IIB Competing Renewal/R&D**
  - Clinical R&D; Complex Instrumentation/Tools to FDA
  - Many, but not all, IC’s participate
  - Varies-$1M per year; up to 3 years

**Commercialization**

- **Phase III Commercialization Stage**
  - NIH, generally, not the “customer”
  - Consider partnering and exit strategy early
Tip #6: Utilizing NIH Information Sources For Your Business
Useful Business Information

- **New Licensing Opportunities RSS Feed:**
  -- http://www.ott.nih.gov/rss/

- **NIH Guide To Grants & Contracts Listserv:**
  http://grants1.nih.gov/grants/guide/listserv.htm

- **RePORTER Database of Awarded Grants**
  -- http://projectreporter.nih.gov/reporter.cfm

- **Exhibiting Your Products at NIH Research Festivals**
  --- www.technicalesalesassociation.org
For Further Reading ....

“Partnering with the NIH: Now part of the ‘Value Proposition’ for start-ups”

And From the Bio Bootcamp ....

“Licensing the Technology: Biotechnology Commercialization Strategies Using University and Federal Labs”
(Chapter 14)
For Start-ups -- Not Hard To Find!
Thank you!

- NIH Information:  www.nih.gov
- Technology Transfer:  www.ott.nih.gov

Thank you!