SBIR/STTR
A non-expert view
Bob Taylor
Disclosures

• Microbial Imaging, Inc. – equity, IP
• Hydrocyanine Dyes – Licensing revenue (at some point in my life...maybe, maybe not)
• Cell Precision, LLC – equity and IP
A few Opening Thoughts

- Focus today primarily on NIH. All federal agencies support SBIR/STTR mechanism.
- NIH SBIR/STTR program is a set aside.
- Funding used to be easier, it is getting much more competitive.
- You need a business person
- After doing this, you will be forever grateful for what OSP does for you
More Thoughts

• It is a shorter timeline from application to funding (compared to RO1’s)
  – Typically 6 months
• This is not a rapid process
  – Funding gaps between phases almost mandatory
• Lots of compliance issues
  – Animals, COI, etc.
• Start 4-6 months prior to submission deadline
• You need a CEO – usually not the faculty member but can be with permission
What is a Small Business Concern?

- It is a company....LLC and others OK
- Must be in US (<40% foreign owned)
- <500 employees
- Other rules apply
- ?? Special advantages to women and minority owned companies—not really
- Must be For Profit
Getting Ready to Apply

• Form a company – Guide on NIH Site
  – Legal Zoom etc. to set up a register your LLC
  – Dunn & Bradstreet number
  – IRS registration (EIN)
  – Approval from Emory SOM COI office
  – SAM registration
  – Registration at Grants.gov
  – ERA Commons registration
  – SBA registration
Good Info
SBIR.NIH.Gov
Alphabet Soup

- SBIR = Small Business Innovation Research
- STTR = Small Business Technology Transfer
SBIR vs STTR

**SBIR**
- Grant is to the small business concern
- Academic partner may get a subcontract
- PI must be employed by the small business
- The pot is bigger
- Minimum 67% of budget to small business in Phase I
- Minimum 50% of budget to small business Phase II

**STTR**
- Grant is to an academic institution
- Small business must get a subcontract
- PI can be employed at either the academic institution or the small business
- Minimum 30% of budget to academic partner and 40% to small business (Phase I & II)
3 Phase System

• Phase I – Feasibility and Proof of Concept
• Phase II – Research and Development
• Phase III - Commercialization
Phase I – R41/R43

• Feasibility and Proof of Concept
• Limited to $150K total costs
  – 6 months for SBIR
  – 12 months STTR
  – Not really true
    • Can go over the cap for “approved topics” – no prior approval
    • SBIR’s end up with 12 month terms
• Strong preliminary data not required
  – Not really true
• Business Plan not Required
  – Must have a chance of being profitable
Phase I (Continued)

• For SBIR - 67% of the work (and the budget) must go to the small business

• For STTR – minimum of 30% to the academic partner, 40% to the small business (i.e., up to 60% to the academic partner)

• A lot of Phase I grants never transition to Phase II
Phase II (R42/R44)

- Research and Development
- Limited to $1,000,000 total costs
  - Can go over the cap for “approved topics” – no prior approval required
- 2 year time period
- 12 pages
- Requires a good business plan
  - Formal, proscribed content, viable and critical
- Can have a Phase IIA and IIB
- Must have a good IP position
Phase II (Continued)

• SBIR – up to 50% of budget to academic partner
• STTR – same as phase I (30/40 minimum split)
• Additional equity a real plus
• The business team becomes much more important.
Variants

• Direct to Phase II
  – Requires equivalent of phase I data
  – SBIR only
• Fast Track
  – Phase I and Phase II Bundled
• Contracts – SBIR and STTR PA’s
• Special Announcements
• DOD has very specific SBIR/STTR programs
### Success Rates (NIH)

<table>
<thead>
<tr>
<th>Year</th>
<th>Program</th>
<th>Stage</th>
<th>Submitted</th>
<th>Funded</th>
<th>Success Rate</th>
<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>SBIR</td>
<td>Fast Track</td>
<td>337</td>
<td>66</td>
<td>19.6%</td>
<td>$18,157,545</td>
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<tr>
<td>2015</td>
<td>SBIR</td>
<td>Phase I</td>
<td>3,425</td>
<td>514</td>
<td>15.0%</td>
<td>$117,110,555</td>
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<td>2015</td>
<td>SBIR</td>
<td>Total Phase II</td>
<td>823</td>
<td>241</td>
<td>29.3%</td>
<td>$179,946,727</td>
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<td>2015</td>
<td>SBIR</td>
<td>Regular Phase II</td>
<td>442</td>
<td>163</td>
<td>36.9%</td>
<td>$113,088,150</td>
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<td>2015</td>
<td>SBIR</td>
<td>Direct Phase II</td>
<td>347</td>
<td>65</td>
<td>18.7%</td>
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<tr>
<td>2015</td>
<td>SBIR</td>
<td>Phase IIB</td>
<td>34</td>
<td>13</td>
<td>38.2%</td>
<td>$11,708,214</td>
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<td>2015</td>
<td>STTR</td>
<td>Fast Track</td>
<td>61</td>
<td>10</td>
<td>16.4%</td>
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<tr>
<td>2015</td>
<td>STTR</td>
<td>Phase I</td>
<td>911</td>
<td>149</td>
<td>16.4%</td>
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<td>STTR</td>
<td>Total Phase II</td>
<td>87</td>
<td>31</td>
<td>35.6%</td>
<td>$21,597,183</td>
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<tr>
<td>2015</td>
<td>STTR</td>
<td>Regular Phase II</td>
<td>87</td>
<td>31</td>
<td>35.6%</td>
<td>$21,597,183</td>
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<td></td>
<td>FY TOTAL</td>
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<td>5,644</td>
<td>1,011</td>
<td>17.9%</td>
<td>$372,766,143</td>
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Observations from NHLB SBIR/STTR Study Section

• The review panel has experts from industry and academia
• If it looks like a “R” grant, it will die
• Smoke and mirror companies are easily detected by the review panel
• You have to have a solid value proposition
• A strong academic leader is a positive
• Publications matter
• You are competing with “SBIR Factories”
More Observations

• Most funded grants are A1’s
• Devices do not seem to do well lately
• Drugs seem to be doing better
• External validation from big companies and experts really helps (i.e., letters of support)
• No foreign subcontracts
• You are not Bill Gates, do not pretend to be
• Don’t forget your day job
Pearls

• Indirect Cost Recovery
  – Set your own rate up to 40%
• “Fee” possible
  – A reasonable profit – maybe 7% or so of directs
• NIH will offer opportunities to other services
  – Market Analysis
  – Toxicology - SLOW
  – Synthesis – SLOW
  – Commercialization Readiness Pilot (CRP) Program
• SAM registration expires annually
  – Cottage industry out there to get you
Beware of “Death by SBIR”
A slow and painful process
Microbial Medical, Inc.

• Bacteria imaging agents
  – Targeted drug delivery
• Taylor, Murthy, Goodman and Wach co-founders
• Started with NIH Nanotechnology U01
• Boosted by GRA Phase IA, IB, II funding and a philanthropic gift
• SBIR Phase I x 2 (180K each)
• Phase II SBIR pending ($1.6M)
• Angel Investors
• Lots of time and effort
• Expert Business Partners
  – Wach, Lowery, Martin