Breast Cancer Startup Challenge

Partnering for Cures
Date: November 4th 2013
Time: 1:45-2:10pm
Introductions

Marc Hurlbert, Ph.D.,
Executive Director
Avon Foundation Breast Cancer Crusade

Rosemarie Truman,
Founder and CEO
The Center for Advancing Innovation

Tom Stackhouse, Ph.D.,
Associate Director for the Technology Transfer Center at the NIH National Cancer Institute
Avon Foundation for Women

Avon Global Philanthropy has donated more than $910 million globally for causes women care about most.

Avon is the largest global corporate supporter of the Breast Cancer Cause, with over $780 million donated worldwide to the cause.

Avon global philanthropy has committed nearly $50 million to end violence against women globally.
Avon Breast Cancer Crusade: Research

Understanding the causes of breast cancer and primary prevention.

Developing new blood tests – and other assays – to assess risk, determine what pre-cancers will progress, and what invasive cancers will recur and metastasize.

Developing new treatments for metastatic breast cancer, inflammatory BC and other unmet needs.
National Cancer Institute

- Largest of the 27 institutes within the National Institutes of Health performing intramural and extramural research

- Technology Transfer Mission: Bringing scientific discoveries to the market place to benefit public health by forming partnerships that integrate basic, translational, and clinical research

- Technology Transfer Center: Facilitates collaborative R&D agreements, material transfer agreements, human material transfer agreements, CDAs, clinical trial agreements as well as other assistance to help collaborators obtain success
NCI Breast Cancer Spend – # 1 disease area

<table>
<thead>
<tr>
<th>Disease</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
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</thead>
<tbody>
<tr>
<td>Total</td>
<td>4827.6</td>
<td>4966.9</td>
<td>5098.1</td>
<td>5058.1</td>
<td>5067.3</td>
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<tr>
<td>Clinical Trials</td>
<td>853.2</td>
<td>846.6</td>
<td>852.3</td>
<td>877.8</td>
<td>753.7</td>
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<tr>
<td>Breast Cancer</td>
<td>572.6</td>
<td>599.5</td>
<td>631.2</td>
<td>625.1</td>
<td>602.7</td>
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<tr>
<td>Lung Cancer</td>
<td>247.6</td>
<td>246.9</td>
<td>281.9</td>
<td>296.8</td>
<td>315.1</td>
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<tr>
<td>Prostate Cancer</td>
<td>285.4</td>
<td>293.9</td>
<td>300.5</td>
<td>288.3</td>
<td>265.1</td>
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<tr>
<td>AIDS</td>
<td>258.5</td>
<td>265.9</td>
<td>272.1</td>
<td>270</td>
<td>271.7</td>
</tr>
<tr>
<td>Colorectal Cancer</td>
<td>273.7</td>
<td>264.2</td>
<td>270.4</td>
<td>265.1</td>
<td>256.3</td>
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<tr>
<td>Leukemia</td>
<td>216.4</td>
<td>220.6</td>
<td>239.7</td>
<td>227</td>
<td>234.7</td>
</tr>
<tr>
<td>Brain and CNS</td>
<td>153.7</td>
<td>151.5</td>
<td>156.8</td>
<td>172.6</td>
<td>177.5</td>
</tr>
<tr>
<td>Non Hodgkin's</td>
<td>122.6</td>
<td>130.9</td>
<td>122.4</td>
<td>126.4</td>
<td>119.5</td>
</tr>
<tr>
<td>Melanoma</td>
<td>110.8</td>
<td>103.7</td>
<td>102.3</td>
<td>115.6</td>
<td>121.2</td>
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<tr>
<td>Ovarian Cancer</td>
<td>100</td>
<td>110.1</td>
<td>112.3</td>
<td>110.8</td>
<td>111.7</td>
</tr>
<tr>
<td>Pancreatic Cancer</td>
<td>87.3</td>
<td>89.7</td>
<td>97.1</td>
<td>99.5</td>
<td>105.4</td>
</tr>
<tr>
<td>Other Funding Areas: Liver Cancer, Head and Neck, Multiple Myeloma, Uterine Cancer, Stomach Cancer, Hodgkin’s Disease</td>
<td></td>
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</tbody>
</table>
NCI Collaboration Assets

NCI Testing Capabilities

Example: The Nanotechnology Characterization Laboratory provides preclinical efficacy and toxicity testing of nanotech cancer therapeutics and diagnostics.

Unique Research and Clinical Grade Materials

Several NCI repositories including those for mouse models and research agents. For instance, the Developmental Therapeutic Program provides resources for: Discovery (compounds, informatics, etc.) and development (formulation, toxicology).

NCI’s Cancer Therapy Evaluation Program

Early Clinical Trials Program 22 sites available for Phase 1/Phase 2 trials

Late Clinical Trials Program 9 Cooperative Groups (8 adult and 1 pediatric), 2 Brain Tumor Consortia and the AIDS Malignancy Consortia
The Center for Advancing Innovation

Mission
• Accelerate and increase the volume of research commercialization in order to ignite entrepreneurship and economic impact

Team Capability:
• Due diligence, portfolio/market/growth strategy and transformation for start-ups and large companies
• More than 20 years experience
• End-to-end, from strategy to realizing results

Team: ~20 people. 90% PhDs and MBAs from Life Sciences companies or the NIH

Team Qualifications and Experience:
• Over 110 strategy projects with ~100 products launched
• $21 billion in profit created for clients
• Trade secrets: due diligence, operational optimization and maximizing commercial launch
Background: Faster Cures for Avon Foundation Grantee and NCI Research

- CAI Performed a Portfolio Review of 10 Years of Avon Foundation Grantee Inventions
- CAI Performed a Portfolio Assessment of NCI’s Thousands of Intramural Inventions
- CAI Created a “Demand Database” to Quickly Match Promising Inventions to Partners

Promising Inventions

MATCH

Partners to License Inventions
Finding #1 – Disconnect Between Unmet Need and Industry R&D Focus

FINDING: For the most part, large pharma partners are not interested in many of the areas addressing unmet needs in Breast Cancer. The best scenario to commercialize Breast Cancer inventions is through start-ups.
Finding #2 – Dilutive Funding is in Decline for Breast Cancer Research

FINDING: Dilutive funding is declining for Breast Cancer research
IMPLICATIONS

1. Start-ups are needed to commercialize commercially relevant inventions

2. Dilutive funding models require innovation

3. The best place to start is to create a new initiative to address both!
The Breast Cancer Start-up Challenge

- International Business Plan and Startup Contest using 10 *near-term, commercially viable* inventions conceived and developed by inventors from the NCI and an Avon Foundation (AF) grantee

- Participants: University students; seasoned entrepreneurs; team members with legal, business, medical/scientific disciplines and ... anyone else

- Phases: Letter of Intent, Business Plan and Start-up
Goal of the Challenge: Launch Start-ups to:

- **Breast Cancer:** Increase survivability and improve the standard of care
- **Economic Growth:** Spur economic growth through new startups and jobs
- **Entrepreneurship Learning:** Provide entrepreneurial education programs for scientists
- **Business Model:** Create new business models in translational research and R&D funding
- **Technology Transfer Memorandum:** “Accelerate and increase the volume of Federally funded technology transfer in support of high growth businesses”
Challenge Phases

<table>
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<tr>
<th>Planning</th>
<th>Phase 1: Letter of Intent</th>
<th>Phase 2: Business Plan</th>
<th>Phase 3: Startup</th>
<th>Post-Contest</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 Inventions</td>
<td>10 Teams for Each Invention</td>
<td>3 Teams per Invention Go to Ph3</td>
<td>3 Startups for Each Invention</td>
<td>“Startup Winner” Has Licensing Agreement and Seed Funding</td>
</tr>
</tbody>
</table>

Invention 1

Invention 1
Challenge Team Participants

Team Design: Mandatory Requirements

- **A Team Leader** is our single point of contact. A Core Team Member is accountable for deliverables.
- **A Mentor** has domain experience and will actively work with the team on a daily/weekly basis to review/complete deliverables.
- **An Advisor** has domain expertise and the team uses for Q&A sessions, e.g., KOL.
- **A Collaborator** is an organization that can improve your probability of success; they will include seed funders, services firms, etc.

**Mandatory Requirements**

- Business
- Legal
- Medical/Scientific
- Seasoned Entrepreneur
Example Invention: Biomedical Engineering

**#3 – Biomedical Material/Therapeutic/Vaccine**

**Invention:** Collagen composite tissue replacement material as a reconstruction platform with anti-tumor capabilities

**Inventor:** Karen Burg, Clemson University

**Patent:** issued in the US, human breast tissue tested in pre-clinical
Timeline

Key Dates

Letter of Intent
Oct 1-Nov 29 2013
- 8/30/13 – 10/1/13: Form team
- 10/1/13: Submit LOI
- 11/29/13: LOIs due
- 12/4/13: Communicate to teams

Business Plan
Dec 2 2013 – Feb 19 2014
- 12/2/13: Launch BP effort
- 2/3/14: Deliverables due
- 2/3/14 – 2/13/14: Virtual pitches with teams
- 2/19/14: Award top teams for each invention

Start-up
Feb 20, 2014- June 27, 2014
- 2/20/14: Launch SU effort
- Ongoing: Revise BP; create SU; apply for funding and license
- 6/17/14: Deliverables due
- 6/27/14: Announce successful start-ups

Anticipated Post-Contest Activities
- Conduct discussions regarding collaborative R&D agreement
- Continue R&D on invention
- Continue raising capital

Ongoing
- Provide mentoring / guidance to teams using rigorous methodologies
- Receive questions and filter to SMEs as necessary
Progress so Far
Next Steps

International Accelerator

Provides Solutions to Help Startups Become Successful

Leverage Wet Labs that Exist
Call to Action!

Join a team –
www.breastcancerstartupchallenge.com

Tell your alma maters!

Partner with us on our accelerator initiative!
NCI Marketed Technologies

Abbott/Others
Schering AG/Berlex
BMS
BMS
Roche
Millennium
Cell Therapeutics
Amgen
20/20 GeneSystems
Molecular Devices
Merck
Medimmune Oncology
Monogram Biosciences
Isis
Ortho Biotech
Biovest/Accentia
Squirrel Free Products

AIDS Test Kits
Fludara®
Videx ® (ddI)
Taxol ® (paclitaxel)*
Hvid ® (ddC)
Velcade® *
Zevalin®
Kepivance ®
Multi-Replica Blotting Kit*
PixCell® Laser Capture Microdissection*
Gardasil®
NeuTrexin®
PhenoSenseTM HIV phenotype tests
Vitravene®
Prezista®
BiovaxID™
Squirrel-free capsaicin-treated birdseed

*Developed under NCI CRADA