How can state and federal governments help industry?

Moderator:

Susan E. Old, PhD, Senior Advisor for Translational Research, National Center for Research Resources, National Institutes of Health

Panelists:

Andrew Kurtz, PhD, SBIR Program Director, National Cancer Institute

Vivian Chenault, PhD, Associate Director, External Expertise and Partnerships, U.S. Food and Drug Administration

Julie Turner Collins, Biosciences Project Manager, SBIR Assistance Program, Enterprise Innovation Institute, Georgia Institute of Technology

Susan Shows, Vice President of the Georgia Research Alliance
NIH Funding Opportunities to Commercialize New Innovations

Academic & Industry Intersection: Accessing Partners

February 3, 2010, Emory Conference Center, Atlanta, GA

Andrew J. Kurtz, Ph.D.
Program Director
Today’s Presentation

- Overview & Eligibility
- NIH SBIR/STTR Funding Opportunities
- NCI SBIR Development Center
- New Initiatives:
  - SBIR Phase II Bridge Award
  - NCI Investor Forum
1. Stimulate technological innovation
2. Use small business to meet Federal R&D needs
3. Increase private-sector commercialization innovations derived from Federal R&D
4. Foster participation by minority and disadvantaged persons in technological innovation

Small Business Innovation Development Act of 1982
Small Business Technology Transfer Act of 1992

Currently extended through 1/31/2010
Set Aside

- **SBIR**: Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization
  - 2.5%

- **STTR**: Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with potential for commercialization
  - 0.3%


~$108 million annually at the NCI

~$650 million annually at the NIH
Reasons to Seek SBIR/STTR Funding

- Provides seed funding for innovative technology development
- Provides recognition, verification and visibility
- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)

- **Not a Loan**
  - No repayment is required
  - Doesn’t impact stock or shares in any way (i.e. non-dilutive)

- Intellectual property rights retained by the small business
  - *Bayh-Dole Act (1980)*
Three-Phase Programs

PHASE I – R41, R43
 • Feasibility Study
 • $100K and 6-month (SBIR) *
 • or 12-month (STTR) Award

PHASE II – R42, R44
 • Full Research/R&D
 • $750K and 2-year Award (SBIR & STTR) *
 • Commercialization plan required

PHASE III
 • Commercialization Stage
 • Use of non-SBIR/STTR Funds

* Note: Actual funding levels may differ by topic.
Applicant must be a Small Business Concern (SBC)
Organized for-profit U.S. business
500 or fewer employees, including affiliates
PD/PI’s primary employment (i.e., >50%) must be with SBC at the time of award and for duration of the project period
At least 51% U.S.- owned by individuals and independently operated

OR

At least 51% owned and controlled by another (one) business concern that is at least 51% owned and controlled by one or more individuals
STTR Eligibility

- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
  - Minimum 40% by small business
  - Minimum 30% by U.S. research institution
- U.S. Research Institution: College or University; Non-profit research organization; Federally-Funded R&D Center (FFRDC)
- Intellectual Property Agreement
  - Allocation SBC of IP rights (to SBC) and rights to carry out follow-on R&D and commercialization
- Principal Investigator’s primary employment may be with either the Small Business Concern or the research institution
Multiple Funding Solicitations

- **NIH SBIR/STTR Omnibus Solicitations for Grant Applications**
  
  *Release:* January  
  *Receipt Dates:* April 5, August 5, and December 5

- **Solicitation of the NIH & CDC for SBIR Contract Proposals**
  
  *Release:* August  
  *Receipt Date:* Early November

- **See NIH Guide for various other Program Announcements (PAs) and Requests for Application (RFAs), i.e. other grants**
  
  *Release:* Weekly  
  *Receipt Dates:* Various
Small Business Research Funding Opportunities


- Congress passed temporary extension for SBA programs, including SBIR/STTR.
- NIH Offers Commercialization Assistance Program to SBIR Phase II Awardees
- NIH/ODC: SBIR Contract Solicitation Now Available
- NIH Offers SBIR Phase III Assessment Program for Phase I SBIR Awardees

Funding Opportunities

2009 SBIR and STTR Omnibus Solicitations of the NIH, CDC, and FDA

- SBIR Parent Funding Opportunity Announcement (PA-09-031)
- STTR Parent Funding Opportunity Announcement (CA-09-031)
- Program Descriptions and Research Topics (PDF - 1.7 MB or MS Word - 1.5 MB)

Recovery Act Opportunities

Special Announcements Page

NIH Policy Change on Threshold for Navigation of Facilities and Administrative (F&A)/Indirect Costs for

What Are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) program is a set-aside program (5.1% of an agency's extramural budget) for domestic small business concerns to engage in research/research and development (R/R&D) that has the potential for commercialization. See more information on SBIR and STTR Programs...
Basic Research & Training Grants

- R01
- R03, R21
- T32, K99
- SBIR & STTR
NCI SBIR Development Center

Michael Weingarten, MA (Director)
Previous
- NASA – Program Manager, NASA Technology Commercialization Program

Ali Andalibi, PhD (Team Leader)
Previous
- NSF – SBIR Program Director, Medical Biotechnology
- House Ear Institute – Scientist & Director, New Technology and Project Development
- Trega Biosciences, Inc. – Research Scientist

Greg Evans, PhD (Team Leader)
Previous
- NHLBI/NIH – Program Director, Translational and Multicenter Clinical Research in Hemoglobinopathies
- NHGRI/NIH – Senior Staff Fellow

Natalia Kruchinin, PhD (Program Director)
Previous
- QIAGEN, Inc. – Molecular Diagnostics Applications Manager
- Motorola, Inc. – Senior Scientist, Gene Expression Assays

Patti Weber, DrPH (Program Director)
Previous
- International Heart Institute of Montana – Tissue Engineering and Surgical Research
- Ribi ImmunoChem Research, Inc. – Team Leader, Cardiovascular Pharmacology

Andrew J. Kurtz, PhD (Program Director)
Previous
- NIH – AAAS Science & Technology Policy Fellow
- Cedra Corporation – Research Associate, Bio-Analytical Assays and Pharmacokinetics Analysis

David Beylin, MS (Program Director)
Previous
- X/Seed Capital Management, LLC, Consultant
- Naviscan PET Systems, Inc., Vice President, Research

Jian Lou, PhD (Program Director)
Previous
- Johnson & Johnson – Research Scientist, Target Validation & Biomarker Development
- Lumicyte, Inc. – Director, Molecular Biology Systems Analysis

Deepa Narayanan, MS (Program Director)
Previous
- Naviscan PET Systems, Inc., Director, Clinical Data Management (Oncology Imaging & Clinical Trials)
- Fox Chase Cancer Center, Scientific Associate (Molecular Imaging Lab)

Todd Haim, PhD (Program Analyst / AAAS Fellow)
Previous
- National Academy of Sciences – Christine Mirzayan Science and Technology Policy Fellow
- Pfizer Research Laboratories – Postdoc Fellow, Cardiac Pathogenesis & Metabolic Disorders
SBIR & STTR: Three-Phase Program

PHASE I – R41, R43
• Feasibility Study
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• or 12-month (STTR) Award

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• $750K and 2-year Award (SBIR & STTR) *
• Commercialization plan required

Phase II Bridge Award

PHASE III
• Commercialization Stage
• Use of non-SBIR/STTR Funds

* Note: Actual funding levels may differ by topic.
EXAMPLE: Drug Development

The “Valley of Death” is the problem

SBIR Bridge Award addresses the problem by bridging the “Valley of Death”
EXAMPLE: Drug Development

SBIR Bridge Award allows NIH to share investment risk by incentivizing Private Investors to evaluate projects and commit funds much earlier
Milestone-Based Awards

Expectation that applicants will secure third-party matching funds (minimum 1:1 match during the entire project)

Phase II Award

Year 1+

Milestones reached? Matching funds secured for year 1?

YES

SBIR Bridge Award

1st Year Portion of funds

YES

Milestones reached? Matching funds secured for year 2?

NO

STOP

2nd Year Portion of funds

YES

Milestones reached? Matching funds secured for year 3?

NO

STOP

3rd Year Portion of funds

YES

Private investor / strategic partner continues to support commercialization
Critical Review of Business Plan

Special Review Criteria

• Balanced consideration of technical and commercial merits
• Detailed requirements for IP, regulatory and financing plans
• Complete disclosure of applicant’s SBIR commercialization history

➤ Applications with strong financing plans are rewarded with higher score

Preferred Third-Party Matching Funds

• Cash, liquid assets, convertible debt

Possible Sources of Funds

• Another company, venture capital firm, individual “angel” investor, foundation, university, state or local government, or any combination
<table>
<thead>
<tr>
<th>Company</th>
<th>Location</th>
<th>Funding Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lpath</td>
<td>San Diego, CA</td>
<td>$3.0M for the commercialization of ASONEP™, a first-in-class monoclonal antibody against the angiogenic growth factor S1P</td>
</tr>
<tr>
<td>OptoSonics</td>
<td>Oriental, NC</td>
<td>$3.0M for the development of a photoacoustic computed tomography (CT) scanner for preclinical molecular imaging</td>
</tr>
<tr>
<td>Guided Therapeutics</td>
<td>Norcross, GA</td>
<td>$2.5M for the development of LightTouch®, a point-of-care device for cervical cancer screening</td>
</tr>
<tr>
<td>GAMMA MEDICA IDEAS</td>
<td>Northridge, CA</td>
<td>$3.0M for the development of a novel molecular breast imaging technique to guide early-stage patient care</td>
</tr>
<tr>
<td>Alter BioScience</td>
<td>Miramar, FL</td>
<td>$3.0M for the development of ALT-801, a fusion protein consisting of IL-2 coupled with a soluble T-cell receptor fragment that recognizes a specific form of processed p53 antigen</td>
</tr>
<tr>
<td>KONYING</td>
<td>West Henrietta, NY</td>
<td>$3.0M for the development of a cone beam breast CT scanner</td>
</tr>
</tbody>
</table>
Applications due March 1, 2010

Technical Scope

• Cancer Therapeutics
• Imaging Technologies, Interventional Devices & In Vivo Diagnostics
• In Vitro and Ex Vivo Diagnostics & Prognostics

Mechanism and Budget

• Uses the SBIR Phase II (R44) competing renewal mechanism
• Available to current Phase II awards & and those ending within last 2 years
• Provides up to $1 M per year for up to 3 years in additional support

Part I Overview Information

Department of Health and Human Services
Participating Organizations
National Institutes of Health (NIH) [http://www.nih.gov]
Components of Participating Organizations
National Cancer Institute (NCI) [http://www.cancer.gov]

Title: SBIR Phase II Bridge Awards to Accelerate the Development of Cancer Therapeutics, Imaging Technologies, Interventional Devices, Diagnostics, and Prognostics toward Commercialization (R44)

Announcement Type
This Funding Opportunity Announcement (FOA) is a reissue of RFA-CA-08-021.

Request For Applications (RFA) Number: RFA-CA-10-009

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (http://www.grants.gov) using the SF-424 Research and Related (R&R) forms and the SF-424 (R&R) Application Guide.

APPLICANTS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement on Grants.gov (http://www.grants.gov) (hereafter called Grants.gov/Applications).

IMPORTANT: A registration process is required prior to submitting applications. Applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission deadline. (See Section IV, A.7.1.)

Catalog of Federal Domestic Assistance Number(s)
03.3N, 93.395

Key Dates
Release/Posted Date: January 5, 2010
Opening Date: February 1, 2010 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date: February 1, 2010
NOTE: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m., local time of the applicant institution's place of business.

Application Due Date: March 1, 2010
Peer Review Date: May-June 2010
Council Review Date: August 2010
Earliest Anticipated Start Date: September 2010
Exclusive opportunity for 14 NCI awardees to showcase their companies to investors

http://sbir.cancer.gov/investorforum/

**Featured Small Businesses**
- Present to and network with >150 investors and potential strategic partners
- Participate in panel discussion with successful Bridge awardees and their investors

**Investors**
- Opportunity to evaluate NCI’s top companies with innovative technologies
- Exclusive one-on-one meetings
Andrew Kurtz, Ph.D.
Program Director
SBIR Development Center
Phone: 301-594-6846
kurtza@mail.nih.gov
How Can State and Federal Government Help Industry?

Government Panel

“Academic & Industry Intersection: Accessing Partners”

Emory Conference Center
Atlanta, GA
February 3, 2010

V. Michelle Chenault, Ph.D.; Associate Director, EEP Technology Transfer Representative
External Expertise and Partnerships
Office of the Center Director
Food and Drug Administration
Center for Devices and Radiological Health
v.chenault@fda.hhs.gov
Food and Drug Administration

Dr. Margaret Hamburg, Commissioner

- Center for Devices and Radiological Health (CDRH)
- Center for Biologics Evaluation and Research (CBER)
- Center for Drug Evaluation and Research (CDER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- (new) Center for Tobacco Products (CTP)
- Center for Veterinary Medicine (CVM)
- National Center for Toxicological Research (NCTR)
- Office of Regulatory Affairs (ORA)

“Public Health is Everybody’s Business”
TOPICS

• FDA BASICS

• Selected Agency Initiatives
  o FDA Critical Path Initiative
  o FDA Sentinel Program
  o SBIR/STTR, Cooperative Agreements, Grants
  o FDA Commissioner's Fellowship Program
  o Fellowship, Internship, Graduate, & Faculty Programs
  o FDA/NCI Interagency Oncology Fellowship (IOTF) Program
  o Technology Transfer

• Selected CDRH Initiatives
Do You Know?

Center for Devices and Radiological Health
FDA regulates a broad range of medical devices, including complicated, high-risk medical devices, like artificial hearts, and relatively simple, low-risk devices, like tongue depressors, as well as devices that fall somewhere in between, like sutures.
Critical Path Initiative (CPI)

Launched in March 2004 to address the steep decline in the number of innovative medical products submitted for approval despite science breakthroughs.

FDA’s landmark report *Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products.*

http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/CriticalPathOpportunitiesReports/default.htm

Critical Path Priority Topics March 2006 publication *Critical Path Opportunities Report and List:*  
(1) Developing Better Evaluation Tools  
(2) Streamlining Clinical Trials  
(3) Harnessing Bioinformatics  
(4) Moving Manufacturing into the 21st Century  
(5) Developing Products to Address Urgent Public Health Needs  
(6) At-Risk Populations—Pediatrics


**Project:** Develop the Sentinel System, a national, distributed, electronic system designed to enable FDA to actively monitor the safety of drug and biological products, medical devices and, ultimately, all FDA-regulated products.
Sentinel Initiative

The FDA’s Web Page on the Sentinel Initiative

FDA Amendments Act (FDAAA) Fall 2007- establish an active surveillance system for monitoring drugs, using electronic data from healthcare information holders. The Sentinel Initiative is FDA’s response to that mandate. Goal: to build and implement a new active surveillance system that will eventually be used to monitor all FDA-regulated products.

Work from contracts is being made available for comment in FDA's docket number FDA-2009-N-0192. You can join FDA’s listserv and receive notifications on updates.


Project Report: Engagement of Patients, Consumers, and Healthcare Professionals in the Sentinel Initiative

Project Report: Evaluation of Potential Data Sources for a National Network of Orthopedic Device Implant Registries
Small Business Innovation Research (SBIR) - The SBIR program is a set-aside program designed to support innovative research conducted by small business concerns that have the potential for commercialization of the subject of the research. The only FDA opportunity is the solicitation with the NIH PHS 2009-2. see [http://grants.nih/grants/guide/pa-files/PA-09-080.html](http://grants.nih/grants/guide/pa-files/PA-09-080.html).

Grants - An award instrument of financial assistance by the Federal Government to an eligible recipient. The term does not include: any Federal procurement subject to the Federal Acquisition Regulation (FAR); technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to individuals.

Cooperative Agreements- An award instrument of financial assistance in which "substantial involvement" is anticipated between the HHS awarding agency and the recipient during performance of the contemplated project or activity. “Substantial involvement" means that the recipient can expect Federal programmatic collaboration or participation in managing the award.

[http://www.fda.gov/ForFederalStateandLocalOfficials/CooperativeAgreementsCRADAsGrants/default.htm](http://www.fda.gov/ForFederalStateandLocalOfficials/CooperativeAgreementsCRADAsGrants/default.htm) or the Office of Acquisitions and Grants Services (Gladys Melendez-Bohler @ 301-827-7168)
**FDA Commissioner's Fellowship Program** - The FDA offers a two-year Fellowship Program, which provides an opportunity for health professionals and scientists to receive training and experience at the FDA. [http://www.fda.gov/CommissionersFellowshipProgram](http://www.fda.gov/CommissionersFellowshipProgram).

**Fellowship, Internship, Graduate, & Faculty Programs** -
- CDER Academic Collaboration Program (CACP)
- Visiting Pediatric Pharmacology Fellows Rotation Program (CDER)
- Veterinary Medicine Student Internships (CVM)
- Biostatistics Fellowships (CBER)
- Medical Device Fellowship Program (EEP, OCD, CDRH)
- Device Evaluation Intern Program (CDRH)
- Postgraduate Research Program, Science Internship Program, Faculty Research Program, Foreign National Training Program, Interdisciplinary Toxicology Program (NCTR)
- Office of Policy and Planning Internship Program (OC)
- Federal Career Intern Program

[http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/default.htm](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/default.htm)

Technology Transfer

“Technology transfer is the process by which existing knowledge, facilities or capabilities developed under federal research and development funding (R&D) funding are utilized to fulfill public and private needs.”

“…for greater interactions and collaborations among federal laboratories, state and local governments, university and the private sector”

- The Stevenson-Wydler Technology Innovation Act of 1980 - established T² as a mission of the federal gov’t
- The Federal Technology Transfer Act of 1986 (FTTA) – created CRADA mechanism
- National Technology Transfer Advancement Act of 1995 (NTTA)- improved attractiveness of CRADAs
- Technology Transfer Commercialization Act of 2000- broadens CRADA licensing authority
Types of Mechanisms
(different disclosure rules for public notification)

- **MOUs**- Memorandums of Understanding (Federal Register Notice upon execution and are publicly available on the FDA website) aka: Memorandums of Agreement (MOAs)

- **CDAs**- Confidential Disclosure Agreements (not publically disclosed)

- **MTAs**- Material Transfer Agreements (not publically disclosed)

- **CRADAs**- Cooperative Research and Development Agreements (only Summary Page (a.k.a. ‘Press Release’ page) is public information, currently not posted on FDA website but will be posted on the CDRH website)

- **External Grants**- external funding provided from a government or private sector organization for a specific project by an application process (may be publicized after awarded)

- **Interagency Agreements** (IAAs formerly IAGs)- contract to transfer funds between government agencies (not generally publicized, some exceptions)

- Patents, Inventions (EIRs)- can be submitted by federal employees
**FDA Technology Transfer Representatives or Specialists**  
http://www.fda.gov/AboutFDA/business/ucm119486.htm

Dr. Alice Welch, FDA Technology Transfer (Development) Officer (OAGS)  
Alice.Welch@fda.hhs.gov

<table>
<thead>
<tr>
<th>Center</th>
<th>Representative</th>
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<tbody>
<tr>
<td>CBER</td>
<td>Dano Murphy</td>
</tr>
<tr>
<td>CDER</td>
<td>Joseph Hanig</td>
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<tr>
<td>CDRH</td>
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<td>CVM</td>
<td>David G. White</td>
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<td>NCTR</td>
<td>Thomas Flammang</td>
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<tr>
<td>ORA</td>
<td>Wen Lin</td>
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</tbody>
</table>

NIH Office of technology transfer handles patents, inventions and provides legal support.
Center for Devices and Radiological Health

http://www.fda.gov/cdrh/
Jeffrey Shuren, M.D., J.D., Director
Ensuring the health of the public throughout the “Total Product Life Cycle”
Office of the Center Director

Office of Device Evaluation (ODE)

Office of In Vitro Diagnostics (OIVD)
  -Personalized Medicine

Office of Communication, Education and Radiation Programs (OCER)
  -DSMICA (www.fda.gov/cdrh/industry/support/index.html)

Office of Surveillance and Biometrics (OSB)
  -MEDSUN

Office of Science and Engineering Laboratories (OSEL)

Office of Compliance (OC)
EEP is the liaison to the FDA Commissioner’s Fellowship and the FDA/NCI Interagency Oncology Taskforce Fellowship.
SBIR/STTR
as a funding strategy

Julie Turner Collins
ATDC/SBIR GA
Not just a funding mechanism
Part of your funding strategy
• SBIR
• Angel Investor
• Venture Capital
When

• In the product life-cycle?
  Proof of Concept to Alpha Prototype
  Product 2.0 to Product 3.0

• To apply?
  Application to Award = 10 mos.
TEAM

- Who should be the PI?
  Faculty, Post-doc, recent Ph.D. graduate

- Consultants?
  Faculty, Industry Representative

- Letters of Support
  Potential Investor or Customer or Partner
Administrative details

• Forming a corporate entity: LLC or C-corp?
  Partners and their equity position
  Patent holders and royalties

• Electronic Registration
  [www.grants.gov](http://www.grants.gov)
  NIH eRA commons

• Center for Scientific Review
  SBIR Special Emphasis Panel

• Budget - Allowable and Unallowable costs
  Subcontract - 1/3 or 2/3 or grant?
Grant Preparation

• Not just an R01

• Not just a business plan

• Who is your audience?

• Did you define?
  Market
  Potential Customers
  Commercial Significance
• helping entrepreneurs launch and build successful companies

• ATDC Seed Capital Fund
  investing in GA-based entrepreneurial companies pursuing innovation in bioscience and advanced technology

• Nina Sawczuck
  nina.sawczuk@innovate.gatech.edu

• Harold H. Shlevin
  harold.shlevin@innovate.gatech.edu

www.ATDC.org
• Julie Turner Collins  
  Bioscience Project Manager  

• julie.collins@atdc.org  

• 404-385-6646
What is the Georgia Research Alliance?

A public-private partnership dedicated to growing Georgia’s economy around university resources

Our principal lines of business:

- Recruiting world-class scientists to the universities
- Outfitting research labs in focused technology areas
- Sparking initiatives with substantial economic potential
- Helping build companies around university discoveries
Distinctive Elements of GRA

**The Spark**  Vision of the business community

**Mission**  Grow Georgia’s economy through investment in research universities

**Leadership**  Guided by strong private sector board

**Objectivity**  Independently balance diverse economic development agendas of universities, government, and business

**Focus**  Fund a small number of high-impact technical thrusts using a small operating staff – 501(c)3
“Typical” Investment Portfolio & Results

RECRUITING:
60 Eminent Scholars
GRA Academy attracted $200M in sponsored research in FY 2009

RESEARCH INFRASTRUCTURE:
>20 new Centers of Excellence, $3B in new federal/private funding

COMMERCIALIZATION:
100 start-ups
500 employees
>$350M private equity

Typical Investment Portfolio & Results

$15M
$10M
$10M
Economic impact starts with people

60 GRA Eminent Scholars on board today

- Attract disproportionate share of research funding
- Attract the best graduate students, post docs, etc.
- Create the most interest with industry
Dr. Rafi Ahmed
Emory University

*His Emory Vaccine Center developed an HIV / AIDS vaccine that’s in Phase II human clinical trials*

- >$260,000,000 in external funding since 1996
- 14 patents issued, 18 pending
- One of most referenced scientists in world
What is VentureLab?

- GRA’s program for commercializing university discoveries
- Milestone-based funding and advice to mitigate technical & market risks at earliest stages of development
- Focus is to create sustainable, Georgia-based companies
- Complementary to activities of tech transfer offices
- Covers the innovation continuum from idea generation to seed investment
How does VentureLab Work?

1. Universities identify technologies with commercial potential and submit **formal proposal to GRA.**

2. University-based VentureLab Directors decide which technologies merit **Phase I funds** (up to $50K).

3. VentureLab External Advisors recommend which technologies merit **Phase II funds** (up to $100K).

4. VentureLab External Advisors recommend which companies receive **Phase III loans** (up to $250K).
VentureLab External Advisors (Biosciences)

- Robert Crutchfield: partner, Harbert Venture Partners
- Greg Dane: private investor; former president & CEO, Somatocor Pharmaceuticals
- Laurence Downey, M.D.: president, Berkshire Pharma Consulting
- Zorina Galis, Ph.D.: Amplinovia Consulting
- Bill Johnston, Ph.D.: president, BioBusiness Strategies; former president/CEO, Inhibitex
- Garheng Kong, M.D., Ph.D.: general partner, Intersouth Partners
- Tom O’Brien: CEO, Axion; former EVP, Intermagnetics General Corp.
- Bruce Robertson, Ph.D.: managing director, HIG Ventures
- Kevin Schultz, DVM, PH.D.: former CSO & VP of Research, Merial Inc.
- Nancy Sousa: former president, Given Imaging Inc.
Technology area: Cancer Diagnostics

**VL Activity:**
($50K – Phase I)
- Preliminary assessment of IP
- Market assessment of technology
- Prepared SBIR grant application

**Results:**
- Received SBIR grant ($300K)
- Attracted $500K in private equity
- Prepping for preclinical trials

VentureLab Example
Another Example

**Technology area:** Medical Device – Orthopedics

**VL Activity:**
($450K –
Phases I, II, III)

- Develop IP strategy
- Prototype development & prelim test data
- Initial regulatory planning
- Initial animal efficacy trials
- Steps to overcome design hurdles

**Results:**
- Attracted $10M equity investment
- Generating modest revenues
- 30+ employees
VentureLab Results*
2002-2009

>500 university technologies considered
250 projects funded (with $15M from GRA)
100 early-stage companies formed
20 companies graduated to/beyond incubator status
500 total employees at VL companies
>$350M private equity investment attracted

*A subset of universities’ tech transfer results
GRA Venture Fund – new in 2009

- GRA Trustees saw huge need for early-stage capital
- $19M initial closing in 2009 – eventually grow to $30M
- Only considers investing in companies in the VL pipeline
- Investor committee makes decisions
- One investment to date, others in queue
Susan G. Shows
Senior Vice President
Georgia Research Alliance
susan.shows@gra.org
404-332-9770