

The NCI Office of Cancer Centers Learning Series

Bringing Science to the Marketplace: The NCI SBIR Program

Dial In: **800-593-9924**

Passcode: **CANCER CENTERS**

For Technical Support, call **800-857-8777** and choose **option 3**.

The NCI Office of Cancer Centers Learning Series Bringing Science to the Marketplace: The NCI SBIR Program

Thursday, September 8, 2011
2:00 to 3:30 pm EDT



Moderator

Shannon L. Silkensen, PhD
Program Director
Office of Cancer Centers
National Cancer Institute
National Institutes of Health
Bethesda, MD

Featured Presenters

Michael Weingarten, MA

Director
SBIR Development Center, NCI
Bethesda, MD

David Beylin, MS, MBA, DABSNM

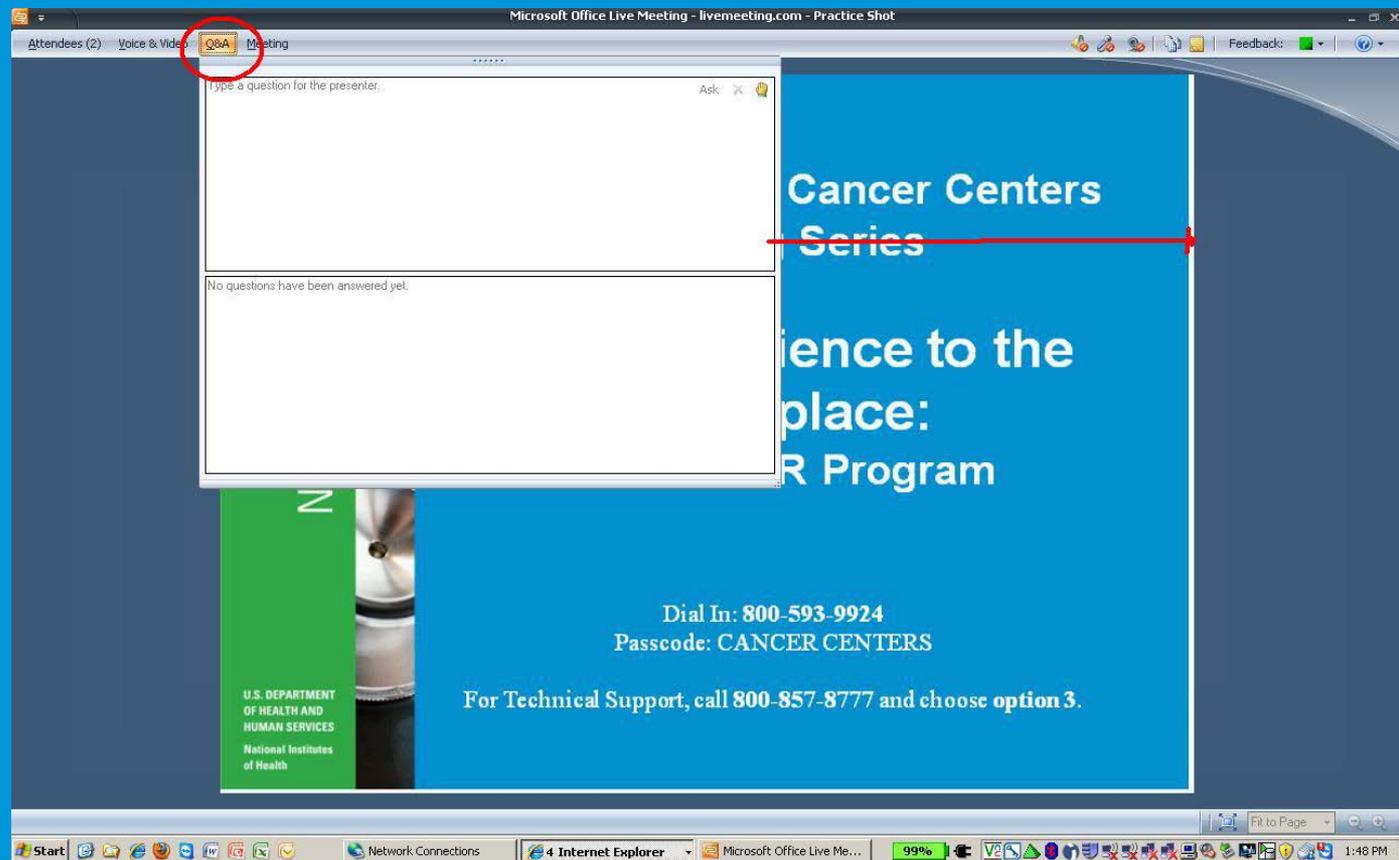
SBIR Program Director
SBIR Development Center, NCI
Bethesda, MD

James Olson, MD, PhD

President and Founder, Presage
Biosciences
Full Member, Fred Hutchison Cancer
Center
SBIR Program Grantee
Seattle, WA

A Quick Guide to Your Screen

- Please submit your question via the Q & A box on the right hand side of your screen. If you do not see the Q&A box, you can expand it by clicking the Q&A on the top navigation panel and dragging the dropdown box to the right side of your screen.



The screenshot shows a Microsoft Office Live Meeting window titled "Microsoft Office Live Meeting - livemeeting.com - Practice Shot". The window has a top navigation bar with "Attendees (2)", "Voice & Video", "Q&A", and "Meeting". The "Q&A" button is circled in red. Below the navigation bar is a Q&A box with a text input field containing "Type a question for the presenter..." and an "Ask" button. Below the input field is a message: "No questions have been answered yet." To the right of the Q&A box is a presentation slide with a blue background. The slide text includes "Cancer Centers Series", "Access to the place:", "R Program", "Dial In: 800-593-9924", "Passcode: CANCER CENTERS", and "For Technical Support, call 800-857-8777 and choose option 3." A red arrow points from the Q&A box to the slide. The Windows taskbar at the bottom shows the Start button, several application icons, and the system tray with the time 1:48 PM.

Bringing Science to the Market: The NCI SBIR Program

NCI Cancer Centers Learning Series

September 8, 2011

Michael Weingarten
Director, NCI SBIR Development Center



Today's Presentation



- **General SBIR/STTR Program Overview**
- **NCI/NIH SBIR Funding Opportunities**
- **NCI Phase II Bridge Award**
- **Program Initiatives**

Set Aside

- **SBIR:** Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization
- **STTR:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with potential for commercialization

2.5%

0.3%

~\$109 million annually at the NCI
~\$650 million annually at the NIH

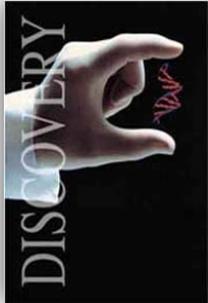
- **NCI's primary resource for enabling commercialization of high impact technologies that can benefit patients, such as:**
 - **Small Molecules and Biologics**
 - **Cancer Diagnostics**
 - **Cancer Imaging**
 - **Electronic Health & Education Tools**

- **One of the largest sources of early stage of life sciences funding in the country.**
 - **A stable and predictable source of funding**
- **Intellectual property rights are retained by the small business concern**
- **Not a loan – no repayment is required**
- **Doesn't impact stock or shares in any way (no dilution of capital)**
- **Provides recognition, verification and visibility**
- **Can be a leveraging tool to attract other funding (VC, etc.)**

Small Business Concern

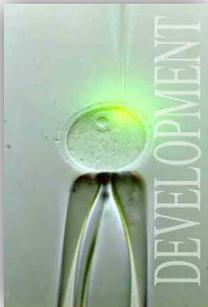
- For-profit U.S. business
- 500 or fewer employees, including affiliates
- Must be:
 - At least 51% owned by US individuals and independently operated
or
 - At least 51% owned and controlled by another business concern that is at least 51% owned and controlled by one or more individuals
- **Principal Investigator's primary employment must be with the Small Business Concern at the time of award**

- **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**
 - **Other non-profit research organization**
 - **Federal R&D center**
- **Intellectual Property Agreement**
 - **Allocation of IP rights 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**



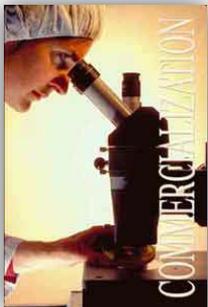
PHASE I – R41, R43

- Feasibility Study
- \$150-250K, 6-12 months



PHASE II – R42, R44

- Full Research/R&D
- \$1-2M, 2-3 years
- Commercialization plan required



PHASE III

- Commercialization Stage
- Use of non-SBIR/STTR Funds

* *These funding levels are guidelines. Companies should request the budget appropriate to accomplish the goals of the project.*

NCI SBIR Funding Opportunities



SBIR Portfolio Summary *(Active as of July 1 2010)*

Grants & Contracts -- \$109M budget



| Classification | Topic Area | Phase I (% of portfolio) | Phase II (% of portfolio) |
|---|------------------------------------|-----------------------------|------------------------------|
| Therapeutics 31% | Biologics | 28 (6%) | 19 (4%) |
| | Small molecules | 59 (12) | 18 (4) |
| | Nanotechnology-based therapeutics | 15 (3) | 9 (2) |
| Devices for Cancer Therapy 9% | Surgical interventions | 4 (1) | 3 (1) |
| | Ablative technologies | 6 (1) | 3 (1) |
| | Radiation Therapy | 12 (2) | 15 (3) |
| Imaging Technologies 19% | Image-guided interventions | 4 (1) | 10 (2) |
| | New imaging technologies | 28 (6) | 49 (10) |
| Diagnostics 24% | <i>In vitro</i> diagnostics | 63 (13) | 53(11) |
| Cancer Biology 6% | Research Tools | 13 (3) | 13 (3) |
| Cancer Control & Epidemiology 12% | Software, Bioinformatics & eHealth | 10 (2) | 25(5) |
| | Educational Tools & Other | 4 (1) | 17 (4) |
| | Total (480) | 246 (51) | 234 (49) |

SBIR/STTR Omnibus Grant Solicitation (NIH)

Release: January

Receipt Dates: April 5, August 5, and December 5

Technology Areas: All, investigator-initiated R&D

Other Program Announcements, RFAs

E.g. Image-Guided Cancer Interventions (NCI)

Program Announcement #: PA-10-079, PA-10-080

Release: January 2010

Receipt Dates: April 5, August 5, and December 5

Technology Areas: IGD, IGT, IGS

SBIR Contract Solicitation (RFP - NIH, CDC)

Release: ***New RFP August 2011***

Receipt Date: November 7, 2011

Technology Areas: Published in the RFP



National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov



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What are the NCI SBIR & STTR Programs?

The goal of the NCI is to eliminate the suffering and death due to cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs are NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

The SBIR & STTR Programs are one of the largest sources of early-stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities and a new spirit of collaboration with the NCI.

[\[Learn More\]](#)

Sign up for Updates

Sign up to receive updates and news about the NCI SBIR & STTR Programs and upcoming funding opportunities.

Latest Announcements

[SBIR Program FY 2011 Contract Funding Available](#)

The FY 2011 NCI solicitation for SBIR contract proposals has been issued:

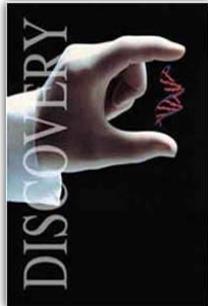
[PHS 2011-1, Solicitation for SBIR Contract Proposals](#)

Receipt Date: November 8, 2010



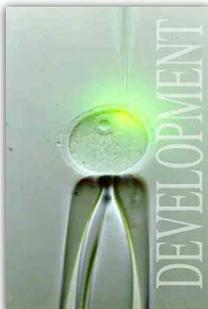
The NCI SBIR will host its second Investor Forum designed to connect the strongest and most promising NCI SBIR funded companies with life science

NCI SBIR Phase II Bridge Award



PHASE I – R41, R43

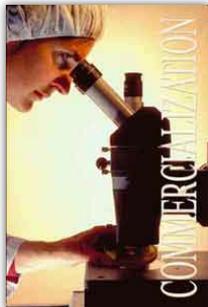
- Feasibility Study
- \$150-250K, 6-12 months



PHASE II – R42, R44

- Full Research/R&D
- \$1-2 million and 2-3 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.

Follow-on to SBIR Phase II

- **Helps early-stage companies cross the “Valley of Death” by:**
 - Facilitating partnerships with third-party investors & strategic partners
 - Incentivizing third-party investments earlier in the development process
 - **NCI is sharing in the investment risk with other investors**

Incentive Structure

- **Gives competitive preference and funding priority to applicants that can raise third-party funds (i.e., 1:1 match)**
 - Affords NIH the opportunity to leverage millions in external resources
 - Provides valuable input from third-party investors in several ways:
 1. Rigorous commercialization due diligence prior to award
 2. Commercialization guidance during the award
 3. Additional financing beyond the Bridge Award project period

Mechanism & Budgets

- Uses the SBIR Phase II (R44) competing renewal mechanism
- **Provides up to \$1 M per year for up to 3 years**
- Available to current Phase II grant awards, and those that ended within last 2 years

Preferred Third-Party Matching Funds

- Cash equity investment
- Contract from strategic partner (partner helps to commercialize)

Sources of Funds

- Another company, venture capital firm, individual “angel” investor, foundation, university, state or local government, or any combination

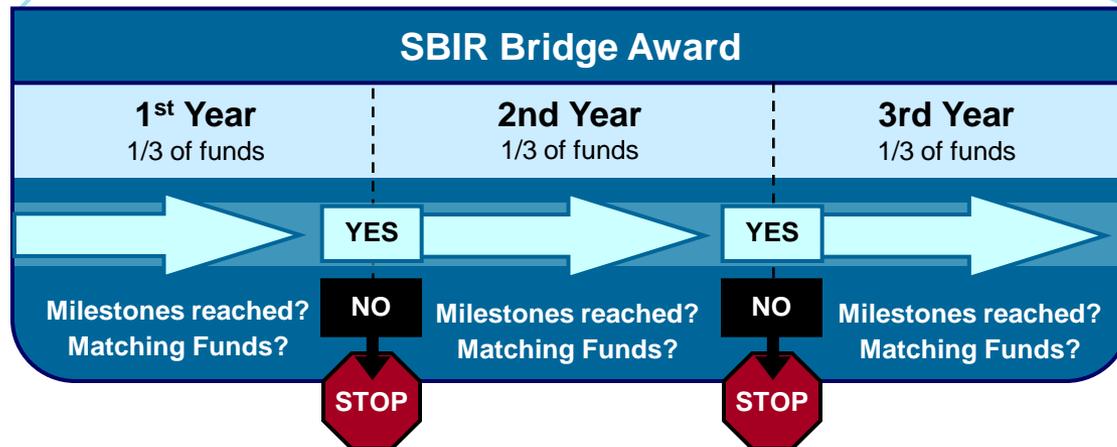
Example: How the Bridge Award Would Apply in the Area of Drug Development



SBIR Bridge Award addresses the problem by bridging the “**Valley of Death**”

SBIR Bridge Award allows NIH to share investment risk by incentivizing investors or strategic partners to evaluate projects and commit funds much earlier

Example: How the Bridge Award Would Apply in the Area of Drug Development



Ten Bridge Awards: FY09/FY10



| FY | Company | Technology/Product | Award Size |
|-----------|----------------------------------|--|-------------------|
| 2009 | Lpath Therapeutics | Humanized monoclonal antibody for treatment of prostate cancer | \$3,000,000 |
| 2009 | Optosonics | Photoacoustic CT for preclinical molecular imaging | \$2,997,247 |
| 2009 | Guided Therapeutics | Fluorescence/reflectance spectroscopy for detection of cervical cancer | \$2,517,125 |
| 2009 | Koning Corporation | High-performance breast CT as diagnostic adjunct to mammography | \$2,986,453 |
| 2009 | Gamma Medica-Ideas | Molecular imaging to detect metabolic activity of breast lesions | \$3,000,000 |
| 2009 | Altor BioScience | Tumor-targeted immunotherapy for treatment of p53-positive cancers | \$2,969,291 |
| 2010 | 20/20 GeneSystems | mTOR companion diagnostic assay | \$2,750,000 |
| 2010 | Advanced Cell Diagnostics | <i>In situ</i> RNA detection assay for analyzing circulating tumor cells | \$2,996,450 |
| 2010 | Ambergen | Expression-based prognostic assay for recurrence of colorectal cancer | \$2,998,830 |
| 2010 | Praevium Research | High-performance imaging engine for optical coherence tomography | \$1,180,420 |

Total \$27,395,816



2 therapeutics
5 imaging technologies
3 diagnostics

New Paradigm for Managing SBIR at NCI



SBIR Development Center Staff



Michael Weingarten, MA (*Director*)

Previous

- **NASA** – Program Manager, NASA Technology Commercialization Program



Greg Evans, PhD (*Branch Chief*)

Previous

- **NHLBI/NIH** – Program Director, Translational and Multicenter Clinical Research in Hemoglobinopathies
- **NHGRI/NIH** – Senior Staff Fellow



Patti Weber, DrPH (*Program Director*)

Previous

- **International Heart Institute of Montana** – Tissue Engineering and Surgical Research
- **Ribi ImmunoChem Research, Inc.** – Team Leader, Cardiovascular Pharmacology



David Beylin, MS, MBA (*Program Director*)

Previous

- **X/Seed Capital Management, LLC**, Consultant
- **Naviscan PET Systems, Inc.**, Vice President, Research



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)



Ali Andalibi, PhD (*Branch Chief*)

Previous

- **NSF** – SBIR Program Director, Medical Biotechnology
- **House Ear Institute** – Scientist & Director, New Technology and Project Development
- **Trega Biosciences, Inc.** – Research Scientist



Andrew J. Kurtz, PhD (*Program Director*)

Previous

- **NIH** – AAAS Science & Technology Policy Fellow
- **Cedra Corporation** – Research Associate, Bio-Analytical Assays and Pharmacokinetics Analysis



Jian Lou, PhD (*Program Director*)

Previous

- **Johnson & Johnson** – Research Scientist, Target Validation & Biomarker Development
- **Lumicyte, Inc.** – Director, Molecular Biology Systems Analysis



Todd Haim, PhD (*Program Manager*)

Previous

- **National Academy of Sciences** – Christine Mirzayan Science and Technology Policy Fellow
- **Pfizer Research Laboratories** – Postdoctoral Fellow, Cardiac Pathogenesis & Metabolic Disorders



Julienne Willis (*Program Specialist*)



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 close to 200 top investors and 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
- ***Follow-Up discussions, MTA's and Due Diligence now underway***



Thank you!

Michael Weingarten
Director, SBIR Development Center
weingartenm@mail.nih.gov

Register for updates at
<http://sbir.cancer.gov>

The NCI Office of Cancer Centers Learning Series Bringing Science to the Marketplace: The NCI SBIR Program

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Michael Weingarten, MA
Director
SBIR Development Center, NCI
Bethesda, MD



SBIR Contract Solicitation, Application Tips

David Beylin, MS, MBA
NCI SBIR Development Center



CC Webinar, September 7, 2011

NEW

FY 2012
SBIR Contract Solicitation



- **PHS-2012-1 “Solicitation of NIH and CDC for SBIR Contract Proposals”**
- **ONE application receipt date per year:** published in late August

Next Receipt Date: November 7, 2011

- **RFP can be found at:**
 - <http://grants.nih.gov/grants/funding/SBIRContract/PHS2012-1.pdf>
- **NCI published twelve topics (listed on the next slide) in the areas:**
 - Drugs
 - Diagnostics
 - Imaging
 - Health IT
 - Research tools

- 255 Development of Anticancer Agents
- (*) 277 Development of Companion Diagnostics
- (*) 291 Development of Radiation Modulators For Use During Radiotherapy
- 300 Reformulation of Cancer Therapeutics using Nanotechnology
- 301 Probing Tumor Microenvironment Using In-vivo Nanotechnology-based Sensors
- 306 Development of Innovative Algorithms for Processing & Analysis of *In Vivo* Images
- (*) 307 Novel Imaging Agents to Expand the Clinical Toolkit for Cancer Diagnosis, Staging, and Treatment
- 308 Automated Collection, Storage, Analysis, and Reporting Systems for Dietary Images
- 309 Development of Low Cost, Small Sample Multi-Analyte Technologies for Cancer Diagnosis, Prognosis and Early Detection
- 310 Simplified Tissue Microarray Instrument For Clinical and Research Settings (NIH Technology Transfer)
- 311 High Throughput Isolation of Antigen Specific T-cells for Cancer Therapy (NIH Technology Transfer)
- 312 Generation and Qualification of Site-specific Post-translationally Modified Proteins for Use as Calibrators in Pharmacodynamic (PD) Assays

Example 1:

Topic 291 Radiation Modulators



- **Budget:** Phase I \$200,000 ; Phase II \$1,500,000
- **Number of Anticipated Awards:** 3-5
- **Project Goal:**
 - Development of radiosensitizers, radioprotectants, radiomitigators
- **Phase I work scope may include:**
 - *In vitro* testing
 - Clonogenic survival studies
 - Preliminary toxicity, etc.
- **Phase II work scope may include:**
 - *In vivo* experiments
 - PK and PD in rodent model
 - GMP drug production/sourcing, IND approval

Example 2: Topic 307 Imaging Agents



- **Budget:** Phase I \$250,000 ; Phase II \$1,500,000
- **Number of Anticipated Awards:** 3-5
- **Project Goal:** Novel imaging agents for:
 - early detection of cancer
 - stratification of patients for selecting cancer therapy,
 - surgical planning
 - evaluation of tumor response to chemotherapy, radiation therapy,
 - detection of cancer recurrence, etc.
- **The work scope may include** animal testing, formulation, GMP production, pharmacokinetic, pharmacodynamic, toxicological studies, etc.

Example 3: Topic 277 Companion Diagnostics



- **Budget:** Phase I \$200,000 ; Phase II \$1,500,000
- **Number of Anticipated Awards:** 4
- **Project Goal:**
 - Companion diagnostics for selecting patients for which a particular therapeutic regimen, including existing drugs and those in clinical development and radiation, will be safe and effective
- **Phase I Work Scope:**
 - Test development and analytical validation
 - If the drug is not commercially available – establish partnership w/ the source
- **Phase II Work Scope:**
 - Full clinical validation

What does it take to get funded?

- SBIR program is highly competitive
- Commercialization potential is important
- Successful SBIR projects are product-focused

Deciding to Apply



➤ Start-up

- Often academic spin-off
- Entrepreneur-founder with experience in the field
- Highly innovative technical solution to significant clinical need
- Significant commercial potential
- **Need more feasibility data**
- Too risky for private investors

- **Chasing solicitations**
- **No luck with academic funding, why not apply for SBIR?**
 - SBIRs are highly competitive
- **Incremental upgrade to existing product**
- **“Me too” product matching competitor’s capabilities**
- **Product is at the stage where it needs investment significantly exceeding SBIR funding levels**

Building the Application

- **Highly innovative, sound, and focused science**
- **Well designed studies**
 - **Phase I : key feasibility question**
 - **Phase II : proceed eliminating technology risks**
- **Significant commercial potential**
 - **Product-focused applications**
- **Strong team, collaborators**
 - **Appropriate for the problem**
 - **Have clinicians involved: Oncologists, Pathologists, Radiologists**
 - **Other relevant scientists/professionals, e.g. Biostatisticians**

Omnibus Solicitation

<http://grants.nih.gov/grants/guide/pa-files/PA-11-096.html>

| | |
|--|---|
| Funding Opportunity Title | PHS 2011-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44]) |
| Activity Code | R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track |
| Announcement Type | Reissue of PA-10-050 |
| Related Notices | <ul style="list-style-type: none">• February 8, 2011 - See Notice NOT-AI-11-030 The purpose of this Notice is to highlight NIAID's interest in receiving grant applications to develop strategies, methods and/or tools to optimize influenza vaccine production. |
| Funding Opportunity Announcement (FOA) Number | PA-11-096 |

SF 424 Application Instructions

<http://grants.nih.gov/grants/funding/424/index.htm>



U.S. Department of Health and Human Services
Public Health Service

SF424 (R&R) SBIR/STTR Application Guide for NIH and Other PHS Agencies

A guide developed and maintained by NIH for preparing and submitting SBIR/STTR applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

- **Strong proposals take time to develop**
- **Seek help early in process**
 - Engage with SBIR Program Staff
- **Need time to fill the gaps**
 - Assemble a strong scientific team
 - Get access to equipment and other resources
 - Get letters of support

- **Start informal discussions to clarify the product vision**
 - Potential customers
 - Technical experts
 - Potential investors & commercialization partners

- **Identify the most important technical risks**
 - Identify approaches to address those risks
 - Study design is critical

- **Choose the Principal Investigator (PI)**
- **Consider building multi-PI team**
 - Multidisciplinary proposals
 - PI lacks certain types of necessary expertise
 - Must appoint Contact PI (SBIR, > 50% of time w/ business)
- **Identify personnel who will carry out the actual work**
- **Partner to fill the gaps**
 - Academic collaborations
 - Consultants
 - Other companies
- **Use SBIR application as engagement tool**
 - Academic researchers understand grants
 - Offer to include them on proposals as consultants/collaborators

- **Specific Aims (1 page)**
 - Focal point of the application
 - Describe goals of the application
 - Accompany by quantitative performance milestones

- **Research Strategy (Phase I: 6 pages, Phase II: 12 pages)**
 - Provide background information
 - Provide detailed technical plan to achieve Specific Aims
 - Propose realistic scope/budget/timeline
 - Preliminary data not required
 - ... but often powerful
 - Describe potential pitfalls and alternative angles of attack

- **Introduction (for resubmissions only, 1 page)**
 - Your response to reviewers' critiques

Key #4 Reviewers only see the application



➤ **Other application components**

- Biosketches for all senior and key personnel (<4pages each)
- Budgets for each project period
- Separate budgets for each subcontract
- **Phase II Commercialization Plan (Phase II, 12 pages)**
- Descriptions of facilities and equipment
- Letters of support
- Human subject research section (if applicable)
- Vertebrate animals section (if applicable)
- Other information as required

➤ **Grants: SF424 R&R SBIR/STTR Application Guide**

- Excellent source of administrative information
- http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_Adobe_VerB.pdf

➤ **Contracts: see respective Request for Proposals (RFP)**

- E.g. <http://grants.nih.gov/grants/funding/SBIRContract/PHS2012-1.pdf>

- **Strongly worded letters of support from:**
 - ALL consultants and collaborators
 - Those who provide access to facilities / administrators
 - KOLs who think highly of your project
 - Customers who will buy the product once it is available
 - Current or potential industry partners
 - Current or potential investors
 - Suppliers of critical technology

- **Good letter of support**
 - Explains who the writer is and why s/he is excited about proposed project
 - Explains the writer's role in the proposal
 - Contains specific support of your story/approach

Key #5 Know your reviewers



- **Who is going to review your application?**
 - Primary reviewers read your application, and lead the discussion
 - All members of the Review Panel will score your application
 - Combination of academic and industry reviewers

- **Identify the most appropriate study section BEFORE you submit your application**
 - See CSR website for SBIR/STTR study section descriptions
 - http://www.csr.nih.gov/Roster_proto/sbir_section.asp
 - Discuss study section selection with NCI SBIR Program Staff

- **What are reviewers looking for?**
 - Readable and understandable application
 - Do not assume they will know everything you know
 - Clear plan for Phase I, II and commercialization
 - Feasible, standard methods
 - Solid letters of support

More Information on NCI SBIR & STTR Website



The screenshot shows the NCI SBIR & STTR website homepage. At the top, there is a red banner with the National Cancer Institute logo and name, and the text "U.S. National Institutes of Health | www.cancer.gov". Below this is a dark blue header with the SBIR & STTR logo, navigation links for "Contact Us", "Site Map", and a search box. A light green navigation bar contains links for "About", "Funding Opportunities", "Resource Center", "News & Events", and "Success Stories". The main content area features a large banner image with the text "Leading small business innovation and commercialization in the fight against cancer". Below the banner are two main sections: "What is the NCI SBIR & STTR Program?" and "Latest Announcements". The "What is the NCI SBIR & STTR Program?" section includes a description of the program's goal and a link to "Learn More". The "Latest Announcements" section lists "NCI SBIR & STTR Funding Opportunities" and provides a list of grant topics (PAS-07-240, PAS-07-241, PAS-07-242) and receipt dates (April 5, August 5, December 5, 2007). It also includes a link to "Read about more NCI SBIR & STTR funding opportunities" and a link to "Click here" to view videos. At the bottom of the page, there is a yellow box with the URL "http://sbir.cancer.gov".

What is the NCI SBIR & STTR Program?

The goal of the NCI is to eliminate the suffering and death due to cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program is NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

The SBIR & STTR program is one of the largest sources of early-stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities and a new spirit of collaboration with the NCI.

[\[Learn More\]](#)

Sign up for Updates

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Latest Announcements

NCI SBIR & STTR Funding Opportunities

The following SBIR Grant Topics have been issued:

- [PAS-07-240](#)
- [PAS-07-241](#)
- [PAS-07-242](#)

Receipt Dates:
April 5, August 5, December 5, 2007

[Read about more NCI SBIR & STTR funding opportunities.](#)

[Click here](#) to view videos from the NCI SBIR & STTR Program about how to apply for funding opportunities.

Tips for Applying

<http://sbir.cancer.gov>

Questions?

David Beylin, MS, MBA

Program Director

Phone: 301-496-0079

beylind@mail.nih.gov

**Register for updates at
<http://sbir.cancer.gov>**

The NCI Office of Cancer Centers Learning Series Bringing Science to the Marketplace: The NCI SBIR Program

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David Beylin, MS, MBA, DABSNM
SBIR Program Director
SBIR Development Center, NCI
Bethesda, MD





Founding Presage

- 6 years of laboratory-based work
- Incorporated November, 2008
- STTR Phase I application December 2008





Feedback from Investors

- Clinical application high risk/high reward
- Challenging regulatory environment
- Too much cash at risk without proof of concept
- Nearer term commercial opportunities in pharma

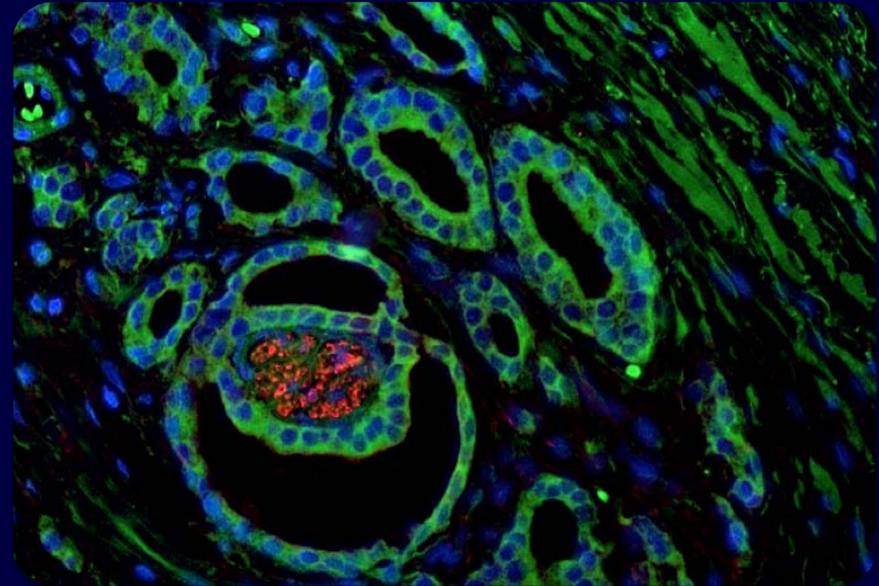


Presage Today

- Helping pharma discover more efficacious drugs and drug combinations
- Already provided data to our partners to make go/no-go decisions
- Diagnostic device on track for first clinical studies in 2012
- 12 FTEs
- \$7M in funding
- Multiple pharma partners



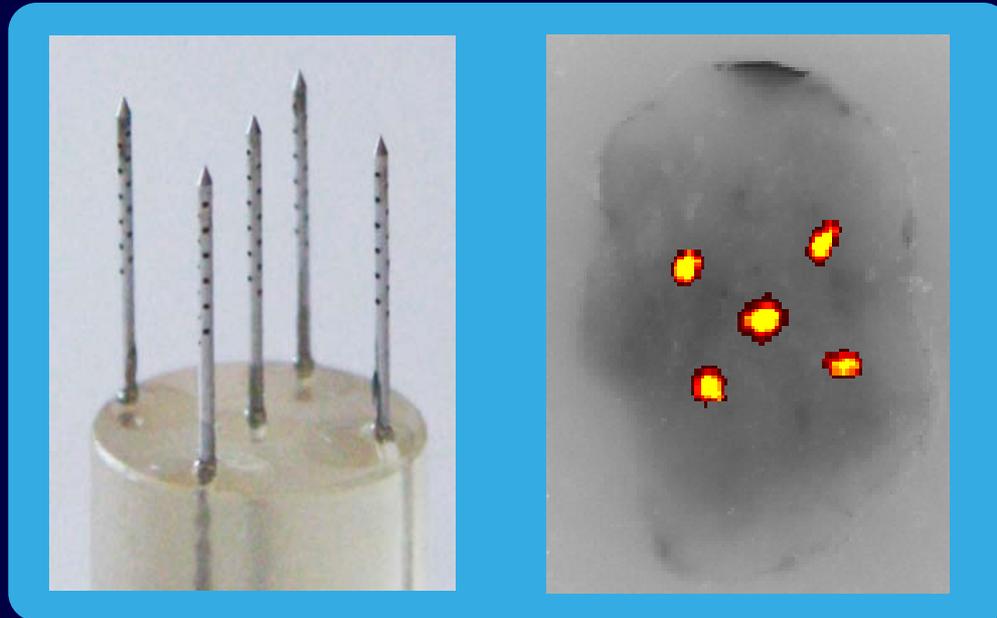
In vitro: fast, cheap, **misleading**



Presage enables use of cancer models that are better correlated to patients' actual tumors rather than artificially manipulated laboratory-based cell models.



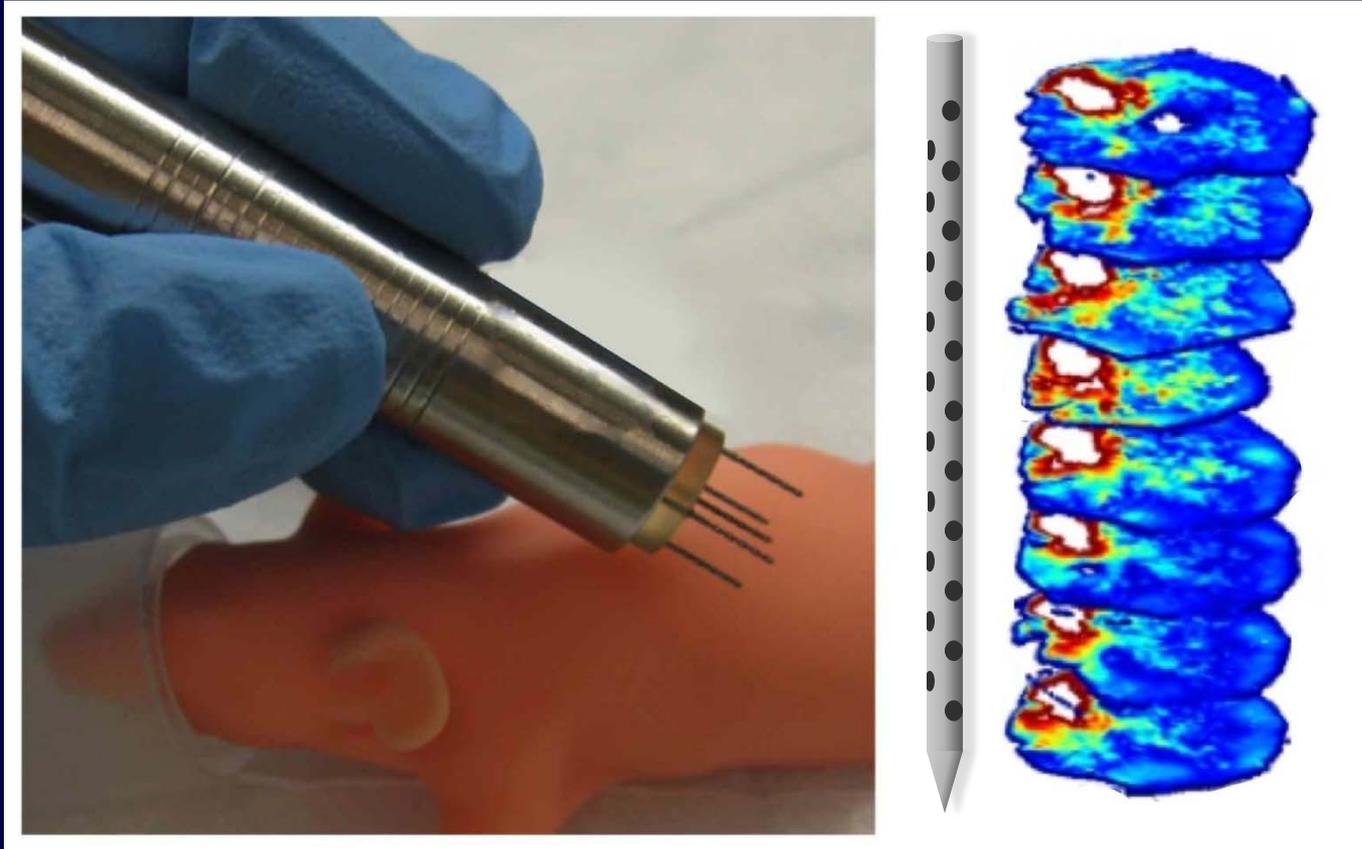
No other known technology allows multiple comparisons in one tumor



Multiple Spatially Constrained Columns
Enable Intratumoral Comparisons



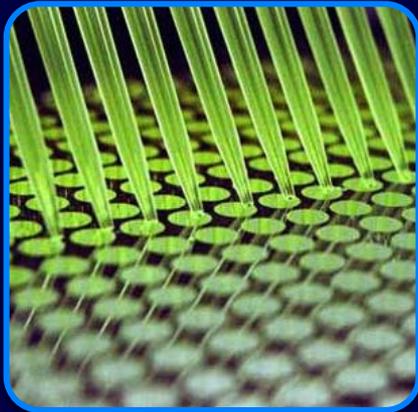
Controls for tumor heterogeneity



Active agents induce a columnar response



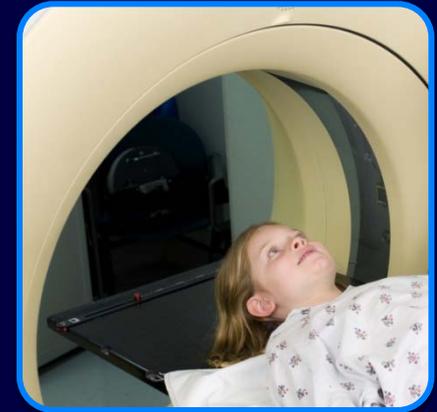
Presage applications



Candidate
& Indication
Prioritization



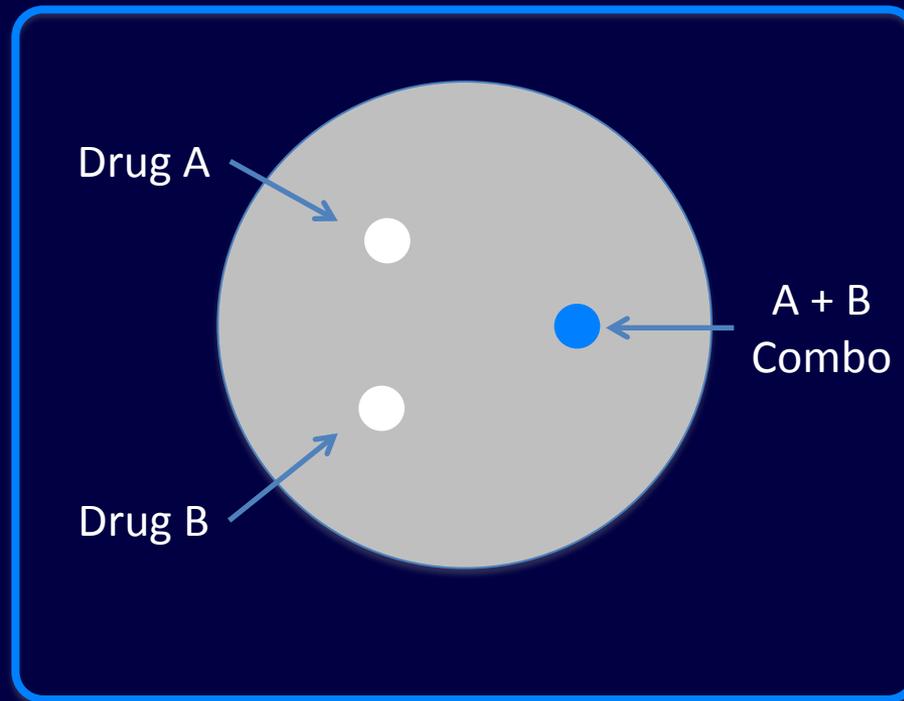
Drug
Combination
Identification



Clinical Drug
Selection



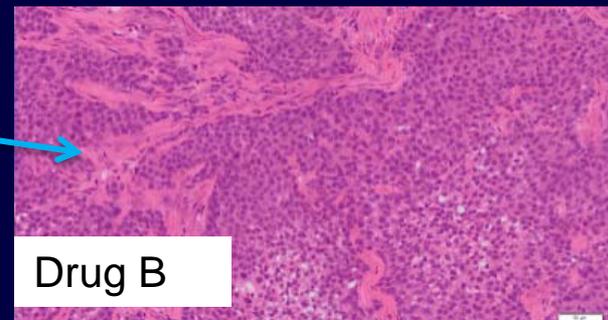
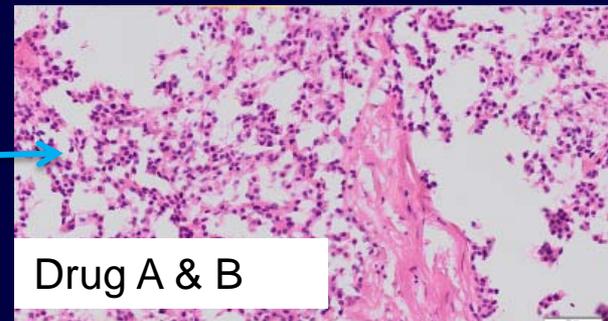
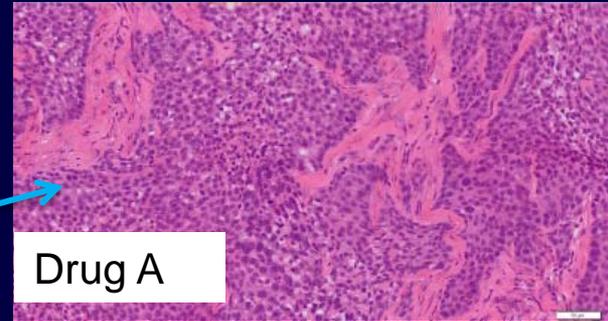
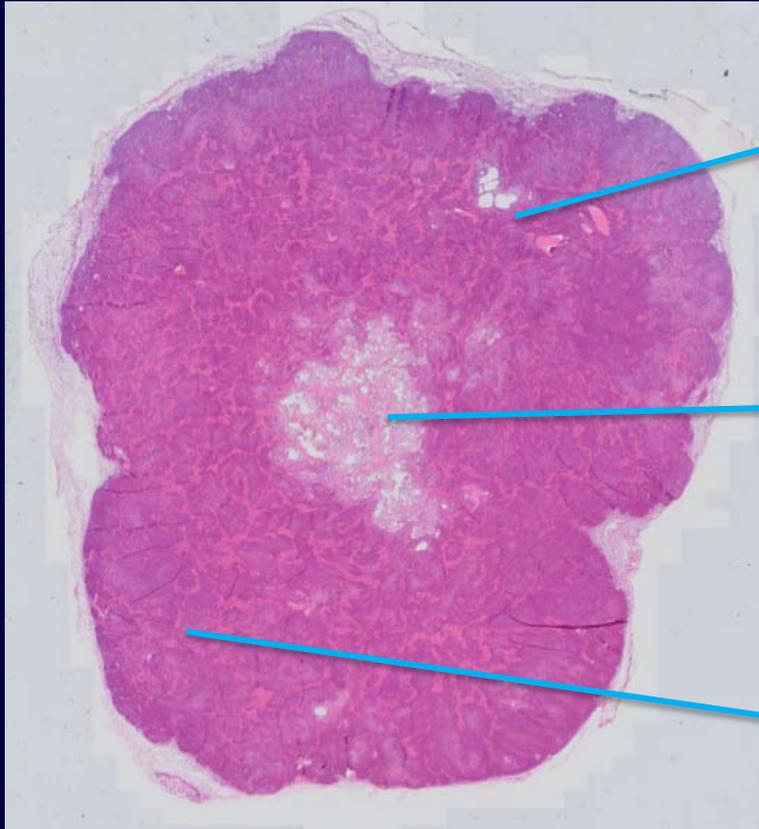
Presage *in vivo* Combos



Multiplexed, internally controlled experiments
provide rapid reliable data



Combined inhibition results in synergistic anti-tumor efficacy

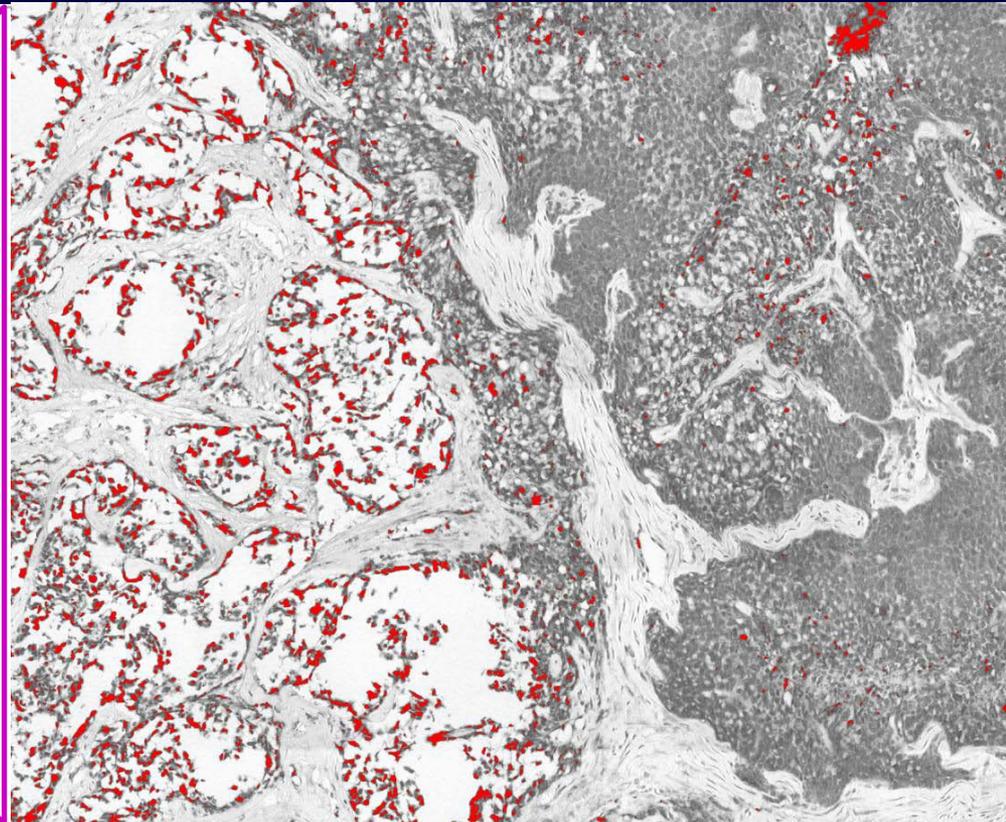
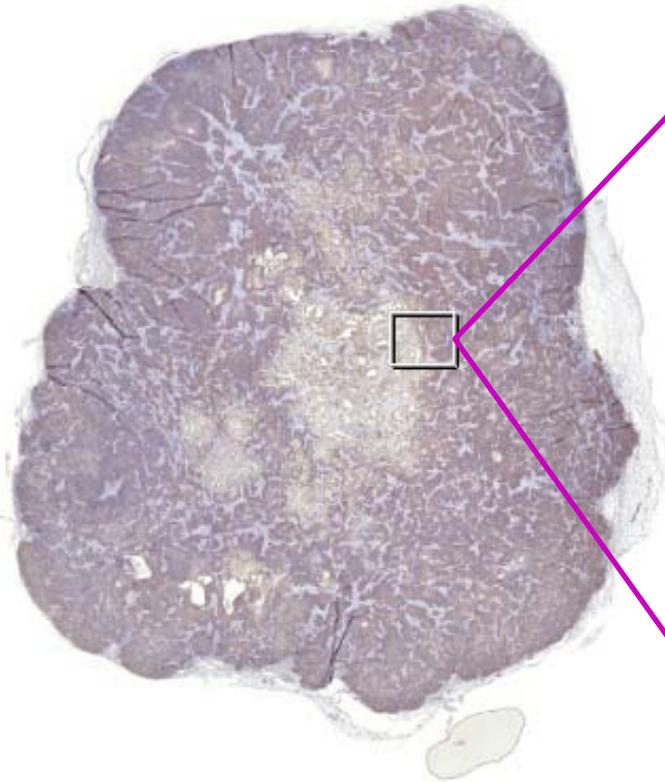


H&E staining

H292 lung carcinoma



Combination is tumor cell specific

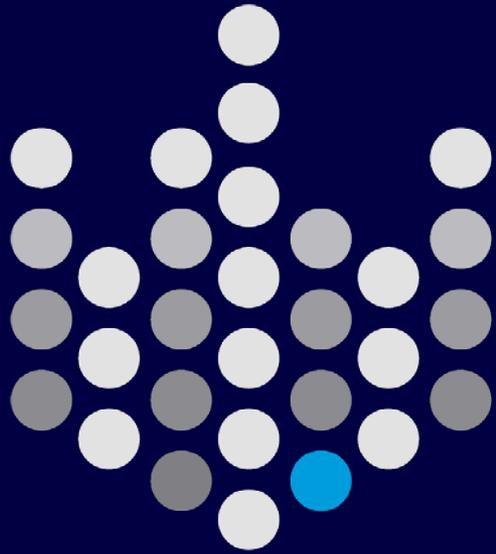


Platform demonstrates context specific killing



Presage STTR History

- \$361,000 Phase I application submitted Nov 2008
- \$1.4M Fast Track application submitted April 2009
- Phase I Award June 2010
- Phase II Award July 2011
- NCI Investors Forum November 2010
- Regulatory Assistance Program



presage

The NCI Office of Cancer Centers Learning Series Bringing Science to the Marketplace: The NCI SBIR Program

Questions?

Please submit your question via the Q & A box on the right hand side of your screen. If you do not see the Q&A box, you can expand it by clicking the Q&A on the top navigation panel and dragging it to the right side of your screen.



James Olson, MD, PhD

President and Founder, Presage Biosciences
Full Member, Fred Hutchinson Cancer Center
SBIR Program Grantee
Seattle, WA

Disclosures

- Michael Weingarten: no relevant financial relationships with commercial interest.
- David Beylin: no relevant financial relationships with commercial interest.
- Jim Olson: a Founder and Director of Presage Biosciences. No patient trials involving Presage are open at this time.

Future OCC Learning Series Events

- **NCI Division of Cancer Treatment and Diagnosis: The Quantitative Imaging Network (QIN)**
October 4th, 2011 2:00 to 3:30 PM EDT
Robert J. Nordstrom, PhD
- **The Cancer Genome Atlas**
November 1st, 2011 2:00 to 3:30 PM EDT
Kenna Shaw, PhD

A vertical strip on the left side of the slide shows a close-up of a microscope lens, with a green bar to its left.

The NCI Office of Cancer Centers Learning Series Bringing Science to the Marketplace: The NCI SBIR Program

**If you have further questions, please
contact**

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