

# 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**

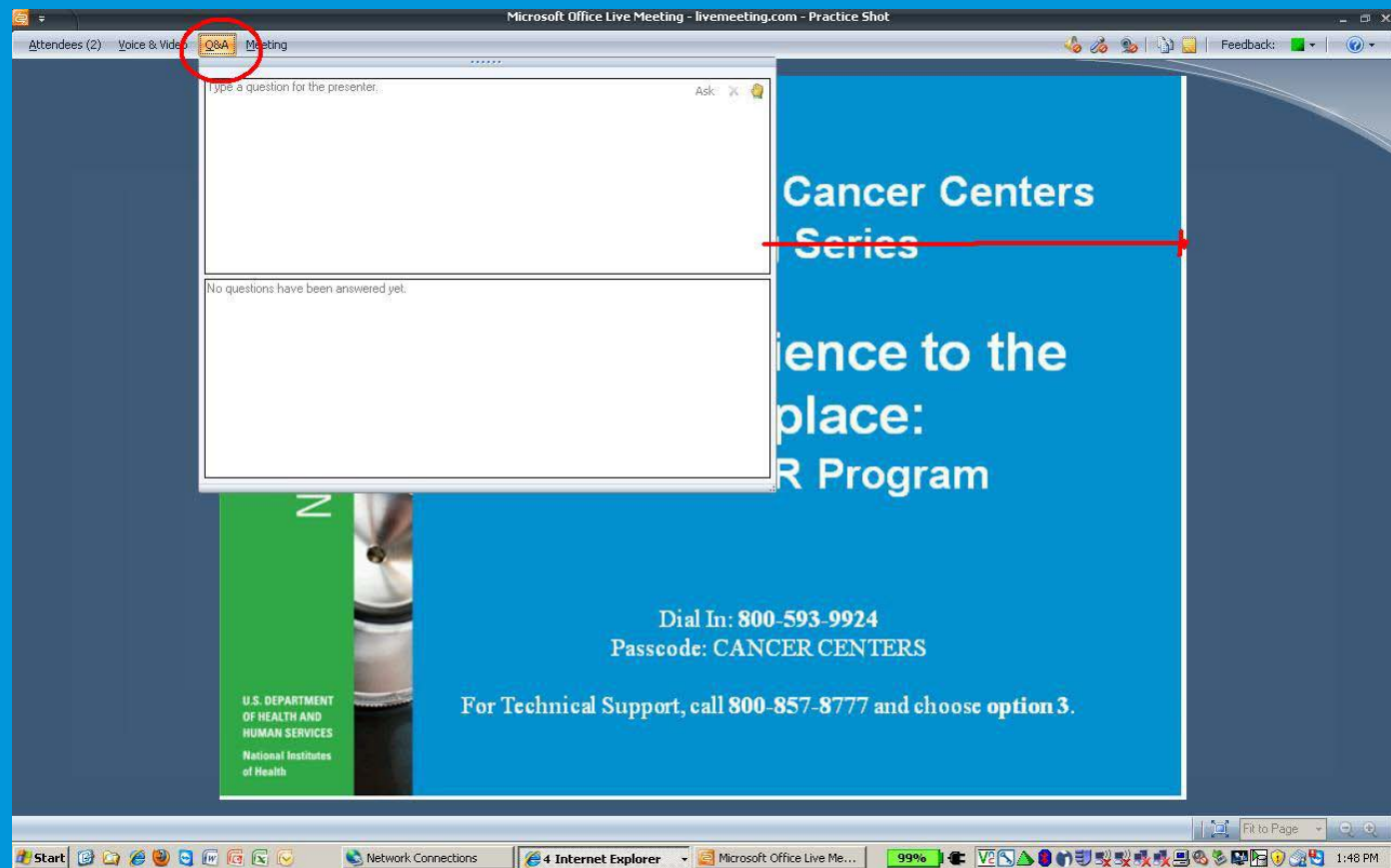
SBIR Program Director  
SBIR Development Center, NCI  
Bethesda, MD

#### **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 menu bar with "Attendees (2)", "Voice & Video", "Q&A", and "Meeting". The "Q&A" button is circled in red. Below the menu 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 "Cancer Centers Series" text to the right. The Windows taskbar at the bottom shows the Start button, several application icons, and the system tray with a 99% battery level and 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**

- **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**

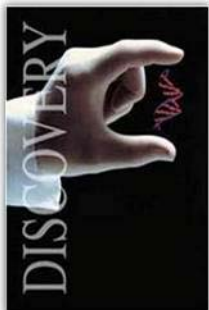
- **One of the largest sources of early stage of life sciences funding in the country.**
  - **A stable and predictable source of funding**
- **Intellectual property rights are retained by the small business concern**
- **Not a loan – no repayment is required**
- **Doesn't impact stock or shares in any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



## Small Business Concern

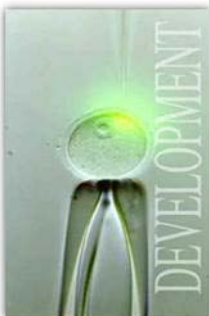
- **For-profit U.S. business**
- **500 or fewer employees, including affiliates**
- **Must be:**
  - **At least 51% owned by US individuals and independently operated**  
**or**
  - **At least 51% owned and controlled by another business concern that is at least 51% owned and controlled by one or more 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**



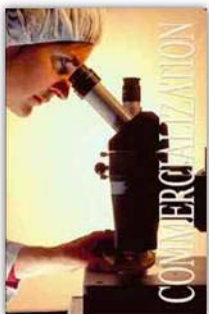
## PHASE I – R41, R43

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

## 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

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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](#)

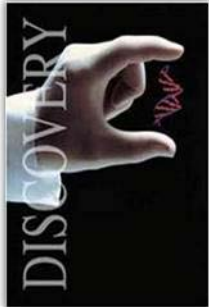
**Receipt Date: November 8, 2010**



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

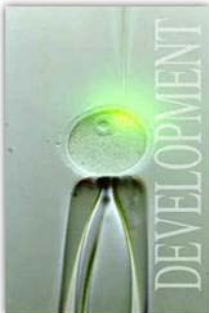
## NCI SBIR Phase II Bridge Award





## PHASE I – R41, R43

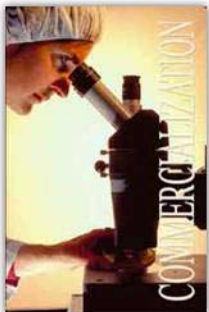
- Feasibility Study
- \$150-250K, 6-12 months



## 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

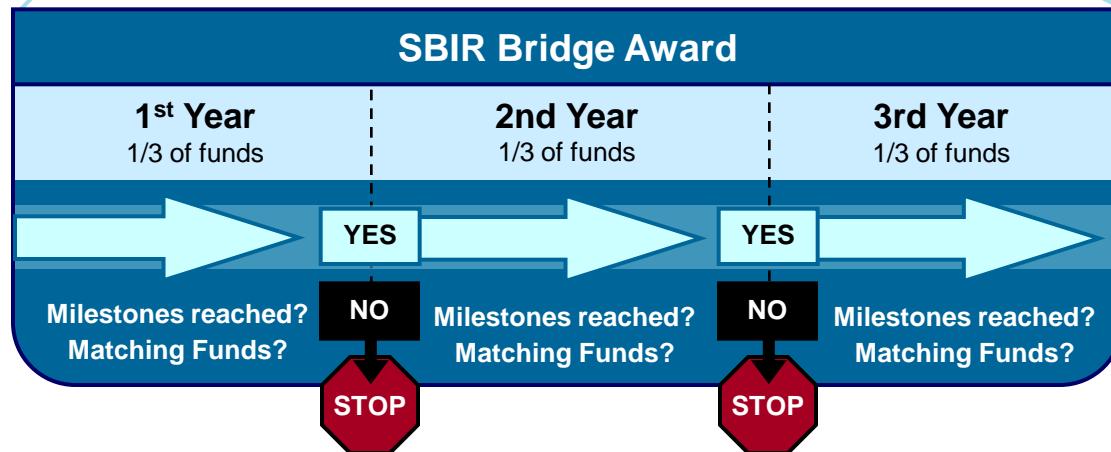
# Example: How the Bridge Award Would Apply in the Area of Drug Development



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

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

## 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.



**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>

<b>Funding Opportunity Title</b>	<b>PHS 2011-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])</b>
<b>Activity Code</b>	<a href="#">R43/R44</a> Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track
<b>Announcement Type</b>	Reissue of <a href="#">PA-10-050</a>
<b>Related Notices</b>	<ul style="list-style-type: none"><li>• <a href="#">February 8, 2011</a> - 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.</li></ul>
<b>Funding Opportunity Announcement (FOA) Number</b>	<b>PA-11-096</b>

## 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](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](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 "Learn More" link. 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). A "Sign up for Updates" section is also present, with a form to enter an email address and a "Go" button. A "Tips for Applying" section is partially visible at the bottom.

**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**

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

**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](mailto: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

## 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.



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

# Presage Biosciences





# 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



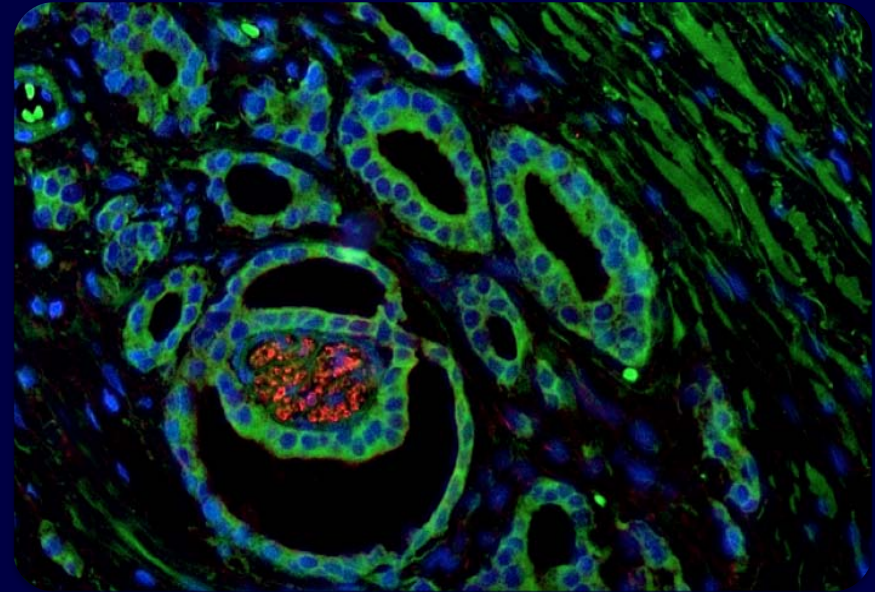


# Presage Today

- 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



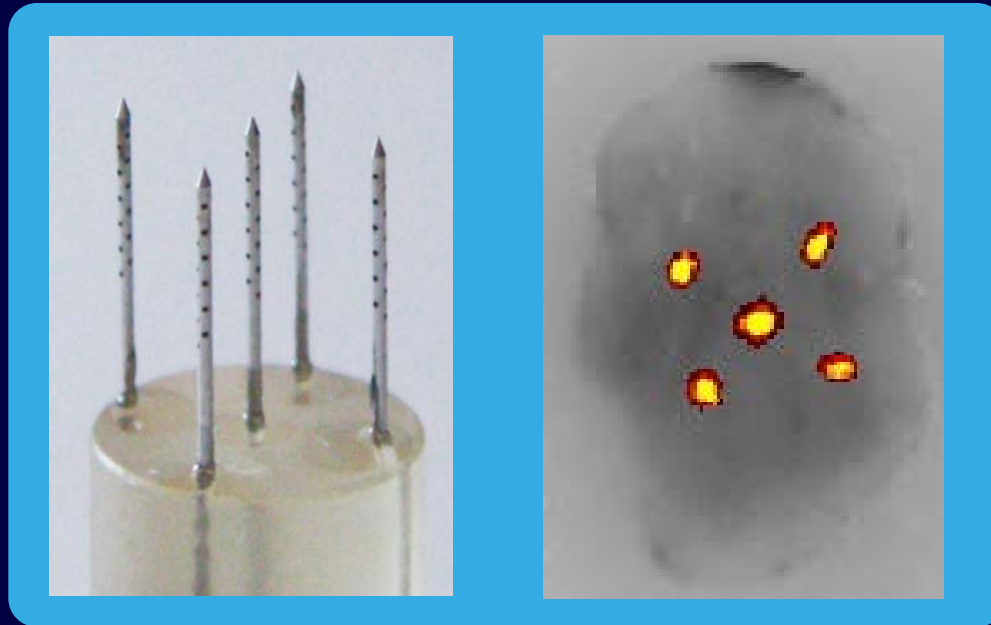
# *In vitro*: fast, cheap, **misleading**



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



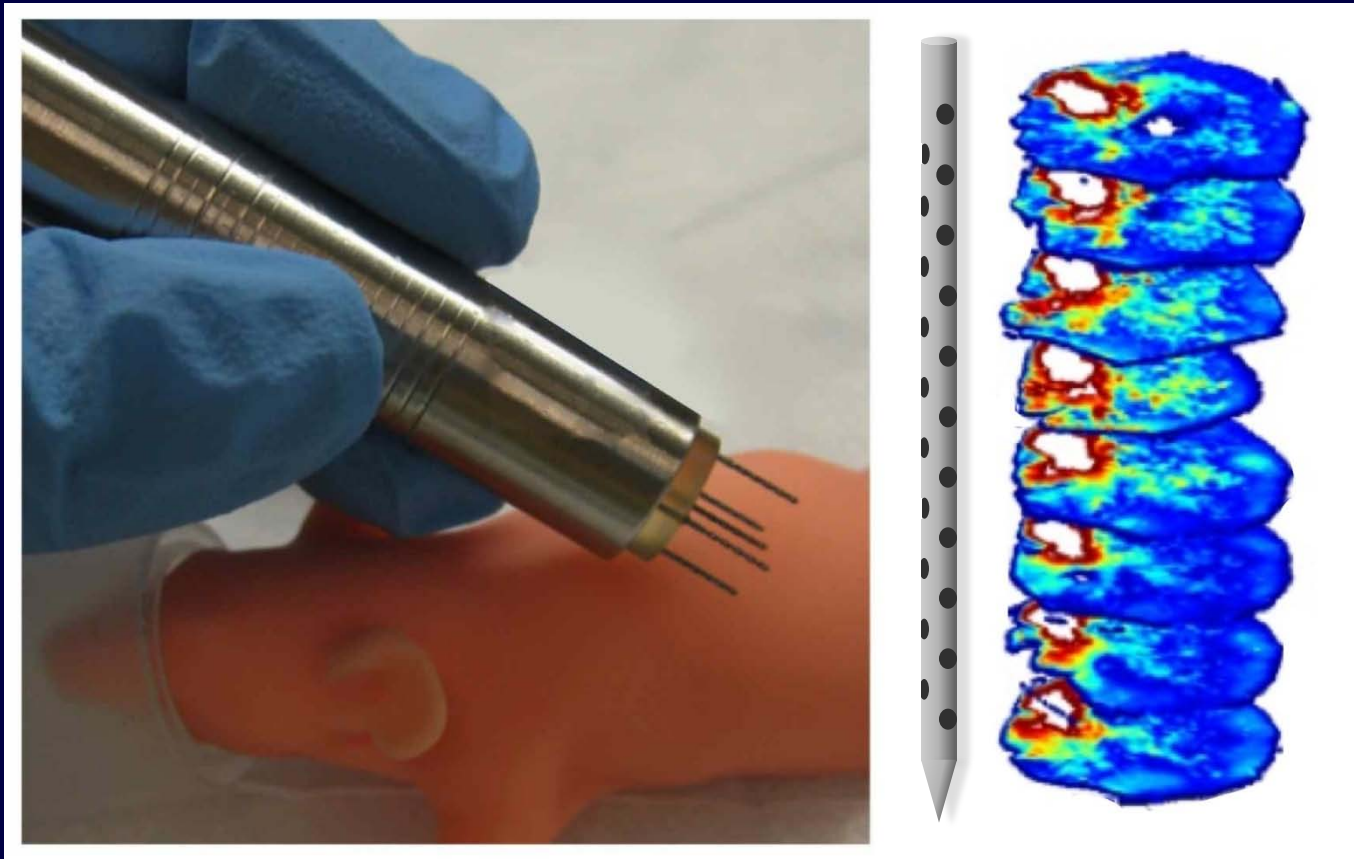
No other known technology allows multiple comparisons in one tumor



Multiple Spatially Constrained Columns  
Enable Intratumoral Comparisons



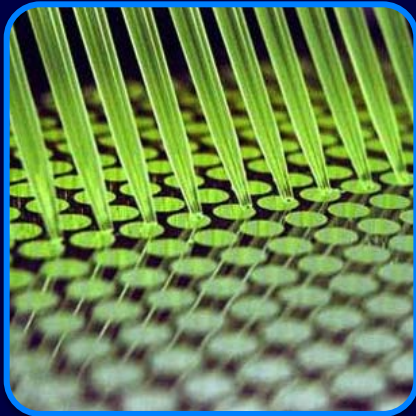
# Controls for tumor heterogeneity



Active agents induce a columnar response



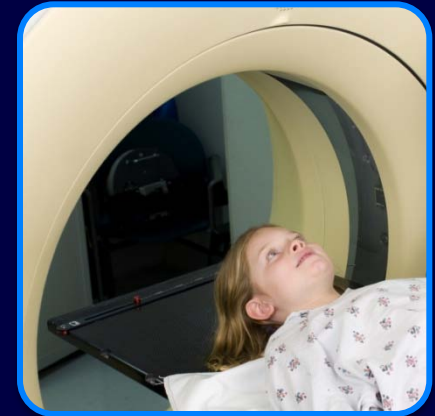
# Presage applications



Candidate  
& Indication  
Prioritization



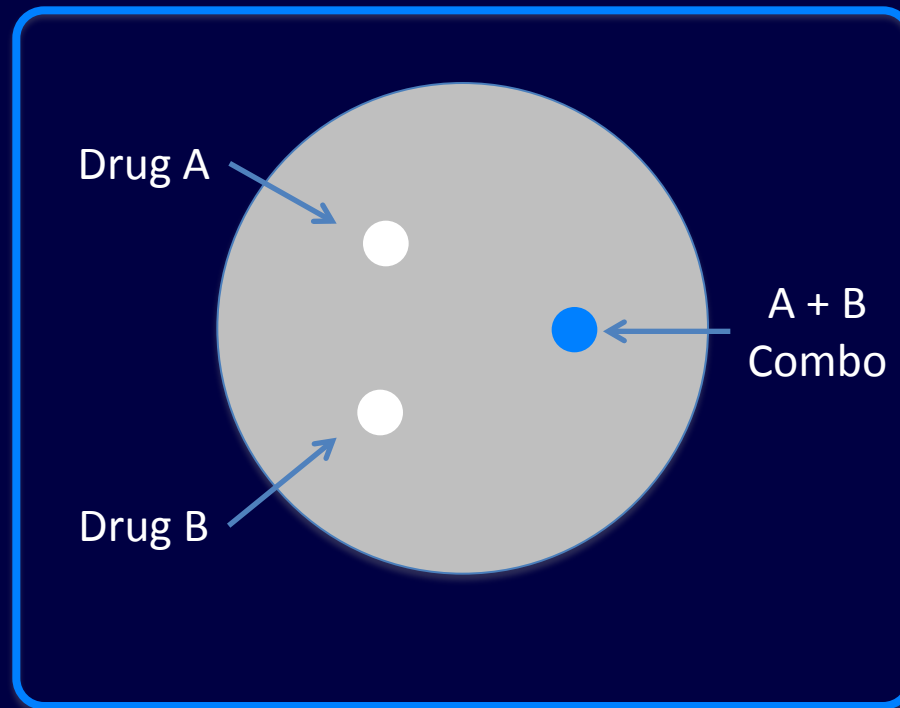
Drug  
Combination  
Identification



Clinical Drug  
Selection



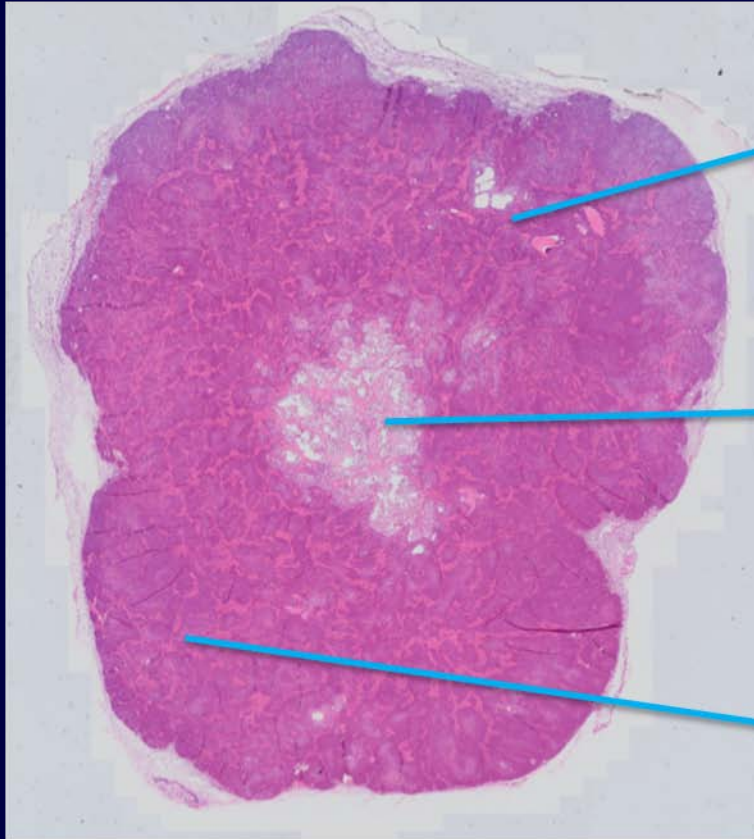
# Presage *in vivo* Combos



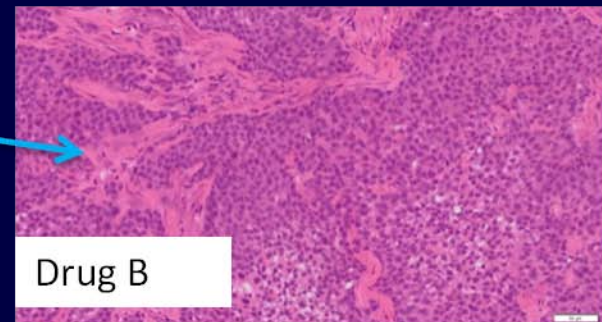
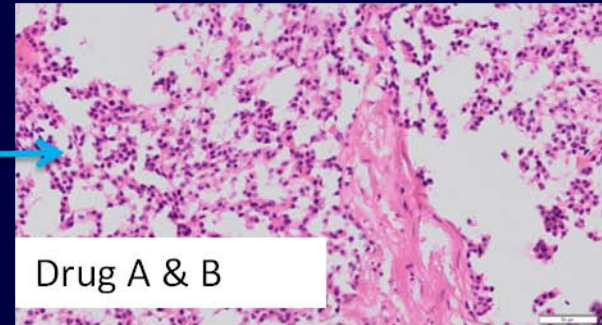
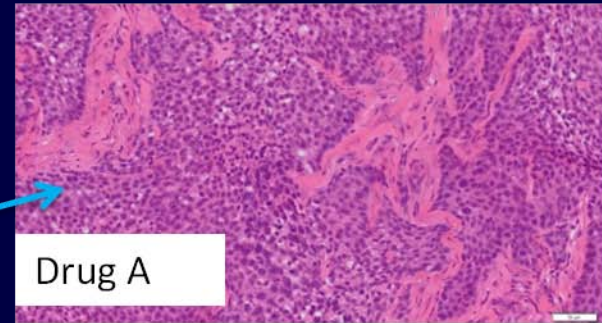
Multiplexed, internally controlled experiments  
provide rapid reliable data



# Combined inhibition results in synergistic anti-tumor efficacy



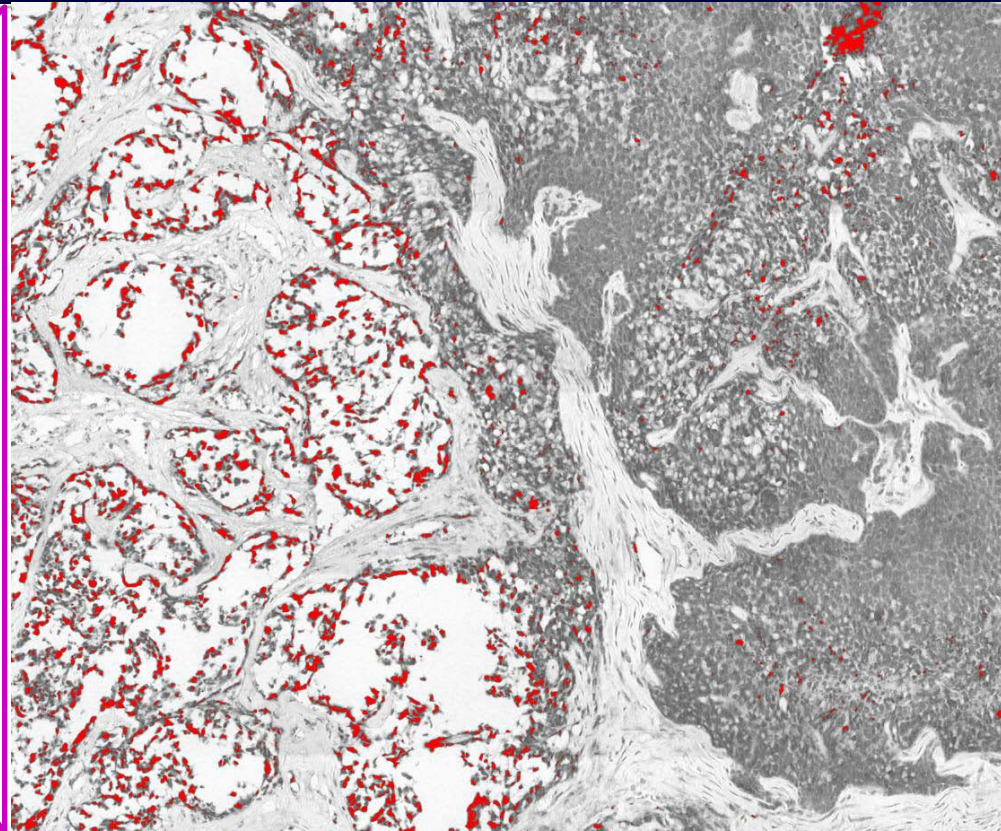
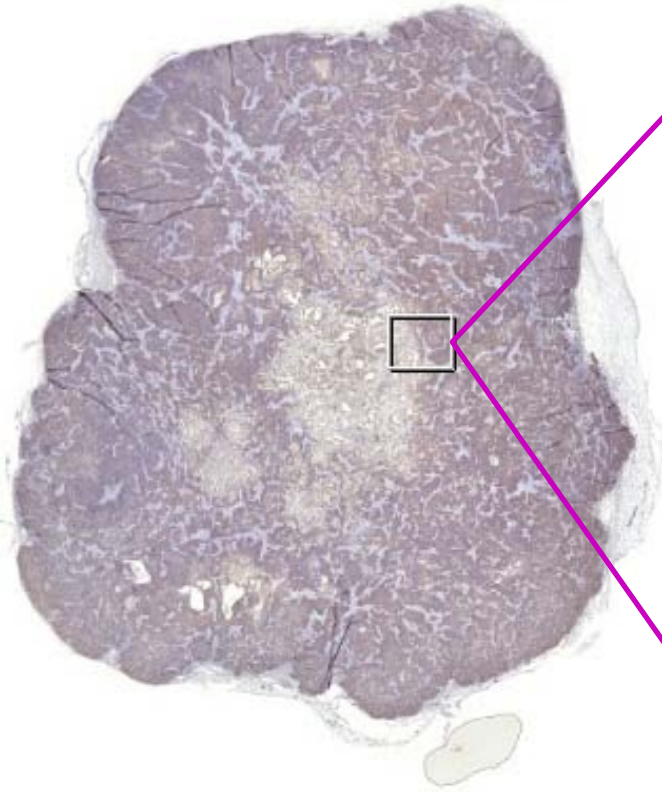
H&E staining



H292 lung carcinoma



# Combination is tumor cell specific



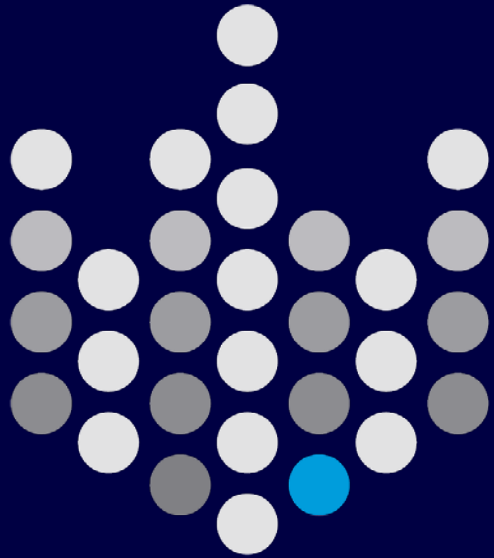
Platform demonstrates context specific killing





# 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

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**James Olson, MD, PhD**


President and Founder, Presage Biosciences  
Full Member, Fred Hutchison 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: I am 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**

Michael Weingarten

[weingartenm@mail.nih.gov](mailto:weingartenm@mail.nih.gov)

This webinar was created by the Office of Cancer Centers  
in the National Cancer Institute

<http://cancercenters.cancer.gov>

For information about the SBIR & STTR grant program  
through the National Cancer Institute, please visit

<http://sbir.cancer.gov>



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