



THE UNIVERSITY OF HONG KONG

Ecom-Icomp Experts Address Series 2012
HKU Visiting Professor Amy Shuen

New Nano-Medicine Cancer Drugs: Business & Technology Overview

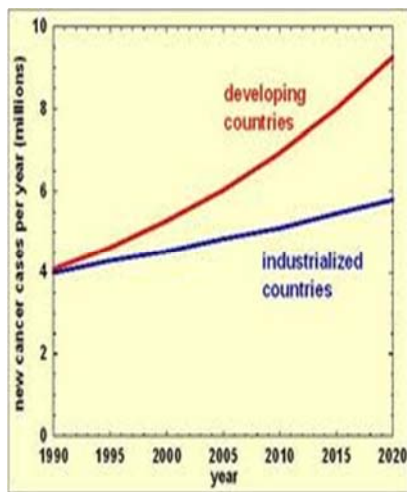


The War Against Cancer Continues

1971 → 2001 → 2012



10M new cases per year



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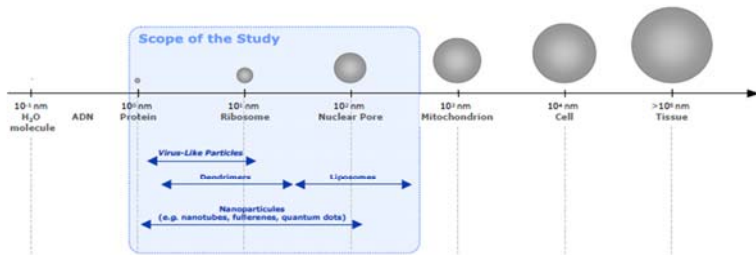
Development cost & time



	earlier	now
Cost of Development	250M	1.5B
Time to Market	10 Yrs	15 Yrs
NCEs	~40	~30
Most Blockbuster Patents expire in next 2-5 years		

Promise of Nanotechnology in Medicine & Cancer Treatment

Nanoproducts size could be beyond the nanometer scale (between 1 and 100 nm)

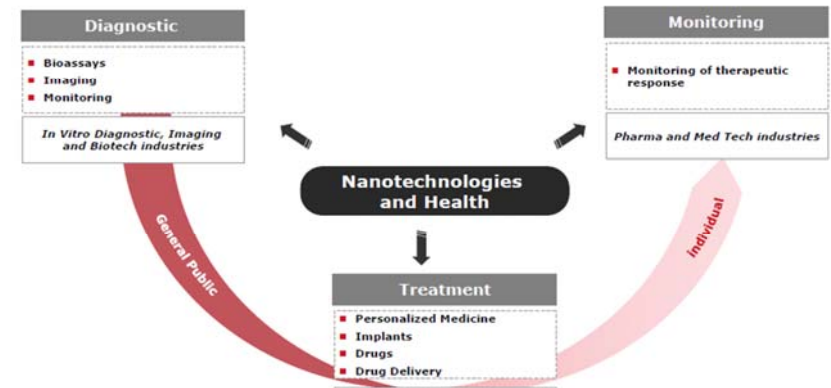


- Nanotechnologies lead to the creation of structures, devices and systems where the size of the active component is comprised between 1 and 100 nanometers (nm)
- Nanotechnologies could also encompass elements of a size that exceeds the nanometer scale (e.g. micrometer) but only if the miniaturization confers them new physical properties (e.g. microfluidics, liposomes)

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Nanomedicines—already 30+ cancer drugs on the market

In healthcare, nanotechnologies applications could range from diagnostic to monitoring of treatments

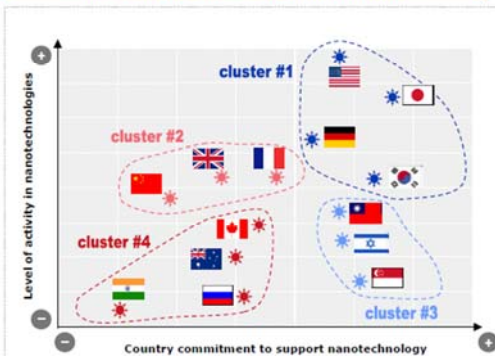


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Global Race for \$70B Nano-Biopharmaceuticals market...

The US, Japan, Germany and South Korea are the most advanced countries in the nanomedicine area

Global competitiveness in nanotechnologies

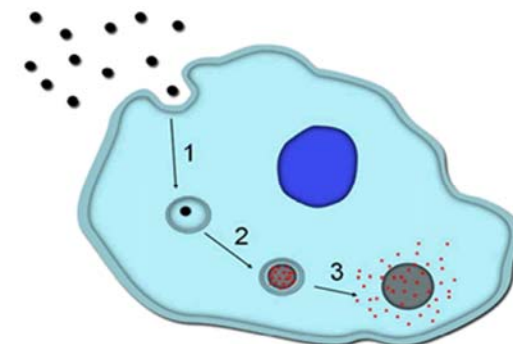


- Cluster #1 : « Dominant countries » where activity, R&D intensity and Government support are very high
- Cluster #2 : « Followers » where effort dedicated to nanotech activities is reasonable
- Cluster #3 : « Niche countries » where limited nanotech activities exist but with an intense commitment of Governments
- Cluster #4 : « Laggards » where development intensity is reasonable but level of activities is low

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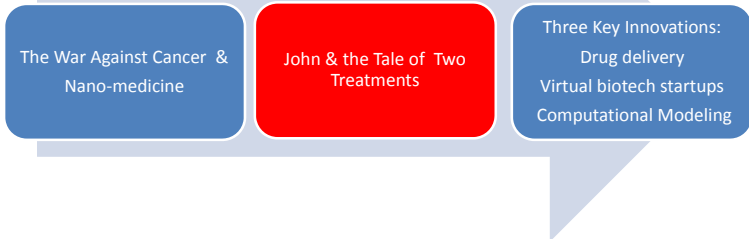
Nano-particles for Cancer

<https://www.youtube.com/watch?v=rIXbiAsG7ik>





New Nano-Medicine Cancer Drugs: Business & Technology Overview



John is a cancer drug trial volunteer

Cancer 'iron man' puts hope in drug trials

FIRST PROSTATE NANOMEDICINE SHOWS POSITIVE RESULTS IN PHASE I TRIALS

Researchers at The David H. Koch Institute for Integrative Cancer Research at MIT, Brigham and Women's Hospital, Dana-Farber Cancer Institute, Harvard Medical School, Weill Cornell Medical College and BIND Biosciences have demonstrated for the first time that it is possible to generate nanomedicines targeted against prostate cancers. Acting as "Trojan Horses," these nanomedicines can navigate directly to malignant cells and concentrate the therapeutic effect of chemotherapy directly in the cancer cells while sparing healthy ones. It is a revolutionary advancement for how complex cancers can someday soon be treated.

This research represents the first time a nanomedicine has moved from the test tube to the clinic to target prostate cancer cells effectively and to deliver docetaxel in high concentrations safely. It was funded in part by a four-year, \$5 million Prostate Cancer Foundation (PCF) Challenge Award supported by philanthropist and PCF Board member, David H. Koch, in 2007.

Results from Phase I clinical trials of BIND-014 led by BIND Biosciences with Dr. Omid Farokhzad and Robert Langer, Sc.D., were published today in *Science Translational Medicine*. These first in field data were also presented

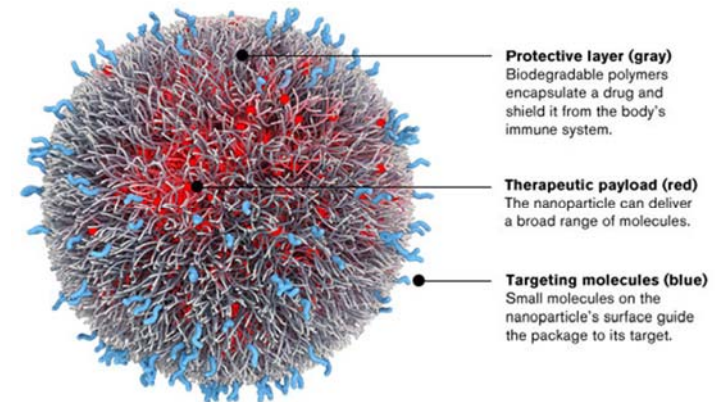
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How to kill the tumor without endangering the patient?

Problem: Major side-effects in 90+ FDA-approved chemo-therapy drugs

Solution: 10x better safety & efficacy with "programmed" nano-engineered DDS

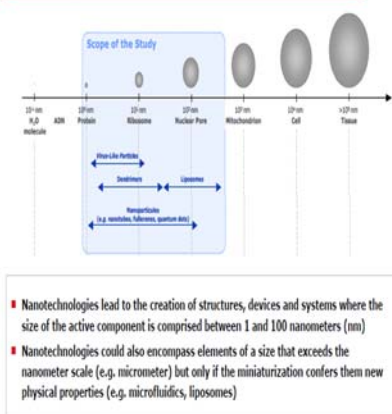
TNP=Targeted polymeric NanoParticles="smart bombs for cancer tumors"



Artist's illustration- Source Google Images URL:

1st Generation: Nano-scale the drugs

Nanoproducts size could be beyond the nanometer scale (between 1 and 100 nm)



Passive EPR effect, 1989 Maeda, Wu et al

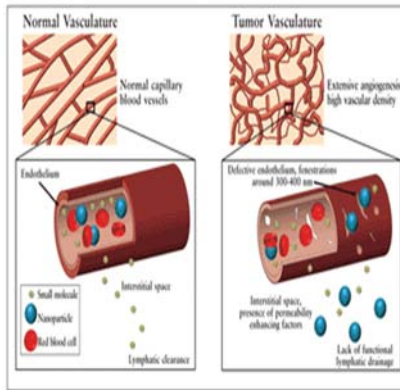
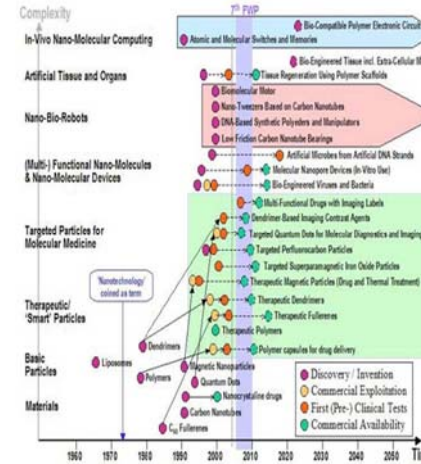


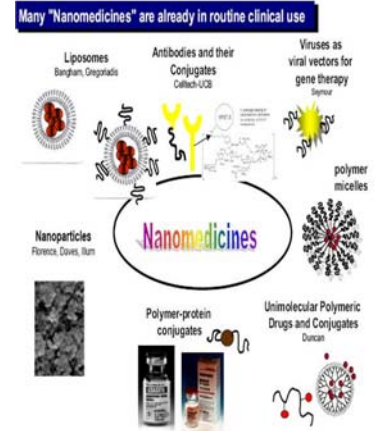
Figure 1. Illustration of the physiological factors that contribute to the enhanced permeation and retention (EPR) effect.

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2nd Generation: Nano-scale the DDS

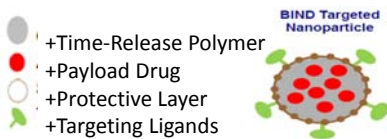


2003-6 Range of Nano Particles



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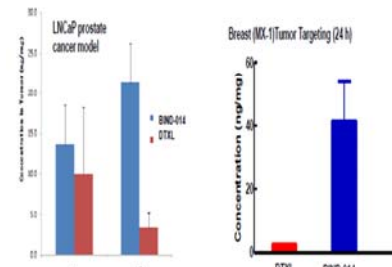
3rd Gen: Nano-engineer the DDS for precise targeting & 10x efficacy



2006-12 Targeting Ligands-Farokhzad Langer

BIND-014 and Taxotere tumor targeting

Safety-controlled Release + 10x Efficacy



Apr 2012 First Targeted Nano-particle Drug in Human Clinical Trials

BIND-014 goal: Taxane

Target: PSMA

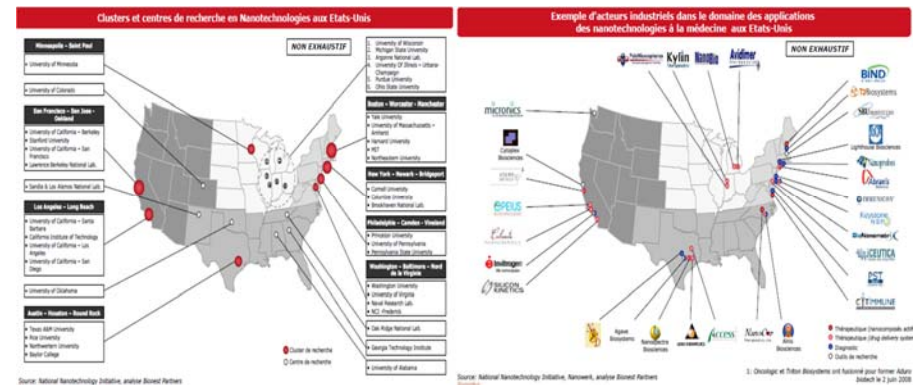
Payload: Docetaxel

Development path:

505(b)(2)

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3rd Gen Human Trials April 2012: BIND-014 MIT Langer & Harvard Med Farokhzad



BIND Biosciences founded in 2007 has received \$85.2M in funding...

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Professor Amy Shuen

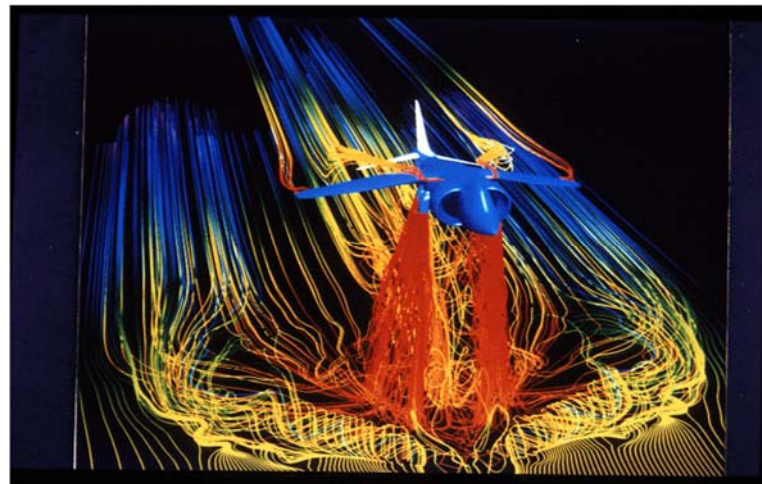
New Nano-Medicine Cancer Drugs: Business & Technology Overview

The War Against Cancer & Nano-medicine

John & the Tale of Two Treatments

Three Key Innovations:
Computational Modeling
Drug delivery
Virtual biotech startups

In 2004, NASA Ames shut its wind tunnels & switched to CFD...

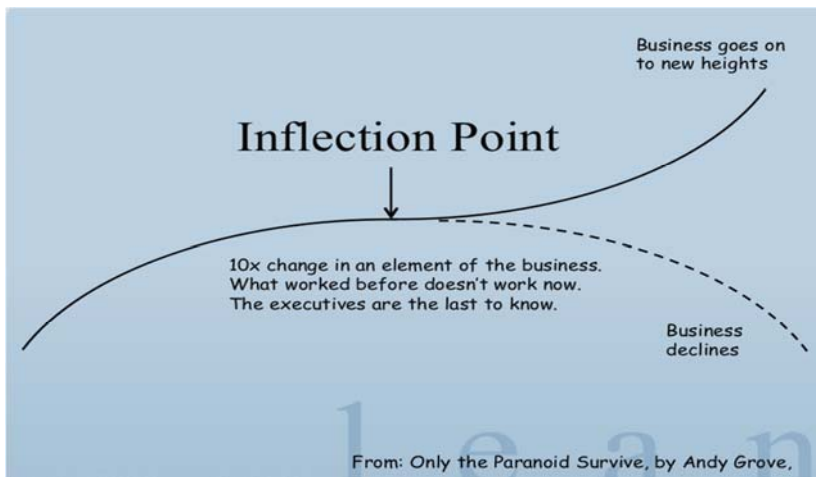


CFD=Computational Fluid Dynamics

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<http://www.starchamber.com/2007/05/seed-science-in-silico.html>

CFD was game-changing: 10x accuracy, 10x speed at 1/10th the cost...



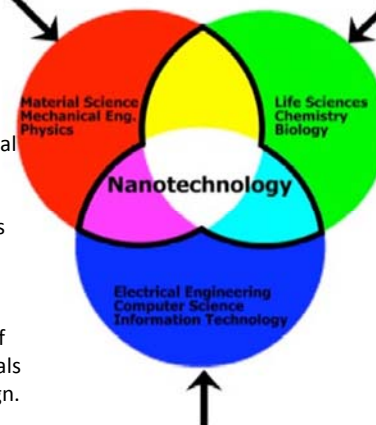
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CFD can computationally “virtualize” nano-drug delivery development



Moore’s Law & exponential learning curve: Physico-chemical characterization, computational fluid, nanoparticle dynamics and membrane interaction.

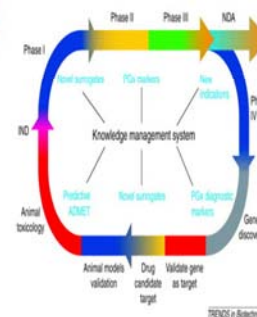
Strong IP protection of novel nanobio-materials with mechanism design.



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Edisonian Trial & Error: Animal experimentation



PREDICI in Biotechnology

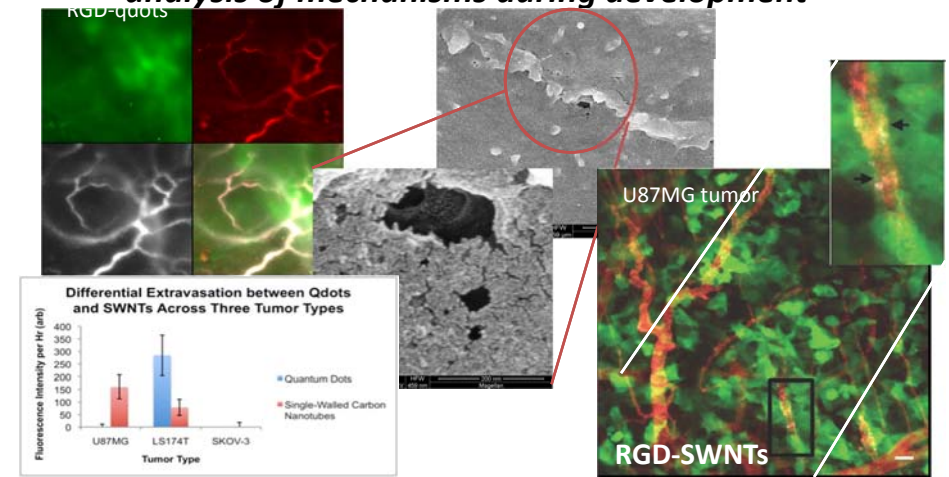
4th Gen: "Virtualize" the nano-engineering of drug delivery

Key Innovations:

- CFD Nano Micro Computational Characterization
- Nano-drug delivery development
- Virtual biotech startup business model—highly capital efficient

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Nano-Computational Characterization for faster analysis of mechanisms during development

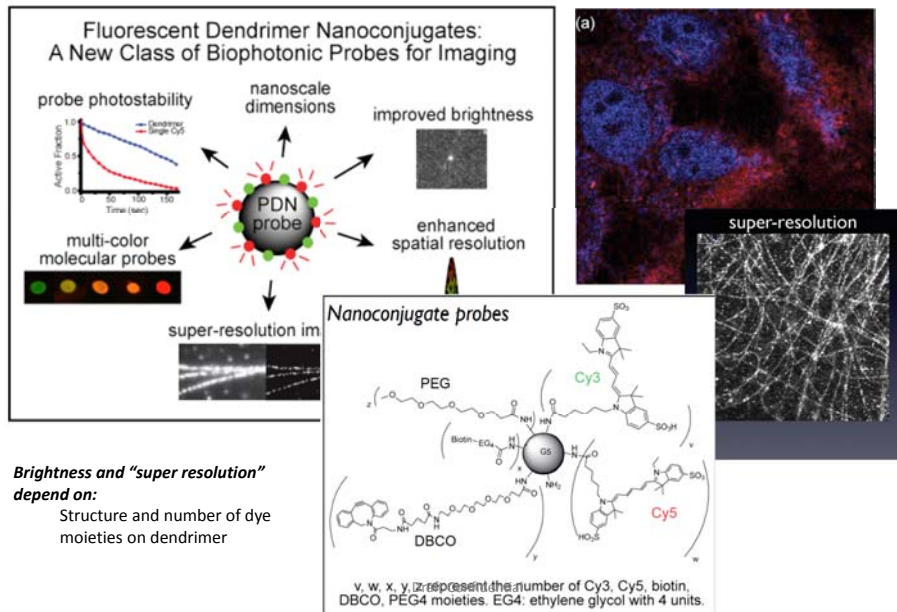


Adsorption & Extravasation to/through tumor vessel is a function of:

- Nanoparticle geometry and size
- Shear flow and interactions with circulating cells
- Margination, ligand size/density, receptor size/density, and ligand-receptor affinity

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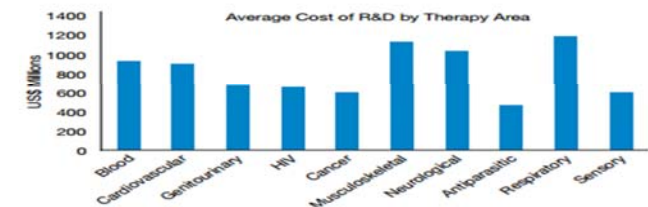
New Fluorescence Nanoparticles for imaging



Value to Users: Shrinking tumors with fewer chemo-therapy side effects

- 12M new cancer patients/yr, 8m die annually
- 90+ chemo-therapy drugs are FDA approved but are dose-limited for safety & side-effects
- Drugs costly due to R&D costs of \$354M/drug.

Figure 3: Costs per drug for medicines in selected therapeutic areas



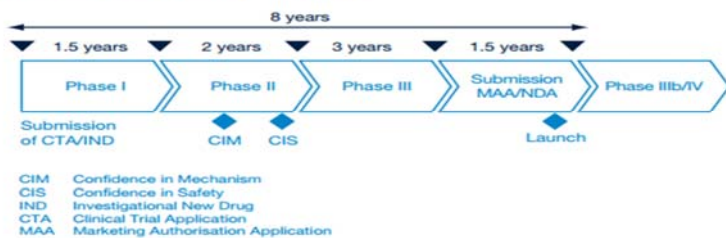
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PWC Report

Value to Corporate Partners: 2x Faster & 10x Safety and Efficacy

- Use FDA-approved chemo drugs + well-known antigens
 - Screen & analyze 100+ DDS nanoparticles
- Cut 6 yrs of time getting to Phase III review of 73 candidates, with 31% unsafe and 57% ineffective...

Figure 7: The current development process



PWC Report

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Atlas Ventures: A model LLC Structure for rapid commercialization & funding



Corporate Limited Partners:

1. Pharmaceutical Company
2. Consumer Healthcare
3. Med Imaging Company
4. Life Sciences IT Company

Subsidiaries C-Corp Startups:

1. Lung Cancer DDS
2. Brain Tumor CNS DDS
3. Imaging

Bruce Booth, Atlas Ventures blog

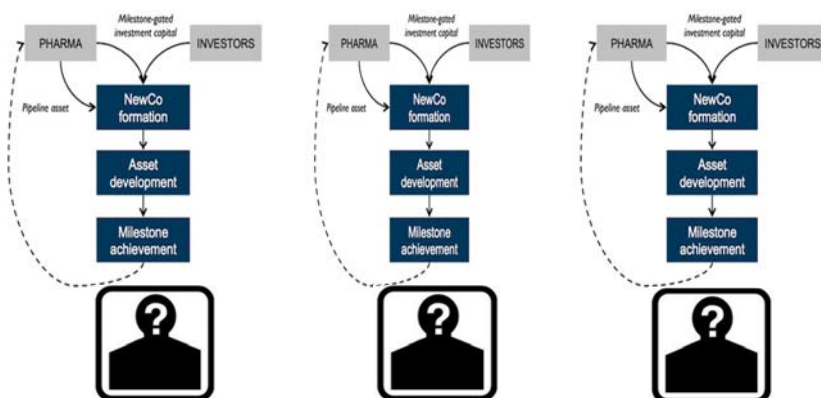
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Each C-Corp start-up in the portfolio is a virtual nano-medicine Build-to-Buy

Start-up #1:

Start-up #2:

Start-up #3:



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Capital-efficient

BIND BioSciences

2007 \$4.7M debt financing
\$16M Series B
2010 \$12.4M Series C
2011 \$47.25M Series D
2012 First Human Trials
\$85.2M in Funding

Computational Virtual Startup

1. Computational Lab 50%
 - a. Large cluster-1000CPUs
 - b. Facilities Setup
 - c. Utilities 1000/mth
2. Lab Personnel 25%
 - i. Computer administrator
 - ii. 3 computational dynamics postdocs
2. Benchmarking Lab 25%
 - a. MRI and Digital MRI file mgt system
 - b. small microfluidics lab setup
 - c. Microscopes & optical tables

TNP Programming Lab = \$2M/year
Operating Expenses

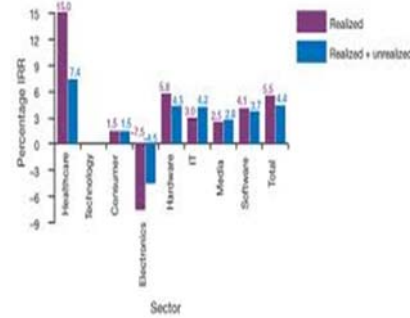
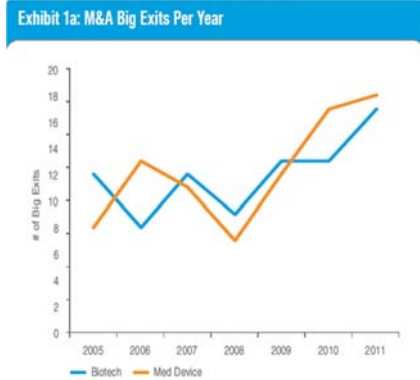
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Virtual Build-to-Buy Approach: Licensing or M&A in 2-3 years



2011 had 35 Big Exits with \$8B Upfront Paid

2000-2010 Healthcare IRR 7.4-15%



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New Nano-Medicine Cancer Drugs: Key Takeaways

Nano-engineered drug delivery systems are key advance in War Against Cancer

Like smart-bombs, these DDS can target tumors making John's cancer treatment 10x more effective

Three Key Innovations:
4th gen Nano-Drug delivery
Virtual biotech startups
Computational Modeling