

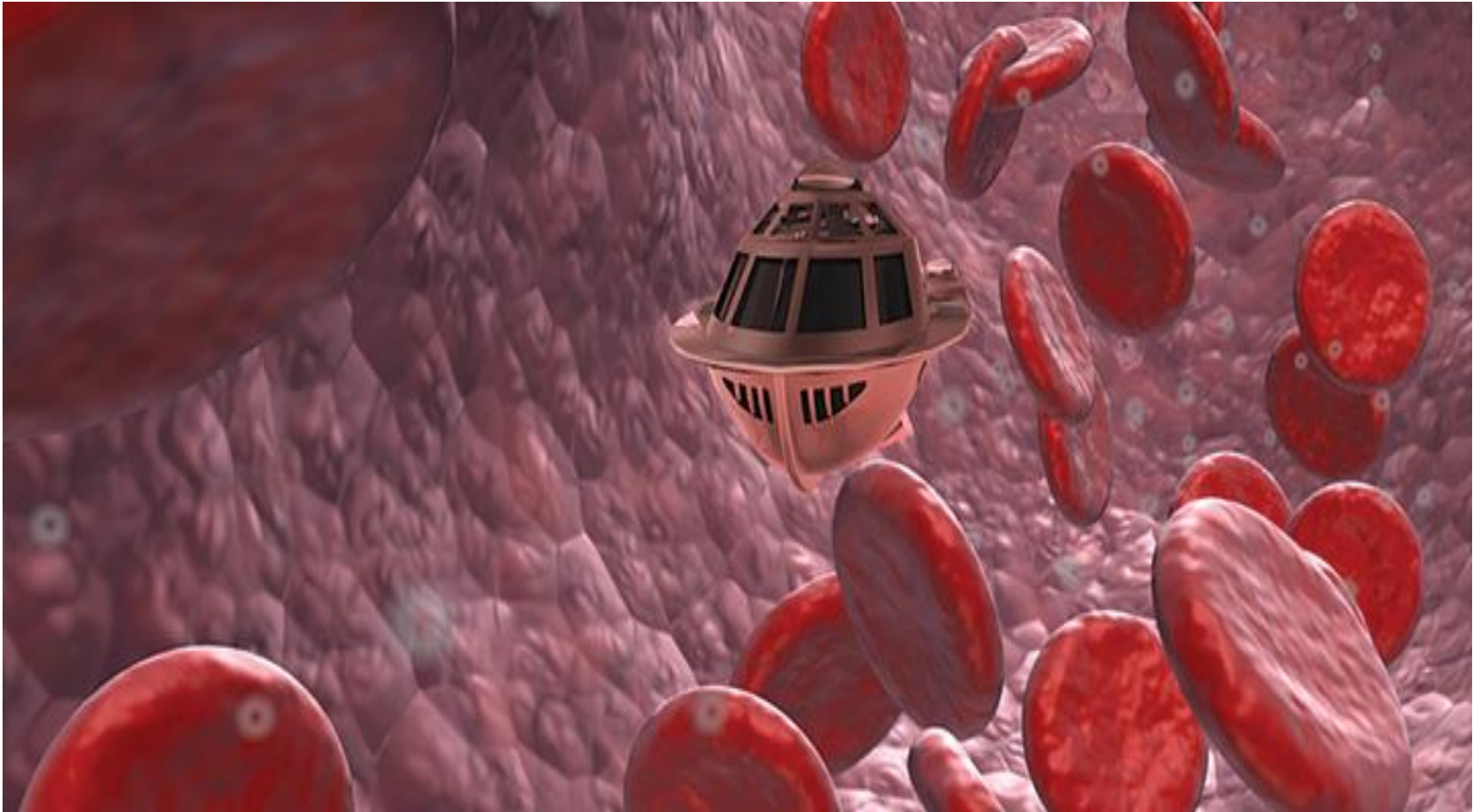
Nanotechnology: A new way to fight cancer?

**Professor Amy Shuen and
CEO, Nanoforma**

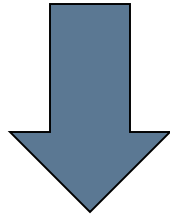
November 11, 2015

A Fantastic Voyage

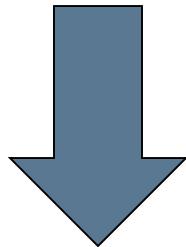
<http://www.tubechop.com/watch/7174947>



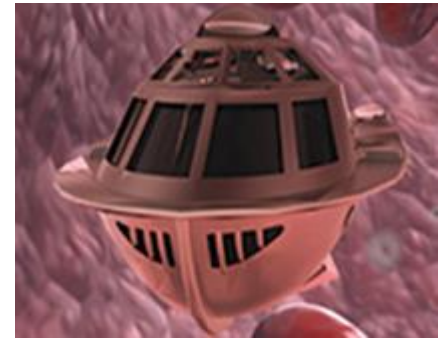
Shrink the vehicle



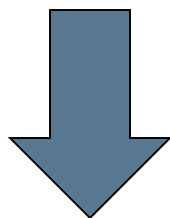
Guide the carrier



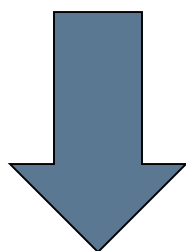
Destroy the disease



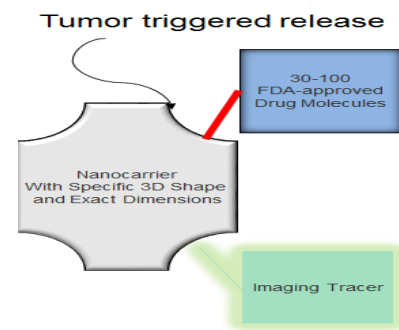
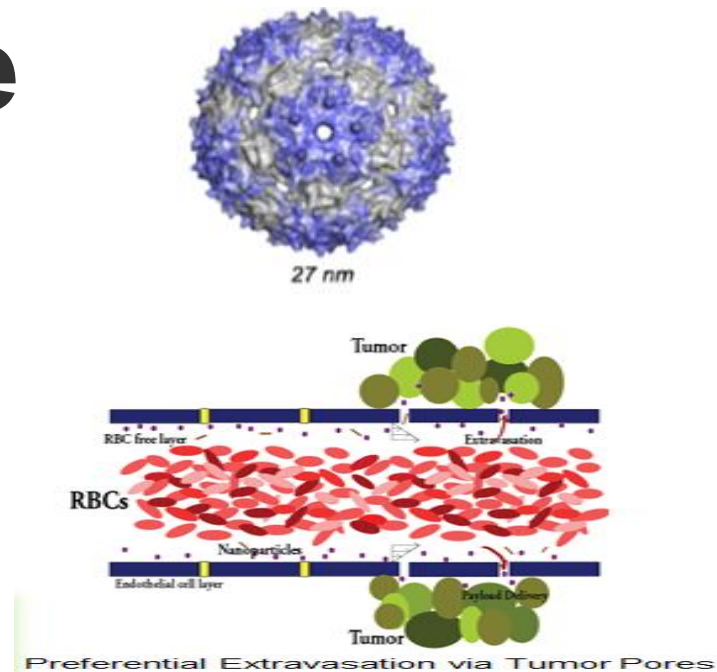
Shrink the vehicle



Guide the carrier



Destroy the disease

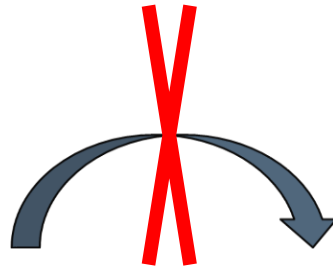


Problem: Chemo-drugs are not reaching tumors



98%

off-target

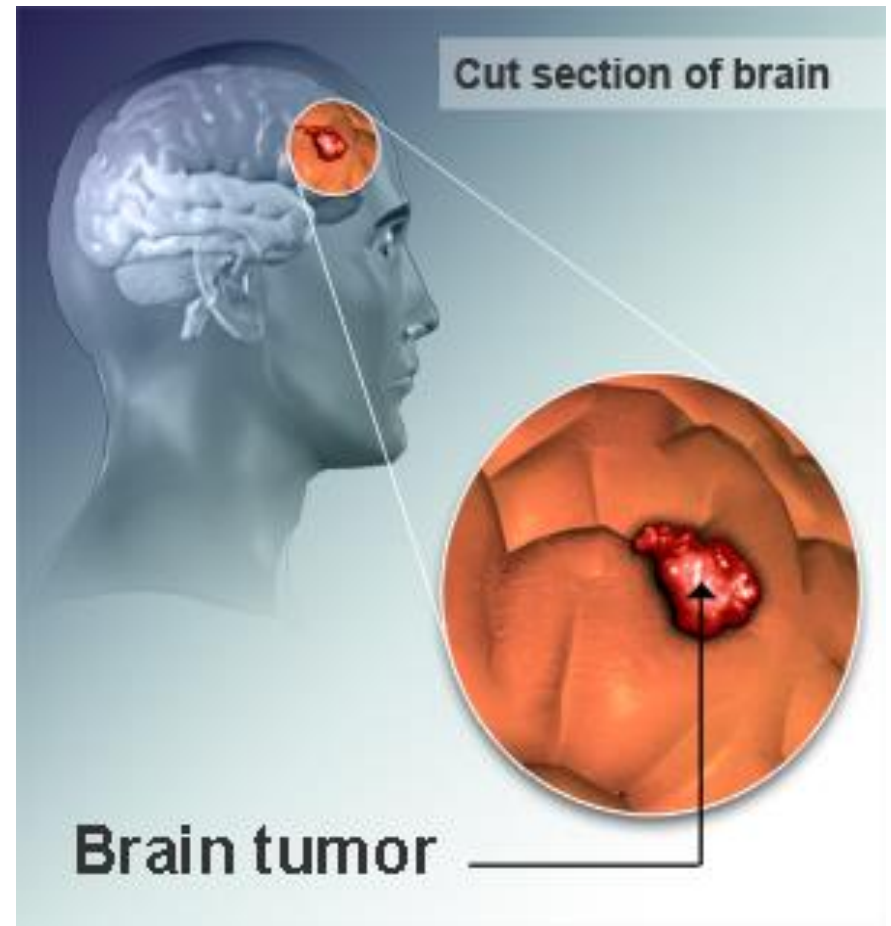


Cost of New Drug

2015

\$2.6

BILLION



Solution: Transformative Nano-Drug Tumor Delivery

100x-500x
Tumor
Uptake

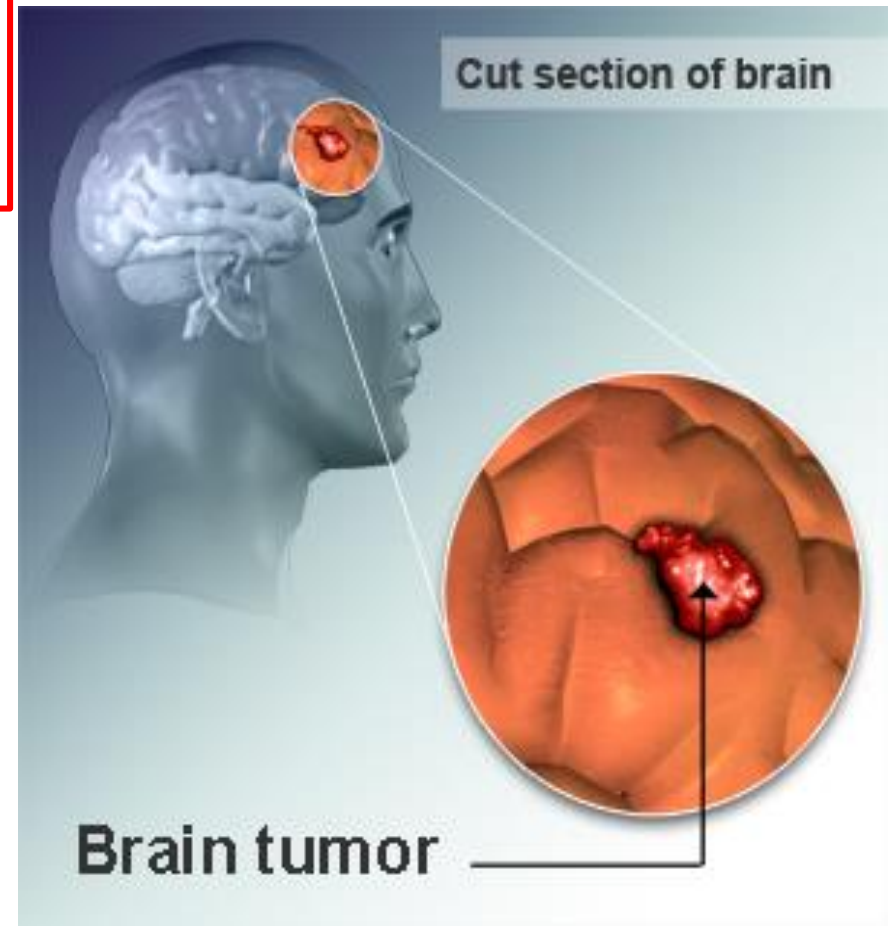
Tumor triggered release

30-100
FDA-approved
Drug Molecules

Nanocarrier
With Specific 3D Shape
and Exact Dimensions

Imaging Tracer

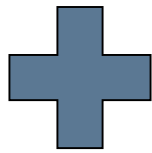
Safer up dosing
& reduced off-
target effects



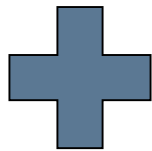
100x-500x
Tumor Uptake

Key Research Breakthroughs

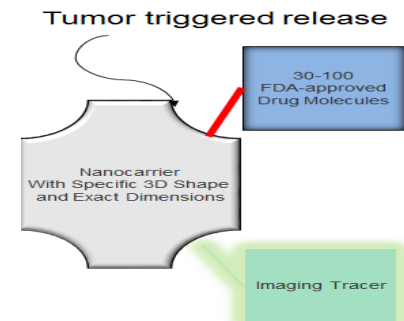
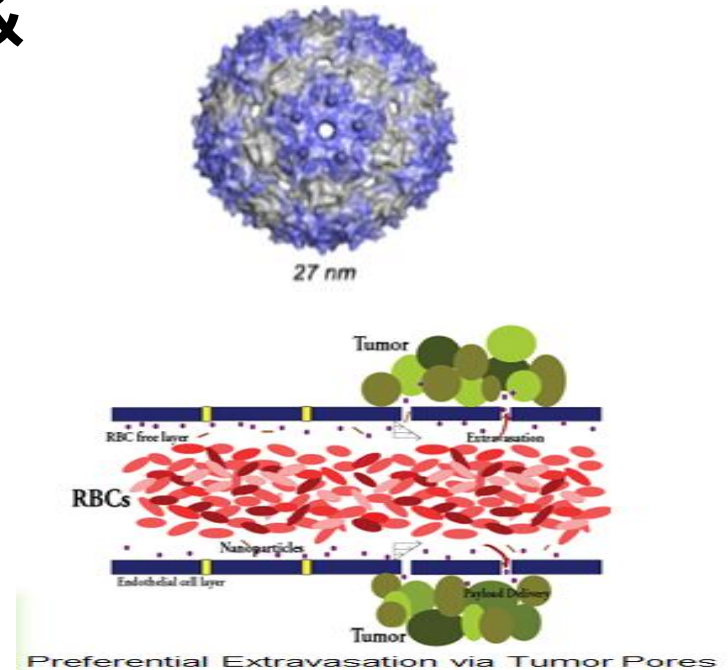
Protein Bio-Synthesis &
Drug Conjugation



Computational
Nano-Physics

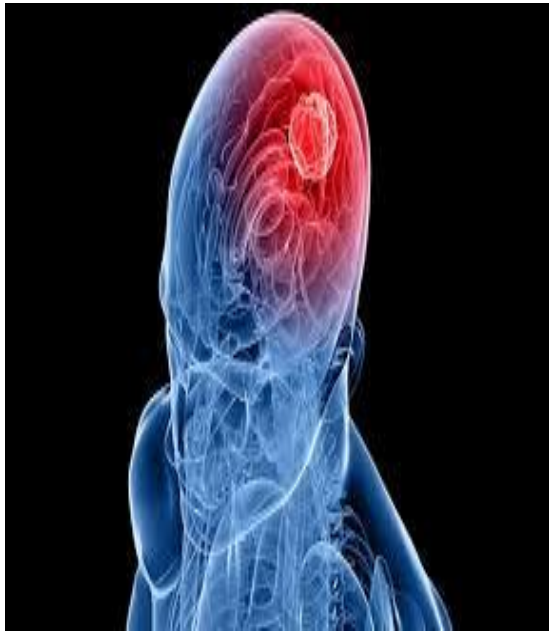


Molecular Imaging &
Translational Science



Game-changing nano-drug delivery...

Glioblastoma Brain Tumor



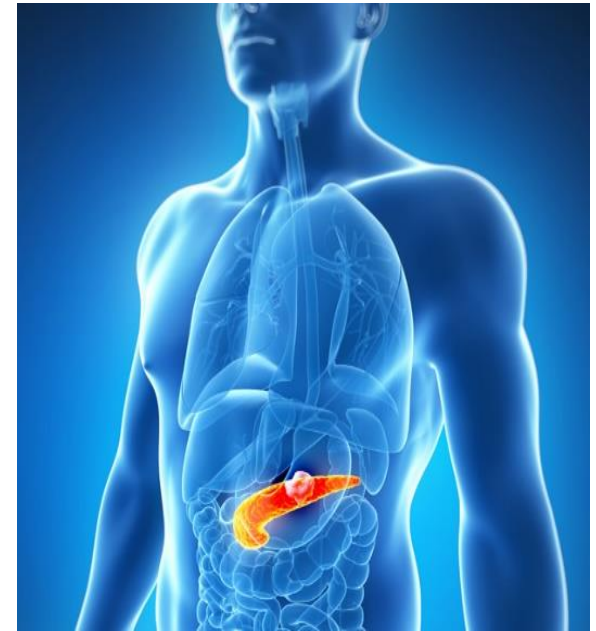
Median Survival 13.5 months
15k U.S Deaths per year

Liver Tumor



Limited treatment options
3rd leading cause of cancer deaths worldwide

Pancreatic Tumor

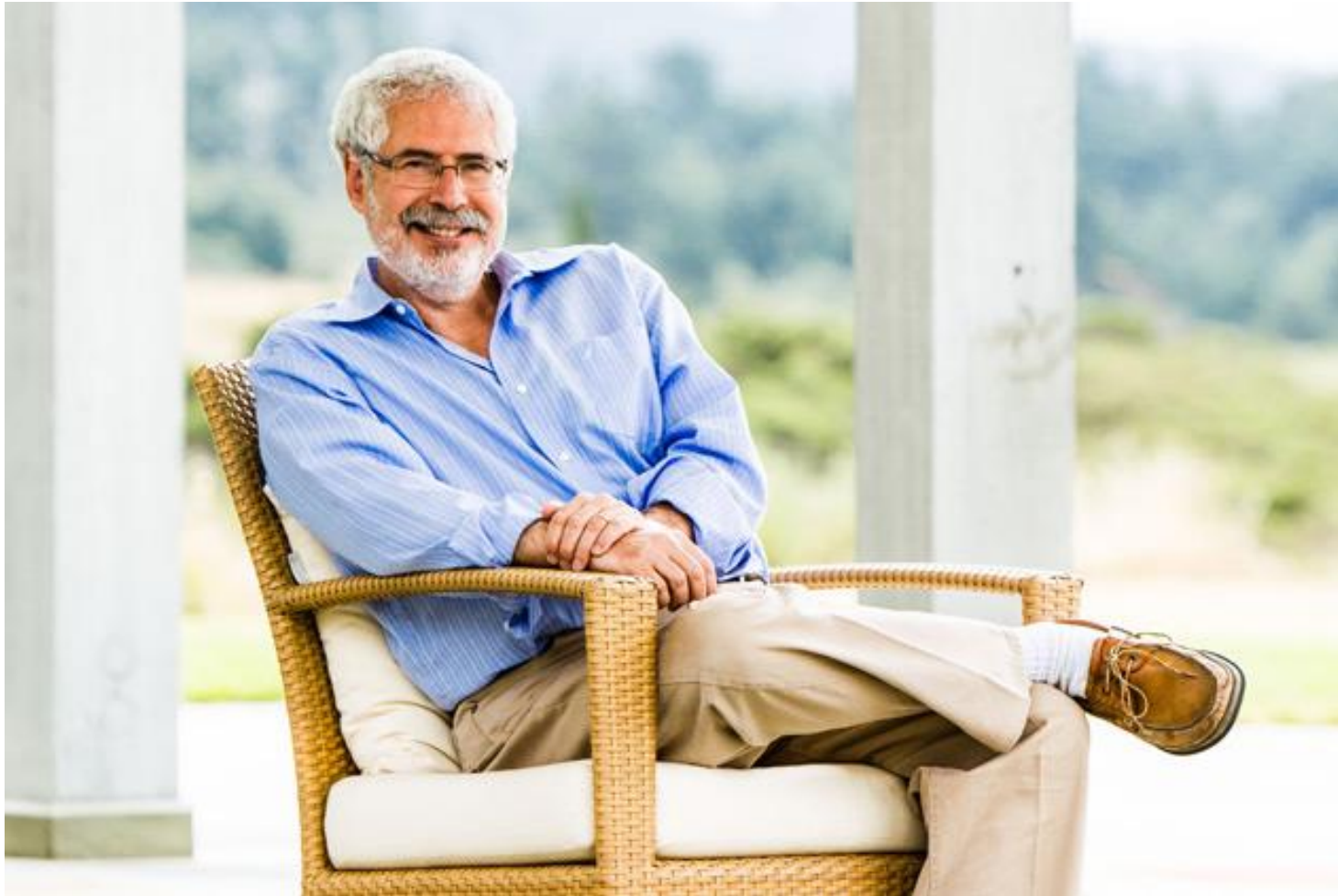


Median Survival 6 months
4th leading cause of cancer deaths

Next Steps: Funding for FDA Approval Process



Score: 500 Successful Life Sciences Startups!



Life Sciences Lean Launchpad Program






<https://vimeo.com/103897623>



Dr. Hobart Harris, UCSF Chief of Surgery and
Lean Launchpad Life Sciences Startup Founder

#24_The Nanoforma Lean Launchpad Team









<https://drive.google.com/file/d/0Bxiz8E1ITfZhWVFMem5JYIJ5bG8/view>

		 <small>UCSF University of California San Francisco</small>		
Amy Shuen Team Lead	Pratixa Joshi, Nanotech Expert	PJ Buske Science Expert	Rodrigo Vilela Business Dev.	Jon Hong Strategy/Finance

71

In-person / webcon: 59
Phone: 12

UCSF-Berkeley-Stanford Founding Team

  TECHNOLOGY In Silico Nano-Physics Tumor Engineering Optimization	  TECHNOLOGY In Vitro Synthesis of Protein Nano-Carriers, Characterize & Drug-Load	  BUSINESS Operations, Business Model, Financials, IP Strategy, Partnerships	  CLINICAL TRANSLATION Preclinical to IND Development, Regulatory to PH1 Human Trials
Prof Eric Shaqfeh Chair, Chemical Engineering	Prof Matthew Francis Associate Dean, Chemistry	Former UCB Prof Amy Shuen CEO, Nanoforma	Dr. Mitchel Berger Chair, Neurological Surgery Director, BTRC; 2012 President AANS

First Business Canvas: Original Idea

Sell to Big Pharma!—IP Licensing revenues

Key Partners

Industry and startup development experts

★ Discovery phase CROs

★ Academic Influencers

★ Industry Partners

Key Activities

★ FDA- Regulatory - pre-clinical to Ind. Phase 1 clinical trials

★ University Relationship - IP management, interinstitutional

★ Business Strategy - competitive analysis, business intelligence ...

Key Resources

★ University resources

★ Supercomputer to run SW of computational engineering.

Value Propositions

Pre-clinical brain tumor drug delivery efficacy and toxicity compared to ...

Tumor-specific drug delivery using customized nanocarriers reduces ...

A wide selection of FDA-approved drug payloads can be delivered to specific ...

PK PD Molecular Imaging

Customer Relationships

★ Oncologists - Make aware of trials, recruit patients, and deliver

★ Surgeons - Influence neuro-oncologist to recommend treatment

★ Hospital best practice guide - Recommend treatment

Channels

★ Clinical Trials

Customer Segments

✓ Big Pharma: Director Oncology R&D

✓ Big Pharma: Early Stage oncology external partnering groups

Big Biotech: Oncology Director R&D

Cost Structure

★ Research Costs - Computational, wet labs, biosynthesis, animal models.

★ Non-biologic Complex Drug Delivery scale-up

★ IP and legal costs

★ People costs

Revenue Streams

★ Licensing: Upfront payments & milestone payments

★ Government or Institutional Grant Funding

★ Foundations with GBM focus

What We Heard

The question you should be asking is:

What would you **partner** with us on: A glioblastoma drug, a nano-carrier delivery platform, or the computational model?

- Neena Kadoba, QB3

Both Genentech and Amgen would ditch their current Antibody Drug Conjugate **platforms** if they had an alternative **tumor targeting** option.

- Joeren Grasman, Genentech
Business Development

Good time to go for funding--all the Pharmas are disenchanted with mABs and looking for the next big breakthrough.

-Devin Huyhn, GE Healthcare

Co-development Partners vs. Licensing Customers



3-5 years

Lead ID

Proof-of-concept

IND

Basic
Research

Development

Preclinical

Co-Development.....Licensing

Preclinical

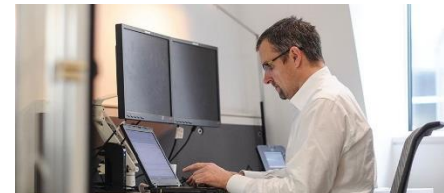
Phase 1

Phase 2

Commercial

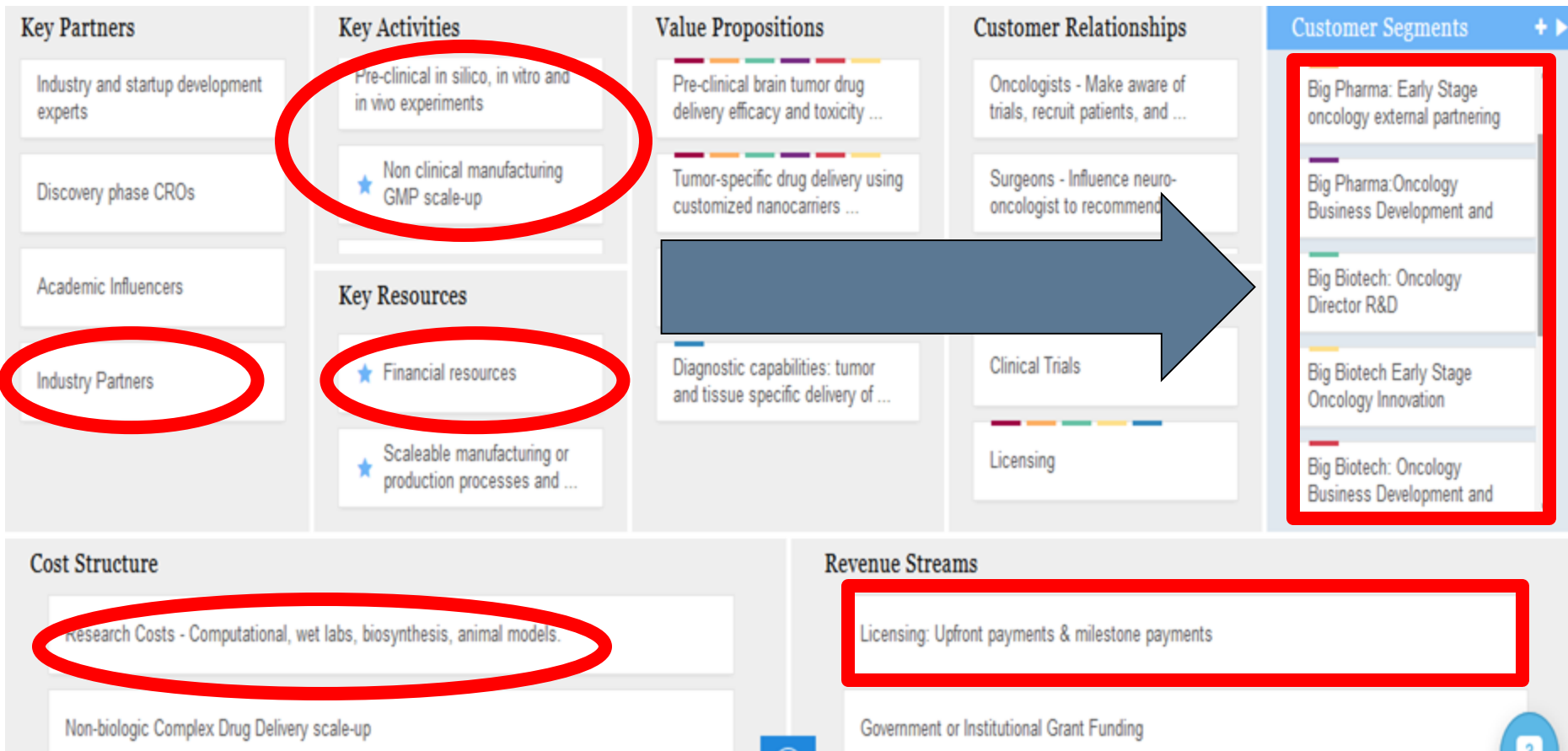
Innovation VC Funds
(preclinical/ early
stage)

Business
Development
(later stage)



Week 5 Business Model Canvas

Co-development Drug Delivery Partnerships Now----->Licensing Customers Later





DebioPharm is a multi-billion dollar Swiss specialty pharma company that looks to partner and invest on novel complex cancer drugs.

-Maria Chiam
Business Development, DebioPharm

Potential Big
Pharma Partner
#1

Merck's
Temodar off
patent in
2013

Potential Big
Pharma Partner
#2

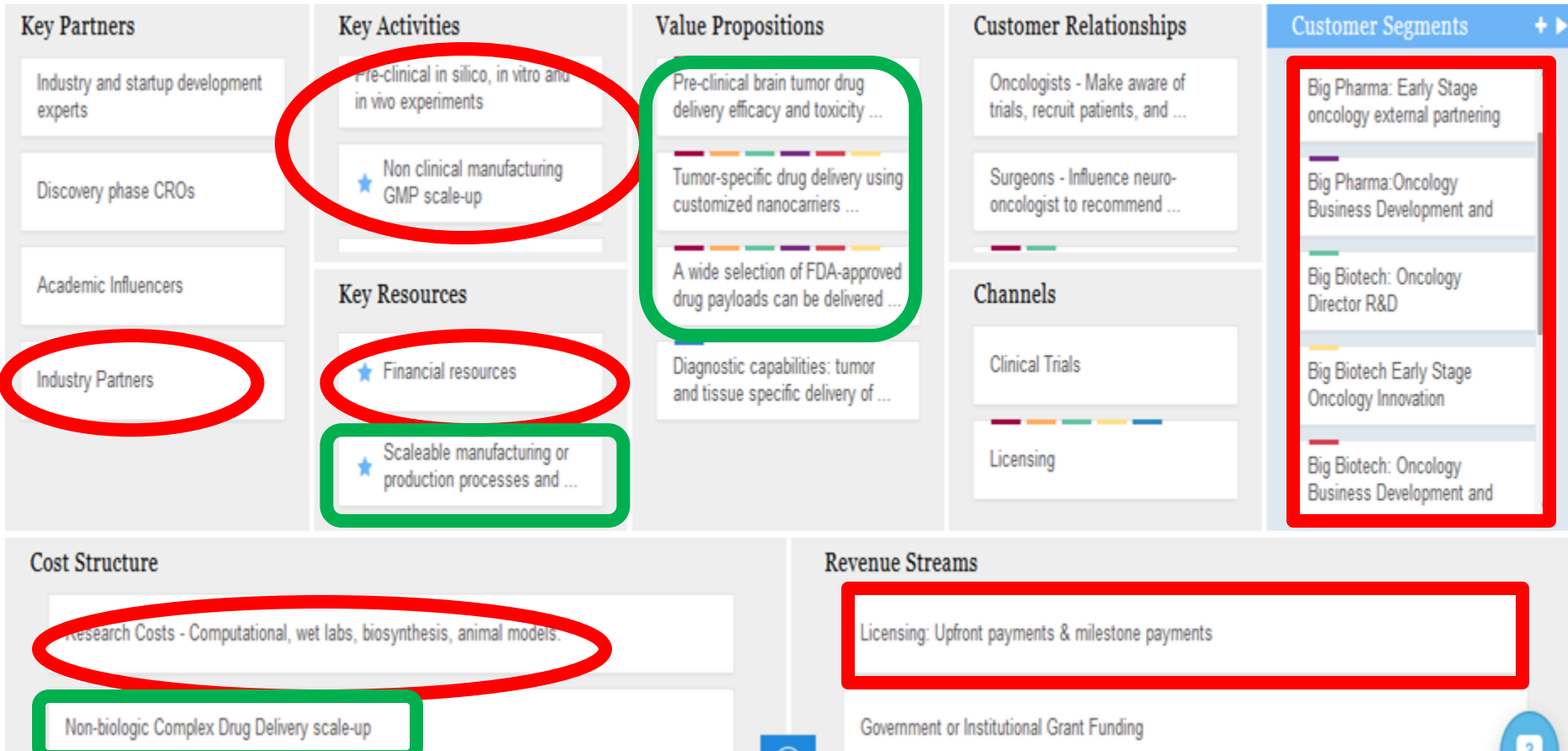
Orphan
Diseases
International
Regulations

Specialty
Pharma Partner
#3

Smaller
Nimble
Private +
Complex
Mfg Skills

Final Business Model Canvas

MVP Nano-drug Tumor Delivery Platform + NCL + Scale-up = Green light Go Ahead



What we heard...

The biologics cost \$250/dose versus 25¢ for small molecule pills. A non-biologic drug platform for targeting tumors would have unique advantages.



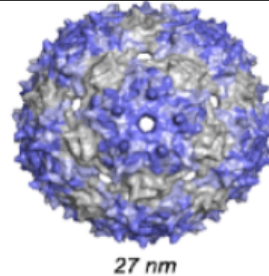
Jeroen Grasman
Marina Dobrovolskaia, Ph.D., Co-Director
Senior Director of Finance - Global Biologics
Nanotechnology Characterization Lab
Manufacturing at Genentech

MVP: Nano-drug delivery platform

Amount of Drug (# of drug molecules) delivered to Brain Tumor vs. Free drug

- ✓ Size
- ✓ Size distribution
- ✓ Topology
- ✓ Molecular Weight
- ✓ Aggregation
- ✓ Purity
- ✓ Chemical Composition
- ✓ Surface Characteristics
- ✓ Functionality
- ✓ Stability
- ✓ Solubility
- ☐ Zeta Potential

Drug-loaded
Nano-carrier



3D Particle Geometry

Radius of maximal cross-section: r

Semi axis of revolution: t

Aspect ratio: ϵ

Eccentricity: e

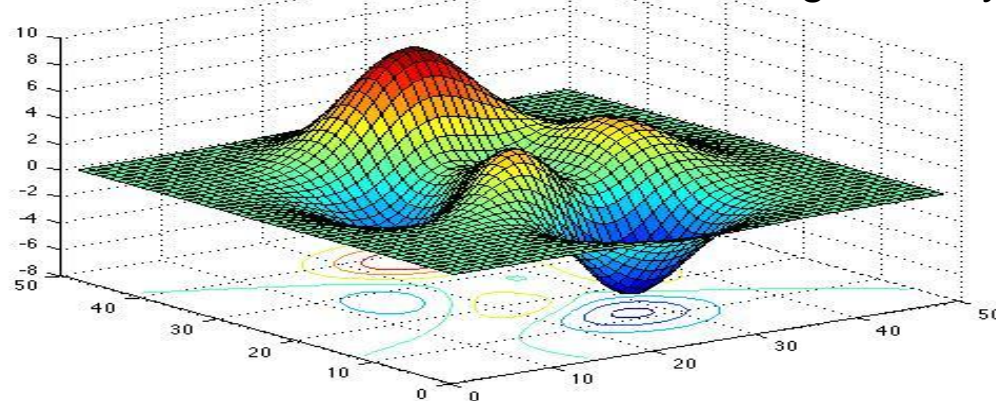
Diffusivity along axis: D_{\parallel}

Diffusivity orthogonal to axis: D_{\perp}

Rotational diffusivity: d_r

Orientation averaged diffusivity: D

Nano-carrier vs. Free drug delivery



Tumor extravasation measurements

Illustrative diagrams
and parameters--not
actual shapes or data
results



Contact Amy Shuen, Nanoforma CEO
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