



# Bio Advance

Biotechnology Greenhouse of Southeastern Pennsylvania

Funding Workshop  
May 27, 2009 (Updated June 2011)

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# Workshop Objectives

- **Explain how we evaluate proposals**
- **Identify questions we will be asking**
- **Help you understand strengths/weaknesses of your business opportunity**
  - ♦ **Some problems are not fixable**
- **Manage expectations and avoid surprises**

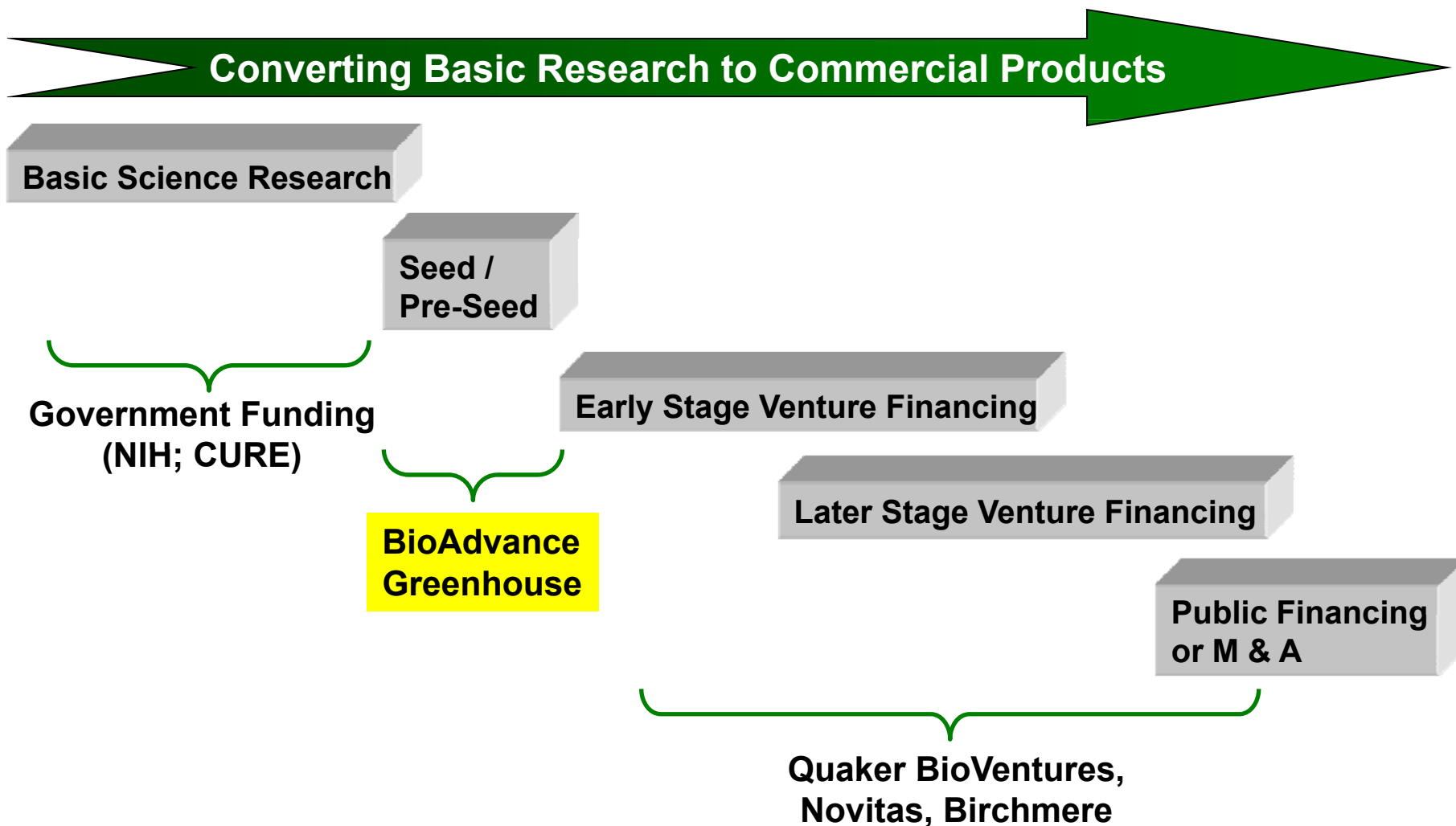
# BioAdvance Team

- **Management**
  - ◆ **Barbara S. Schilberg, J.D.**
  - ◆ **Marie A. Lindner, M.D.**
  - ◆ **Shahram Hejazi, Ph.D.**
  - ◆ **Marnie McCoy**
- **Entrepreneurs not-in-residence**
  - ◆ **Hal Broderson, M.D.**
  - ◆ **Jeff Edelson, M.D.**

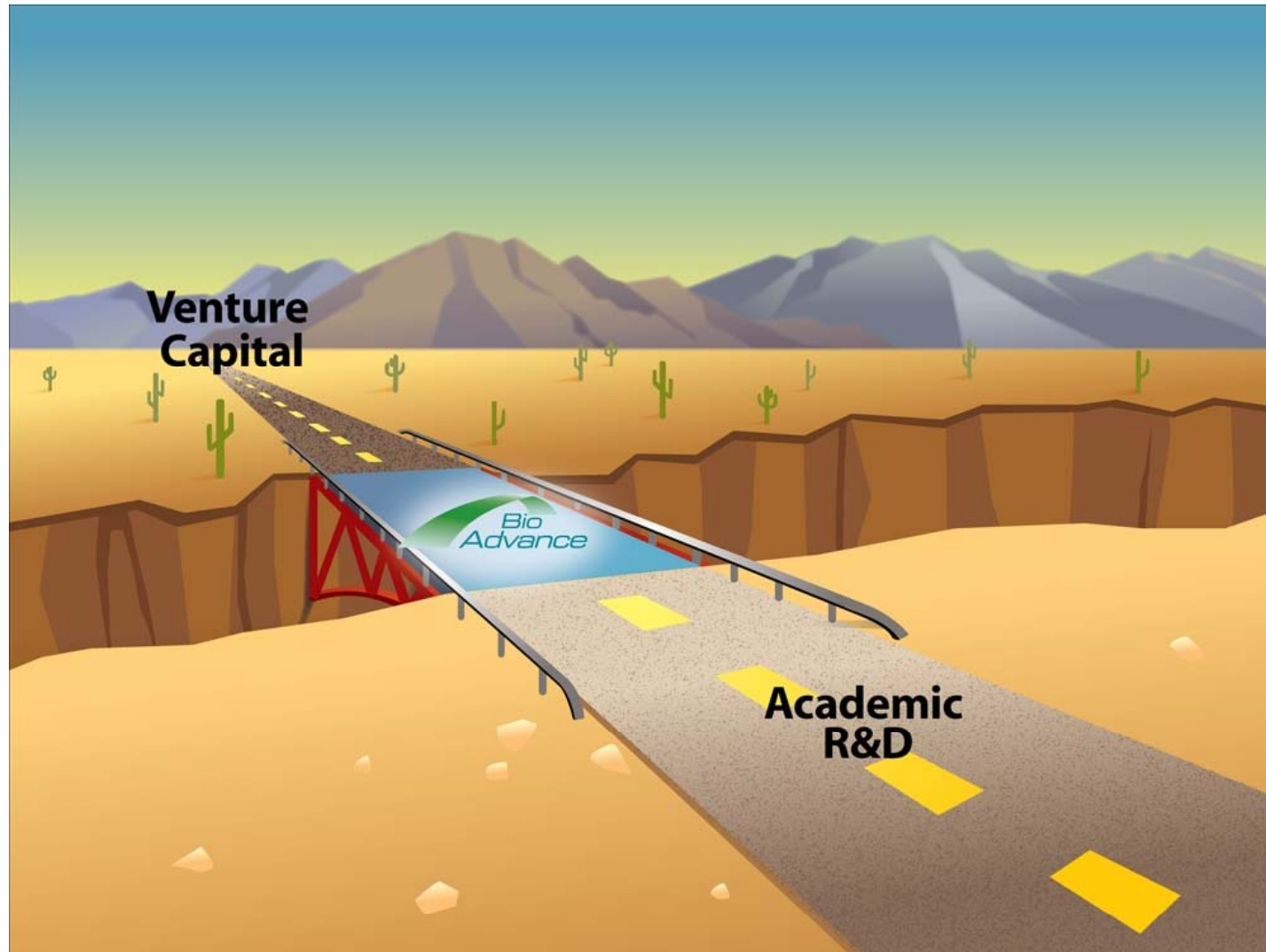
## Who We Are

<b>History:</b>	<b>Established in 2002</b> <b>– PA Tobacco Settlement</b>
<b>Fund Size:</b>	<b>\$20M for investment</b>
<b>Fund Model:</b>	<b>Evergreen: returns recycled</b>
<b>Focus:</b>	<b>Drugs, devices, diagnostics to improve human health</b>
	<b>Investment Stage: Pre-seed and seed (before venture)</b>
<b>Investment size:</b>	<b>\$5,000 – \$1,250,000</b>

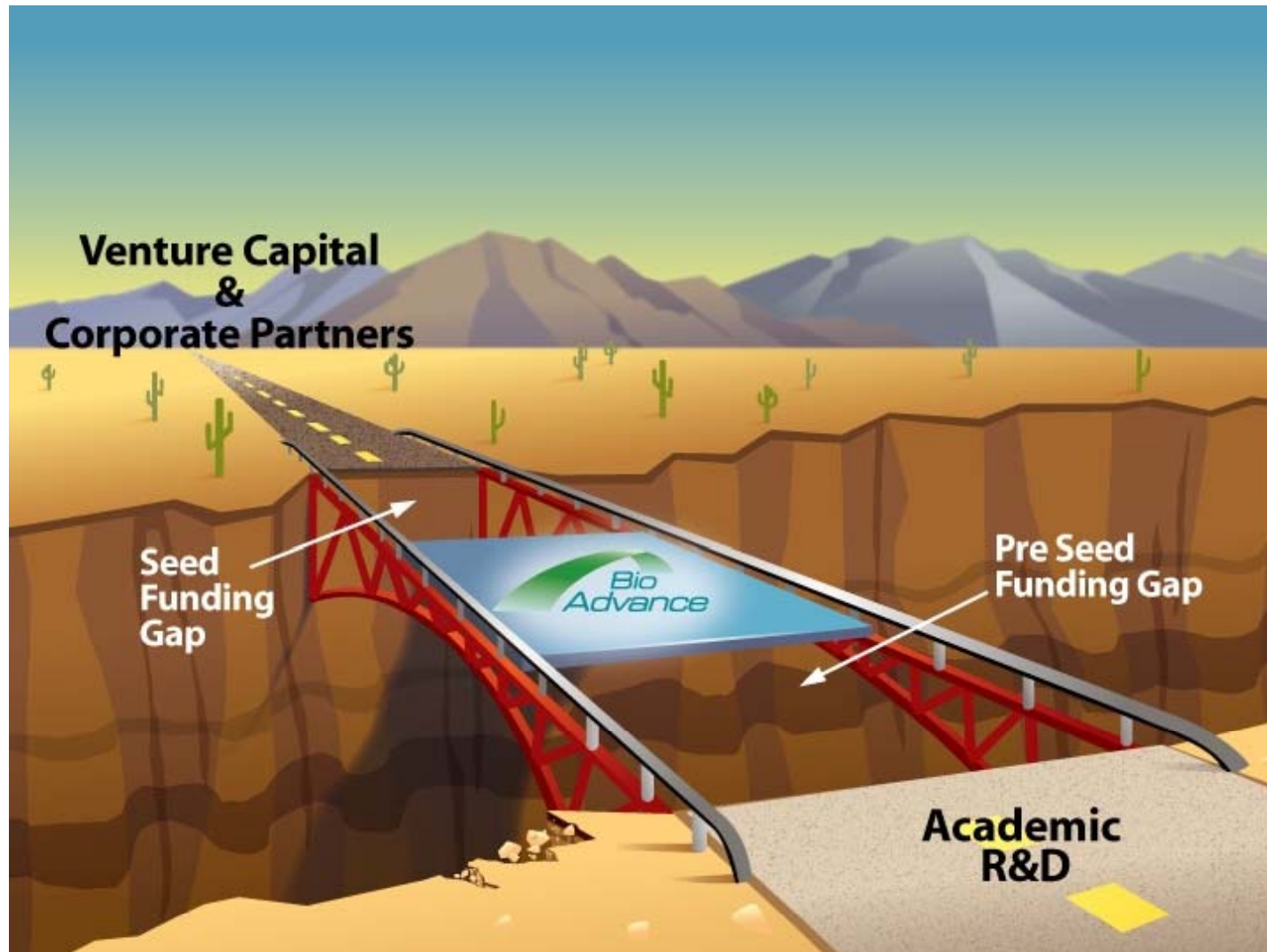
# The Funding Continuum



# Goal: Bridge to Somewhere



# Reality: Valley of Death



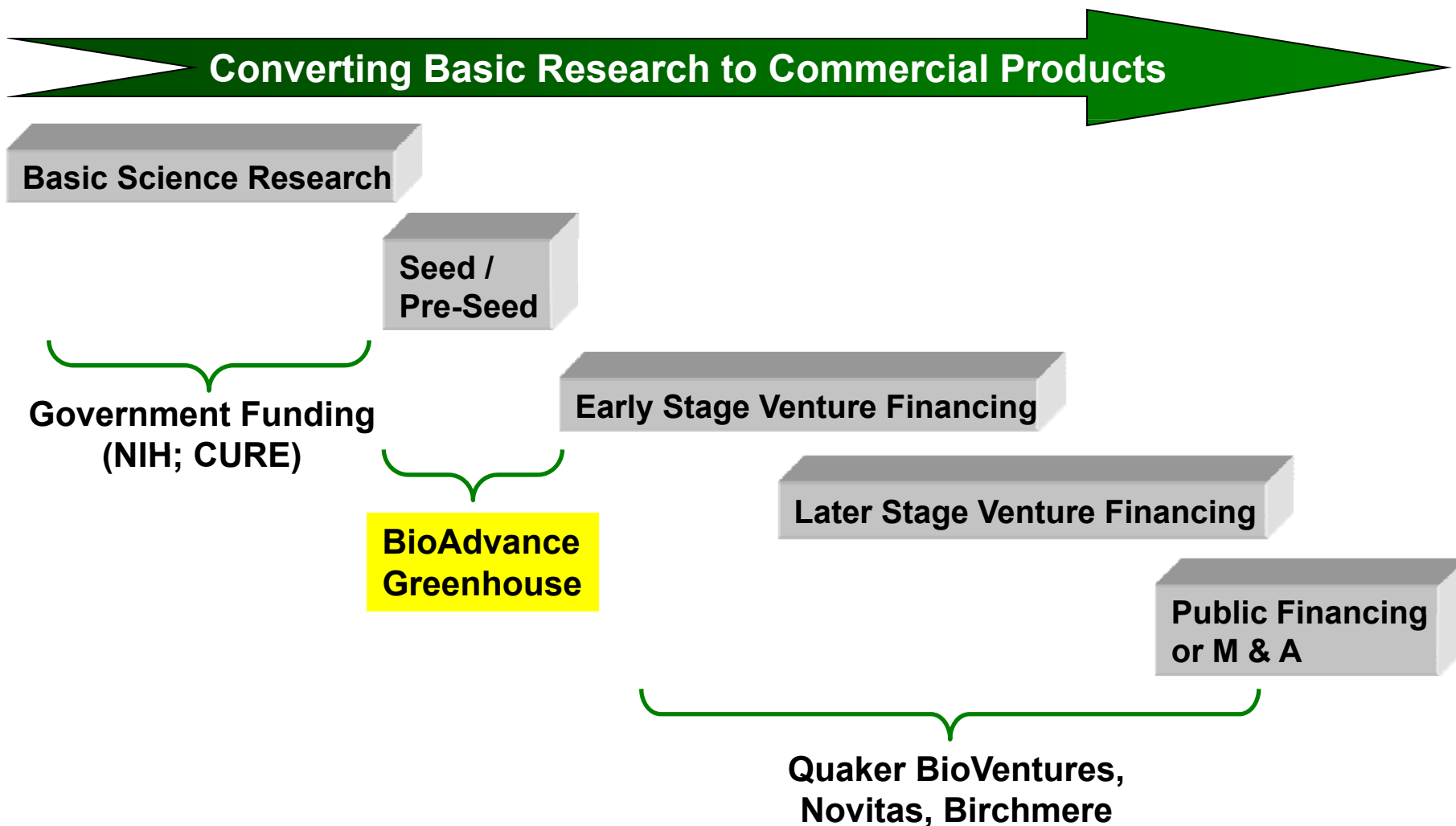
# Investment Strategy

- **Key decision drivers**
  - ♦ **Company is able to reach key milestone to obtain next stage of funding with BioAdvance funding + other resources available at this stage**
  - ♦ **The opportunity provides follow-on investors/partners with enough return to compensate for the risk**
- **Not every opportunity fits the landscape**
  - ♦ **Average of 4 seed financings each year**
- **We work backwards from the destination to figure out if you can get there from here**
  - ♦ **Every disease area and technology is different**
  - ♦ **We don't expect you to have all the answers**
  - ♦ **We will provide feedback on key challenges regarding funding decision**
  - ♦ **It's more art than science so it is subjective**

# Results to Date

- **\$19.4M invested**
  - ◆ 29 seed investments
  - ◆ 15 pre-seed investments
- **Competitive**
  - ◆ Significant demand - ~\$1.1B requested to date
  - ◆ Over 727 proposals
  - ◆ <5% selected for seed funding
- **Seven exits**
- **\$1.4BM in total leverage to date**
  - ◆ >\$415M in subsequent capital raised by portfolio
  - ◆ >\$985M in acquisition value

# The Funding Continuum



# Common Pitfalls

- 1. Insufficient scientific / technical foundation**
- 2. Solution looking for problem**
- 3. Even if you can do what you say, no one will pay for it**
- 4. Development path is not feasible**
- 5. Commercial/business development strategy is not feasible**
- 6. Great idea, but you can't stop others from doing the same thing**
- 7. Management team shortfalls**
- 8. You can't get there from here ...**
- 9. The reward does not justify the risk**

# Pitfall 1

## Insufficient technical feasibility

Christopher J. Damm, M.D.  
Shahram Hejazi, Ph.D.  
Jeff Edelson, M.D.

# Technical Foundation

- **Scientific / Technical work is based on a sound hypothesis**
  - ♦ Begins with a review of the relevant literature
  - ♦ The synthesis/reasoning behind the hypothesis is convincing to peer reviewers
- **The hypothesis is testable using seed-stage funds**
- **Proving the hypothesis will attract follow-on funding**
  - ♦ Good proposals generate technical data that reduces risk, defines utility
  - ♦ We fund “early” projects, but not so early that they are “a bridge to nowhere”
  - ♦ Assessment will vary by therapeutic area

# Levels of Evidence - Therapeutics

Stage of Development	Example
Proof of mechanism	Binds to $\beta$ receptor
Proof of principle -- in vitro -- in vivo	Relaxes smooth muscle in tissue bath
	Mean art pressure reduced in hypertensive mouse model
Proof of concept	Reduces BP in 4 week clinical study
Proof of profile	QD dosing, no impotence, reduces cardiovascular mortality in 1 year study

## Levels of Evidence – Devices

Proof	Evidence	Example
Technical feasibility	This should be demonstrated by credible data.	An in vitro diagnostic device; needs bench data demonstrating that technology works
The technology can be reduced to a “product”	An “alpha” prototype within the scope of the plan	If the sensor requires a mass spectrometer to work, then it won't be for home testing
Clinical feasibility: Can product work under “real world” conditions	In vitro/in vivo data needs to be achievable	If need to do animal testing, does the animal model even exist?

## Pitfall 2

Solution looking for problem  
or  
Wrong solution for right problem  
or  
Wrong problem to solve

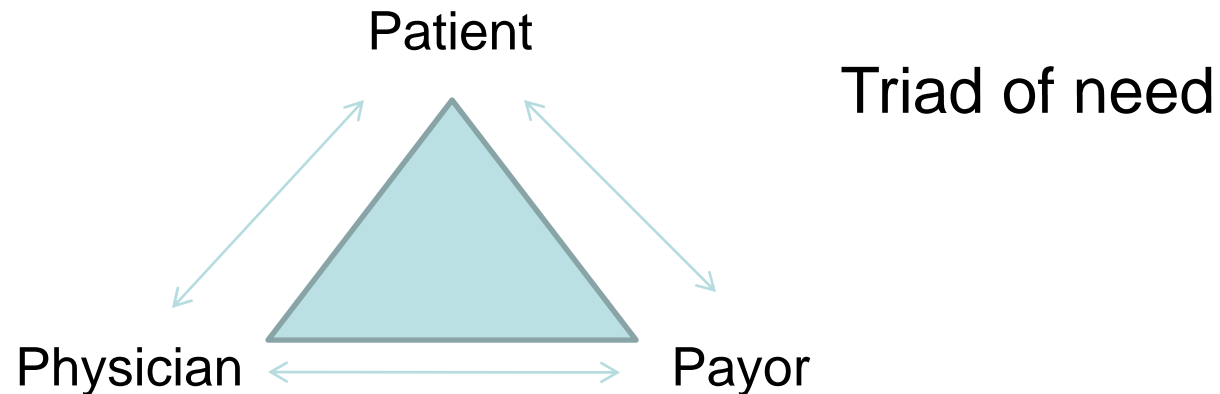
Marie A. Lindner, M.D.

# In search of the “killer app”



- **Some technologies ≠ product**
    - ♦ Just because it's “cool” doesn't mean you can make a product out of it that someone will want to use/pay for
  - **Platform technology:**
    - ♦ What product will your technology make?
    - ♦ Is it worth developing and selling?
    - ♦ Does your solution actually solve an important problem?
- Examples:
    - Nano particle drug delivery:
      - What is worth delivering at a nano range and will it be worth something if technically feasible?
    - Subcutaneous drug delivery device:
      - Are there drugs you can deliver in a small volume through a small needle that people will really pay for?
    - Combination drugs:
      - Why would physicians want to prescribe a fixed dose of your two drugs for their patients?
      - Convenience of reducing by just one pill doesn't pay

# Unmet Medical Need: Finding the right problem to solve



- **Must solve a problem for one or more of the above**
- **Different points of pain for each group**
  - ◆ **Must convince physicians to prescribe and payors to pay**
  - ◆ **Problem solved for patient must be significant to both other groups**
- **Must be better, faster, cheaper than current treatment**

# Work backward: Knowing where you are going helps you get there

- **Once you figure out the right problem to solve with your technology, how do you know you can solve it?**
- **R&D activity focused on the *ultimate* goal is key**
  - ◆ **Medical need addressed with a *claim* or *indication for use***
  - ◆ ***Claims* and *IFU* come from clinical trial endpoints**
  - ◆ **Clinical plans are important to product seller (future acquirer)**



If you start with the bricks...without a plan...you end up with a wreck... instead of a well-built house

# No right drug/device for wrong indication

- **FDA's decision to approve a new drug/device for marketing boils down to two questions:**
  - ♦ **Do the results of adequate and well-controlled studies provide substantial evidence of effectiveness?**
  - ♦ **Do the results show the product is safe under the conditions of use in the proposed labeling?**
    - **Safe means that the benefits appear to outweigh the risks, and that those risks are predictable**
- **Once a drug/device is approved for marketing, a sponsor (or manufacturer) may promote the use for the approved indication**
- **After initial approval, if a sponsor wants to change how its product is manufactured or the indications for which it is approved, a sponsor must submit a supplement**
- **Third-party payers will reimburse for approved uses of drugs and devices**
- **A sponsor's ability to get its drug included in the HMO's formulary is significantly enhanced by approval**
- **The correct plan for the correct indication starts at phase I through proof of concept trials**

# Medical Need Examples



## Well defined solutions

- ◆ **Nupathe: Migraine treatment for patients with nausea** → patch providing fast, sustained dermal delivery of sumitriptan
- ◆ **Protez: Multi-drug resistant organisms** → antimicrobial agents
- ◆ **Formae: Osteoarthritis** → hydrogel cartilage replacements more like natural cartilage
- ◆ **Novira: HIV, HCV, other viruses** → Antiviral treatments with new mechanism of action
- ◆ **Treventis: Alzheimer's disease** → Disease-modifying treatments based on latest understanding of disease



## Poorly defined solutions

- ◆ **“Cure for” cancer, diabetes, etc.**
- ◆ **Tx for brain cancer** requiring surgery to place tx, when that type of cancer is treated with radiation tx
- ◆ **Diagnostic or screening tool** without therapeutic or known outcome of disease
- ◆ **New treatment for disease** in healthy people when adequate generics or OTCs available
- ◆ **Combination drugs** when there is no meaningful benefit over drugs used separately
- ◆ **Prodrug/active metabolite** without clinical or safety benefit

## Pitfall 3

Even if you do what you say you can,  
no one will pay for it

Marie A. Lindner, M.D.

# Will someone pay for your product even if you can make it?

- **You picked the right indication for your technology but you still need to develop it right**
  - ♦ Even if you pick the right development plan, it may cost more to develop it than it will be worth
  - ♦ If your product is a device or diagnosis, getting it approved may not be enough to get someone to pay for using it
  - ♦ If you develop it incorrectly, no one will want it either
- **Target Product Profile (TPP)**
  - ♦ Tool which sets the goal of your plan: to make a product that someone **WILL** pay for because it has the right attributes
  - ♦ Product development plan must deliver the attributes you seek
  - ♦ TPP defines claims which will be received and dictates available market
  - ♦ Identifies attributes needed for adoption and reimbursement

# Target Product Profile

- **Key elements**

- ♦ **Indication: specific definition of how and in whom product is used**
- ♦ **Efficacy statement: specific description of what product does and how well it must perform**
- ♦ **Form of dose/how supplied/device description: specific description of product attributes with regard to delivery, frequency, size of dose or specific description of device characteristics**
- ♦ **Outcomes: specific statement of benefits received in terms of efficacy, safety, quality of life, pharmacoeconomics**
- ♦ **Safety profile: safety parameters that are critical to meet or overcome**
- ♦ **Pricing/reimbursement characteristics: pricing parameters needed to be competitive**

# Target Product Profile Example: ITI-111

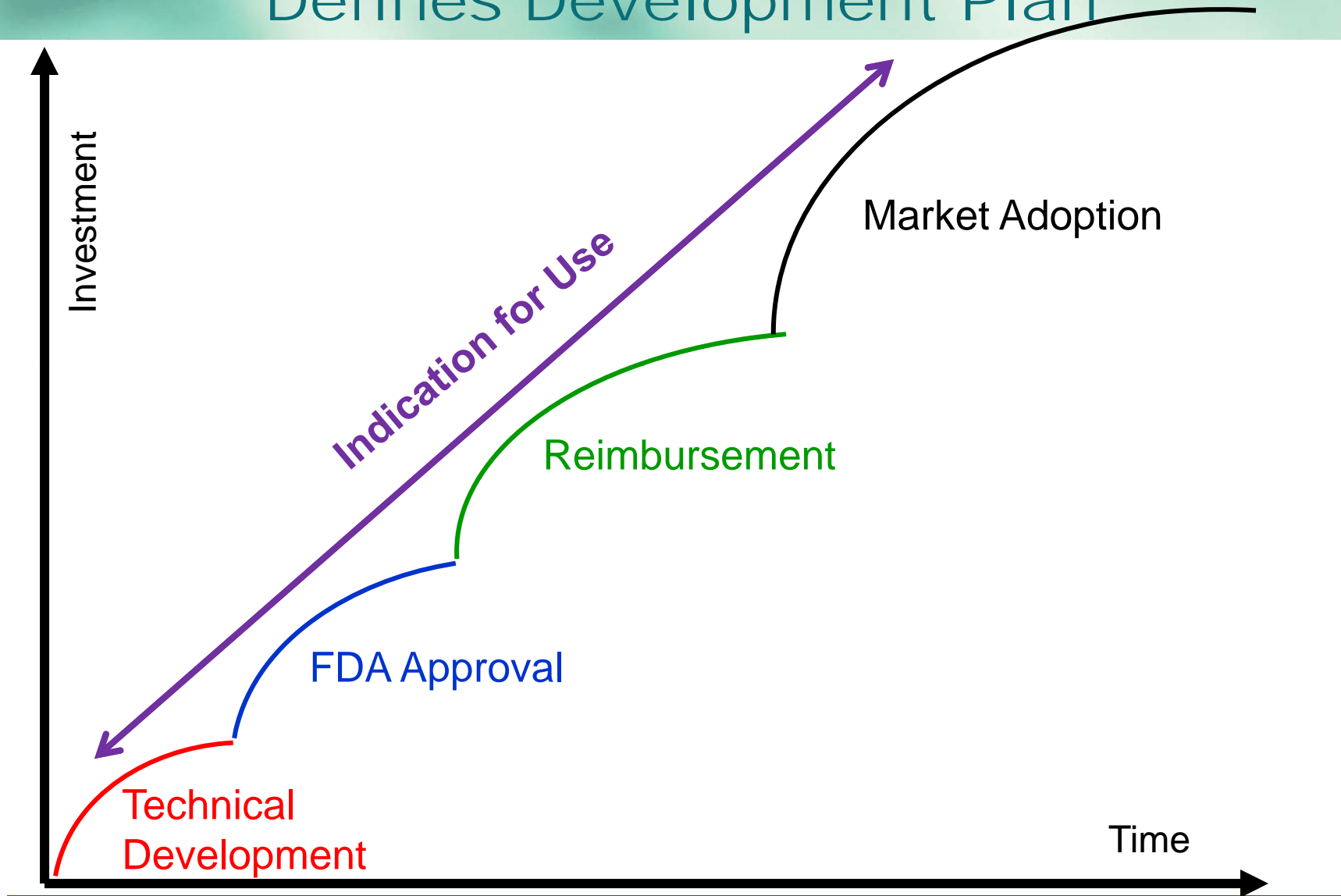
Description	
<b>How Supplied</b>	single-dose, disposable, nasal spray unit
<b>Indication</b>	For rescue treatment of seizures in patients with Epilepsy on stable regimens of AEDs who require control of intermittent bouts of increased seizure activity
Efficacy	
<b>Seizure Termination</b>	Seizure termination within 10 minutes after drug administration
<b>Seizure Recurrence</b>	No seizure recurrence during a follow-up period of six hours
Safety / Side Effects	
	<5% of patients experience respiratory depression; short duration of sedation
Outcomes	
	<ul style="list-style-type: none"> <li>•Decreased severity of their post-ictal period (including less fatigue, muscle ache and pain) due to the shorter duration of their seizure</li> <li>•Quality of Life benefits: including a more positive attitude toward work, leisure and social activities and greater independence due to decreased anxiety over the inability to control their seizures</li> </ul>

# Pitfall 4

## Development plan not feasible

Shahram Hejazi, Ph.D.  
Jeff Edelson, M.D.

# "Indication for Use" Drives Adoptions and Defines Development Plan



# Development plan must focus on achieving Key Value Drivers

- **Milestones the company needs to focus on**
- **The scope of work required**
  - **Technical proof-of-concept (must have)**
  - **Alpha & *in vitro* data**
  - **Beta animal efficacy**
  - **Human data**
  - **FDA Approval**

# Execution of the Development Plan

- **Does the company understand what it takes to execute the development plan?**
- **Can the company address all the needs such as technology, business, regulatory to achieve milestones?**
- **Do you have access to resources to augment your knowledge and experience (e.g. Partnerships)?**
- **How much money and time to get to each Key Value Driver (milestone)?**

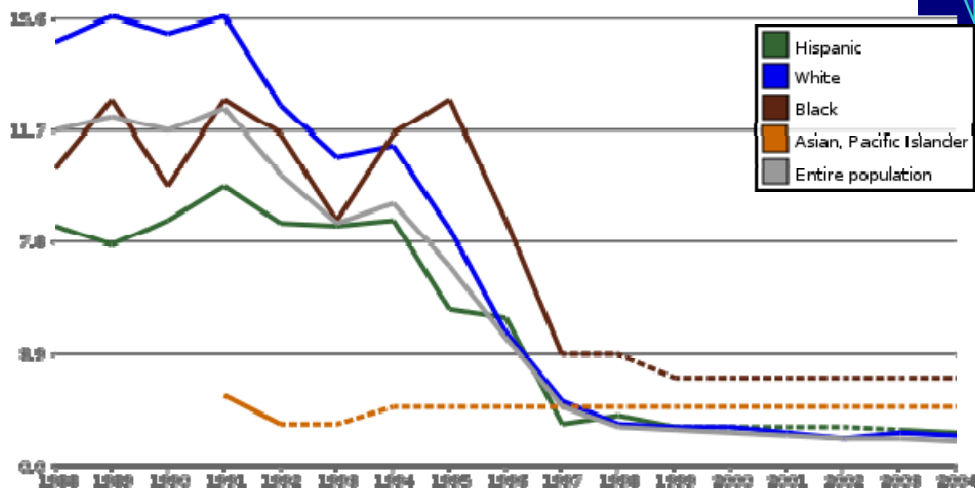
# Development Plan Feasibility

- **Tough study**
- **Regulatory miscue**
- **Big jump**

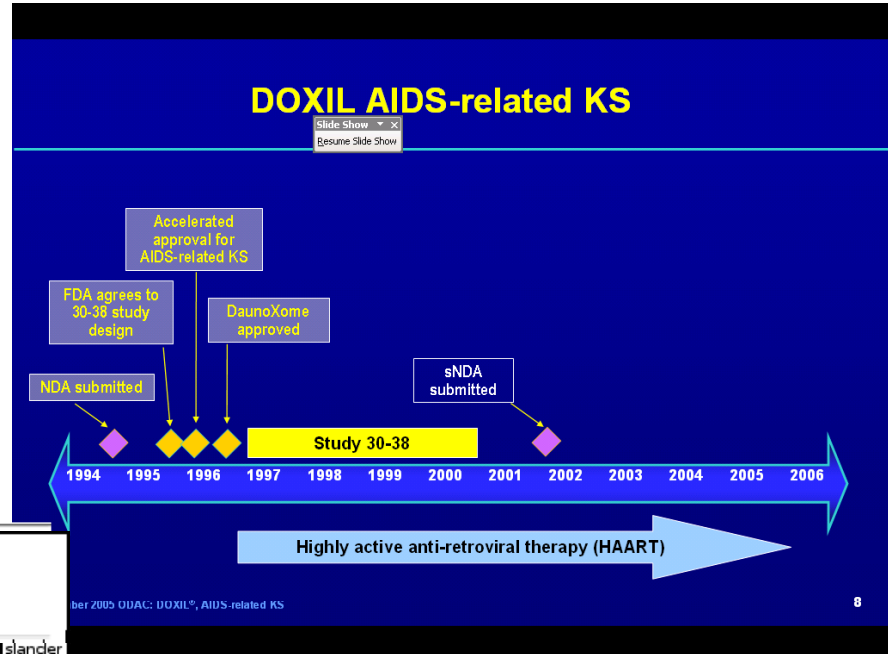
# DOXIL: Kaposi Sarcoma Confirmatory Study



[http://timothyministries.org/images/Kaposi\\_Sarcoma.jpg](http://timothyministries.org/images/Kaposi_Sarcoma.jpg)



[http://images.google.com/imgres?imgurl=http://www.openfindings.org/graphs/nccc/incidence2007/kaposi\\_sarcoma/year5.png&imgrefurl=http://www.openfindings.org/blog/id/4/&usq=\\_\\_rgcCdBoA\\_0ydkZDiaySQ4JUK7c=&h=300&w=600&sz=37&hl=en&start=15&sig2=KU2YBpnVnSKsK\\_Ud8l9z2Q&tbnid=cALuN\\_\\_pjj7u4M:&tbnh=68&tbnw=135&prev=/images%3Fq%3Dkaposi%2Bsarcoma%2Bincidence%26gbv%3D2%26hl%3Den&ei=fAUXSvSDL5zflQewo9nUCw](http://images.google.com/imgres?imgurl=http://www.openfindings.org/graphs/nccc/incidence2007/kaposi_sarcoma/year5.png&imgrefurl=http://www.openfindings.org/blog/id/4/&usq=__rgcCdBoA_0ydkZDiaySQ4JUK7c=&h=300&w=600&sz=37&hl=en&start=15&sig2=KU2YBpnVnSKsK_Ud8l9z2Q&tbnid=cALuN__pjj7u4M:&tbnh=68&tbnw=135&prev=/images%3Fq%3Dkaposi%2Bsarcoma%2Bincidence%26gbv%3D2%26hl%3Den&ei=fAUXSvSDL5zflQewo9nUCw)

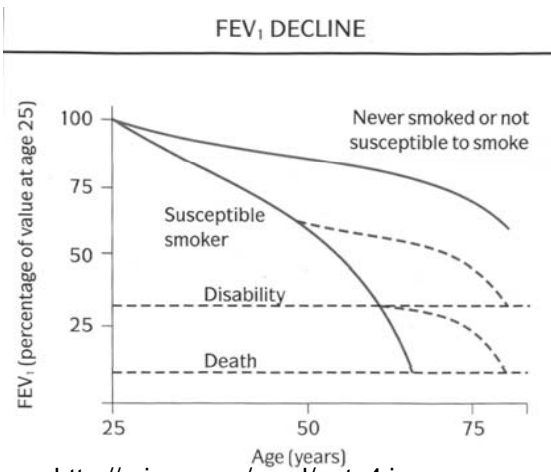


[http://www.fda.gov/OHRMS/DOCKETS/AC/05/slides/2005-4191S1\\_04\\_01-Johnson-Johnson.ppt#763,8,DOXIL AIDS-related KS](http://www.fda.gov/OHRMS/DOCKETS/AC/05/slides/2005-4191S1_04_01-Johnson-Johnson.ppt#763,8,DOXIL AIDS-related KS)

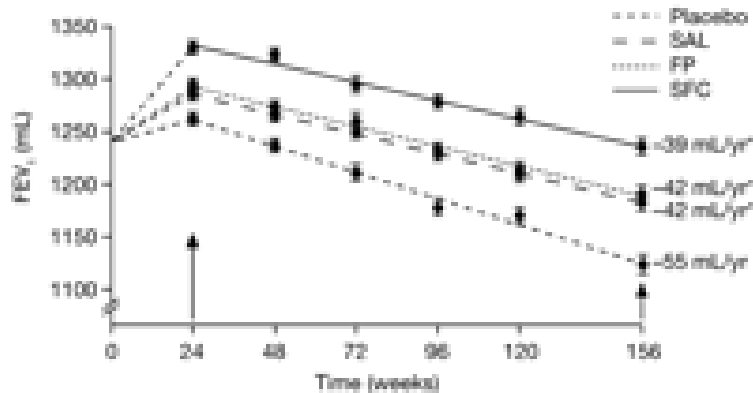
# Midazolam Nasal Spray: Regulatory Strategy

- **Versed approval:**
    - ♦ Roche
    - ♦ 1985
  - **IV is de facto standard for 2<sup>nd</sup> line treatment of status epilepticus**
  - **Nasal delivery system provides good bioequivalence, PK, PD**
  - **Only product approved in this space is a rectal gel**
  - **Therefore a 505(b)2 approach is feasible**
- BUT-**
- **Midazolam has never been approved for seizure treatment in any jurisdiction**
  - **Intermediate cost with high probability POS**
  - **Active P3 program at Ikano Therapeutics Inc.**

# COPD Disease Modifier



<http://priory.com/cmof/peto4.jpg>



No. of patients

Placebo	1201	1248	1128	1049	979	900	819
SAL	1234	1217	1218	1127	1084	1012	934
FP	1256	1248	1220	1157	1078	1006	908
SFC	1282	1275	1281	1180	1138	1073	975

- **Big, expensive studies**
- **Methodology and operationally complex**
- **No good surrogate for disease progression**
- **Difficult to support without shorter term clinical benefit**

*American Journal of Respiratory and Critical Care Medicine* Vol 178, pp. 332-338, (2008)

*BioAdvance*

## Pitfall 5

Commercial/business development  
strategy isn't feasible

# Commercial Strategy

- **Defines how your product will make money**
  - ♦ **Who buys it**
    - ... not just who uses it
  - ♦ **Who sells it**
  - ♦ **Cost of sales**
- **New companies use both established and novel commercial strategies**
  - ♦ **Established strategies require less elaboration**
  - ♦ **Novel strategies can represent a pivotal source of risk**

## Why Important?

- **A clear description makes the company look less risky / more credible**
- **Primary input for valuation**
- **Commercial strategy influences exit strategy**
  - ◆ **Firms acquire products that match an existing or desired commercial strategy**
  - ◆ **Products that improve the firm's strategic position can command a premium price**
  - ◆ **Barring an acquisition, some commercial strategies require an IPO**

# Objections

- **“If we meet a need, the customers will be there”**  
... ignores the inevitable barriers to entering markets
- **“We are exiting to a partner who will take care of the commercial strategy ...”**  
... does not recognize that acquisitions are based on commercial strategy

# Established Commercial Strategies

- **“Build the product, and they will come”**
  - ◆ Not unreasonable in the context of an established commercial strategy and well-defined unmet needs
  - ◆ Response to promotion is easy to envision / estimate
- **Example**
  - A new disease modifying drug for Alzheimer’s Disease**
  - ◆ Requires a primary care sales force
  - ◆ Established customers and metrics
  - ◆ Best exit - Trade sale to a major pharmaceutical company

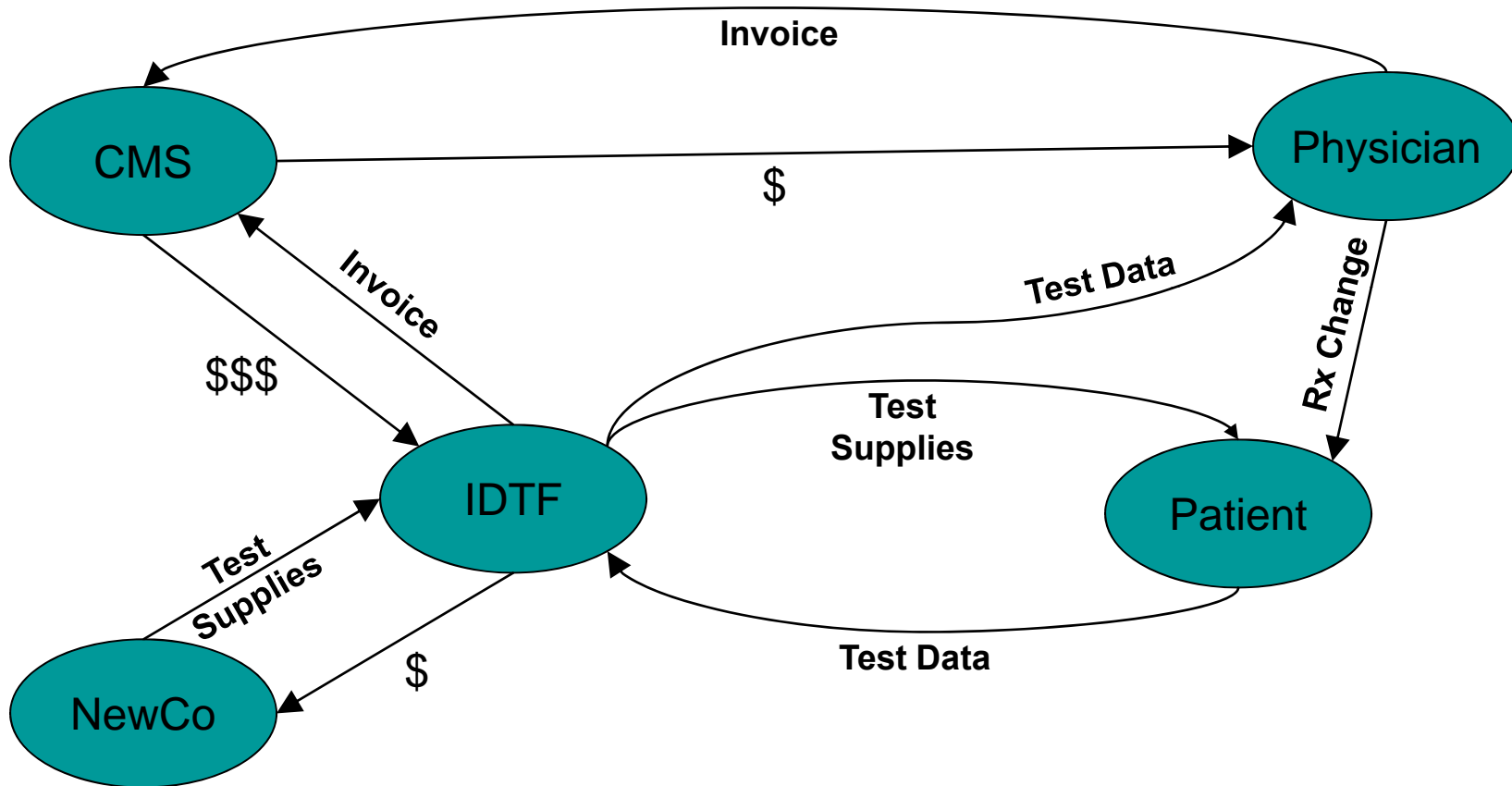
# Novel Commercial Strategies

- **“Build *the market*, or they will *never come*”**
  - ◆ Concrete identification of customers in terms of point-of-sale
  - ◆ Potential revenues from customers
  - ◆ Selling costs – via analogues / competition
- **Example**

A new vascular access device for dialysis patients

  - ◆ Unmet need: with current technology, dialysis grafts clog
  - ◆ Target customer: general / vascular surgeons
  - ◆ Reimbursement, market concentration will be a critical determinants of success

# Example: Coagulation Testing



# Coagulation Testing

- **Should the company sell the device or the service?**
  - ◆ What is the resulting point-of-sale?
  - ◆ Who will pay?
  - ◆ What are the barriers to entry for each strategy?
  
- **How should the company price the offering?**
  - ◆ What dollar value?
  - ◆ Should the device and consumables be sold separately?
  - ◆ Subscription?
  - ◆ Risk sharing?

## Pitfall 6

Great idea, but you can't stop others  
from doing the same thing

Barbara S. Schilberg, J.D.  
Marie A. Lindner, M.D.

# Do you have robust intellectual property?



**Company needs to own IP or have option/license in place**

- ◆ Rights should be exclusive

**IP should be provide competitive advantage (“strong, high fence”)**

- ◆ US and key international markets
- ◆ Sufficient patent life
- ◆ Claims are robust and appropriate for product
  - Composition claims are critical for therapeutic agents
  - Business method patents are not useful outside US
  - Target/tool patents low value because difficult to enforce

■ **IP should be sound**

- ◆ Patentability (novel; inventive; useful?)
- ◆ Freedom to operate



# Licensing Terms

- **Get the right kind of help with your license!**
- **License or option to patent rights and know-how**
  - ◆ **Terms must be favorable to company for investors and acquirers to accept**
    - Terms according to value of patent (tool patents don't add value because difficulty in enforcement)
    - Upfront cash payments and milestones should be reduced to enhance your ability to use your cash to answer key questions
    - Exclusivity
  - ◆ **Royalties to licensors come out of investors and founders' pocket**
    - Royalty stacking provisions: get licensors to reduce their royalty if you have to pay more than one
    - Typical need for antibody and protein manufacturing

# Pitfall 7

## Management team shortfall

Shahram Hejazi, Ph.D.

# Management Team

- **Do they have the right domain knowledge?**
  - Industry specific
  - Regulated industry
- **Do they have the operating experience?**
  - R&D, operations, business development, etc.
  - Early stage experience
- **Can they operate a virtual team?**
  - Hire and motivate the right people
- **Do they have a history of success?**

# What We Look For-Intangibles

- **Ability to listen and collaborate**
- **Creative**
- **Able to deal with adversity**
- **Know your strengths and weaknesses**
- **Ability to delegate**
- **Mutual respect**

## Common Issues

- **The management is a family team**
- **The company hires a CFO**
- **The wrong people for the stage of the company; e.g. sales & marketing professionals founding a drug discovery company**
- **Scientist partners with wrong business person**
- **The company is a hobby for the founder**
- **Addiction to the founder's comfort zone**

# We can help to strengthen your team

- **It's better to have no team than the wrong team**
- **We can help you with**
  - ◆ **Business experts**
  - ◆ **Boards (Advisory and Directors)**
  - ◆ **Attorneys (corporate and patents)**
  - ◆ **Access to other experts: regulatory, clinical, marketing, business development, etc.**
  - ◆ **BioAdvance Talent Database**

## Pitfall 8

You can't get there from here ...

# Milestones and Funding

- **How to get there?**
  - ♦ Break the project into milestones that either add value or reduce risk
  - ♦ Match each milestone with a funding source
  - ♦ Match milestones to earliest, most likely exits
  - ♦ This process can be optimized ...
- **We cannot build a bridge to nowhere**
  - ♦ Completing the seed stage syndicate is our immediate concern
  - ♦ BioAdvance will not fund a company that is unlikely to get Series A funding or a corporate partner
  - ♦ Some early milestones can attract funding

# Milestones and Funding

- **Problems – the market is imperfect**
  - ♦ *At each stage*, projects must generate returns that investors require
  - ♦ Therapeutic areas fall in and out of fashion
  - ♦ IPO markets open and close
  - ♦ Company strategy and pipelines change
- **Result – even good projects may be hard to match to funders / exits**
- **Attractive early milestones**
  - ♦ Predictive animal models
  - ♦ Preclinical exit opportunities
  - ♦ Interest from Series A funders

# Examples

- **Oncology is difficult ...**
  - ♦ Late clinical signal means that early milestones do not reduce risk
  - ♦ Exit markets require phase II data
  - ♦ Funders react accordingly ...
- **Platforms that are not easily validated at preclinical stages**

# BioAdvance Support

- **BioAdvance will help companies define milestones during the application process**
- **Review panel of Series A investors**
- **Syndication**
  - ◆ **Seed Funders**
  - ◆ **Angels**
  - ◆ **Venture Capital**
- **Business Development**
  - ◆ **Market test with corporate partners**

# Pitfall 9

## Unattractive Risk to Reward Ratio

Hal Broderson, M.D.

## Sources of Risk

- **Finance Risk – Bridge to nowhere?**
- **Technical Risk – Can it be done?**
- **Business Risk – Feasible business?**
- **Regulatory – Is it thought thorough and doable?**
- **Management – Proper skills?**
- **Intellectual Property – Can you own it?**
- **Market Risk – What is the unmet need and how big is it?**
- **Reimbursement Risk – Will someone pay for it?**

# Necessary Rewards

- **Investors invest for one reason—to make money**
- **What is an adequate return on investment?**
  - ♦ **LPs require 15-25% annual returns on a *portfolio* of companies but....**
  - ♦ **Winners pay for losers**

# Exit Multiples

To yield 40% annualized return

		Company Failure Rate			
		0%	15%	30%	45%
Exit Year	1	1.4	1.6	2.0	2.5
	2	2.0	2.3	2.8	3.6
	3	2.7	3.2	3.9	5.0
	4	3.8	4.5	5.5	7.0
	5	5.4	6.3	7.7	9.8
	6	7.5	8.9	10.8	13.7
	7	10.5	12.4	15.1	19.2

# Examples

Type	Therapeutic	Device
Exit milestone	End of Phase IIa	PMA
Years to exit	4-5	4-5
Cost to exit	\$40-50MM	\$20-30MM
Required multiple	8x	8x
Calculated exit requirement	\$320-400MM	\$160-240MM
Acquisition value (based on market size)	\$200MM (up front only)	\$75-100MM



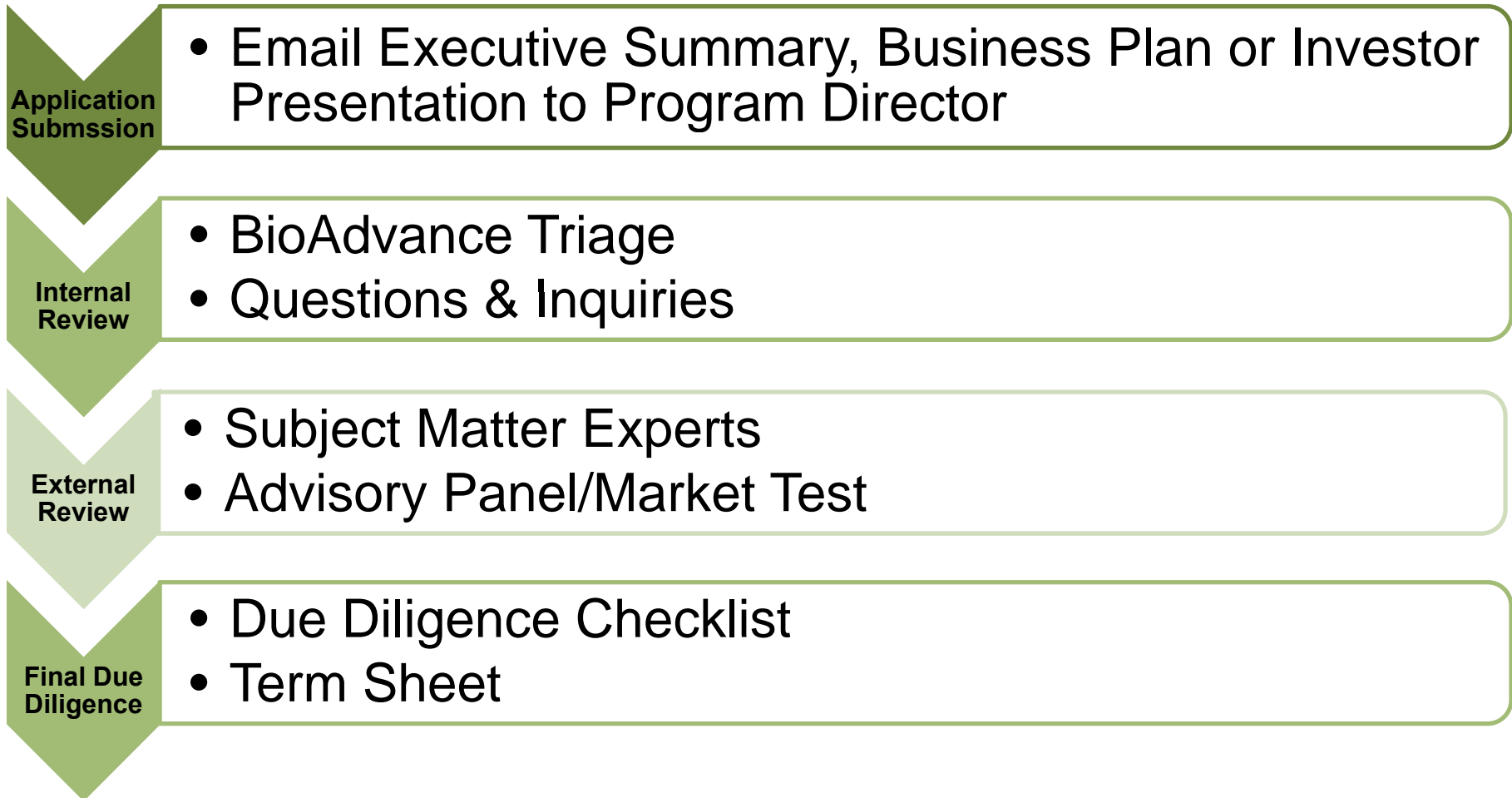
The risks must match  
the expected reward




# Application Process

Marnie McCoy

# BioAdvance Process



# Type of BioAdvance Investment

- 
- **Pilot Investment**
    - ◆ **Amount: Up to \$50,000**
    - ◆ **Goal: Answer Critical Question for Seed Investment**
      - Market Assessment
      - Freedom-to-operate analysis
      - Pre-clinical testing
    - ◆ **27% of Pilot Investments have rolled into Seed Investments**
  - **Seed Investment**
    - ◆ **Initial Investment of up to \$500k (\$1.2M over life of project)**
    - ◆ **Goal: Meaningful Milestone**

BioAdvance may recommend Pilot Investment at any stage of its review.

# Registration/Application

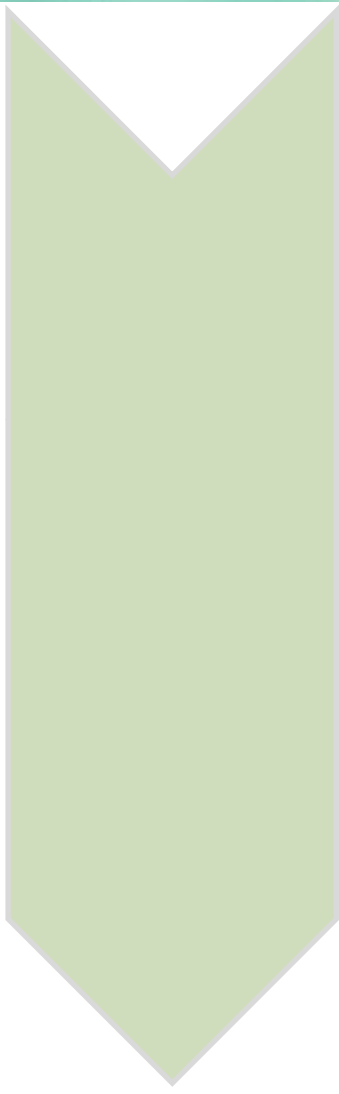
- **Email business plan, executive summary, investor presentation to Program Director.**
- **Elements of Opportunity BioAdvance will review:**
  - ◆ **Technical Plan**
  - ◆ **Commercial Opportunity**
  - ◆ **Intellectual Property & Licenses**
  - ◆ **Management Team**
  - ◆ **Financials and Budget**

# Internal Review

- **BioAdvance Triage**
  - ◆ **Program Meeting Review**
  - ◆ **Assign Team Lead**
- **Questions & Queries**

BioAdvance may invite company to present opportunity during this stage of review.

# External Review

- 
- **Subject Matter Experts**
    - ◆ **Scientific**
    - ◆ **Intellectual Property**
    - ◆ **Regulatory**
    - ◆ **Market**
    - ◆ **Reimbursement**
  - **Venture Path → VC Advisory Panel**
  - **Alternate Path → Corporate Partner**

# Corporate Due Diligence

- **Due Diligence Checklist**
  - ◆ **Review Corporate Documents**
  - ◆ **Contracts**
  - ◆ **Background Checks**
- **Term Sheet**
  - ◆ **Convertible Promissory Note**
  - ◆ **Default Valuation**
  - ◆ **Discount Factor**

# Timeline to Funding



**Better  
Information  
Provided**

**=**

**The Less Time  
We Take**

# Questions ???

## Contact:

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