

**\*Please Silence Your Mobile Phones\***

# Agenda

- |                          |   |
|--------------------------|---|
| <b>Introduction</b>      | <b>Anthony Johnson, Partner<br/>Buffalo BioSciences</b>   |
| <b>UB STOR</b>           | <b>Mike Fowler, Commercialization Manager<br/>UB Office of Science, Technology Transfer and Economic<br/>Outreach</b> |
| <b>Taconic</b>           | <b>Dr. Megan MacBride, Assistant Product Manager</b>  |
| <b>Q&amp;A / Wrap Up</b> | <b>Anthony Johnson</b>  |

# Taconic

Smart Solutions To Improve Human Health

## Distribution Pathways for Mouse Models

Megan MacBride, Ph.D

Associate Product Manager  
Taconic Transgenic Models™ and Emerging Models



Founded in 1952

# Taconic

Headquartered in Hudson, NY

**800 + Specialists, including DVM and PhD Scientists**

# Taconic Sites, Partnerships, Distributors



# Innovation: The Taconic Difference

- Unique Isolated Barrier Units
- Efficient transportation methods
- Genetically Modified Models
- Breeding expertise



# Colony Production

- Efficient Breeding
- Known Health Status
- Expert Colony Management
- Worldwide Accepted Distribution



# Colony Production

- Isolated Barrier Unit (IBU™) Production
- Taconic Murine Pathogen Free health status



# Custom Solutions

- Custom model generation
- Quarantine
- Rederivation
- Cryopreservation
- Colony production and maintenance
- Phenotyping
- Research Studies
- Molecular Analysis
- Surgery
- Health testing

# Distribution of Transgenic Animal Models

- Goals:
  - Facilitate sharing of research tools
  - Maintain control of your IP
  - Reduce the hassle involved in sending mice and rats to other researchers (for investigators **and** the tech transfer office)
  - Recover breeding and distribution costs and even gain money to fund continuing research at your institution

# Distribution of Transgenic Animal Models

- Several distribution pathways available
- To determine the best pathway, consider:
  - Transgenic Model Market
  - Product Considerations
  - Commercialization Process

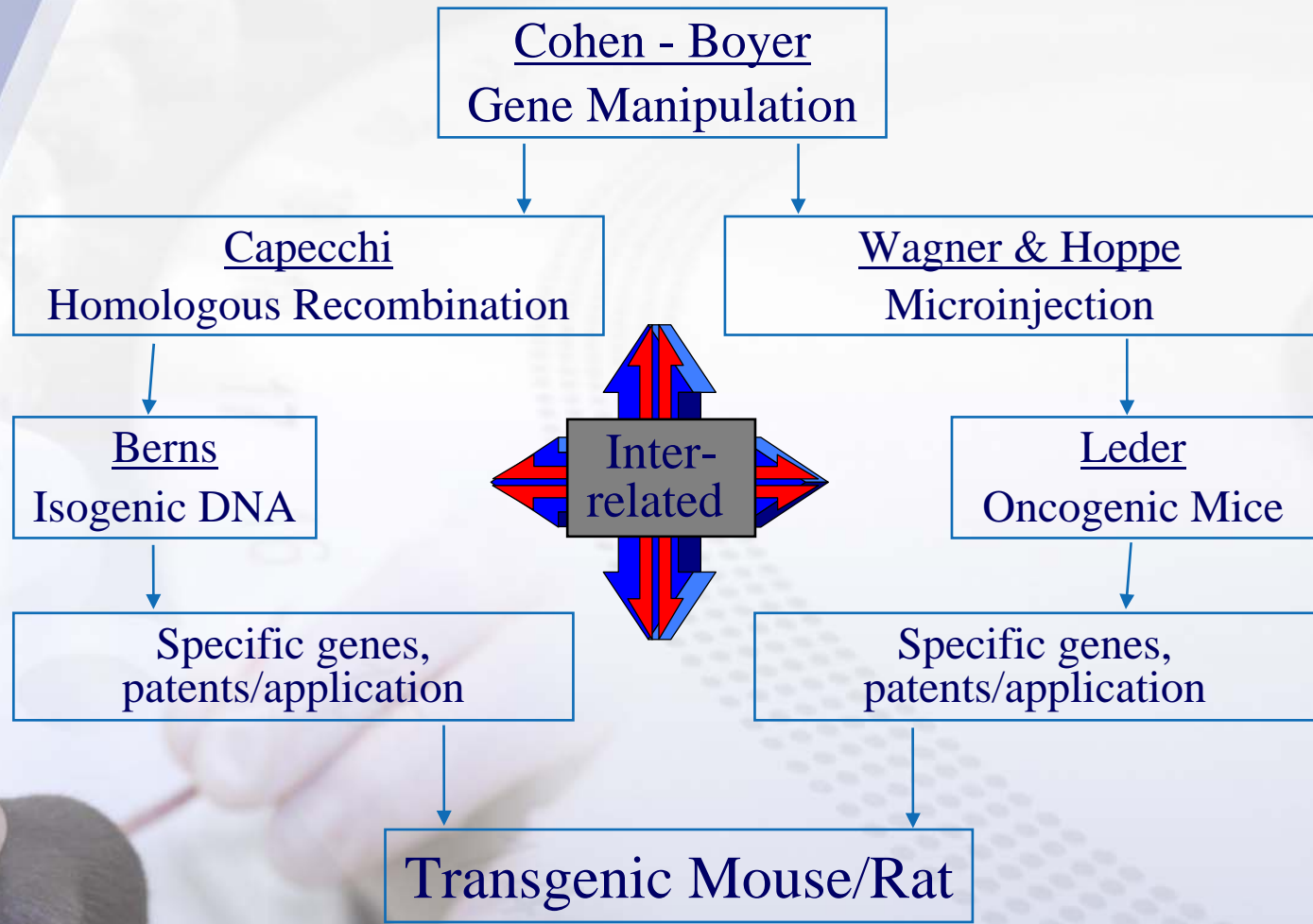
# Transgenic Model Market

- Market size
  - Genetically modified models represent \$1.3 billion market
  - Most of this is in-house production
- Points to consider
  - Academia
  - Industry
  - Does the model have broad application?

# Transgenic Model Market

- Model Development
  - Health Status
  - Genetic Stabilization
  - Reproductive Biology and Breeding Strategies
  - Genotype Identification
  - Phenotypic Expression
  - Wild Type Control
  - Legal Issues

# Intellectual Property Hierarchy



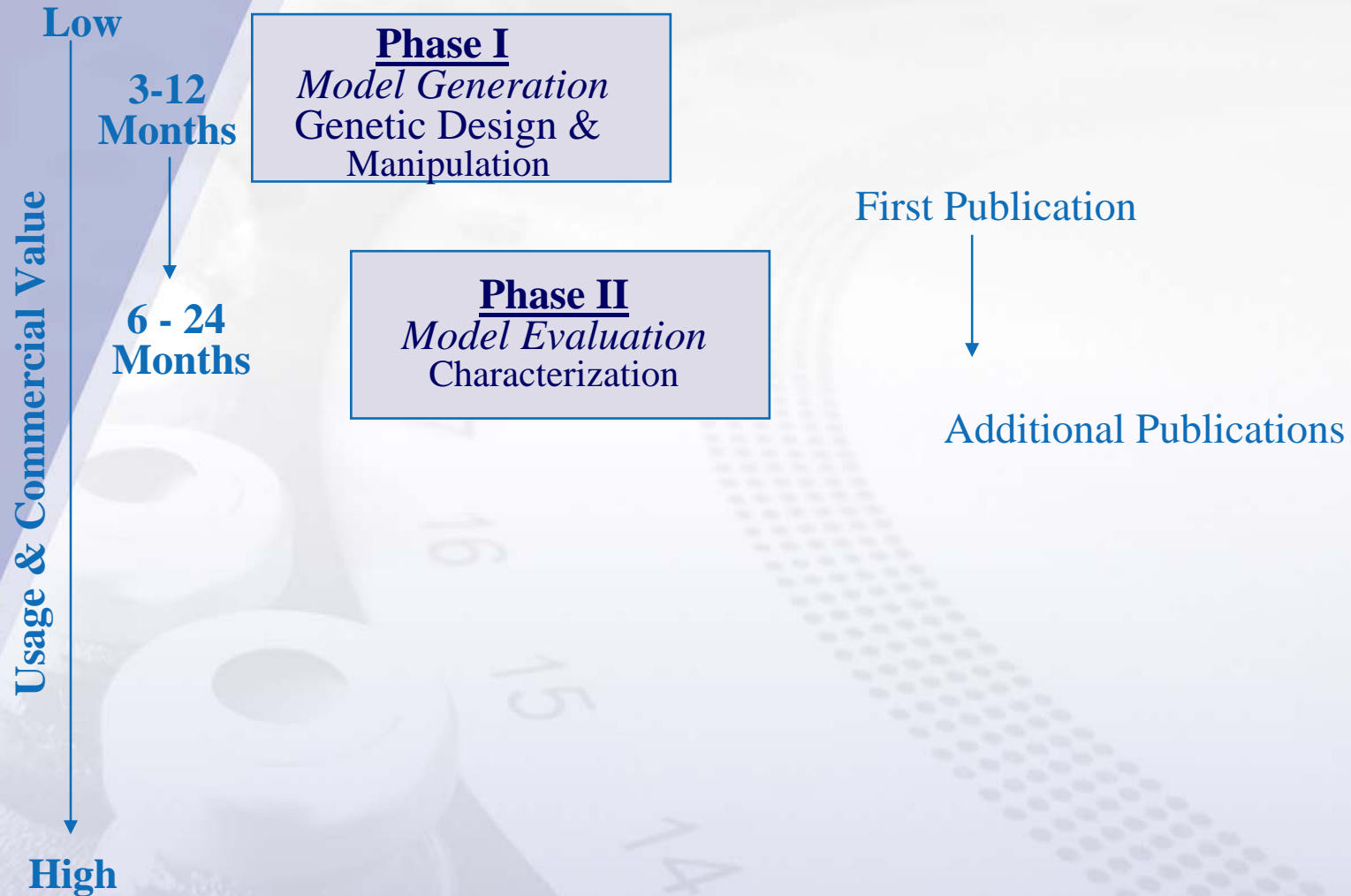
# Phases of Model Development

Low  
3-12  
Months  
Usage & Commercial Value  
High

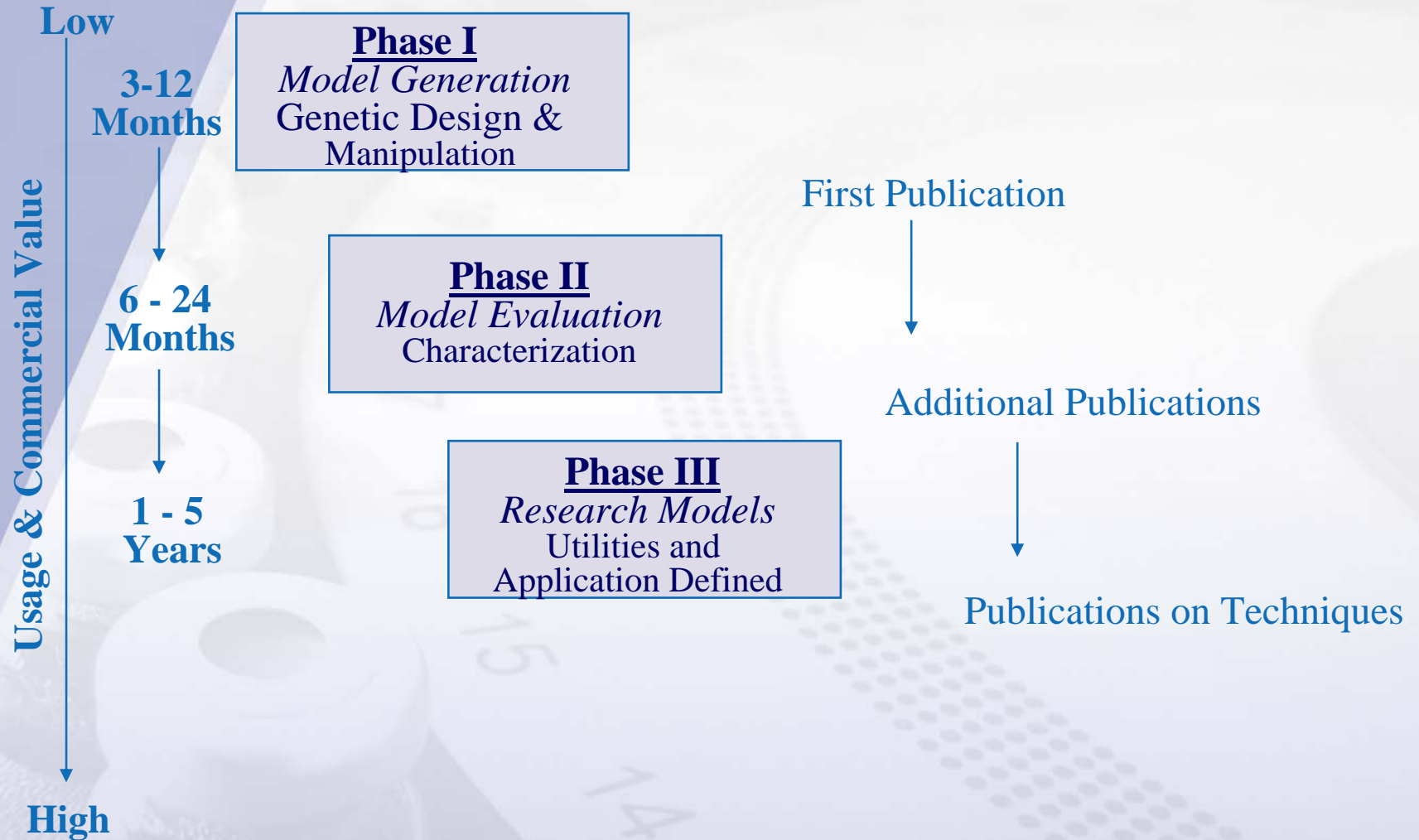
**Phase I**  
*Model Generation*  
Genetic Design &  
Manipulation

First Publication

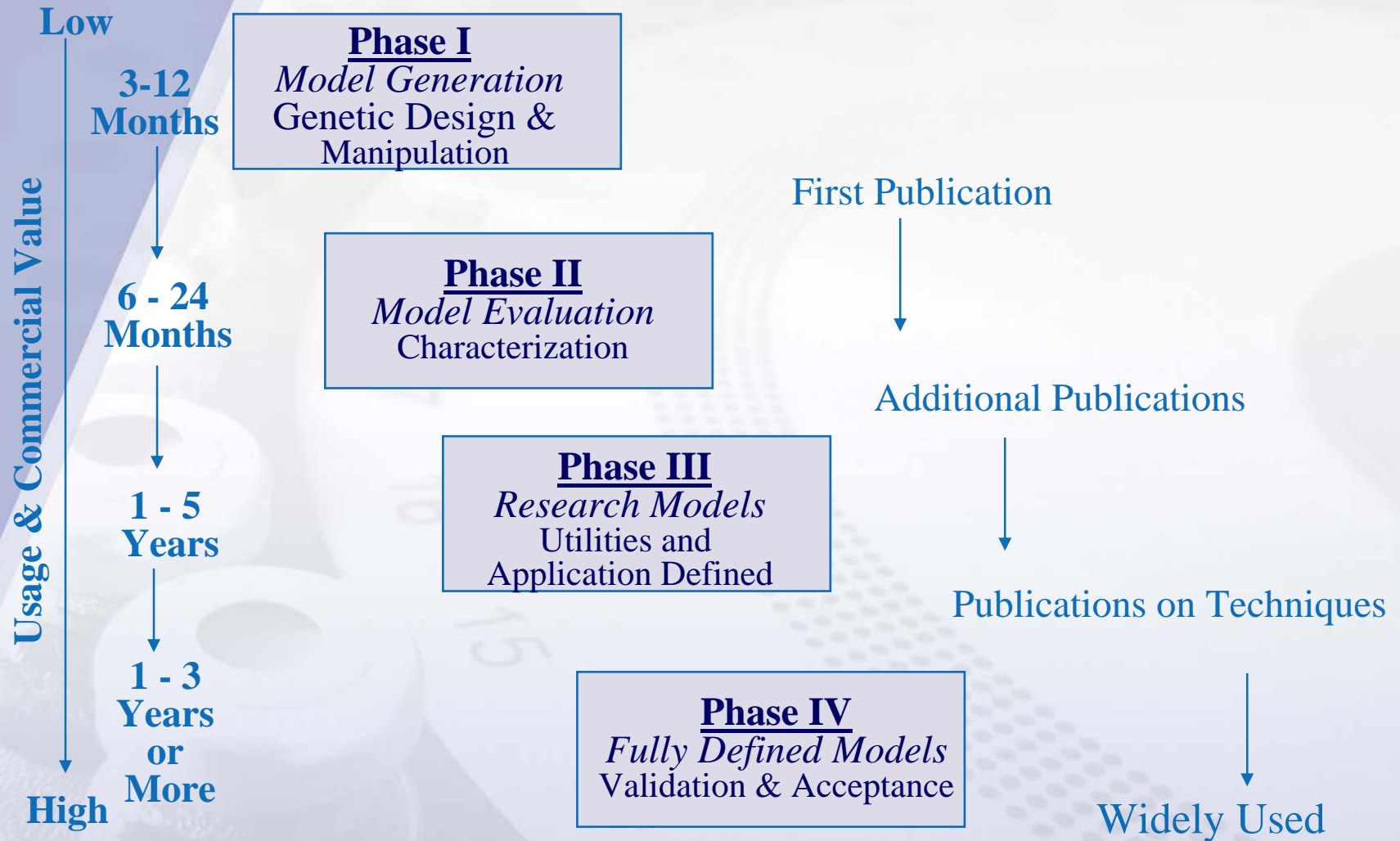
# Phases of Model Development



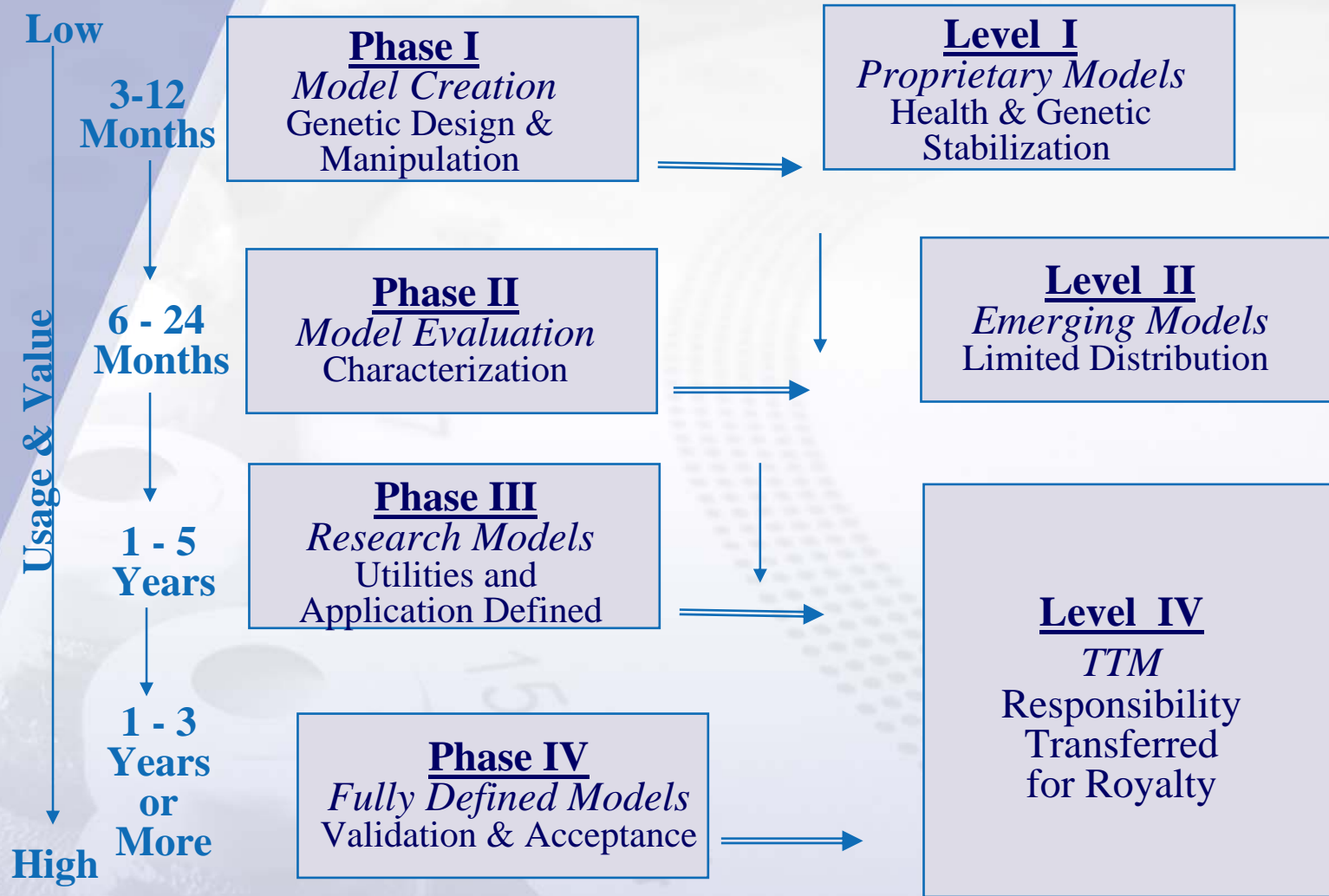
# Phases of Model Development



# Phases of Model Development



# Taconic Transgenic Exchange

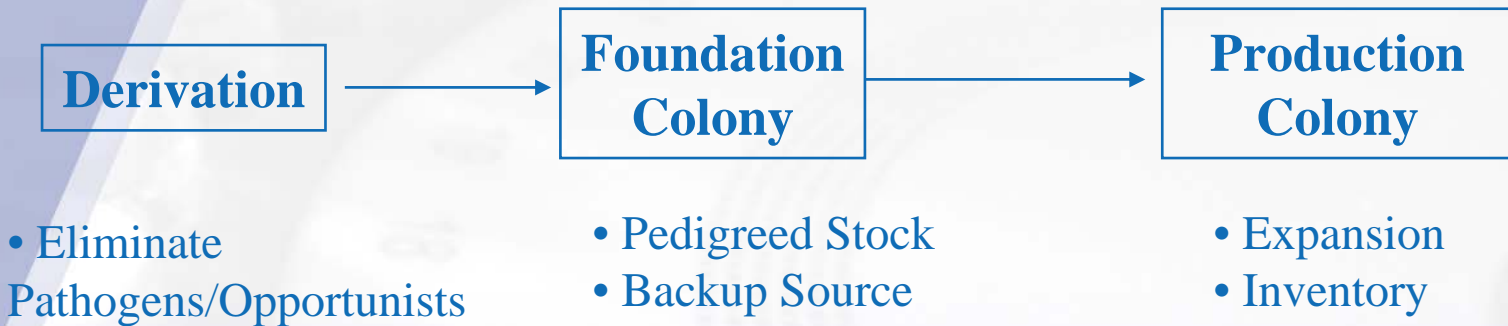


# Taconic Transgenic Exchange

- Provides:
  - Defined animal health (MPF production)
  - Stabilized genetic background
  - Access to intellectual property rights
- Facilitates:
  - Distribution
  - Offsetting production costs
  - Transgenic model exposure



# Production: Efficiency vs Costs



## ■ Cost/risk issues

- Breeding issues particular to a strain
- Genotyping
- Background strain definition
- Inconsistent market demand

# Distribution Pathways

- What is the best fit for a particular model?
- Two pathways most relevant to you:
  - Emerging Models
  - Taconic Transgenic Models™ (TTMs)
- Product life cycle considerations
  - Newer models may be best suited for EM program
  - As they develop and mature, may progress to TTM
  - Product life cycle may be lengthy; success of particular model not guaranteed
  - Irrelevant models should be retired

# Distribution Pathways

- What are your goals and needs for each model?
  - Licensing restrictions?
  - Limited or wide distribution?
  - Breeding/crossbreeding rights

# Emerging Models Program

- Taconic can help sponsors:
  - get inventory levels right
  - define MTAs
  - identify market
  - price models
- Better for models that may require certain restrictions

# Emerging Models Program

- Benefits

- Taconic handles MTA administration, order taking and fulfillment and invoicing
- Removes the burden of MTA administration from the Tech Transfer office and distribution burden from investigator/animal facility
- Sponsor retains control of the line – animals not sent without executed MTA

# Emerging Models Program

- Benefits

- Taconic animals can be accepted directly into most animal facilities without quarantine
- Allows for cost recovery on your distribution efforts
- Distributing your model with MPF health standard through Taconic allows for greater acceptance of model and use by the research community



# Taconic Transgenic Models™ (TTMs)

- Commercial mice offered off-the shelf with full licensing
- Candidates for TTM™ program must have significant commercial applications
- Taconic looks for models that complement our current research area portfolio
- We in-license these models and pay royalties
  - Must be sold under TTM Conditions of Use
- Taconic bears significant start up costs and time
  - Need to have good idea about potential market before investing in a model

# Taconic Transgenic Models™ (TTMs)

- Short term carcinogenicity
- Tumor biology
- ADME-Tox
- Cellular signaling/transcription
- Immunology
- Disease
  - Cardiovascular and metabolic disease
  - Inflammatory disease
- Endocrinology
- Neurology

# Taconic Transgenic Exchange

	Level I <u>Proprietary Model</u>	Level II <u>Emerging Model</u>	Level III & Level IV <u>ITM</u>
<b>Distribution Limited</b>	Yes	Yes	No
<b>Marketing</b>	No	Yes	Yes
<b>Order Processing</b>	PI	Taconic	Taconic
<b>Invoicing</b>	N/A	Taconic	Taconic
<b>Production Costs</b>	PI (offset by distribution)	PI	Taconic
<b>Revenue Sharing</b>	N/A	Yes	Royalty May Apply

# Taconic Transgenic Exchange

- The best distribution pathway will be different for each model, and may change throughout the life cycle of that model



# Mouse Models: the Money Factor

- Let's consider several cases:
  - Emerging Model (development phase)
  - Typical TTM™
  - Blockbuster TTM™



# Emerging Model

## ■ Hypothetical Case

	# of Users	Studies per users	Mice per study	Saleable Pups Produced	Number of Mice Sold	Price per animal	Revenue to Sponsor	Costs	Net Revenue to Sponsor
Year 1	5	3	10	200	150	\$ 50.00	\$ 6,000	\$10,582	<b>-\$4,582</b>
Year 2	8	4	10	520	300	\$ 50.00	\$ 12,000	\$10,956	<b>\$1,044</b>
Year 3	10	5	10	520	500	\$ 50.00	\$ 20,000	\$10,956	<b>\$9,044</b>

## ■ Assumptions

- Year 1 includes rederivation and start of production colony (fewer saleable mice avail.)
- Colony sized to produce 5 mice/sex/week
- Study size and colony size remain constant
- No yearly cost/price increases

# Evaluating a model

- Broad appeal and multiple applications are best
- Models with primarily an academic market often are well suited as EMs, but rarely make good TTM
- We evaluate current Emerging Models for movement on to TTM program on regular basis

# Your Favorite Model

- Taconic will evaluate models and recommend the best distribution pathway
- Contact your Area Technical Representative or call me



**Thank you!**

## Upcoming Events

*May 6-9 BIO 2007 Boston, MA  
Stop by the NY Loves Bio Pavilion #1833*

*May 10, 2007 – Empowering Genomic Discoveries with the Agilent  
Microarray Platform  
Dr. Iman Kishawi, Senior Applications Consultant, Agilent*

*May 24, 2007 - NutriCyte Corporation  
Putting it all Together From New Launch to  
BioManufacturing Business Within One Year!  
Vic Nole, President & CEO*

**Immediately Following this Presentation  
Stop over to Doubletree Hotel for Beakers n' Beer and  
network with medical campus professionals 5-7pm**