

Corporate Medical Product Development: Some Lessons Learned

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Focus: Medical Product Development

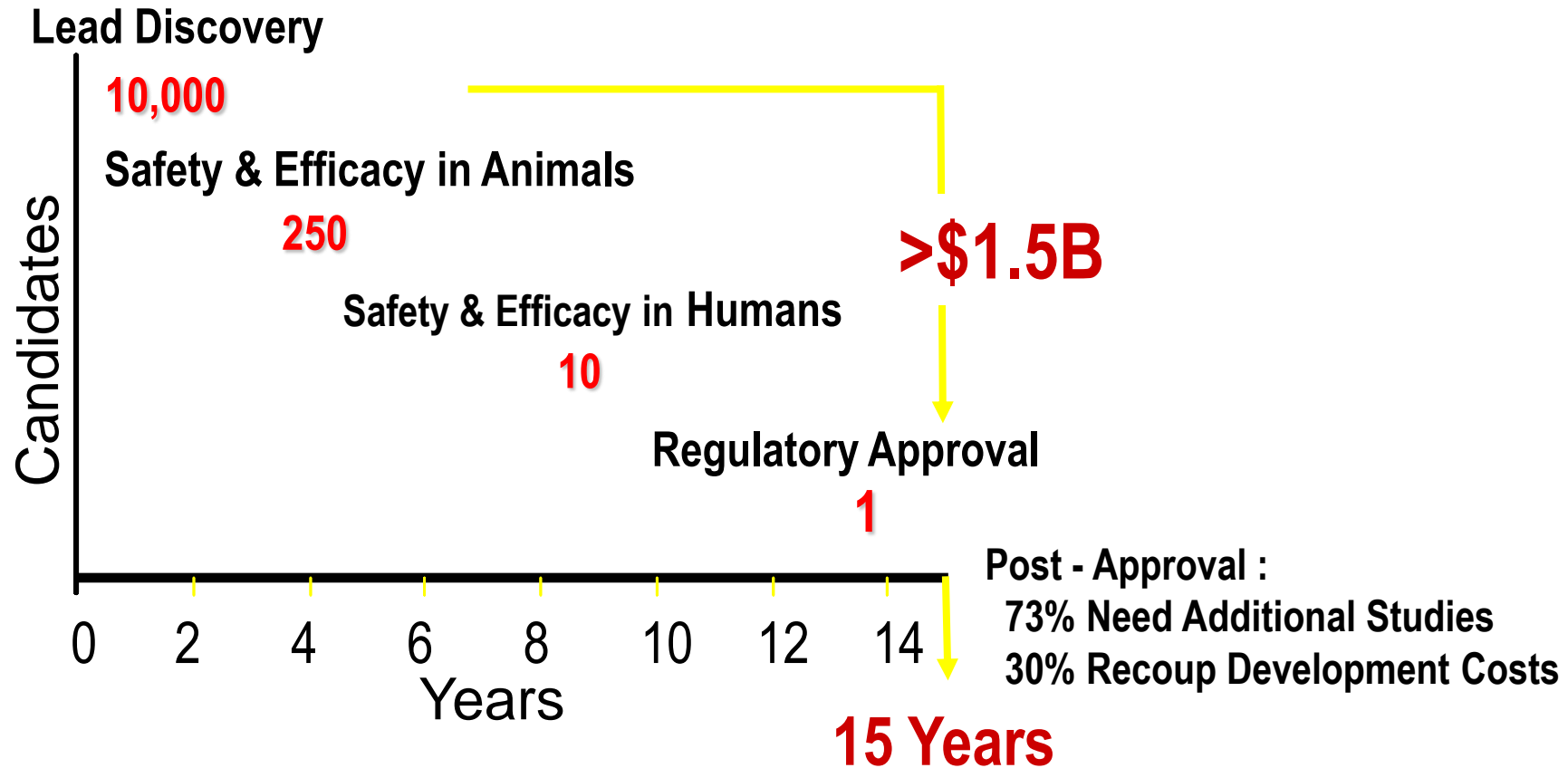
Statistics, World Market Revenues

Pharmaceuticals-	~\$700	Billion (2008)
	~\$825	Billion (2010 Est.)
	~\$925	Billion (2013 Est.)
▪ Medical Devices-	~\$250	Billion (2008)
	~\$290	Billion (2009)
	~\$312	Billion (2010 Est.)
▪ Biotech Products-	~\$80	Billion (2007)
	\$89.7	Billion (2008)
	\$79.1	Billion (2009) (-Genentech)
	\$128	Billion (2009) (+Roche/Genentech)
▪ Combination Products-	\$5.9	Billion (2004)
	~\$9.5	Billion (2009 Est.)
▪ Cell-Based Products-	<\$1	Billion (2010)

<http://www.businesswire.com/news/home/20110121005863/en/Research-MarketsBiotechnology-Industry-2010-Yearbook->
http://www.hospimedica.com/business/articles/294732858/global_medical_device_revenue_to_top_us300_billion.html
<http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=500e8fabadf24210VgnVCM100000ed152ca2RCRD&vgnnextchannel=b5e57900b55a5110VgnVCM10000071812ca2RCRD&vgnnextfmt=default>
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<http://www.bharatbook.com/detail.asp?id=82963>
<http://www.vfa.de/en/statistics/pharmaceuticalmarket/>
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<http://bioingredients.com/articles/2007/04>
<http://www.pharmameddevice.com/App/homepage.cfm?apname=100485&linkid=23294&moduleid=3162>
<http://pharmtech.findpharma.com/pharmtech/Article/Bleak-Times-for-the-Global-Biotech-Industry/ArticleStandard/Article/detail/601471>

Development Costs

Pharmaceuticals/Biopharmaceuticals



Typical Development Costs for New Class III Medical Device (Rough Estimate)

- Preclinical Costs- \$10-\$20M
- Clinical/Regulatory Costs- \$20-\$40M
- Sales, Marketing, Finance, Etc.- \$10-\$20M
- Manufacturing Development- \$10-\$15M
- **Total Costs to Launch- \$50-\$95M**

Timescale: 5-10 Years

Combination Products (Reed Life Sciences, 2007)

Estimated 30% of New Medical Products

Recent FDA Combination Product Approvals Include:

- Absorbable Collagen Sponge With Genetically Engineered Human Protein
- Antibiotic Bone Cement
- Catheter Lock / Flush Solutions
- Dental Bone Grafting Material With Growth Factor
- Daytrana Transdermal Patch for ADHD
- Dermal Collagen Implants For Aesthetic Use
- Dermal Iontophoresis System
- DUPLEX Drug Delivery System for use With Cefoxitin
- Emsam Transdermal Patch for Depression
- Exubera Inhaled Form of Insulin (rDNA)
- Fibrin Sealant
- FluMist Influenza Virus Vaccine, Live, Intranasal
- Glucose Monitor / Insulin Pump
- Human Fibroblast-Derived Dermal Substitute
- Infuse Bone Graft
- Iontophoretic Drug Delivery Patch And Controller
- Lumbar Tapered Fusion Device With Human Protein
- Methyl Aminolevulinate Cream With Halogen Light Source
- Paclitaxel-Eluting Coronary Stent System
- Peginterferon Alfa-2a in combination with Ribavirin
- Photodynamic Therapy
- Sirolimus-Eluting Coronary Stent
- Spinal Fusion Putty
- Surgical Mesh With Antibiotic Coating
- Tositumonab and Iodine I 131 Tositumomab
- Vitagel Surgical Hemostat

Efficiency of Corporations, 2009*

(Net Cost Per Employee for Operations)

Firm	2009			<u>R-E/# =</u> <u>Cost/Employee</u>	
	Revenues (R)	-Net Earnings (E)	Employees (#)	2009	2007
Medtronic	\$14.599 B	\$2.169 B	38,000	\$327,000	\$297,000
Boston Sci.	\$8.188 B	\$-1.025 B	26,000	\$354,000	\$354,000
C.R. Bard	\$2.535 B	\$0.461 B	11,000	\$188,000	\$176,000
J&J	\$61.9 B	\$12.9 B	114,000	\$351,000	\$435,000
Genzyme	\$4.5 B	\$0.4223 B	11,000	\$371,000	\$406,000
Amgen	\$14.64	\$5.01 B	17,200	\$560,000	\$663,000
Novartis	\$44.267 B	\$10.3 B	100,000	\$440,000	\$261,000

Focal, Inc.(1992-2001), Peak Burn Rate/Peak # Employees:~\$19M/125 = ~\$152,000

*Sources: Corporation Websites

Product Development Pathway



*Discovery

**** Implementation:**
Manufacturing
Sales
Marketing

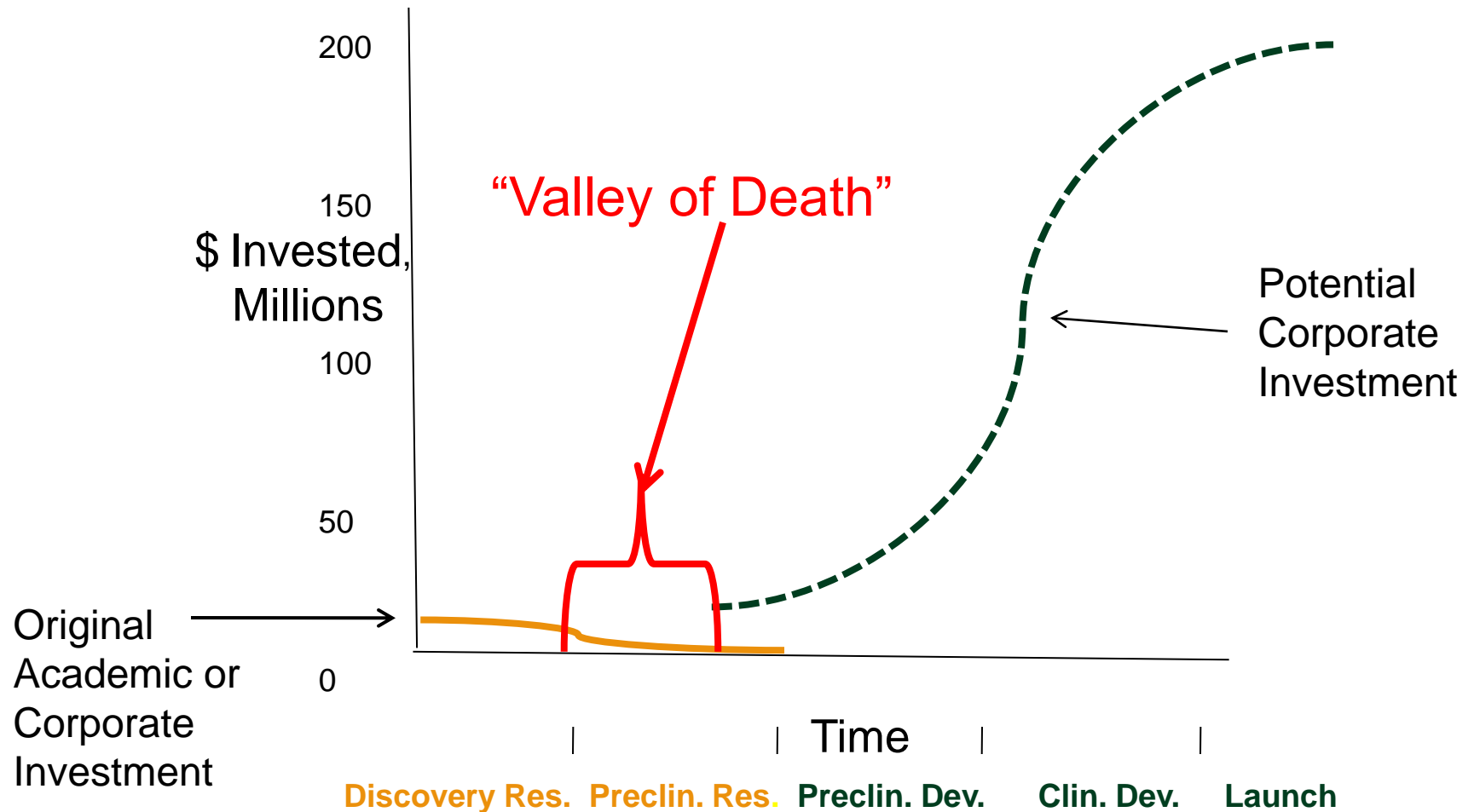
Hypothetical Case: New Biologic/Device Combination Product

Assumptions:

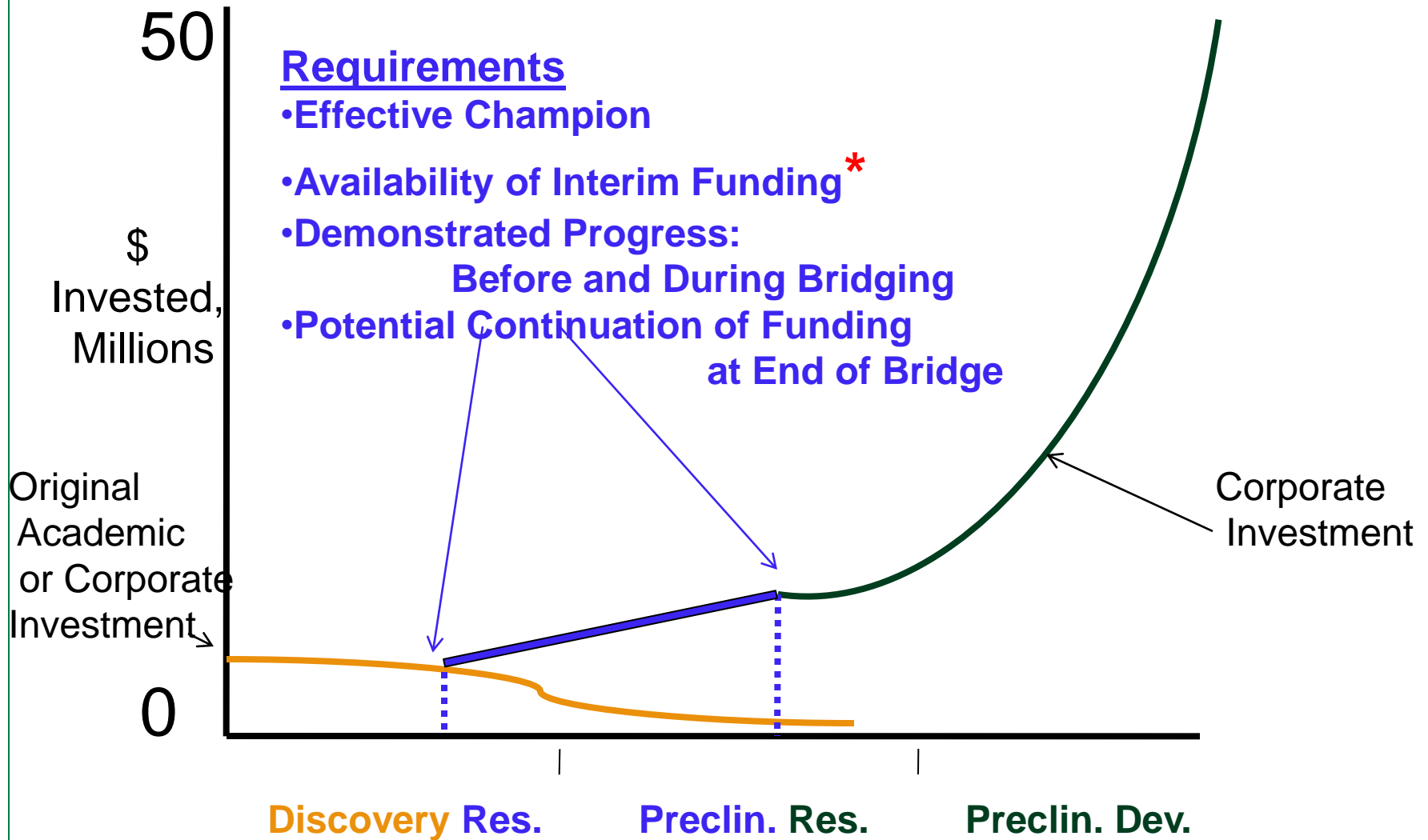
- Existing Delivery Matrix/ Recombinant Natural Protein (e.g., BMP-2)
- ~\$200 Million Development Costs
- Initial R&D with VC, “Angel,” or Government Funding
- Initial Funding Only Covers Discovery Research +
Limited Preclinical Research
- Follow-On Funding needed to Bridge Discovery → Development



Most Product Development Fails in the “Valley of Death”

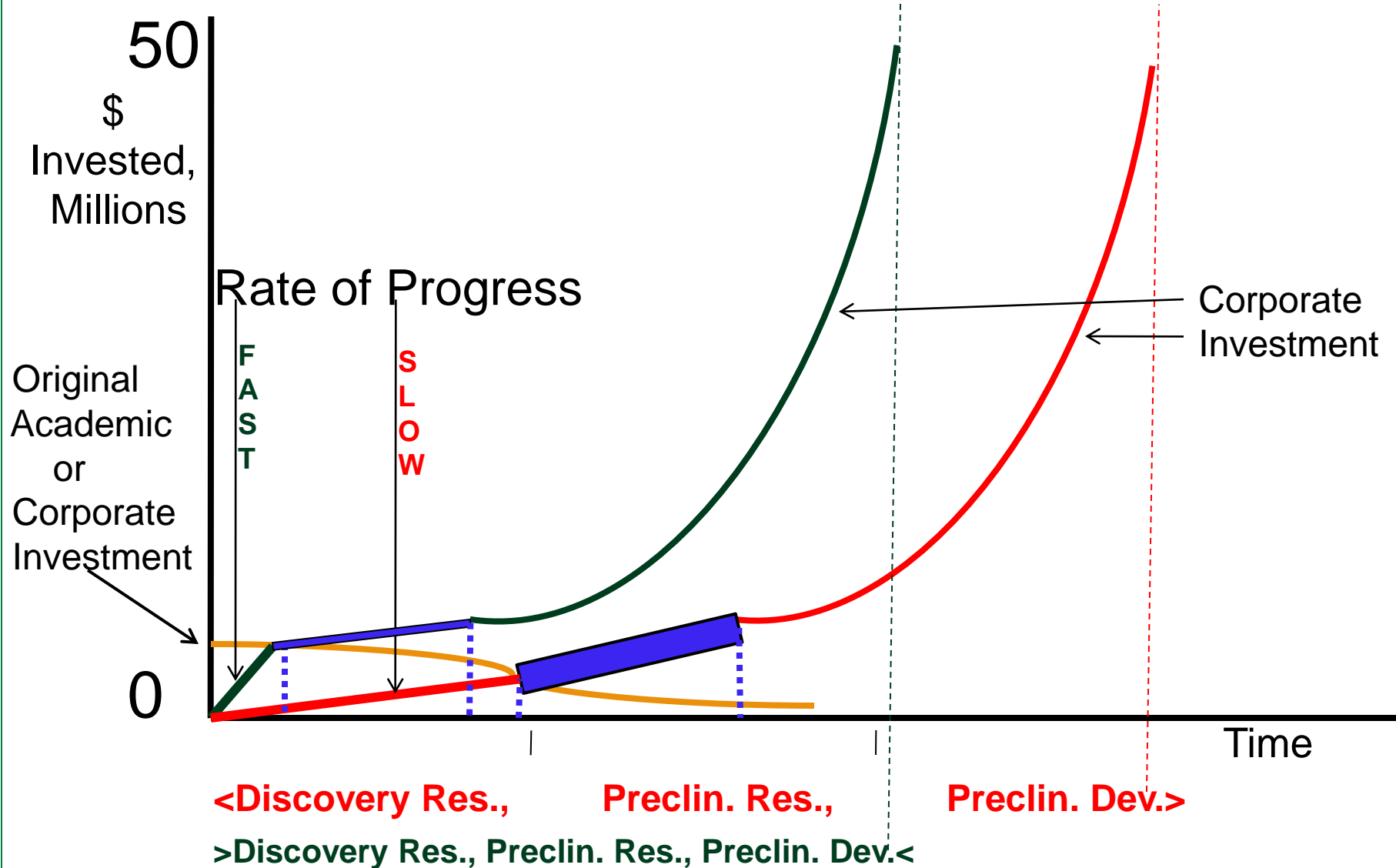


Bridging “Valley of Death”



*VC, Government, “Angel,” Foundation, Corporate, Etc.

Translation Requirements



Product Development: Selection Criteria

- Mission, Vision, Culture
- Product Mix Strategy
- Fiscal “Health,” (Finances, Stock Movements, Etc.)
- Maturity: Start-up → Mature
- Potential Adoption Curve
- Market Potential
- Reimbursement Potential
- Intellectual Property, Internal or External
- Competition
- Project Champion
- Staff Capabilities: Lab, Clinical, Manufacturing (Scalability), Sales, Marketing, Etc.
- Availability of Staff for Project, Staff Mix
- Availability of Materials, Products from Outside
- Physical Plant: Equipment, Space, Etc.
- Project Costs
- Timing Considerations: Handoffs, Funding, Regulatory, Clinical, Marketing, Etc.
- Publication Strategy
- Business Climate: Economic, Societal, Regulatory, Liability, Image, Morale, Etc.
- Exit vs Survival Strategy

Strategic Product Choices

Comparing 2 Products

Market	# Patients
Product Sophistication	High-Low
Development Costs	\$\$\$-\$
Regulatory Pathway	PMA-501K
Implementation	Elective-Imperative
Utilization	%
Unit Price	\$
Market Potential	\$
New Product Intro	Timing
Implications	Product Improvements, Pipeline , etc

Limits to Value of Academic Licenses

Comparing Academic vs. Corporate Investment

- University vs Corporate Expenditures
- Funding Sources, University vs. Company
- Contribution of University vs. Company to Intellectual Property
- Stage of Development at Time of Licensure
- Totality of Licenses for Product
- Projected Revenues and Profits at Time of Licensure
- Degree of Risk Assumption by Company
- Profitability of Product when Marketed

Concluding Remarks

If medical product is goal:

- Be product-focused from the start
- Select product/project based on meeting **Product Development Selection Criteria** *a priori*
- Urgently make as much progress as possible with initial funding
- Appoint effective, articulate “Champion” to advance project, develop bridge funding, strategic partners
- Use “bridge” funding to make maximum product-oriented progress
- Collaborate with strategic partner during project transfer and for problem solving thereafter if applicable
- Have realistic expectations of state of progress and value of technology if academic-corporate transfer: Medical products may be derived from many patents
- Expect goals, project plans and evaluations to be driven by quality system (e.g. ISO 13485) imperatives in development stage
- Realize that, no matter how great the staff and promising the product, most programs change original direction, but:
- The experience, knowledge and reputations gained are never lost for future enterprises.

Thank You!

