

Virtual Integration

Transforming the Pharmaceutical Industry

November 18-19, 2010
University of California, Berkeley
Haas School of Business

Ted Torphy, Ph.D.
Vice President & Head
External Innovation
Research Capabilities
Johnson & Johnson Pharmaceutical R&D, L.L.C.

Pharma

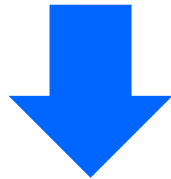


The Messages

- ❑ The pharmaceutical industry is in a state of crisis
- ❑ The basis for the crisis is a lack of innovation
- ❑ Obsolete R&D business models underlie the innovation gap
- ❑ Revitalizing the industry will require Open Innovation to create a “virtually integrated” R&D ecosystem

The Pharmaceutical Industry in Crisis

- ❑ Downward pricing pressure
- ❑ Redistribution of healthcare outcomes information
- ❑ Ever increasing regulatory requirements
- ❑ Patent expiries
- ❑ Insufficient R&D productivity

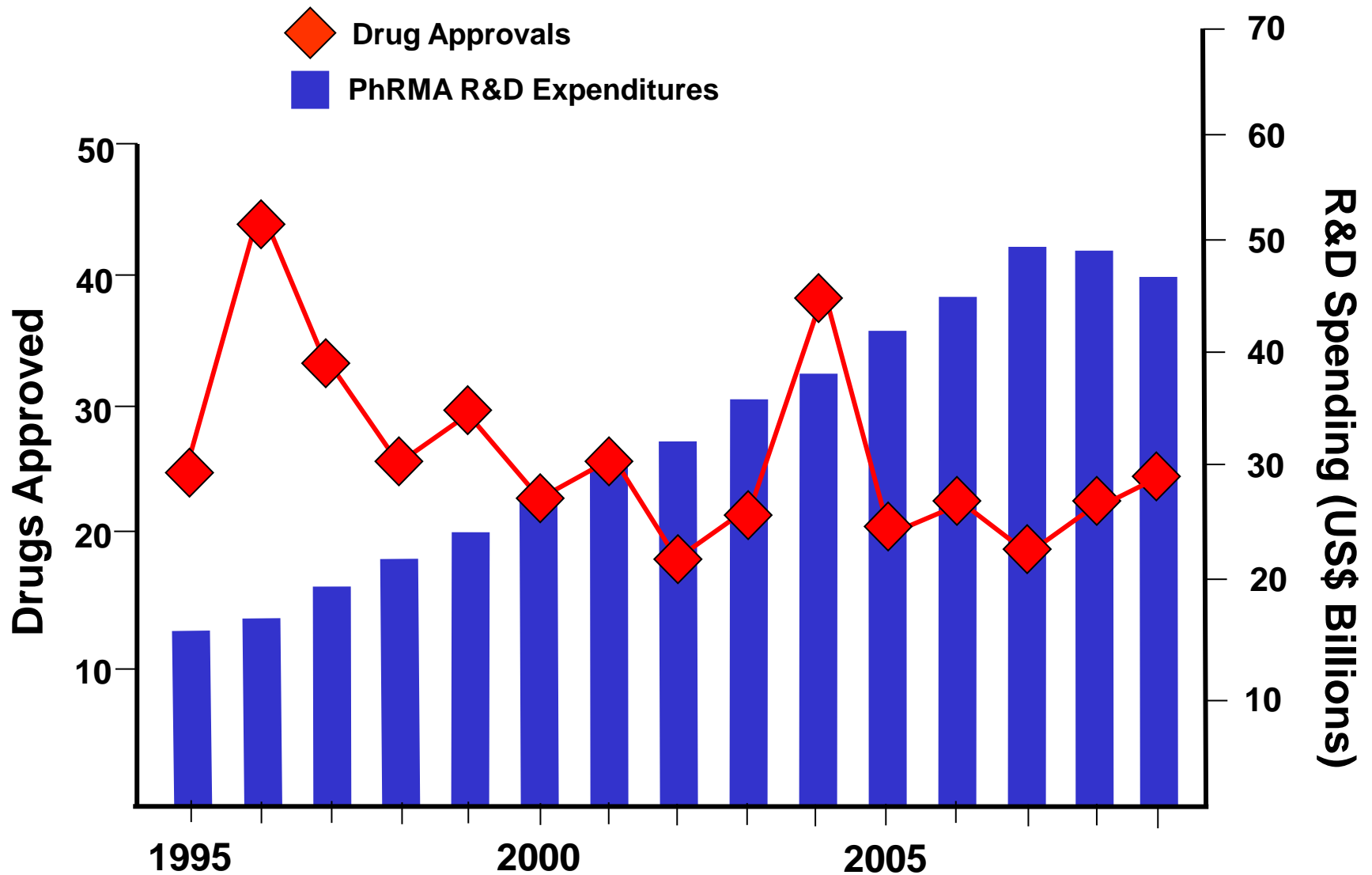


- ❑ Creation of new R&D business models



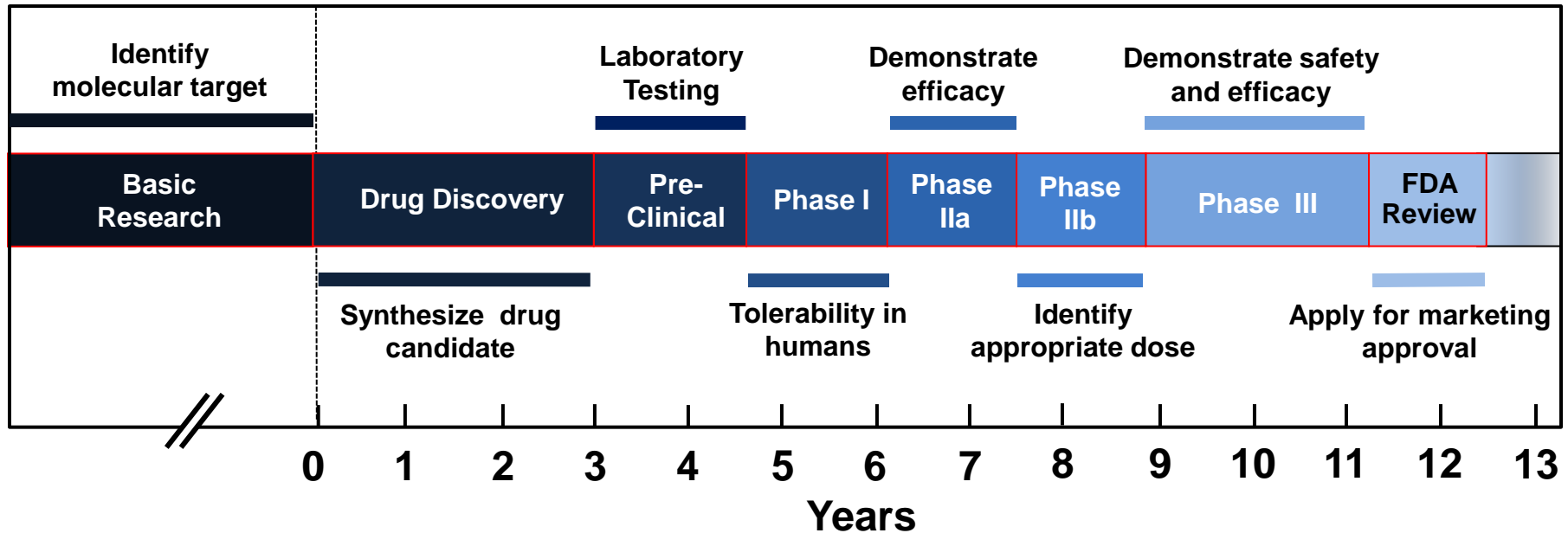
- ❑ Opportunity for industry transformation

Productivity of the Pharmaceutical Industry¹



¹Sources: PhRMA, BIO, Burril & Co

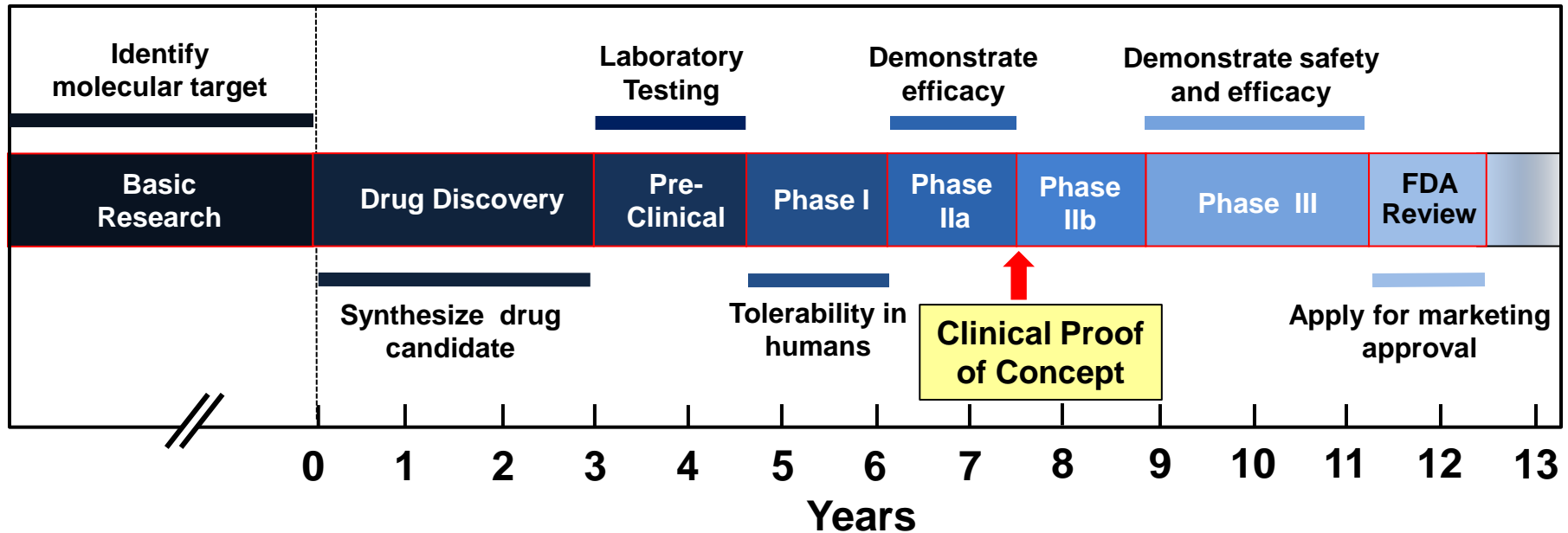
Pharmaceutical R&D Is a Long, Expensive Process



- ❑ Developing a new drug is a lengthy process
 - Product cycle times are extremely long
 - The 20-year limit on patent protection means there is a limited number of years during which a marketed product can generate an attractive ROI
- ❑ The cost of putting a new drug on the market is \$0.8 to \$1.3 bn¹

¹Adams C, Brantner V (2006). "Estimating the cost of new drug development: is it really 802 million dollars?" *Health Aff* 25 (2): 420–8

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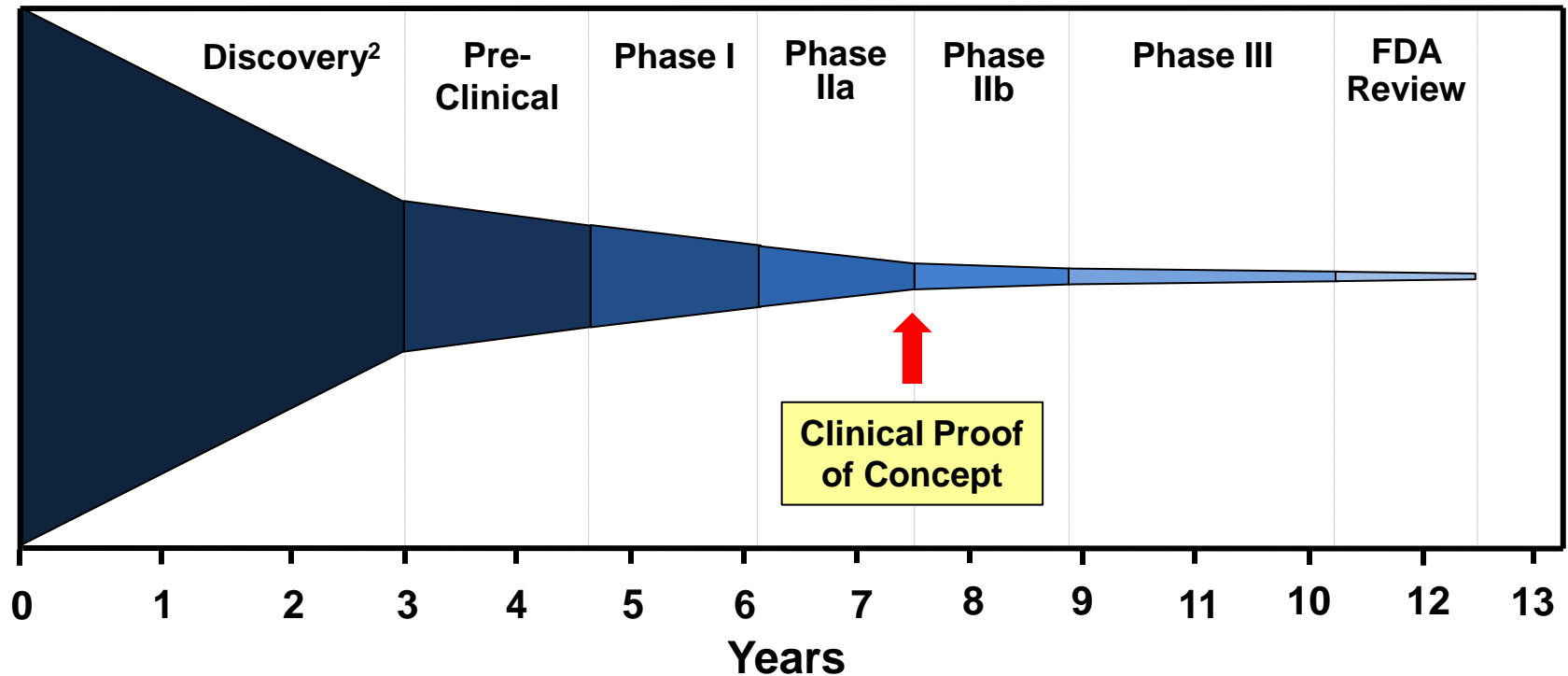


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Pharmaceutical R&D Is High Risk

Cumulative Risk Profile through Key Stagegates¹

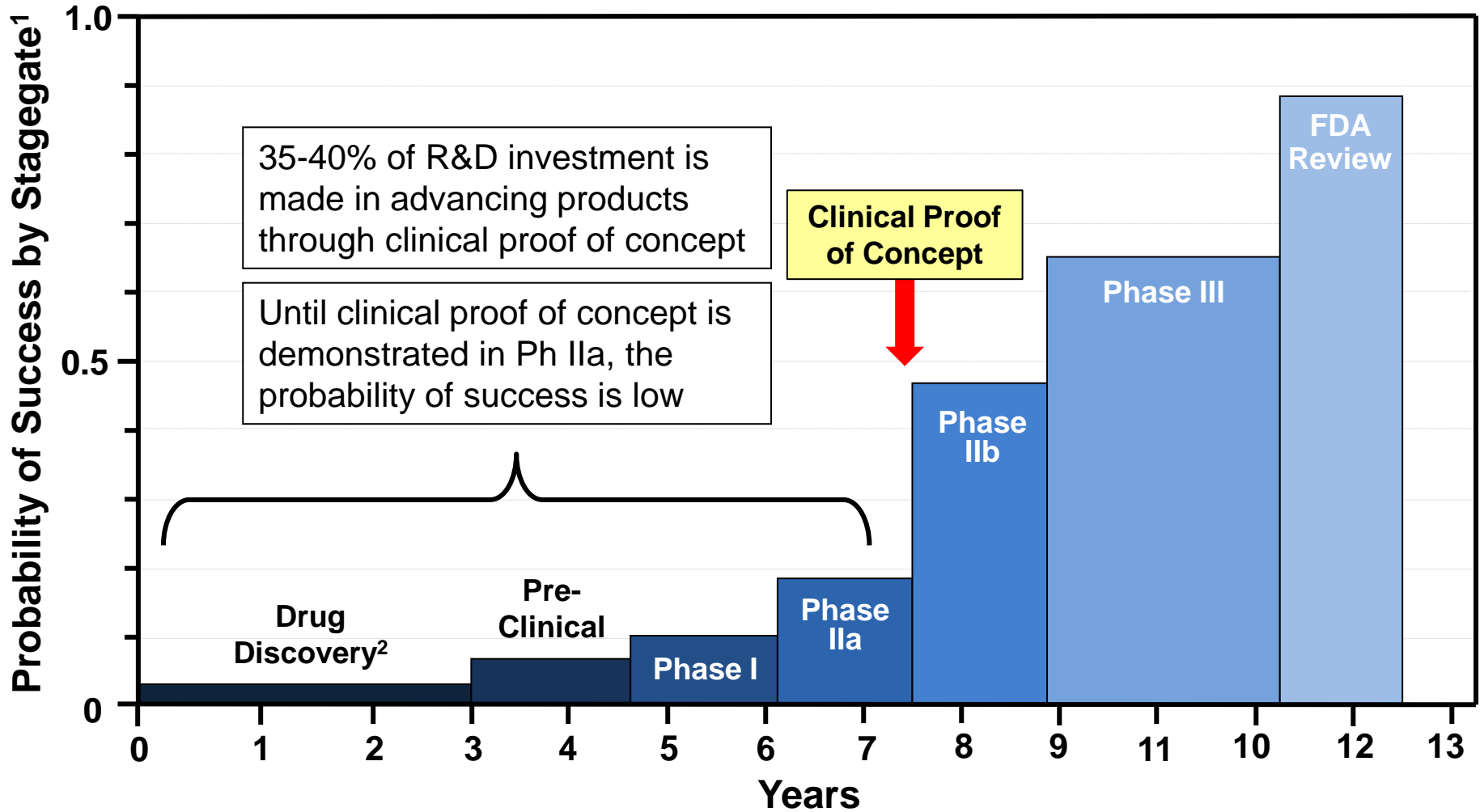


- ❑ Developing a new drug is a risky process
 - When a new drug discovery program is initiated the overall probability of launching a new product is 1.5%
 - 10,000 to 30,000 compounds must be synthesized for every one that reaches the market

¹CMR benchmarks used to calculate risk-adjusted values at various stages

²Internal estimate of 30% PoS

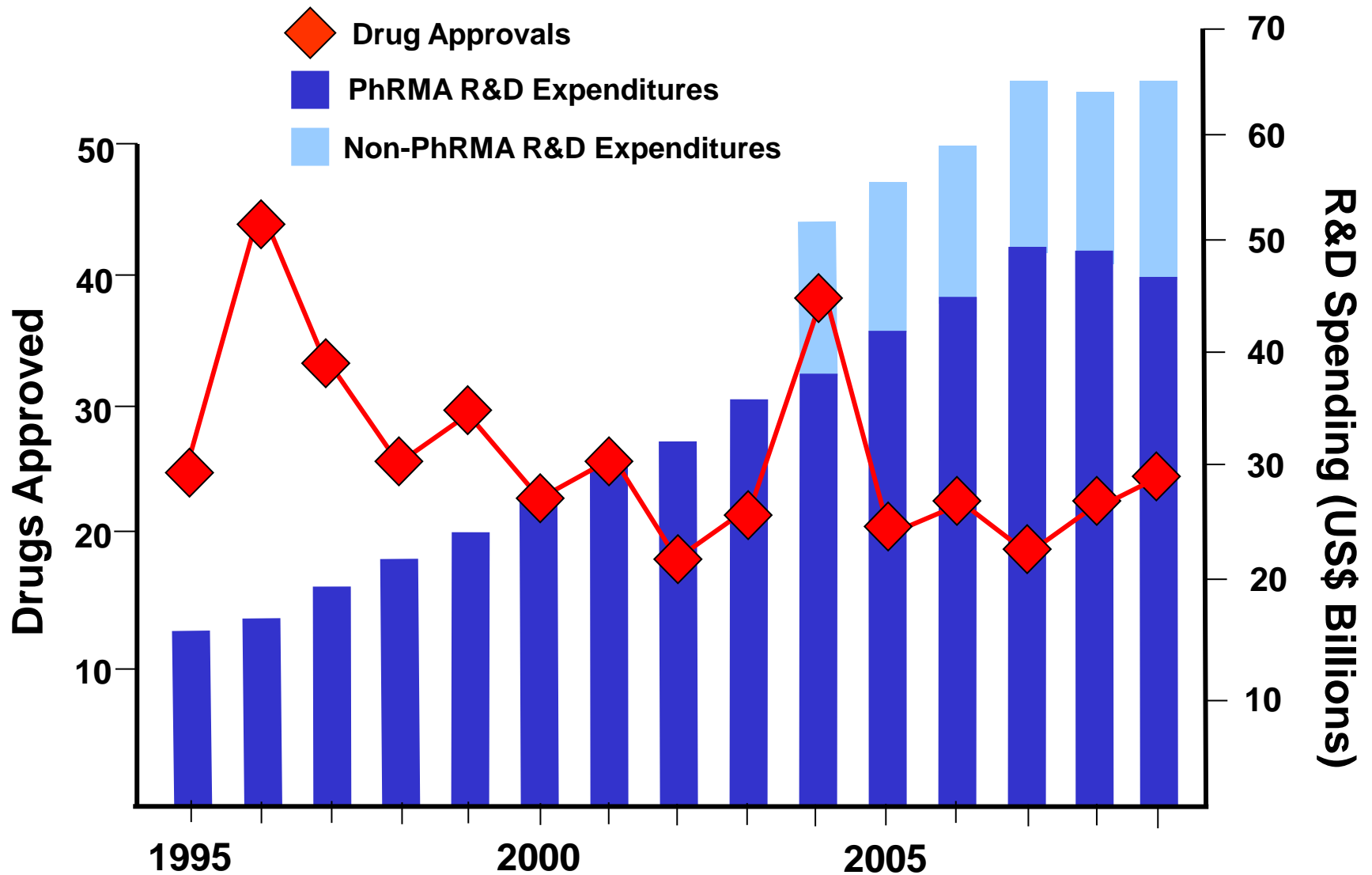
R&D Risk Profile



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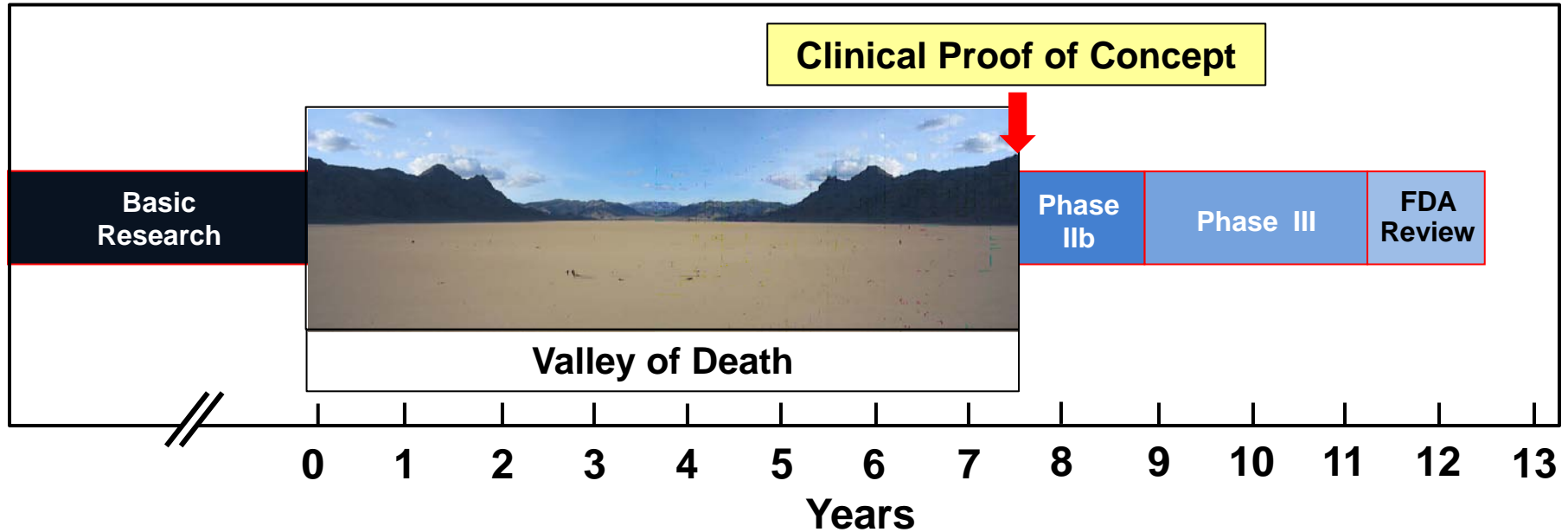


Pharmaceutical R&D – Current State

- ❑ R&D productivity is decreasing, leading to...
- ❑ ...industry consolidation and fewer Large Pharma R&D organizations...
- ❑ ...and the remaining R&D organizations are shedding infrastructure and reducing investment
- ❑ Increasingly, biotech organizations are the source of new products...
- ❑ ...but the traditional venture capital model is faltering
 - Building fully integrated Biotech companies is not a capital efficient way of generating new products
 - Other than strategic acquisitions, Large Pharma wants products, not companies
 - Insufficient capital is being invested in early-stage product opportunities, thus worsening the long term outlook for industry productivity

Improving R&D Productivity

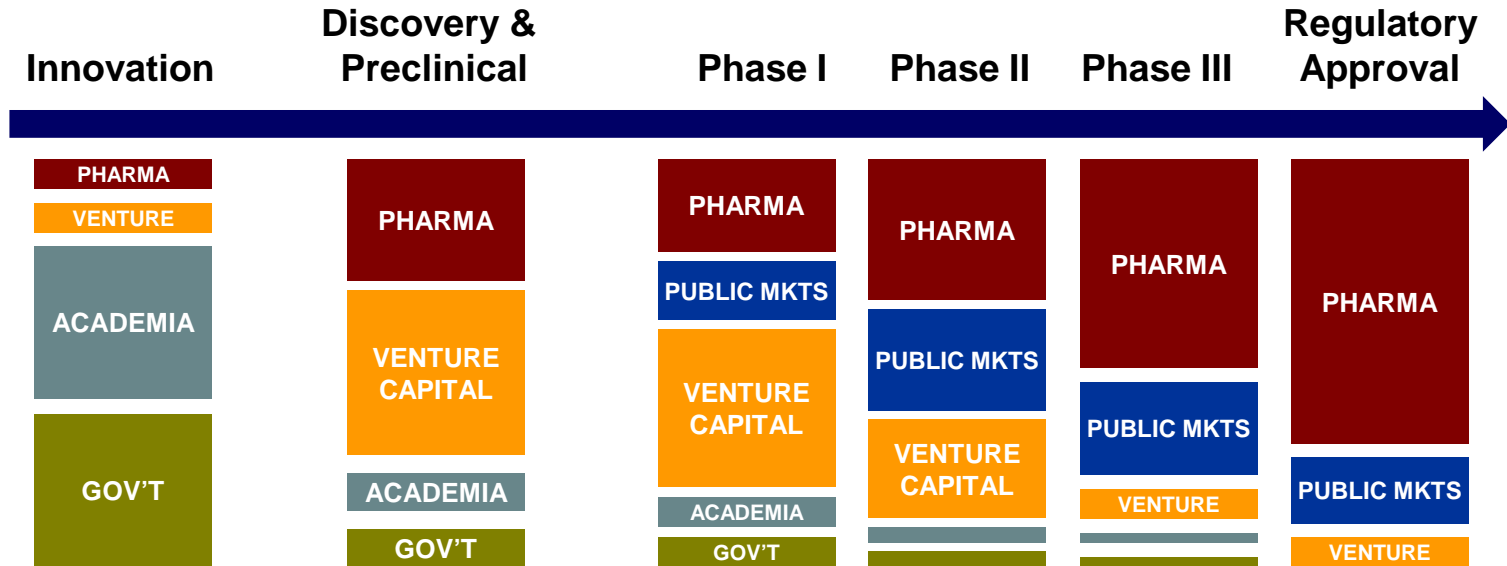
Bridging the Valley of Death



Paul, SM, et al.: How to improve R&D productivity: the pharmaceutical industry's grand challenge. *Nature Rev. Drug Disc.*, 9:203-214, 2010

- ❑ Substantial changes in productivity can be achieved by increasing the number of opportunities pursued from discovery through clinical proof of concept, i.e., bridging the Valley of Death

The Traditional R&D Paradigm¹

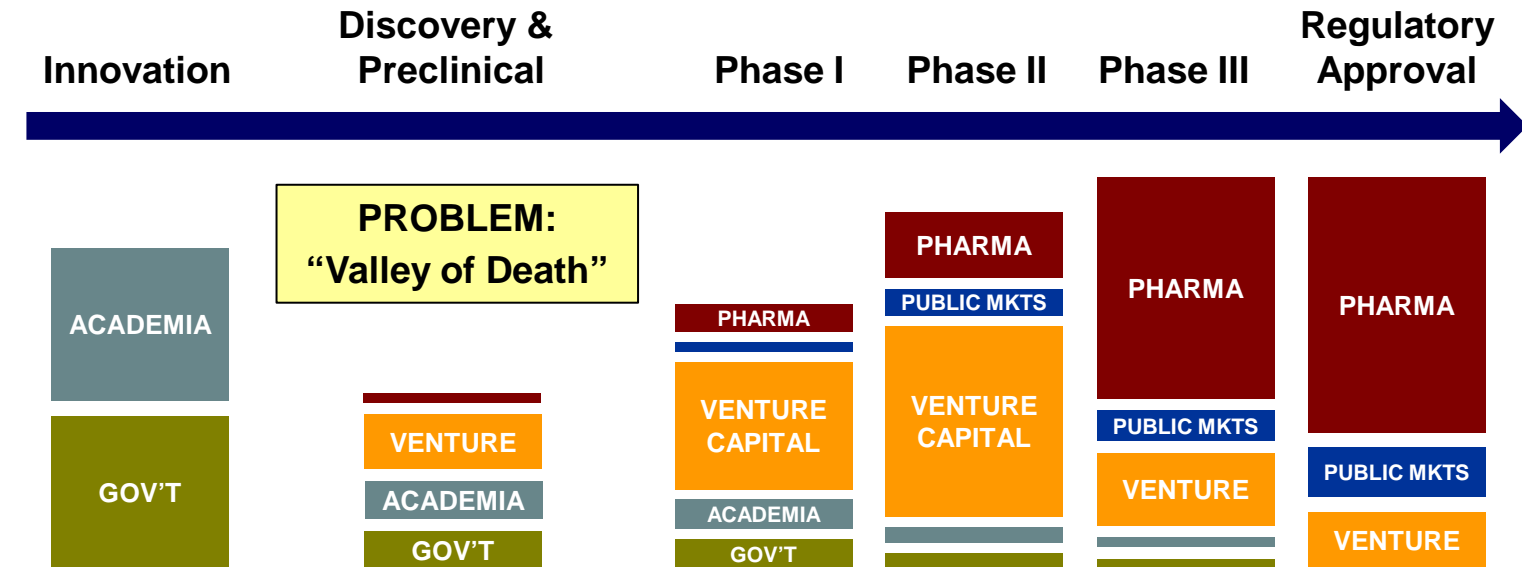


- Life sciences innovation primarily originated from basic research conducted in university and government institutions

- Translating innovation from basic research into drug candidates was funded by pharma and venture capital

- As development progressed, risk was reduced and expenses increased
- A funding shift occurred from venture capital to public investors and large pharma

The Current State of Pharmaceutical R&D¹



- ❑ Innovation still generated by universities and government
- ❑ Growing cache of untapped innovative discoveries

- ❑ Pharma research funding has decreased
- ❑ Venture funding has decreased

- ❑ More complicated and conservative regulatory environment
 - Larger size, complexity, and cost associated with clinical trials in US/EU
- ❑ Pharma, public investors, Venture Capitalists are increasingly risk averse
- ❑ Public investors have abandoned development stage companies; Venture Capitalists are stuck or leaving



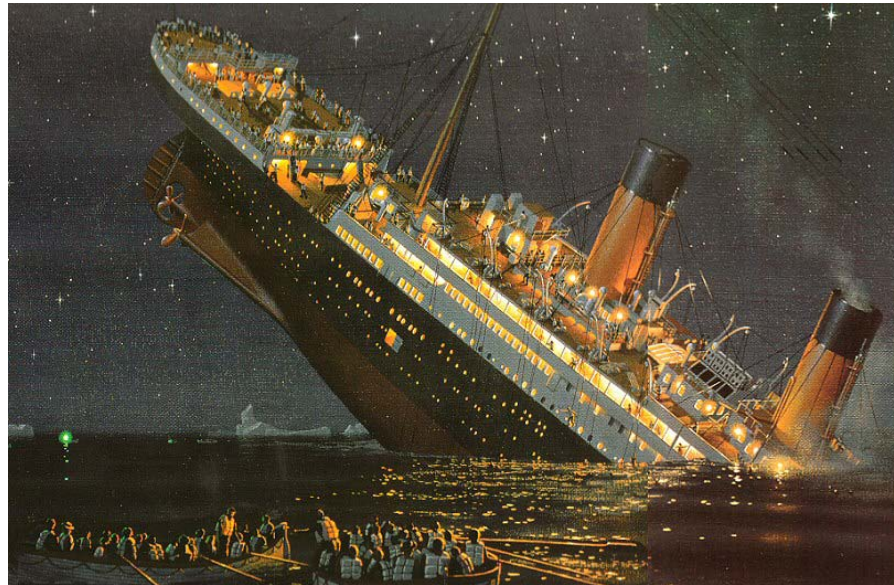
Pharma

Biotech

Venture Capital

Improving R&D Productivity

- ❑ Unless new R&D business models are created that align the interests and capabilities of all members of our ecosystem, we risk entering a prolonged period of dwindling new drug approvals and industry decline



The End of Vertical Integration in Large Pharma

An Opportunity to Transform Our Industry

- ❑ **Vertical Integration** – Firms attempt to own and control all aspects of making, selling, and delivering their core product or service
- ❑ **Vertical Disintegration** – Industries in which companies access from independent suppliers some or all of the materials, intellectual capital, and/or human resources that are essential to delivering their finished product or service

Integrated vs. Disintegrated Industries

Integrated

- Automobiles →
- Movies →
- Steel →
- Telecommunications →
- Oil - - - - - →
- Large Pharma ····· → ?

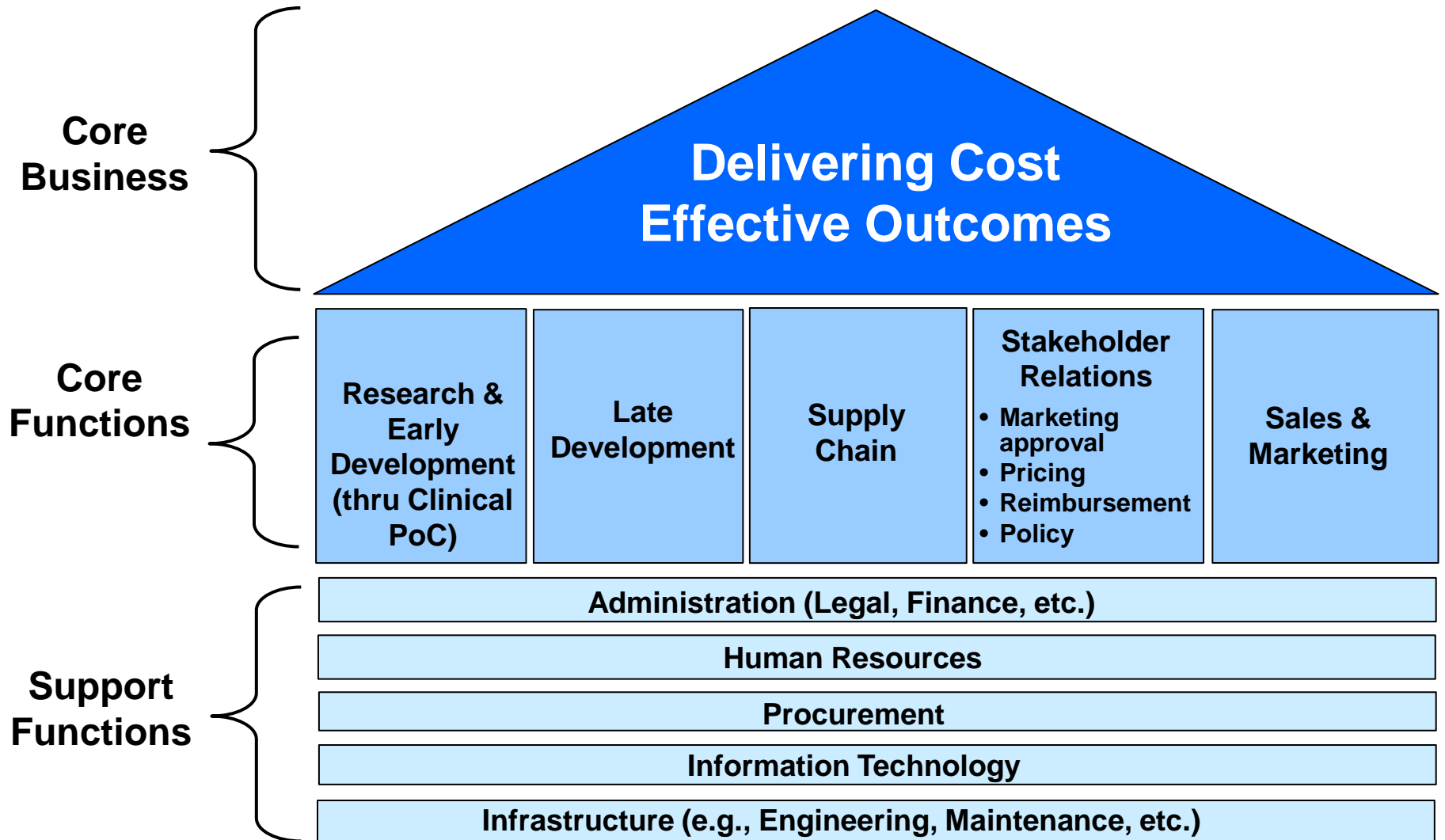
Disintegrated

- Automobiles
- Movies
- Steel
- Telecommunications
- Oil
- Large Pharma
- Computers
- Semiconductors
- Electronics
- ...and many, many more

What does history tell us?

Vertically Integrated Value Chain in Large Pharma

Is it Time to Disintegrate?



Virtual Integration

A New Model for Research & Early Development?

- ❑ **Virtual Integration** – Businesses in which there is an advantage for independent members of the industry's value chain to share competencies, infrastructure, intellectual capital, risk and reward that are essential to deliver the finished product or service
 - An inherent characteristic of a virtually integrated industry is that enabling the success of a partner helps ensure ones own success
 - This quality tends to drive alignment of all constituencies

Virtual Integration – A New Model for Early R&D

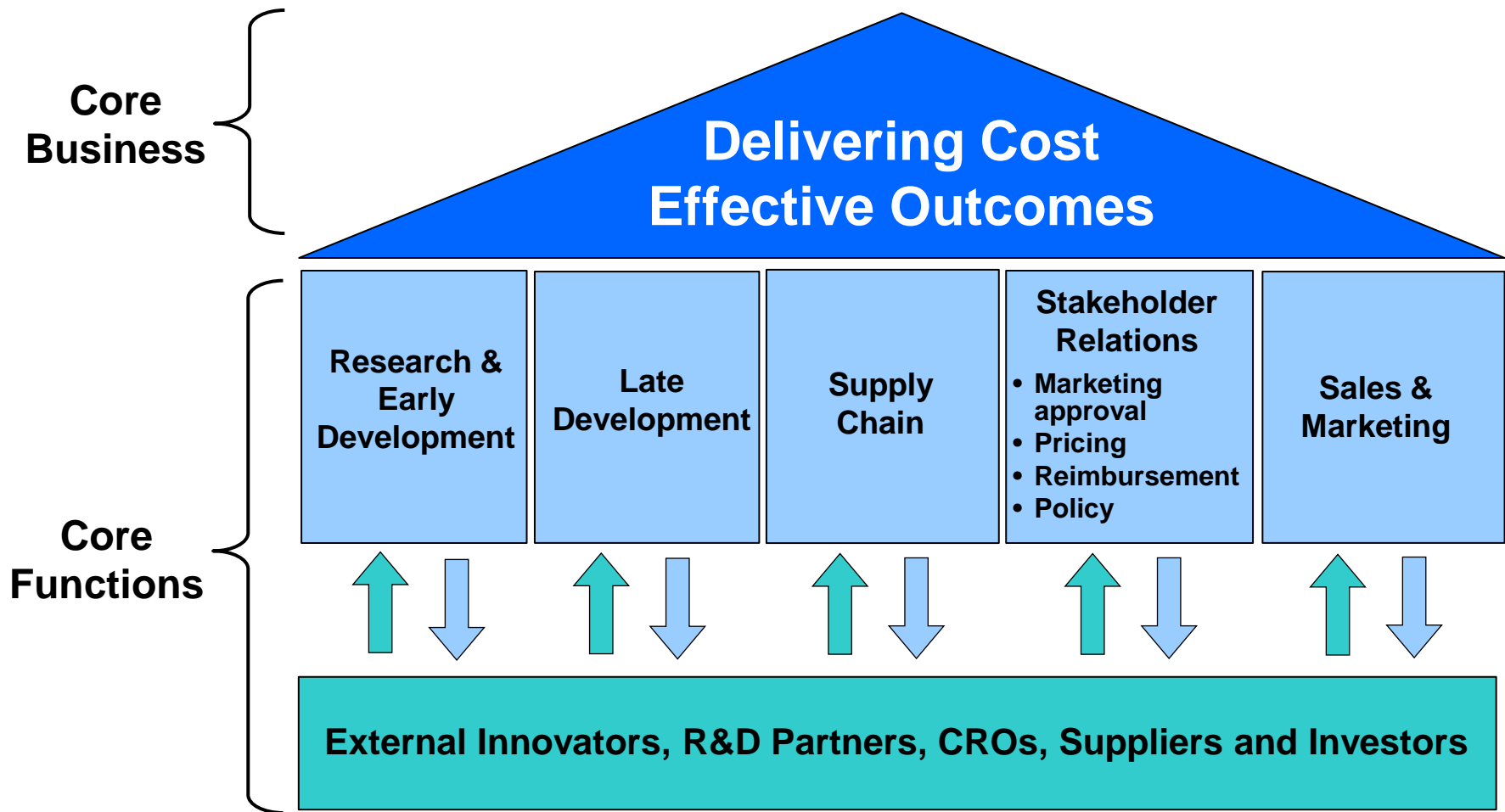
The Opportunity

New and creative R&D business models must be created that expand the pool of early stage assets

- ❑ Pharmaceutical R&D has become too costly and complex for either a vertically integrated model or a pure disintegrated model
- ❑ Academia and biotech are leading sources of innovative assets, but are under-valued and under-resourced
- ❑ Creative R&D investment models and partnerships must be formed that leverage, rather than replicate, the unique core competencies of the individual members of our ecosystem

Value Chain in Research & Early Development

Virtual Integration



Virtual Integration – A New Model for Early R&D

Core Principles

- ❑ New partnering models directed at advancing innovative products should be guided by the following operating principles:
 - Open Innovation
 - Networked partnering based on virtual integration
 - Lean, flexible and shared infrastructure
 - Capital efficiency
 - Fast-to-fail strategies
 - Financial risk and reward sharing



The Open Innovation Mindset¹

Closed Innovation

- ❑ We must discover, develop, manufacture and distribute innovations ourselves in a vertically integrated model
- ❑ The requisite expertise in R&D must exist inside of our company
- ❑ If we invent and fund everything internally we will win
- ❑ We must control and conceal our innovation processes, technologies and tools, so that our competitors don't profit from our ideas

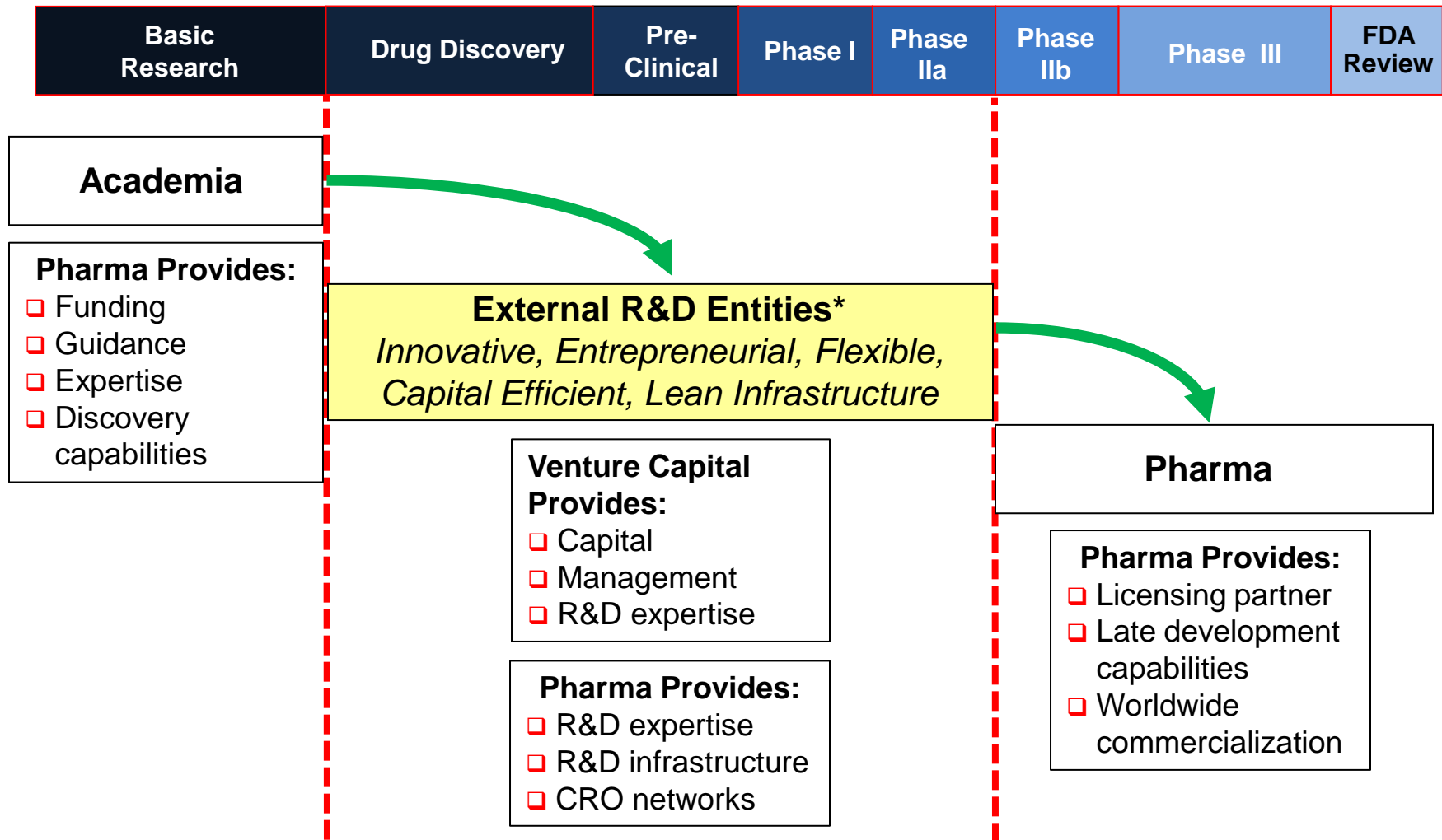
Open Innovation

- ❑ Enormous value can be unlocked from external R&D and innovation networks
- ❑ Pharmaceutical R&D has become far too complex for us to employ all the expertise needed
- ❑ Creating a better business model for partnered innovation can trump internal invention
- ❑ We will profit from others' use of our innovations and knowledge, and we will leverage others' intellectual property whenever it advances our own business model

¹ Adapted from *Open Innovation*, by Henry Chesbrough
Harvard Business School Press, 2006

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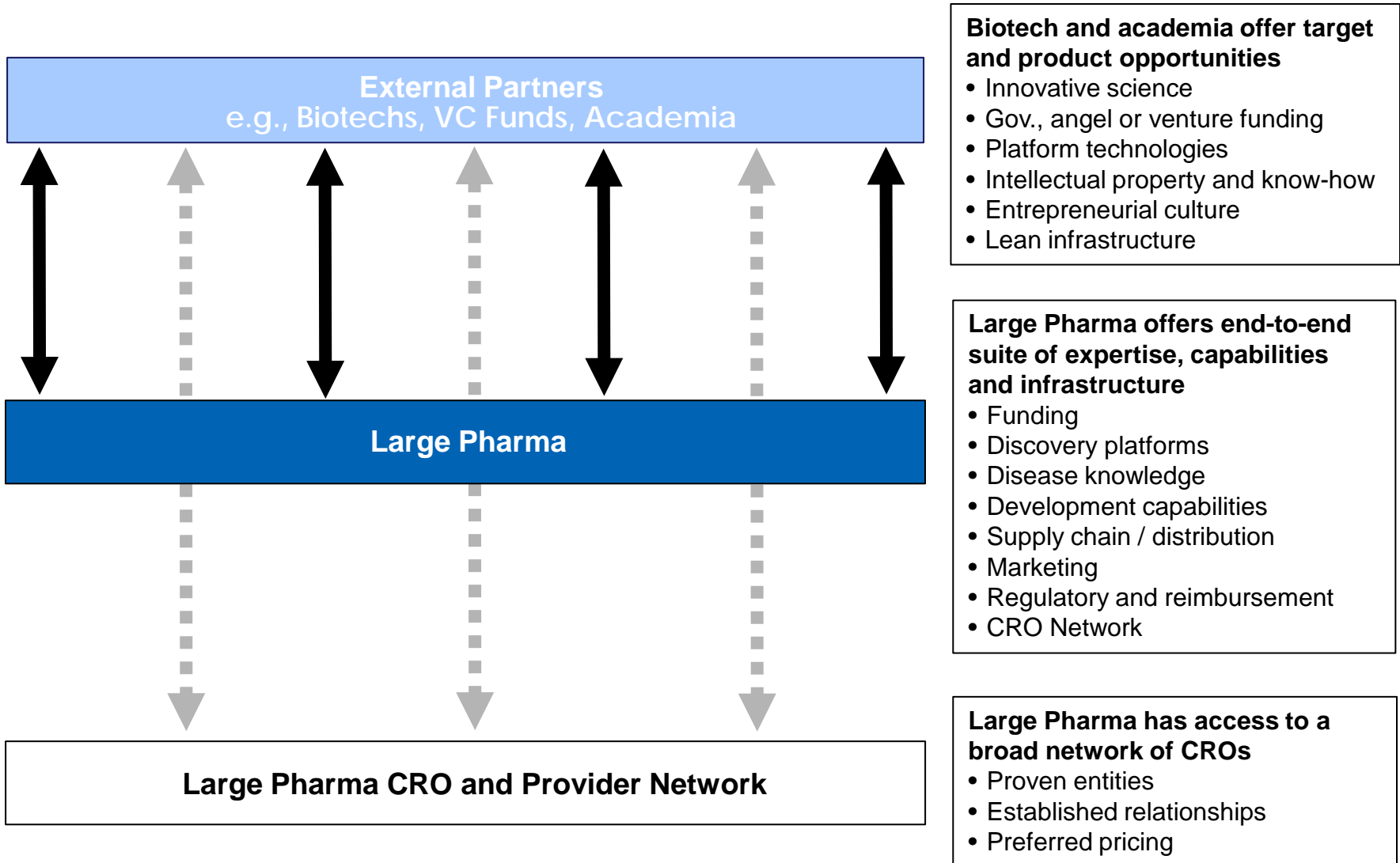
Leveraging Complementary Capabilities



* External R&D entities could include academic accelerators, public economic development funds, biotech companies, venture funds

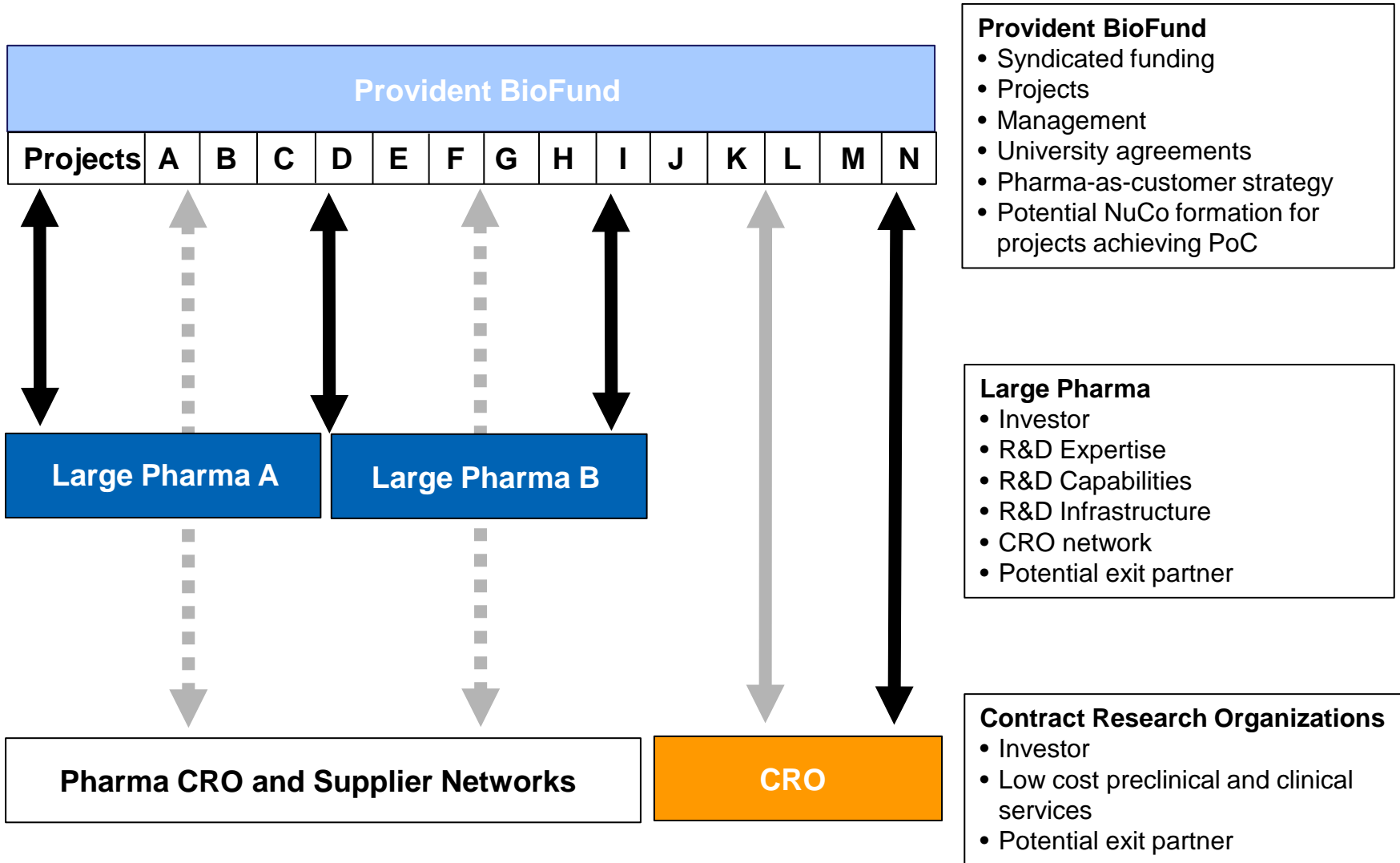
Virtual Integration

Leveraging Complementary Expertise and Capabilities



Virtual Integration

Example: Early-stage Venture Fund – Ph IIa Exit



Virtual Integration

Benefits to Stakeholders

- ❑ Large Pharma
 - Expand pipeline with an external portfolio of product opportunities
 - Leverage existing infrastructure and expertise
 - Minimize fixed costs and infrastructure while maximizing flexibility
- ❑ Venture Capital and Biotech
 - Opportunity to invest in market scarcity, e.g., “Valley of Death”
 - Assets monetized at an early stage of the R&D process to yield attractive returns with a mid-term horizon
 - Capital investment reduced by accessing Pharma infrastructure and expertise
 - Risk reduced by managing a portfolio of product opportunities, i.e., multiple shots on goal
- ❑ Academia
 - Progress opportunities that would otherwise stagnate
 - Access to external funding vehicles

Creating a Culture of Open Innovation

Key Learnings

- ❑ Open Innovation must be driven from the top
- ❑ Do not assume that everyone in your organization has embraced Open Innovation just because they say they have
- ❑ The fear that competitors will profit from Open Innovation can outweigh the promise it holds for your organization
- ❑ Do not underestimate the organization's capacity to mount an immune response
- ❑ Run pilot programs outside of the traditional organizational structure
- ❑ On occasion, castles must be destroyed to break through entrenched behaviors and business practices
- ❑ Do not assume that all external stakeholders in your industry share your vision

Message



From: Executive, Very Senior [PRDUS]
To: Torphy, Theodore J. [PRDUS]
Cc:
Subject: Open Innovation Workshop Invitation – Torphy

Sent: Fri 7/30/2010 12:20 PM

TED – what is this??? I don't see why we are talking about Open Innovation to our competitors. I really think that this is not the best use of your time.

Please let me know if you see otherwise. I know the legal team has expressed concerns to me on this.

Creating a Culture of Open Innovation

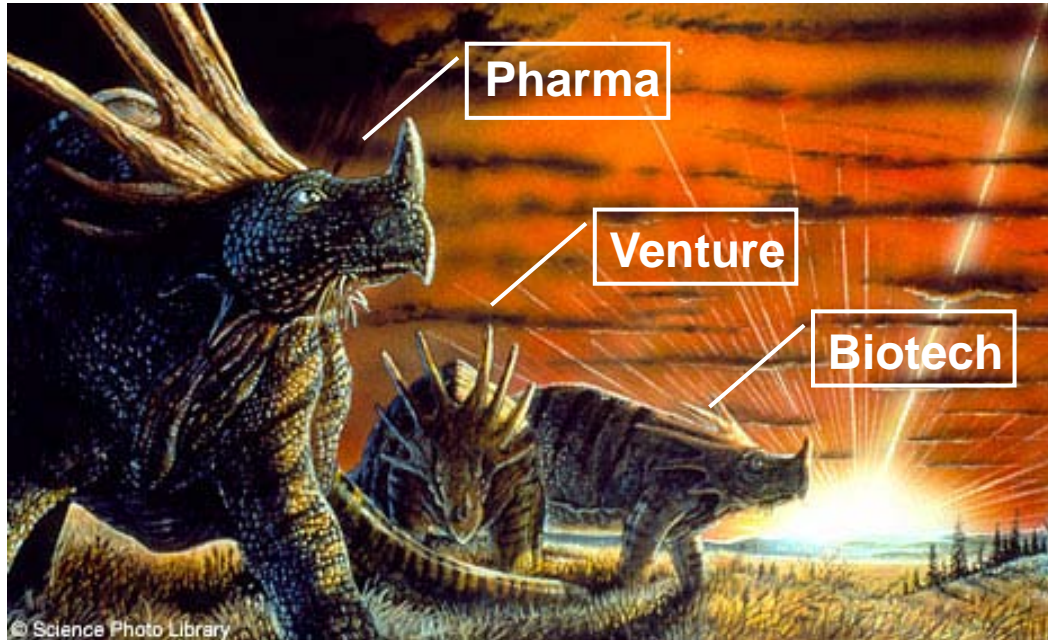
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Re-engineering Pharmaceutical R&D



“It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change.”

Charles Darwin
(1809-1882)

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