Open Innovation: An Imperative for the Pharmaceutical Industry

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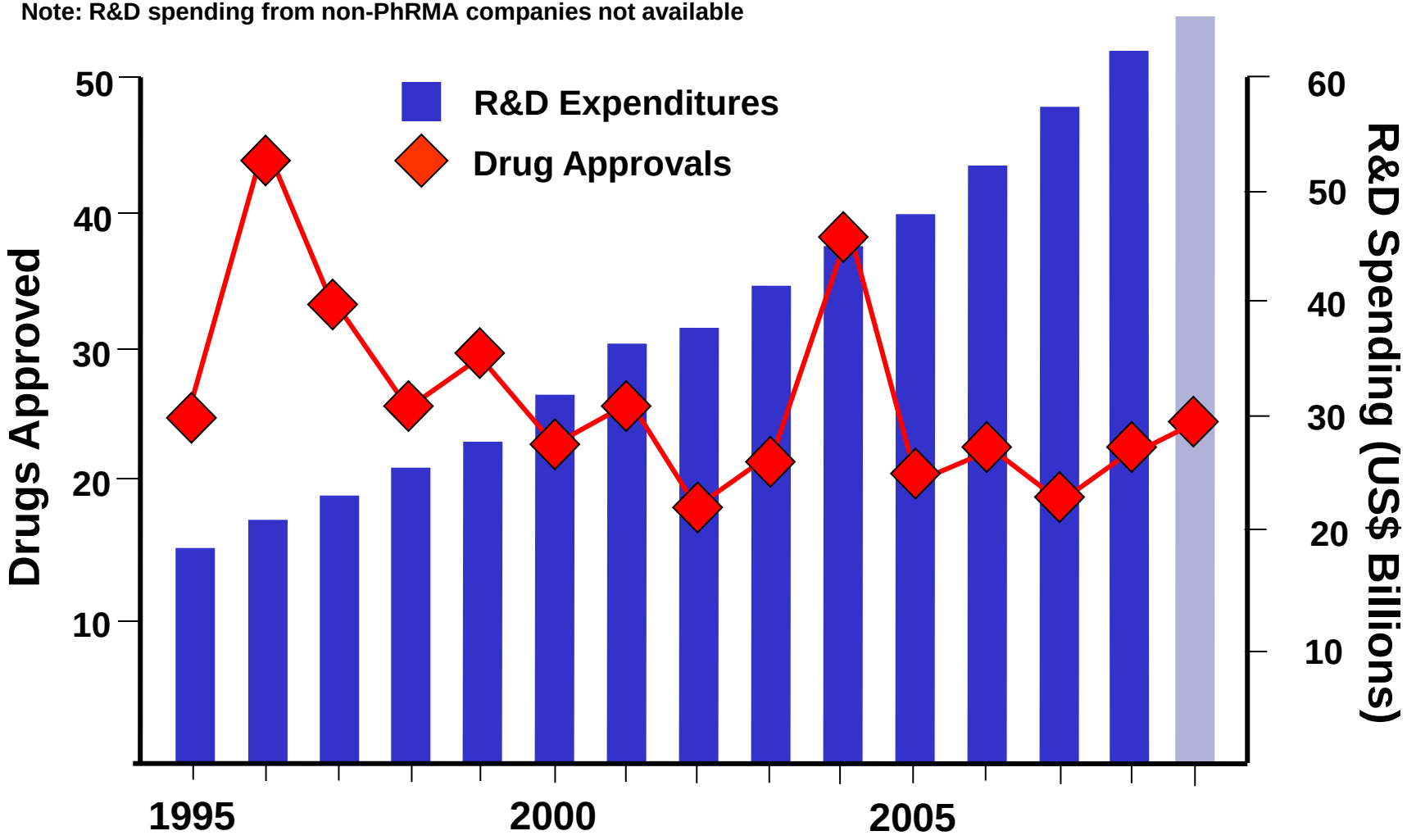
Our Industry Is Being Transformed

- Spiraling R&D costs coupled with decreased productivity
- Ever increasing regulatory requirements
- Reimbursement driven by medical and economic outcomes
- Expectation of personalized medicine
- Proliferation and redistribution of healthcare outcomes information

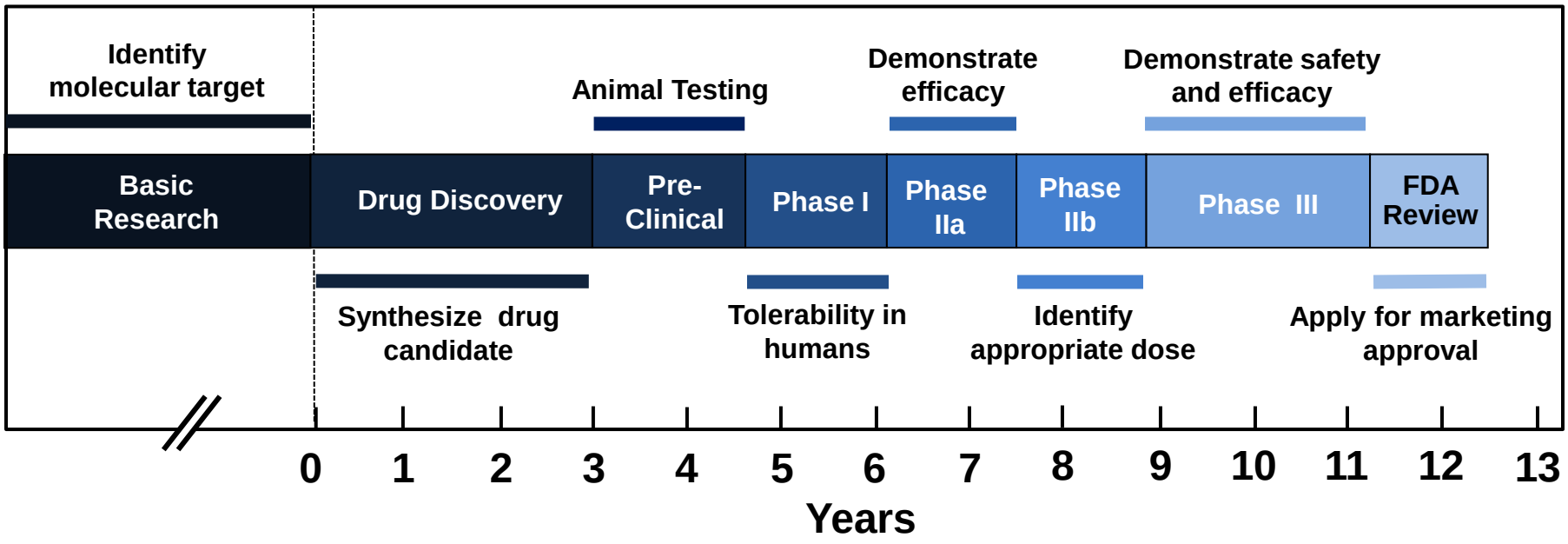
Productivity of the Pharmaceutical Industry

Sources: FDA/CDER, PhRMA, PricewaterhouseCoopers

Note: R&D spending from non-PhRMA companies not available



Pharmaceutical R&D Is a Long Process

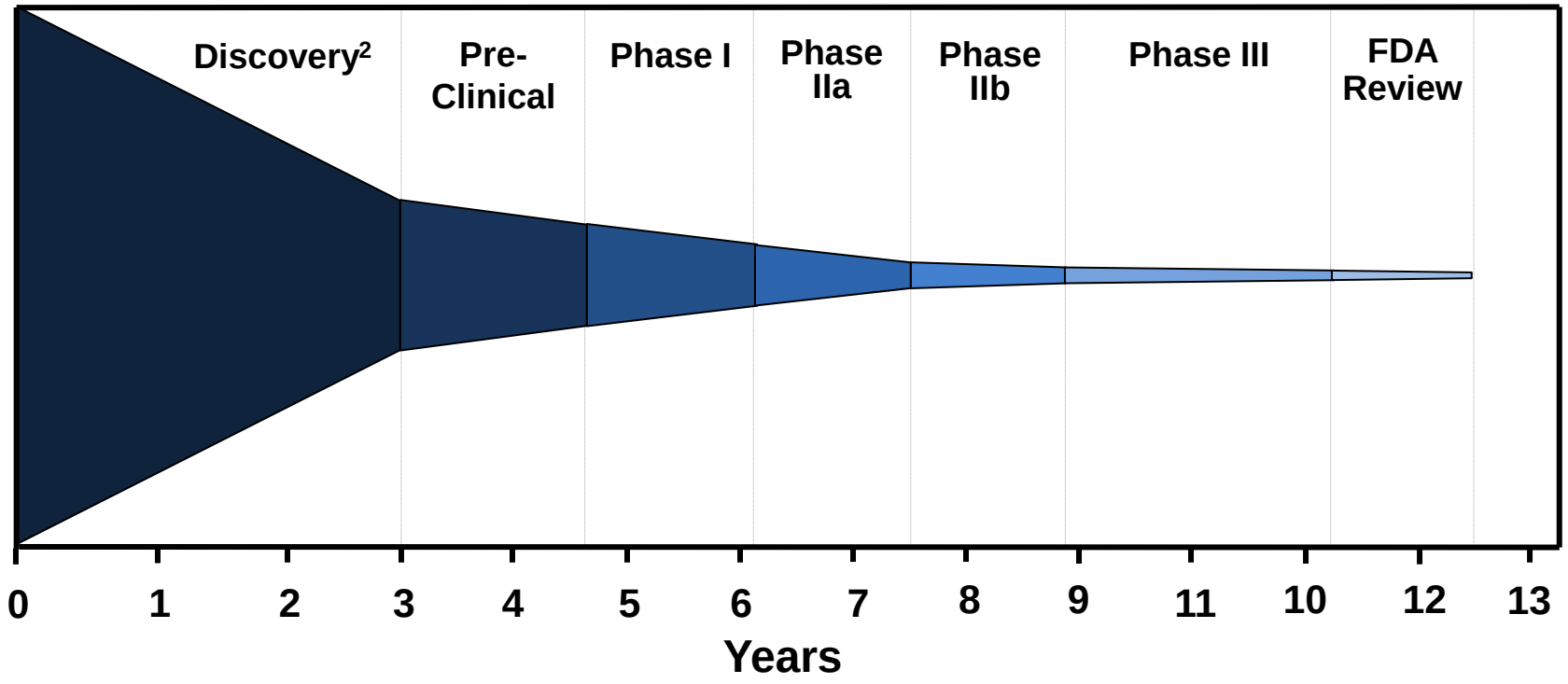


- Developing a new drug is a lengthy process
  - Product cycle times are extremely long
  - The 20-year limit on patent protection means there is a limited number of years during which a marketed product can generate an attractive ROI
- The cost of putting a new drug on the market is $0.8 to $1.3 bn[1]

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

Pharmaceutical R&D Is High Risk

Cumulative Probability of Success through Key Stagegates[1]

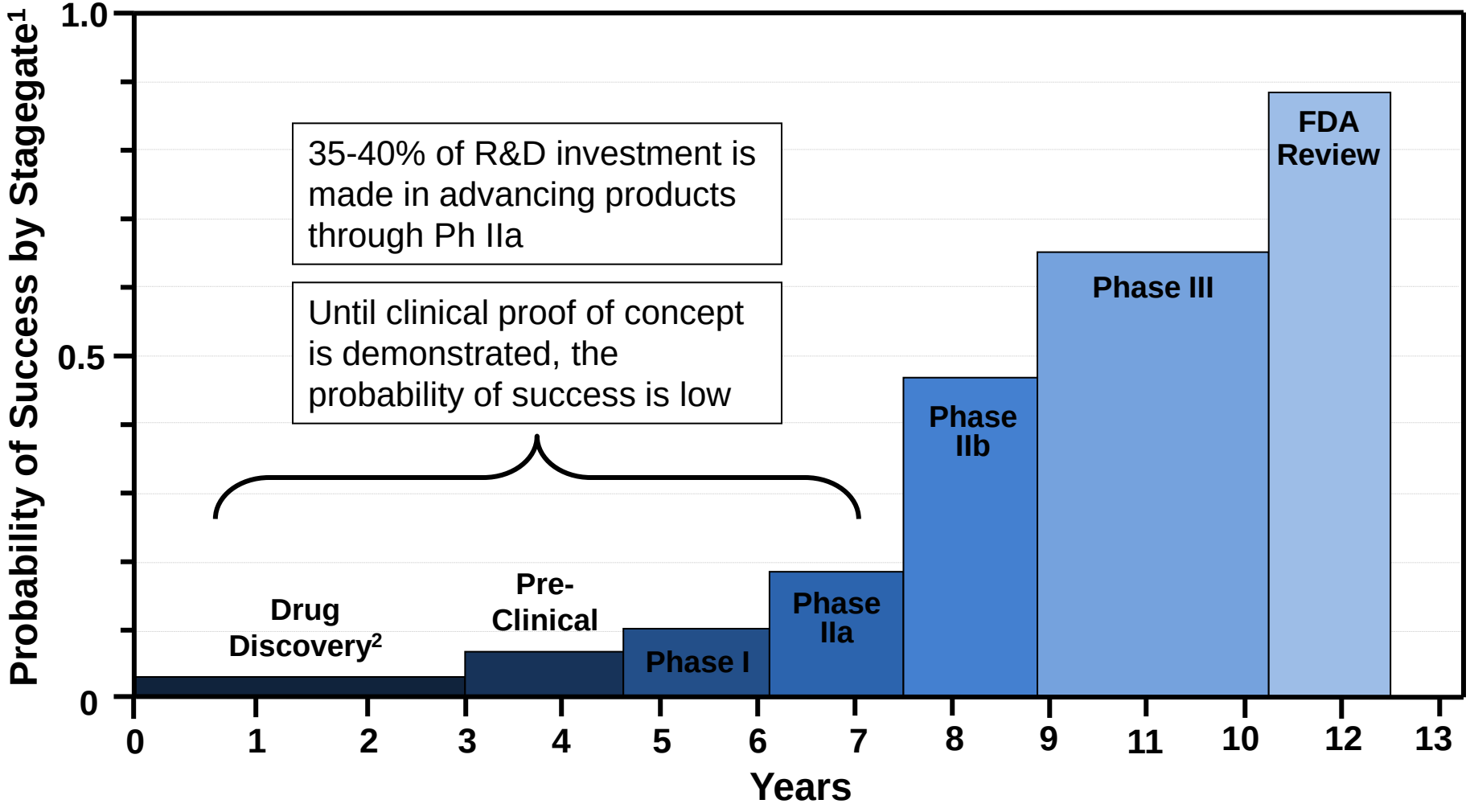


- Developing a new drug is a risky process
  - When a new drug discovery program is initiated the overall probability of launching a new product is 1.5%
  - 10,000 to 30,000 compounds must be synthesized for every one that reaches the market

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

[2] Internal estimate of 30% PoS

R&D Risk Profile



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Pharmaceutical R&D – Current State

- R&D productivity is decreasing and is not sufficient to drive future growth of the industry
- Industry consolidation is leading to fewer Large Pharma R&D organizations…
- …and the remaining R&D organizations are shedding infrastructure
- Increasingly, venture capital backed biotech organizations are the source of new products…
- …but the traditional venture capital model of creating, funding, and monetizing biotech companies is faltering
  - Large Pharma wants to acquire products, not companies
  - Building fully integrated Biotech companies is not a capital efficient way of generating new products, making product acquisition by Large Pharma prohibitively expensive
  - There is insufficient funding for innovative early-stage product opportunities emerging from academia

Our Ecosystem Is Interdependent and Fragile

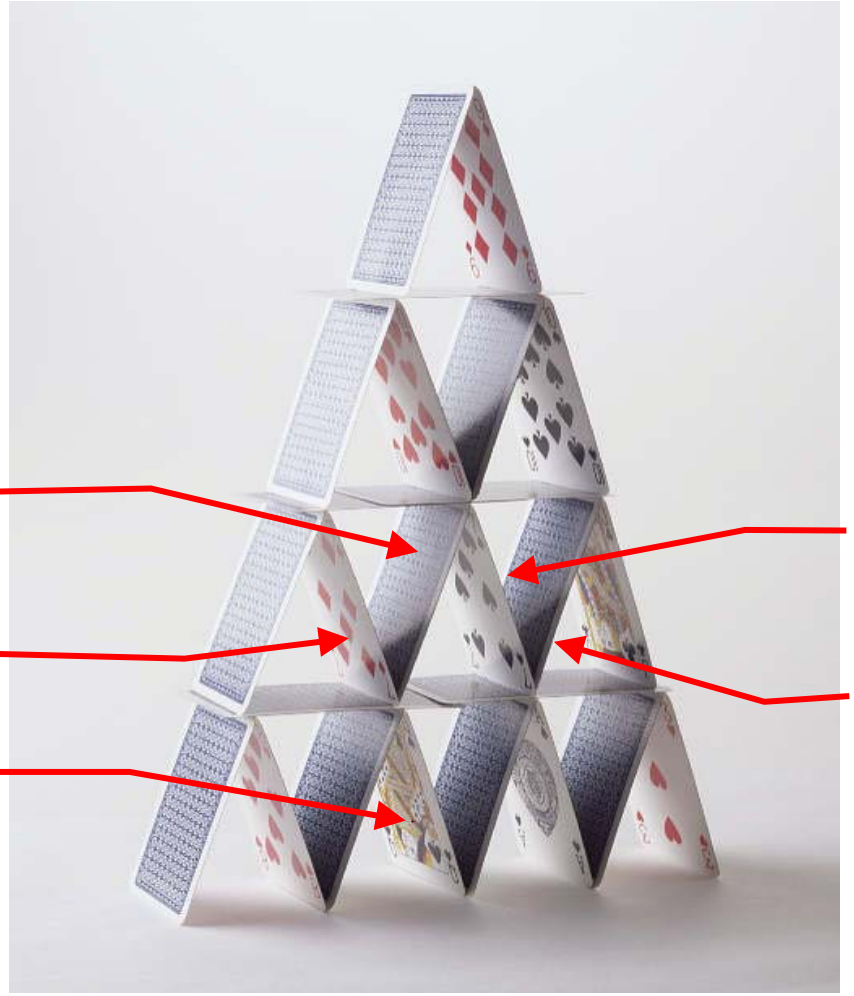

Image from the *Huffington Post*

Improving R&D Productivity

Without a new R&D business model, our industry will not supply an adequate number of innovative new products to drive growth and increase shareholder value

- Pharmaceutical R&D has become far to costly and complex for any individual company to sustain its business by operating under our traditional model of vertical integration
- Applying the principles of Open Innovation to align the incentives of all constituents of the ecosystem is essential to creating a new, capital efficient and productive model of pharmaceutical R&D

The Open Innovation Mindset[1]

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' IP whenever it advances our own business model

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

Vertical Integration of Large Pharma
Is it Time to Disintegrate?

- **Vertical Integration** – A characteristic of industries in which firms attempt to own and control all aspects of making, selling, and delivering the product or service that constitutes their core business
  - Examples: Ma Bell, Oil, Steel, Large Pharma

- **Vertical Disintegration** – A characteristic of industries in which there is an advantage for companies to access from independent suppliers some or all of the materials, intellectual capital, and/or human resources that are essential to delivering the finished product or service that constitutes their core business
  - Examples: Semiconductors, Automobiles, Electronics, Movies

Vertical Integration of Large Pharma

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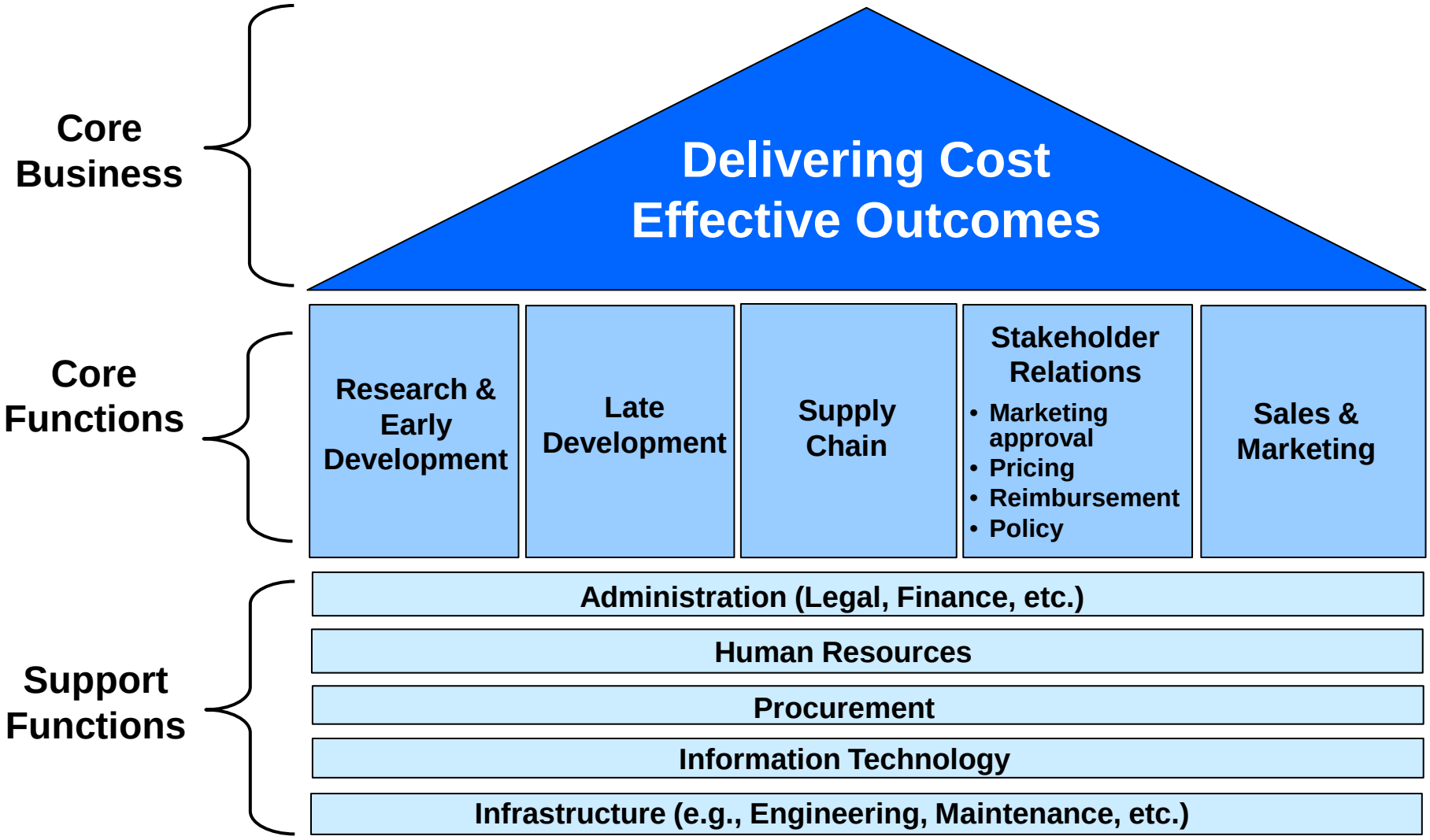
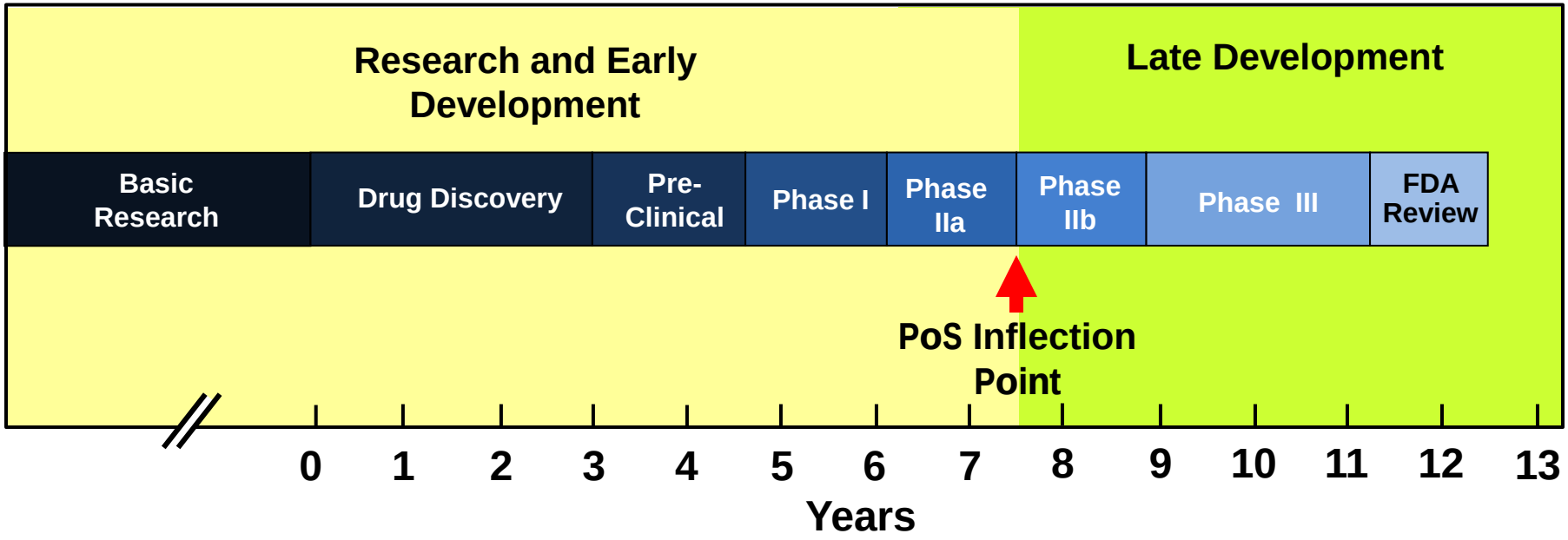


Research & Early Development

Disintegration as an Opportunity



- Large pharma no longer leads in the area of research and early development
- Innovation in this stage of the pharmaceutical R&D cycle is spread among thousands of Biotechs and academic laboratories
- Elements of the research and early development process are becoming commodities

J&J's External Innovation Initiative

"By working with experts at other companies, universities, and research institutes, we tap a wider range of expertise, capabilities, and resources. "[1]

- Aggressively pursue licensing activities at all stages of drug development
- Initiate extensive in-depth collaborations with academia, Biotech companies and CRO's
- Create new business models for research & early development: the Open Platform

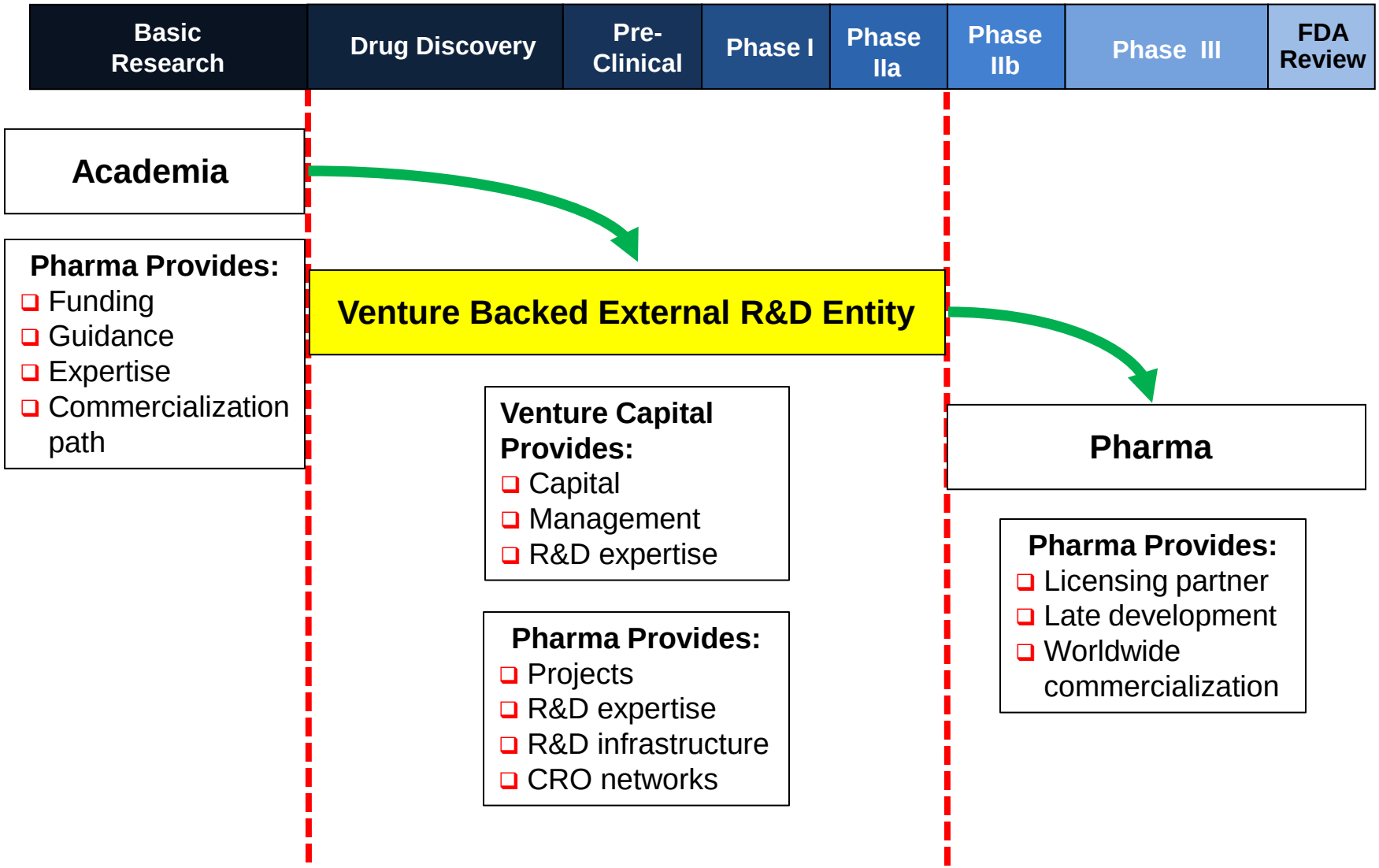
[1] Paul Stoffels, Chairman of Pharmaceutical R&D, Johnson & Johnson, Boston Globe, February 2, 2009

Open Platform – A New Model for R&D
Networked Partnering

In partnership with external innovators and investors, build and manage an external portfolio of early-stage product opportunities

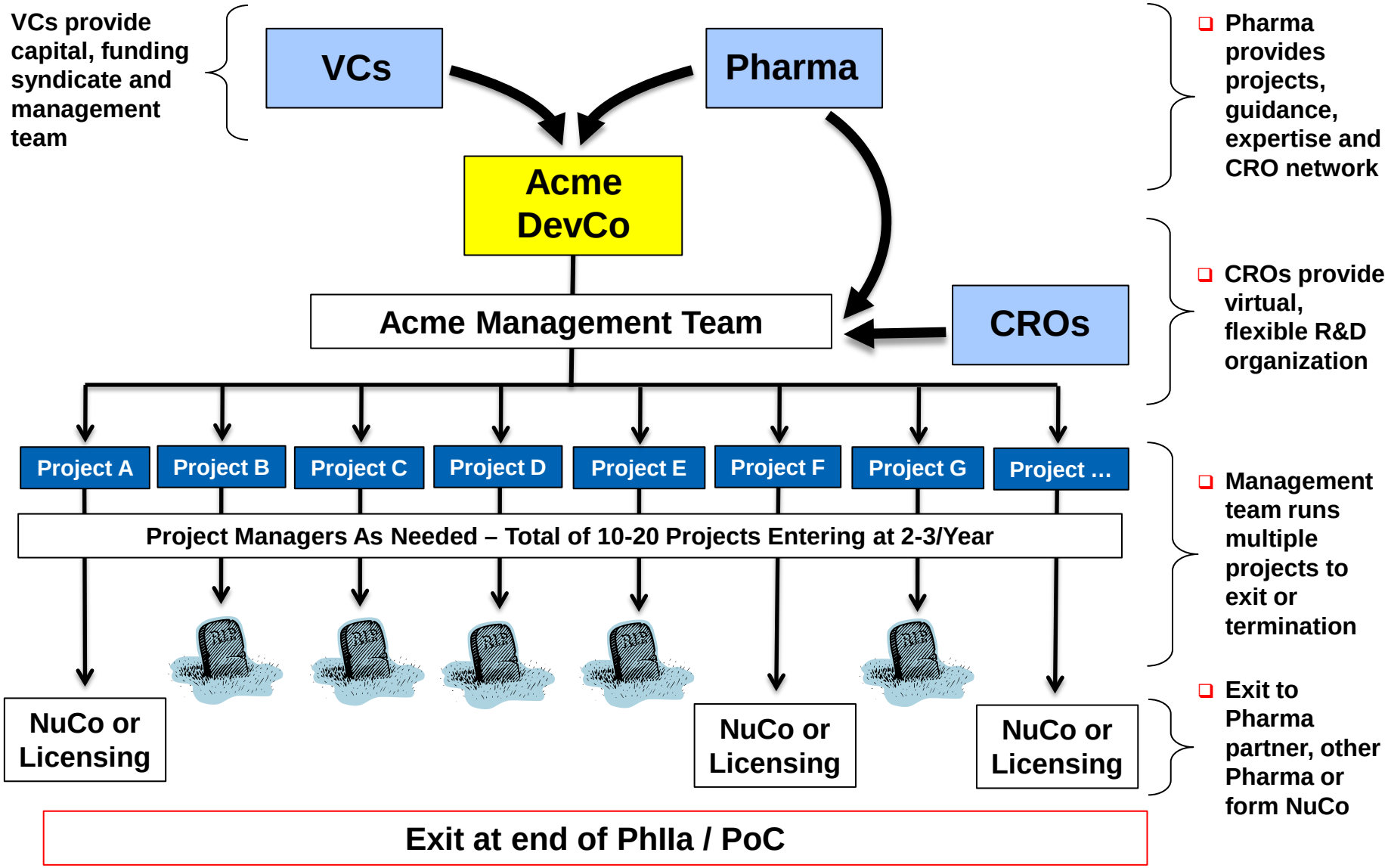
- Employ the principles of Open Innovation to identify and advance early-stage innovative product opportunities
- Link these opportunities with external management expertise and capital
- Apply internal expertise, capabilities and alliance networks to facilitate the success of our partners
- Institute innovative financial risk-sharing strategies with external investors to support the development of products
- Retain options to acquire these opportunities under financial terms that are attractive to both Pharma and its partners

The Open Platform Concept



Open Platform – A New Model for R&D

Example of Networked Partnering



Benefits 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
  - Opportunity to invest in market scarcity
  - 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
- Academia
  - Progress opportunities that would otherwise stagnate
  - Access to external funding vehicles
  - Attractive financial incentives for innovators and universities
- Contract Research Organizations
  - Expand business
  - Opportunity to risk share

Key Learnings

- Open Innovation must be driven from the top
- Do not underestimate the organization's capacity to mount an immune response
- The fear that competitors will profit from Open Innovation can outweigh the promise it holds for your organization
- Run pilot programs outside of the traditional organizational structure
- On occasion, ships must be burned to break through entrenched behaviors business practices
- Do not assume that all external constituents in your industry share your vision