Open Innovation: An Imperative for the Pharmaceutical Industry

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Research Capabilities
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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
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\(^1\)

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
35-40% of R&D investment is made in advancing products through Ph IIa

Until clinical proof of concept is demonstrated, the probability of success is low

1.0
0.5
0

Probability of Success by Stagegate

Years

Drug Discovery
Pre-Clinical
Phase I
Phase IIa
Phase IIb
Phase III
FDA Review

Years

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

Internal estimate of 30% PoS
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
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 too 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
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.

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.

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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
Is it Time to Disintegrate?

Delivering Cost Effective Outcomes

Core Business

Research & Early Development
Late Development
Supply Chain

Stakeholder Relations
• Marketing approval
• Pricing
• Reimbursement
• Policy

Sales & Marketing

Core Functions

Support Functions

Administration (Legal, Finance, etc.)
Human Resources
Procurement
Information Technology
Infrastructure (e.g., Engineering, Maintenance, etc.)
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.”

- 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

<table>
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<th>Basic Research</th>
<th>Drug Discovery</th>
<th>Pre-Clinical</th>
<th>Phase I</th>
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**Academia**

- Pharma Provides:
  - Funding
  - Guidance
  - Expertise
  - Commercialization path

**Venture Backed External R&D Entity**

- Venture Capital Provides:
  - Capital
  - Management
  - R&D expertise

**Pharma**

- Pharma Provides:
  - Licensing partner
  - Late development
  - Worldwide commercialization

- Pharma Provides:
  - Projects
  - R&D expertise
  - R&D infrastructure
  - CRO networks
Open Platform – A New Model for R&D
Example of Networked Partnering

- VCs provide capital, funding syndicate and management team
- Pharma provides projects, guidance, expertise and CRO network
- CROs provide virtual, flexible R&D organization
- Management team runs multiple projects to exit or termination
- Exit to Pharma partner, other Pharma or form NuCo

VCs

Pharma

Acme DevCo

Acme Management Team

CROs

Project A
Project B
Project C
Project D
Project E
Project F
Project G
Project …

Project Managers As Needed – Total of 10-20 Projects Entering at 2-3/Year

NuCo or Licensing

NuCo or Licensing

NuCo or Licensing

Exit at end of PhIIa / PoC
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