Breaking the mold: Reinvigorating biopharmaceutical innovation

The Dbriefs Health Science series
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Agenda

• Setting the stage: The challenges of R&D returns
• Trends in industry: Efforts to increase pipeline value
• Moving forward: Approaches to increase R&D productivity regardless of scale
Setting the stage:
The challenges of R&D returns
Research tracks a cohort of 16 pharma companies over time to assess research and development (R&D) spend and return on investment over time.

**Original cohort**
12 largest companies by Pharma R&D spend 2009

**Extension cohort**
Four, mid-to large-cap companies in top 25 companies by Pharma R&D spend 2012 to 2014

Source: Deloitte *Measuring the return from pharmaceutical innovation 2016: Balancing the R&D Equation*
The analysis relies on publically available data to provide consistent, reliable year-on-year trends.

- **Comparability**: Project *returns on R&D investment remains* as critical as ever.
- **Availability**: Provides an *objective performance measurement tool*.
- **Accessibility**: Helps *demonstrate shareholder value*.
- **Accessibility**: Justifies the *allocation of capital to R&D*.
- **Accessibility**: Helps to determine the *value for money* from innovative medicines and understand the *impact of declining incentives* for innovation.
The internal rate of return (IRR) figure is a static snapshot in time of projected future returns for the current late-stage pipeline.

Static IRR:
Snapshot calculation based on investment costs and expected returns.

Dynamic IRR:
Illustrates the impact on underlying levers on changes in IRR over time.

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Polling question #1

What is top of mind for your organization when evaluating your investments in R&D?

• Using effective strategies to have strong returns on R&D
• Innovating cures for debilitating diseases
• Curbing health care costs for employers and consumers
• We don’t think about the ROI of R&D
• Other/No opinion
IRR continues to decline with the extension cohort currently outperforming the original cohort; however, the extension cohort may be starting to experience some of the same challenges.

**Return on late-stage portfolio, 2010–16—original and extension cohort**

![Graph showing the absolute IRR for both the original and extension cohort from 2010 to 2016.](image)

- **Absolute IRR**
  - **Extension Cohort**
  - **Original Cohort**

Key considerations

Challenging external environment. Balancing pricing with unmet clinical needs continues to challenge biopharma companies.

Overall performance continues to decline. Since 2010, Deloitte tracked the performance of 12 companies. Despite launching 233 products with $1,538 billion in revenue, overall returns on pharmaceutical innovation continues to fall.

M&A may be about to increase. Since 2013, there has been a steady decrease in the proportion of projected late-stage pipeline revenue derived from externally-sourced assets, a trend which accelerated in 2016.

Source: Deloitte *Measuring the return from pharmaceutical innovation 2016: Balancing the R&D Equation*
Trends in industry:
Efforts to increase pipeline value
Polling question #2

In your opinion, what is driving the decline in R&D ROI?

• Increasing costs
• The policy and regulatory environment
• Fewer opportunities (incidence of disease) for ‘blockbuster’ products
• Pricing
• Other/No opinion
R&D costs remain high and revenues continue their decline
Blockbuster costs without blockbuster sales

Average annual peak sales per asset have more than halved since 2010

Average annual cost to develop an asset from discovery to launch has increased by 30 percent since 2010

Source: Deloitte Measuring the return from pharmaceutical innovation 2016: Balancing the R&D Equation
With a three fold improvement in productivity required to balance the R&D equation, fundamental change may no longer be an option but a necessity.

High R&D spend is not a good predictor of returns as a negative relationship between company size and both R&D costs per asset and returns continues to exist.

A large number of externally sourced assets have been commercialized; with late-stage pipelines close to empty the temptation may exist to refuel through M&A.

...But given the negative relationship between company size and returns, getting bigger through M&A may not be a good evolutionary strategy for future productivity...

Source: Deloitte Measuring the return from pharmaceutical innovation 2016: Balancing the R&D Equation
Polling question #3

In your opinion which of these is most likely to happen for large biopharma companies?

• Increasing the number of assets
• Reducing R&D costs per asset
• Increasing M&A
• Limiting M&A
• Other/No opinion
To achieve a return of 10 percent, key levers in the R&D productivity equation would need to move by:

**Increasing average peak sales**

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<th>Result required to achieve 10 percent ROI</th>
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**Decreasing cost per asset**

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<th>(in $100,000)</th>
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Source: Deloitte proprietary research
Moving forward:
Approaches to increase R&D productivity regardless of scale
Balancing the R&D equation: Learn from assets that outperformed expectations and identify practices that can eliminate diseconomies of scale

What changes can R&D organizations make to balance delivering new drugs and costs to payers and investors?

What strategies can be employed to ensure the maximum incremental increase in commercial value of the current pipeline?

Source: Deloitte Measuring the return from pharmaceutical innovation 2016: Balancing the R&D Equation
A tiered strategy advances from focusing on a therapeutic area (TA) to developing a product strategy and R&D program design

- Cultivate a **focused portfolio strategy** and align BD efforts
- Build **depth of disease and customer knowledge** to improve development **program efficiency**
- Leverage prior experience to **refine protocols**

- Focus on a **first indication that balances** unmet need with commercial barriers
- **Target a sub-population** to expedite time to market and increase the likelihood of clinical success and reimbursement
- Consider the impact of including a **biomarker and companion diagnostic** as a requirement
- **Clearly differentiate clinically and/or economically** from current, and future, treatment options

- Develop and **adhere to a robust target product profile (TPP)** that incorporates customer perspectives
- **Include a multi-year evidence blueprint** to show clinically meaningful and value-creating endpoints
- **Engage** global regulators **early** and aim to **align endpoints**
- **Recognize the differences** in development strategy and defining value for accelerated pathways
- **Engage with payers early** to understand how they define value beyond price
- **Differentiate products** to payers, patients and physicians
- Consider the evolving role of **non-physician clinicians**
- Develop and validate tools to **capture patient reported outcomes early** in development

Source: Deloitte *Measuring the return from pharmaceutical innovation 2016: Balancing the R&D Equation*
Regardless of scale, addressing some of the main challenges facing the industry can help develop assets more efficiently.

**Decision-making**

Larger companies tend to be saddled with **intensive governance processes** which can be **time-consuming, inefficient** and do not provide an environment that rewards creativity...

**Staffing and outsourcing**

**Greater outsourcing** in R&D has **not always** resulted in **greater efficiencies**...

**Data complexity**

The **data landscape** within biopharma R&D is becoming **ever more complex** which places a **huge cost burden** on organizations...

Source: Deloitte *Measuring the return from pharmaceutical innovation 2016: Balancing the R&D Equation*
The following key lessons can be applied to help overcome these industry challenges and reduce the cost to launch:

**Think small, win big to optimize decision-making**
- **Empower** key decision makers and align incentives
- **Accept risk** to reduce development timelines
- **Make quick kills** to benefit other competing programmes with greater commercial potential
- **Embed a rigorous** but dynamic **process to fund projects**

**Staffing and outsourcing: strike the right balance**
- **Balance** internal and external resources
- **Treat CROs like partners** and staff
- **Build rapport** with partners and align incentives
- **Give greater control to partners** to fully utilise expertise
- **Actively manage and track expectations** with partners

**Lift the burden of data complexity**
- **Ensure data safety, accessibility** and availability
- **Implement master data management principles**
- **Create end-to-end data architecture**
- **Prioritise data for integration** post-M&A
- **Evolve the role** of the IT organization

Source: Deloitte *Measuring the return from pharmaceutical innovation 2016: Balancing the R&D Equation*
Polling question #4

In your opinion which of these are the hardest for a large biopharma company to implement?

• Optimize decision-making
• Striking the right balance between staffing and outsourcing
• Limiting the burden of data complexity
• Other/No opinion
Considerations moving forward

Life sciences

Government

Health plans

Consumers

Health care providers

Technology companies
Question and answer
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