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# Precompetitive Collaborations:

# Round Table on Cross Pharma Collaborations

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# Precompetitive Collaborations: Definition and Value Statement

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*Precompetitive Collaborations are a subset of translational research that is focused on improving the tools and techniques needed for successful translation, and not on the development of a specific product*

*Janet Woodcock, Clinical Pharm & Therapeutics, 817 (5), 2010 521-523*

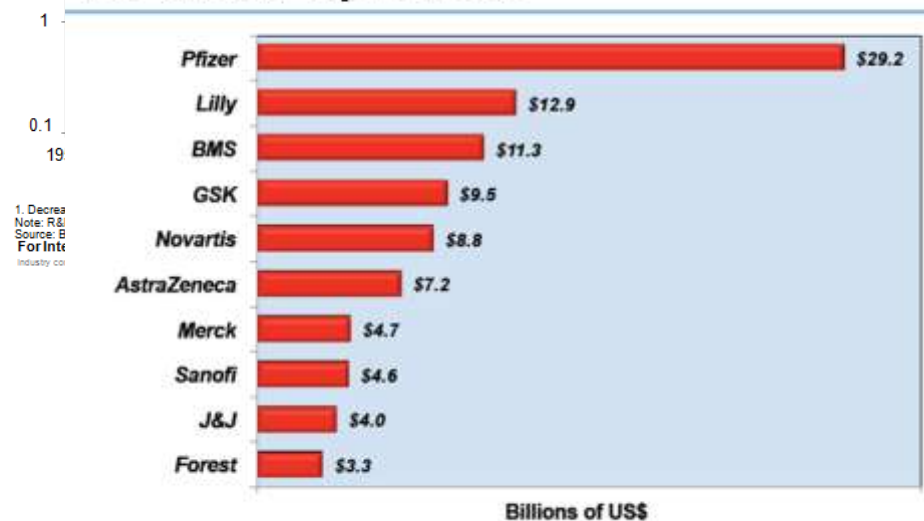
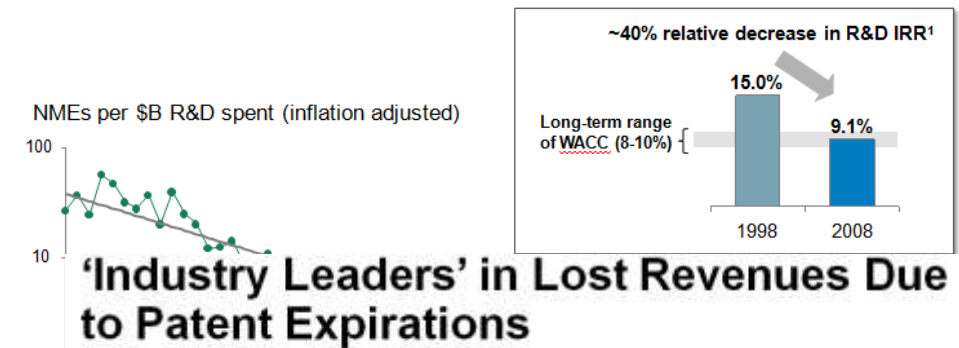
## Value Statement

- A Precompetitive Collaboration will provide a positive benefit to each party (impact to \$\$, IP, time, expertise) that exceeds what might be achieved by proceeding independently

# Rationale for Engaging in Precompetitive Collaborations

- Internal R&D under pressure to deliver new therapeutics more efficiently
- Patents on many top-selling products are expiring
- Marketplace is highly competitive and reimbursement environment is increasingly restrictive
- Cost to meet safety and efficacy is rising due to increased regulatory hurdles are increasing
- Growing need to get new drugs to treat rare diseases and diseases in developing countries
- Pharmaceutical R&D remains a long, risky, and expensive process

## R&D returns have declined in the last decade



Sources: Kaitin, *Clin Pharmacol Ther*, 2010;87:356-361; Medco; FDA Orange Book; (sales data): MedAdNews; www.drugs.com/top200; Medco

***What opportunities lie in the Precompetitive Space?***

# Current Amgen Investment in Precompetitive Collaborations

Consortia	Area of Focus	Consortium Objectives
IQ Consortium	Clinical & CMC	Innovation and Quality in Drug Dev
Zenith	CMC	To predict chemical degradation & mechanistic pathways
Innocentive	CMC	Forum for Problem Solving in Precompetitive Environment
Allotrope Foundation	IS	Develop a common laboratory open information framework
Rx360	Manufacturing	Management of integrity & quality of the supply chain
Biomarkers Consortium	Clinical	Develop Biomarkers for disease & Drug Dev
Predictive Safety Testing Consortium	Toxicology	Identify Preclinical & Translational Markers

# An Assessment of Precompetitive Collaborations

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Advantages	Challenges
Shared risk across Industry, Academics & Govn't to address key problems	Controlling the direction of research due to different business drivers
“Disruptive Innovation” and opportunity to move field forward	Timeline to implement & deliver misaligned with current industry model
Introduces efficiency avoids duplication	Logistical & managerial complexity
Shared costs structure	Define & agree on financial expectations for different contributors
Opportunity to leverage broad SME pool to collaborate & develop best practices that support Drug Dev.	Management of IP. Output is open source, business model to maintain needs to be defined.
Standardization of methods/data	Alignment on what to standardize, and metrics to measure outcomes
Communication and recognition of collaboration enhances public support	Timing of communication

# Opportunities for Precompetitive Collaboration in CMC Drug Development

Precompetitive	Competitive
<ul style="list-style-type: none"><li>• Lab Standards</li><li>• LOTF</li><li>• Analytical and Purification Instrumentation</li><li>• GTI Predictive data &amp; analytical methods</li><li>• Novel Excipients</li><li>• Enabling Technologies</li><li>• Quality and Mfg</li><li>• Continuous Process Reactor Design</li><li>• Synthetic Route Design</li><li>• Lab Notebooks &amp; Information Management</li><li>• Automation for Chemical Research</li><li>• <i>Experimental Design Software Tools</i></li><li>• <i>Process Modeling Software</i></li></ul>	<ul style="list-style-type: none"><li>• IP for Mfg Ds/DP</li><li>• Eng technologies in miniaturization e.g. nanotech &amp; nanoformulation</li><li>• Target delivery approaches</li><li>• Particle engineering equipment/methodologies</li><li>• Crystallization screening technologies</li></ul>

**To add value we need to identify opportunities to differentiate where the investment is high, creation of IP is minimized but there is a tangible benefit to Drug Development**