



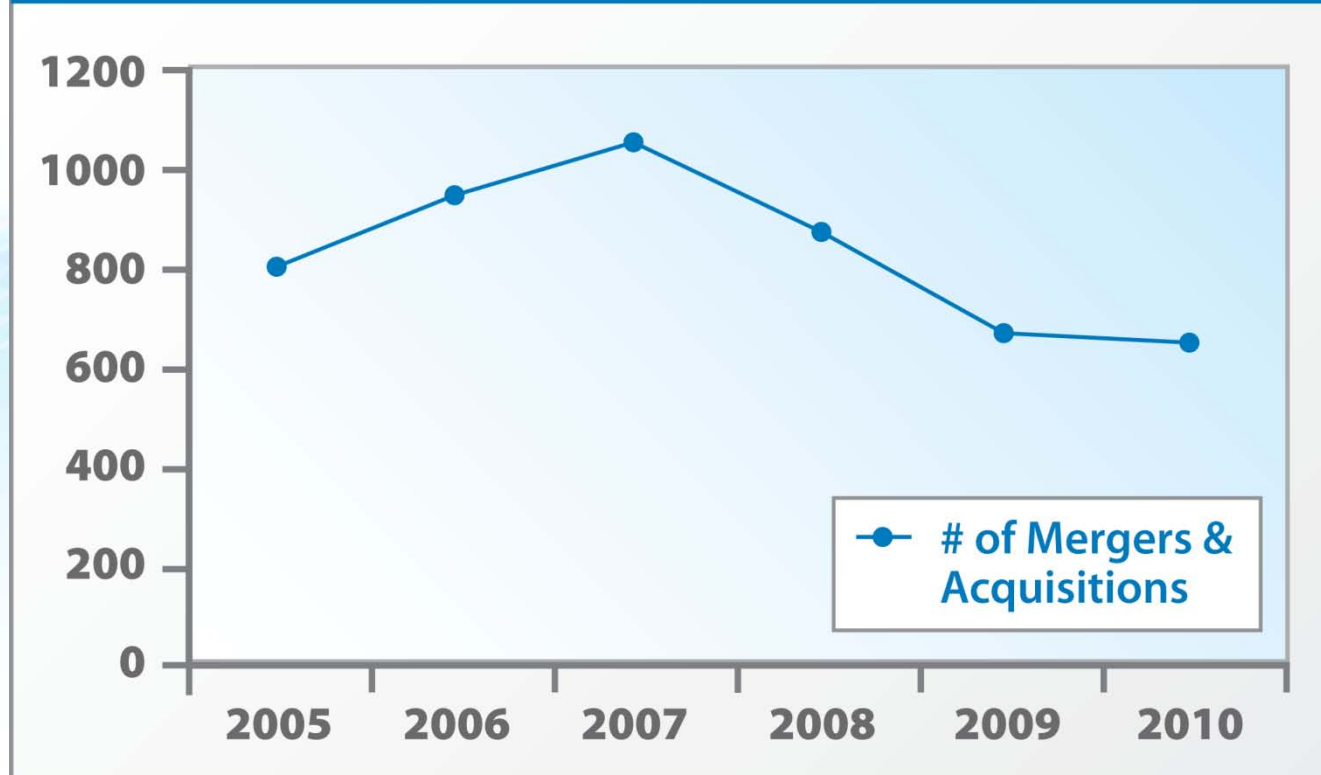
**pSivida Corp**

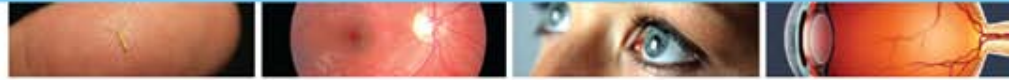
# **The Changing Pharma-Biotech Dealmaking Landscaping in the U.S.**

Investor Presentation  
Dr. Paul Ashton  
President and CEO  
October 2010

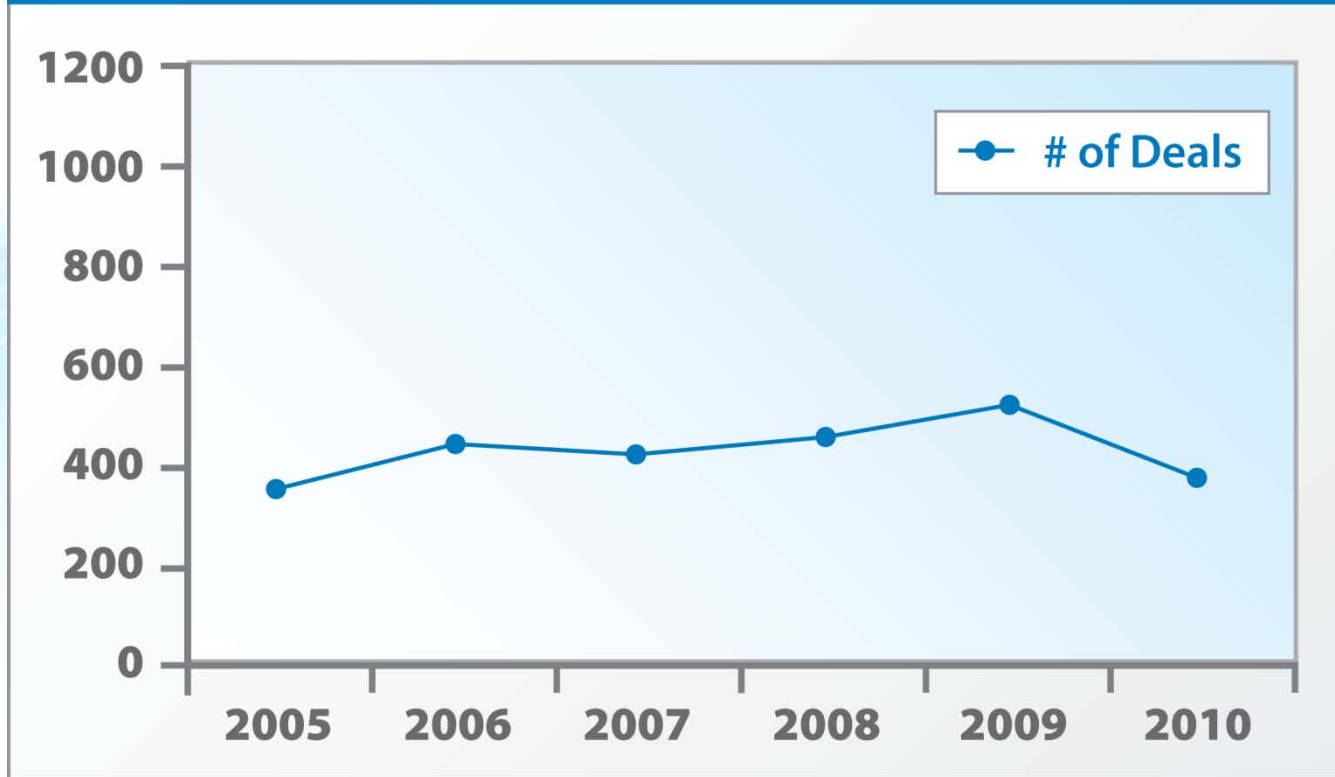


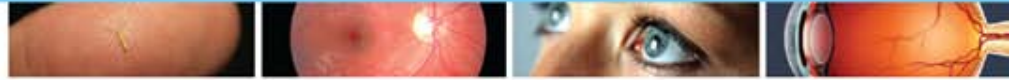
## MERGERS & ACQUISITIONS



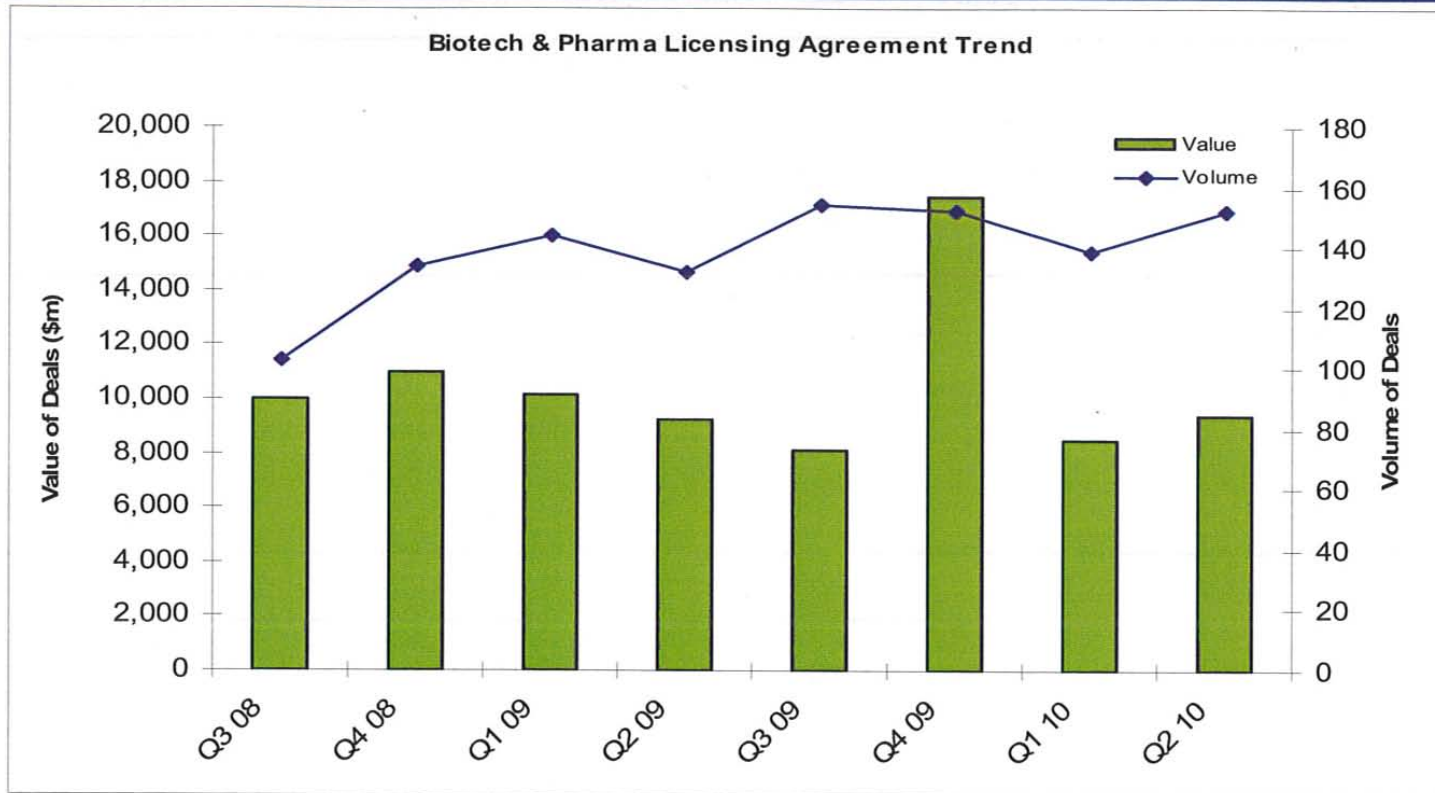


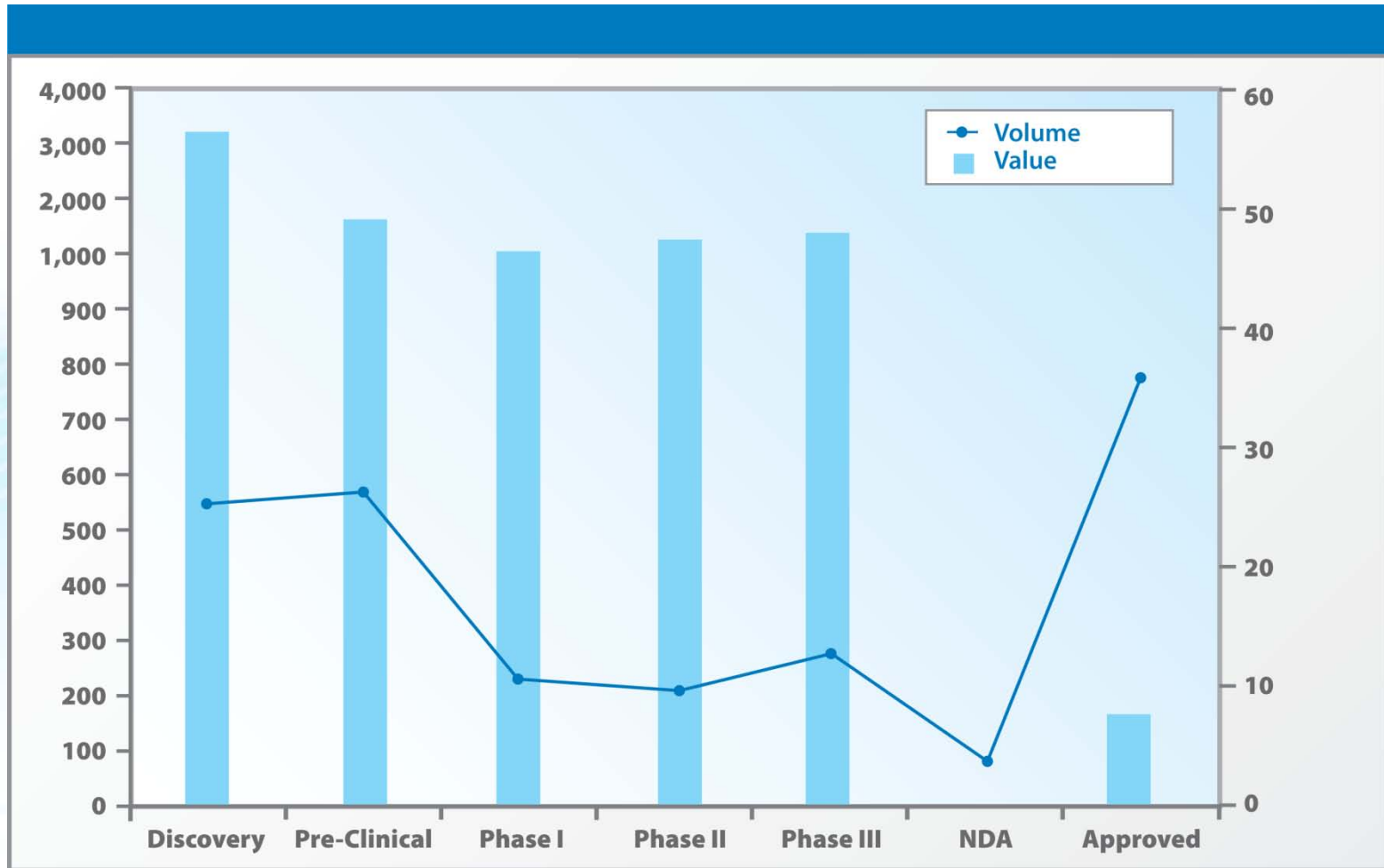
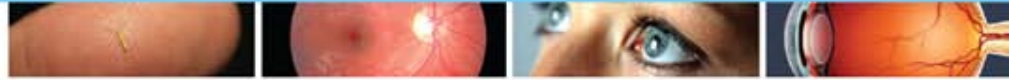
## DRUG LICENSING





## Licensing Activity Volume and Value - Quarterly



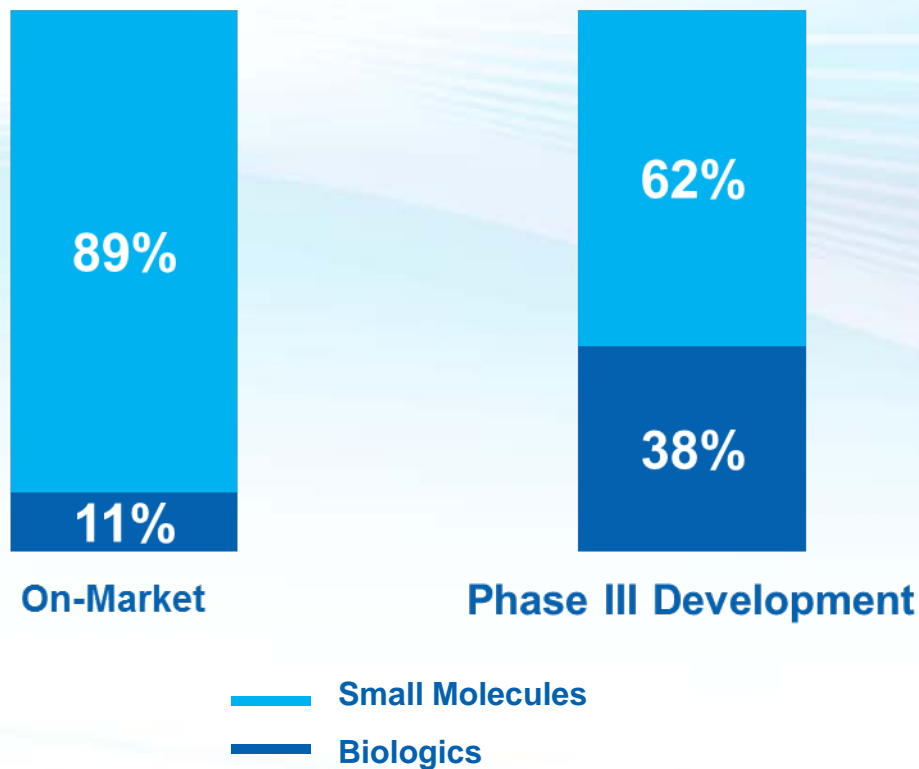


# Changing Direction of Pharma Pipeline



## Biologics: A Growing Share of Pharma Pipeline

Percent of Product

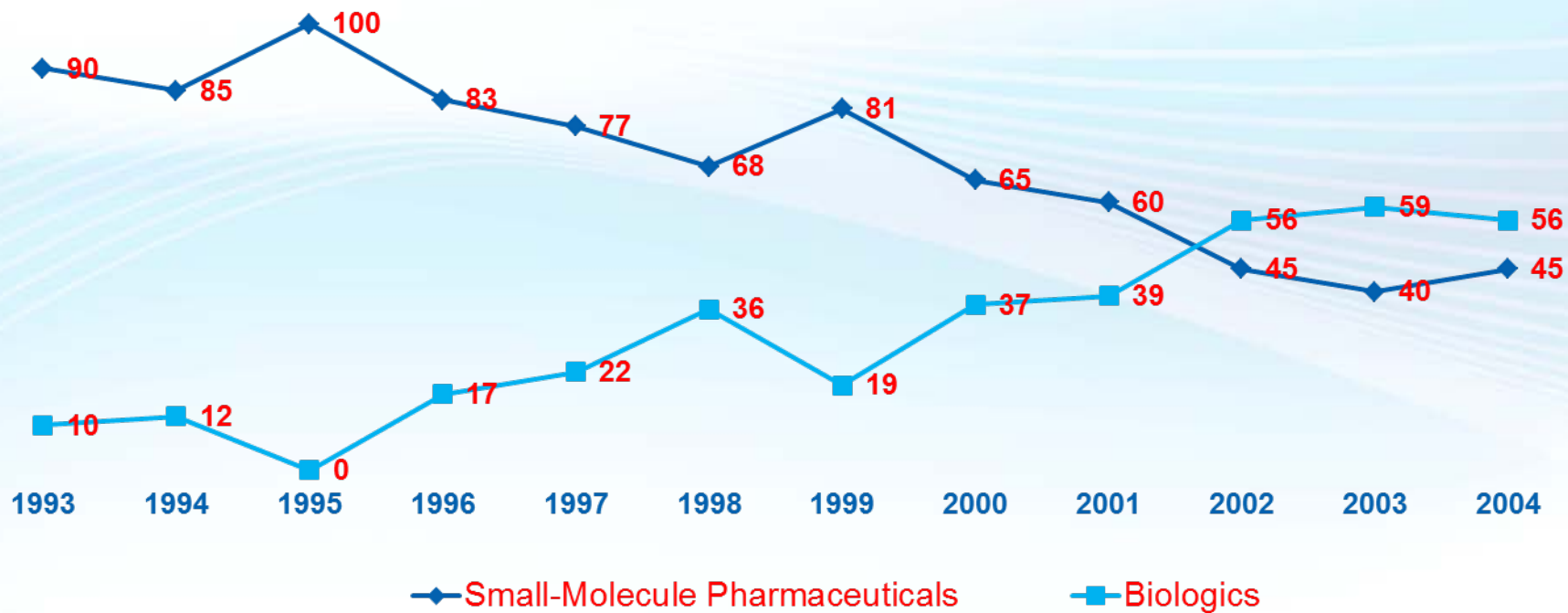


# NCEs versus Biologicals

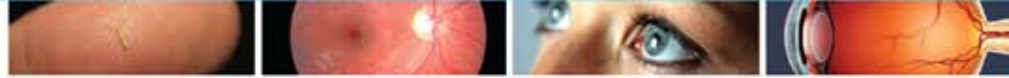


## Products Receiving FDA Approval

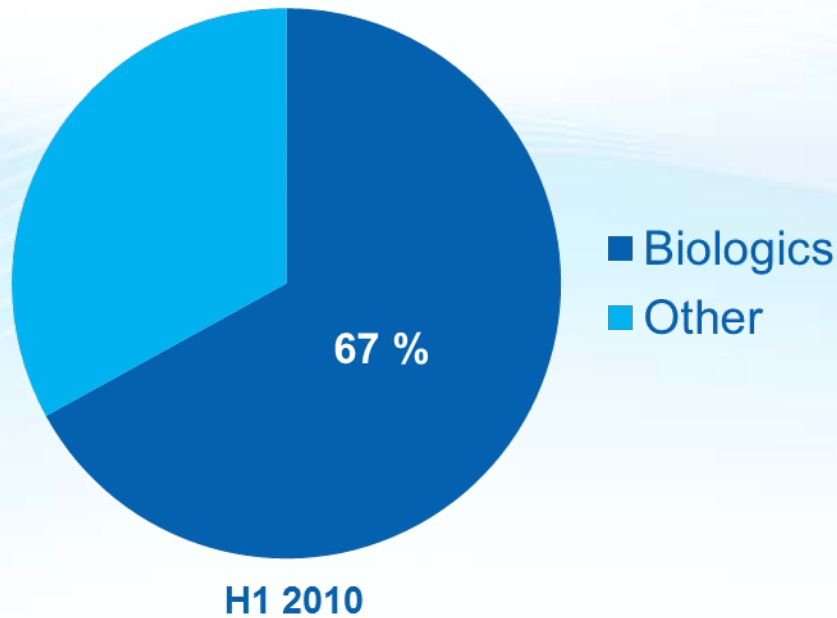
Percent



# Roche's boast: "The leader in Biotech"



## Biologics as proportion of Pharma sales



## Roche: Leader in Biotech

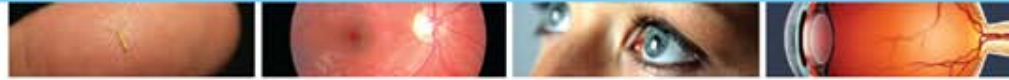
- 67% of Pharma sales from biotech products
- Approximately 85% of Diagnostics sales related to biotech products

# Top Global Biologic Categories



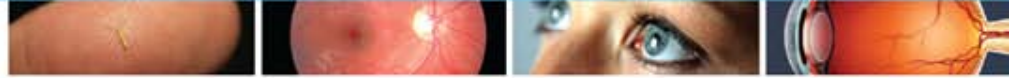
Disease Group <sup>1</sup>	2009 Sales <sup>2</sup> (\$B)	Patent Expirations <sup>3</sup>	
		U.S.	EU
Oncology	\$23.8	2010 - 2019	Expired – n/a
Immunology & Inflammation	\$22.6	2012 – 2016	n/a
Diabetes	\$14.0	2013 - 2017	2010 - 2014
Multiple Sclerosis	\$9.2	Expired - 2026	Expired - 2015
Erythropoiesis-Stimulating Agent	9.1	2015 - 2024	Expired - 2014
Others	22.0	--	--
Total:	<b>\$100.7B</b>		

# FDA Pathway Considerations

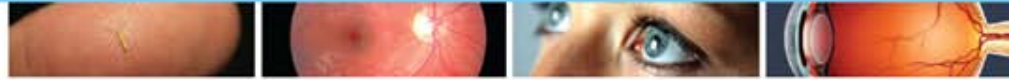


- **BLA pathway exists for biologic products**
- **Patent Protection and Affordable Care Act of 2010 created abbreviated BLA pathway**
- **No established timeline requiring the FDA to develop guidance**
  - **Potential Workshop in November 2010**
- **Companies engaging FDA early in biosimilar program development**

# BLA vs. ABLA Route Considerations



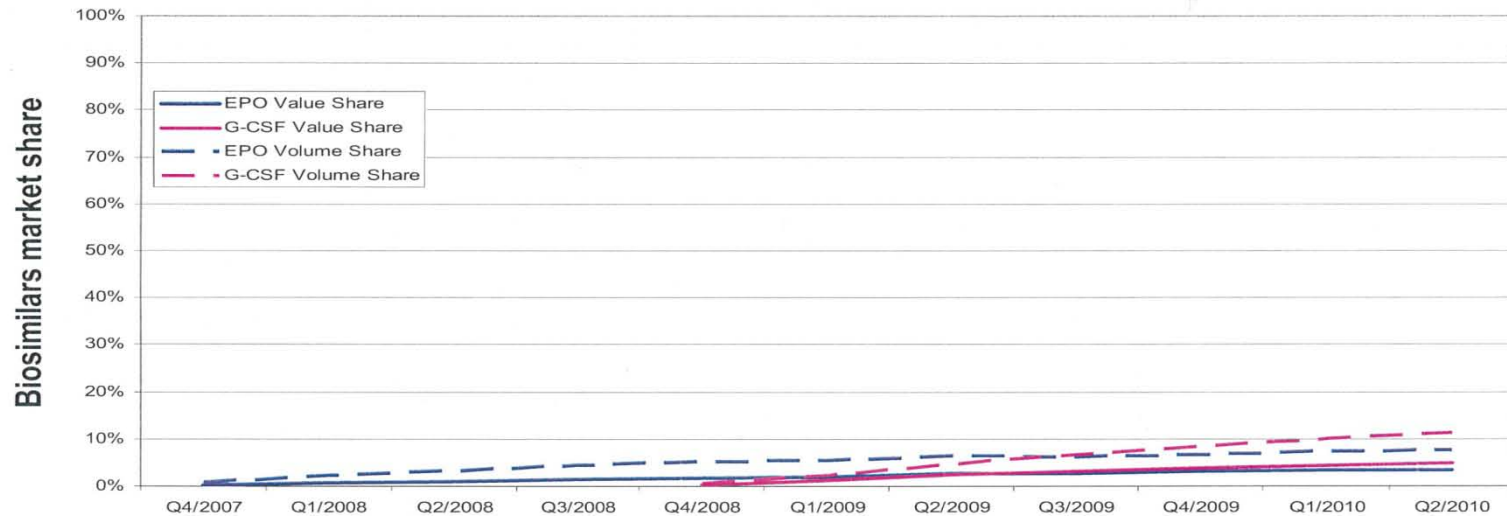
- **Three issues relative to ABLA route:**
  - **12+ years of data exclusivity for the originator**
  - **Evergreening**
  - **Patent dispute process**
- **Companies *should be* open to utilizing both the BLA and the ABLA pathway depending on individual product clinical requirements**



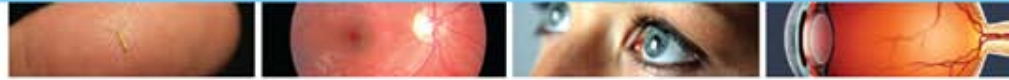
# Market penetration of biosimilars in Europe



## Biosimilars (EPO, G-CSF) in Western Europe

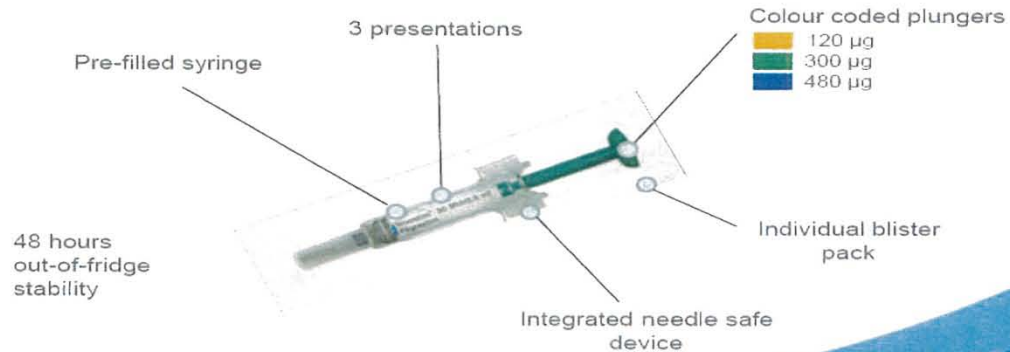


Source: IMS MIDAS Sales in PADDs



## Building Noticeable Differentiation

### Nivestim differentiating factors



Non-clinical differentiators can be designed to improve on originator products