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# Eight Thoughts On Biosimilars

SCB Biosimilars Conference Call

December 9, 2008

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**SEE DISCLOSURE APPENDIX OF THIS REPORT FOR IMPORTANT  
DISCLOSURES AND ANALYST CERTIFICATIONS**

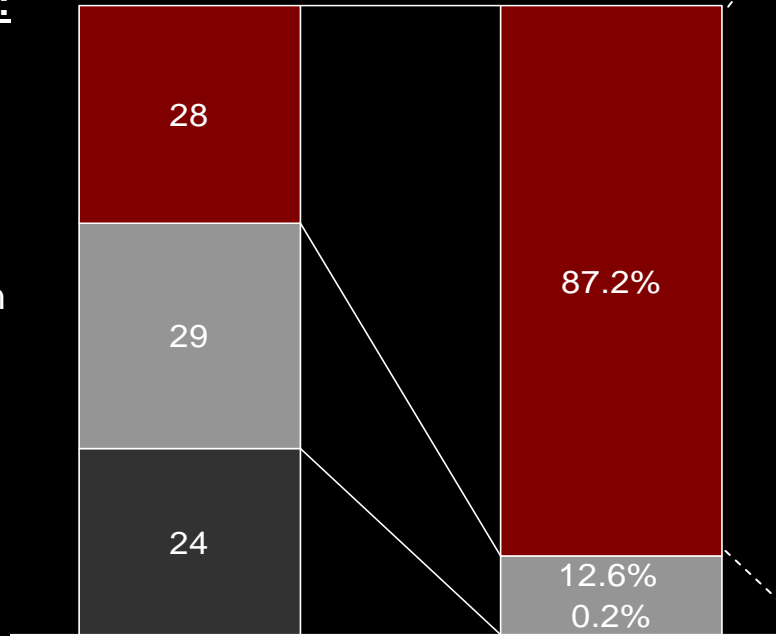
# Biologics: Too Big To Ignore

28 Molecules make up 87.2% of value of biologics

\$112 billion

Peak Sales:

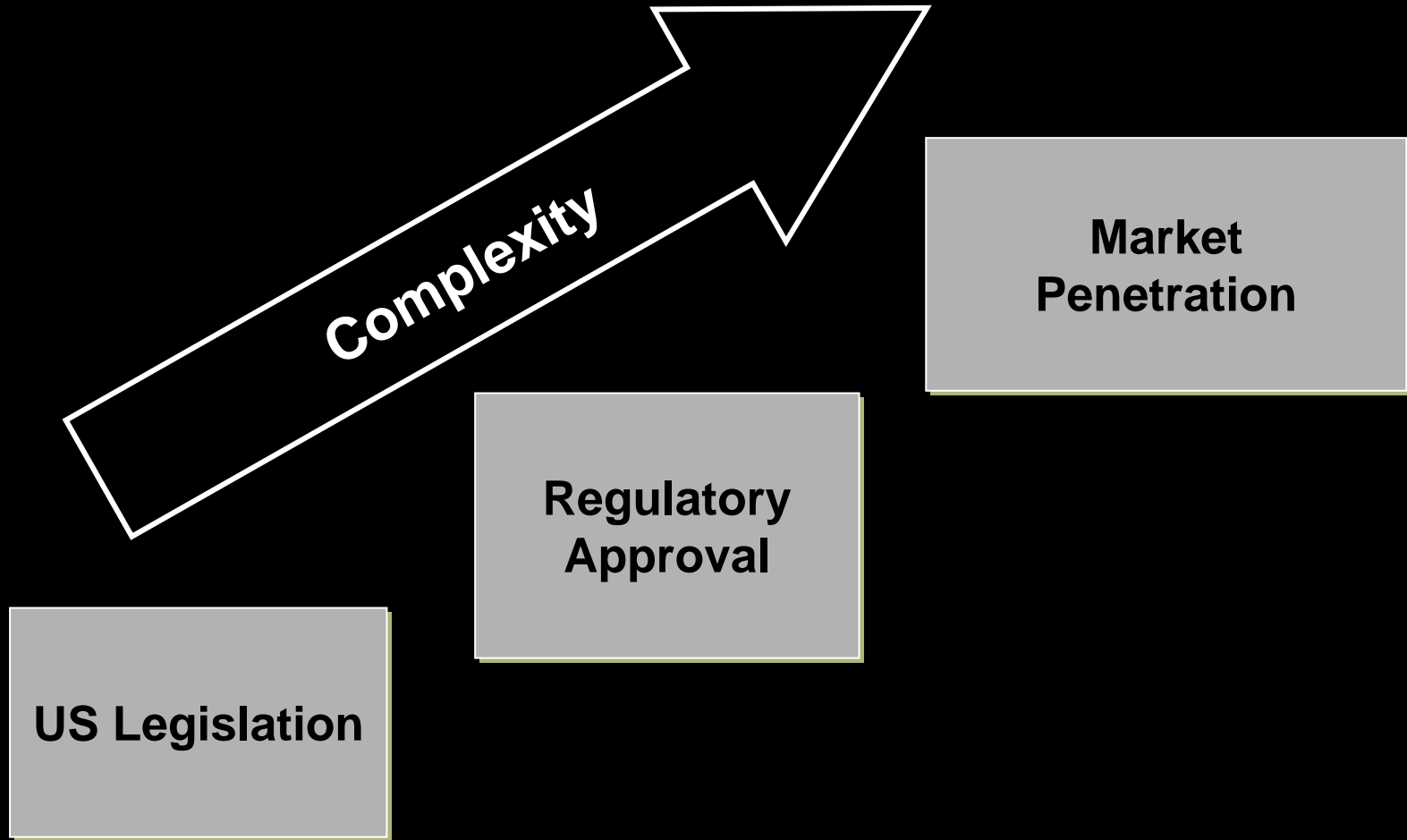
\$100 million  
- \$1 billion



Brand Name	Global Peak Sales > \$1 Bil	Brand Name	Global Peak Sales > \$1 Bil
Avastin	9.2	Avonex	2.6
Enbrel	8.0	Novolin	2.5
Remicade	6.5		

# Ready, Set...For A Marathon, Not A Sprint

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# Eight Thoughts On Biosimilars

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- ! US legislation: Details Matter
- ! The FDA: The unknown regulatory hurdle
- ! Market structure: PBM as the king-makers?
- ! Costs: Time and money, capacity at a premium
- ! Targets: Now, Later and Never
- ! Market share: Benchmarks and wrinkles
- ! Market participants: The usual and unusual suspects
- ! Impact on the Generic Group: Is It All Worth It?

# US Legislation: Watch For Details To Determine Market Structure

## Approval Requirements

- Agreement: FDA will determine requirements case-by-case
- Definition of Biologic still open (vaccines? DNA? mixtures?)
- Innovators want to tack on process requirements (guidance docs, clinical trial, all patent resolution)
- Generics want requirements for timely FDA actions (PDUFA dates, citizen petition)

## Approval Standards

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# The FDA – Mixed Signals

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## Agency is clearly interested in Biosimilars

**Engaged**

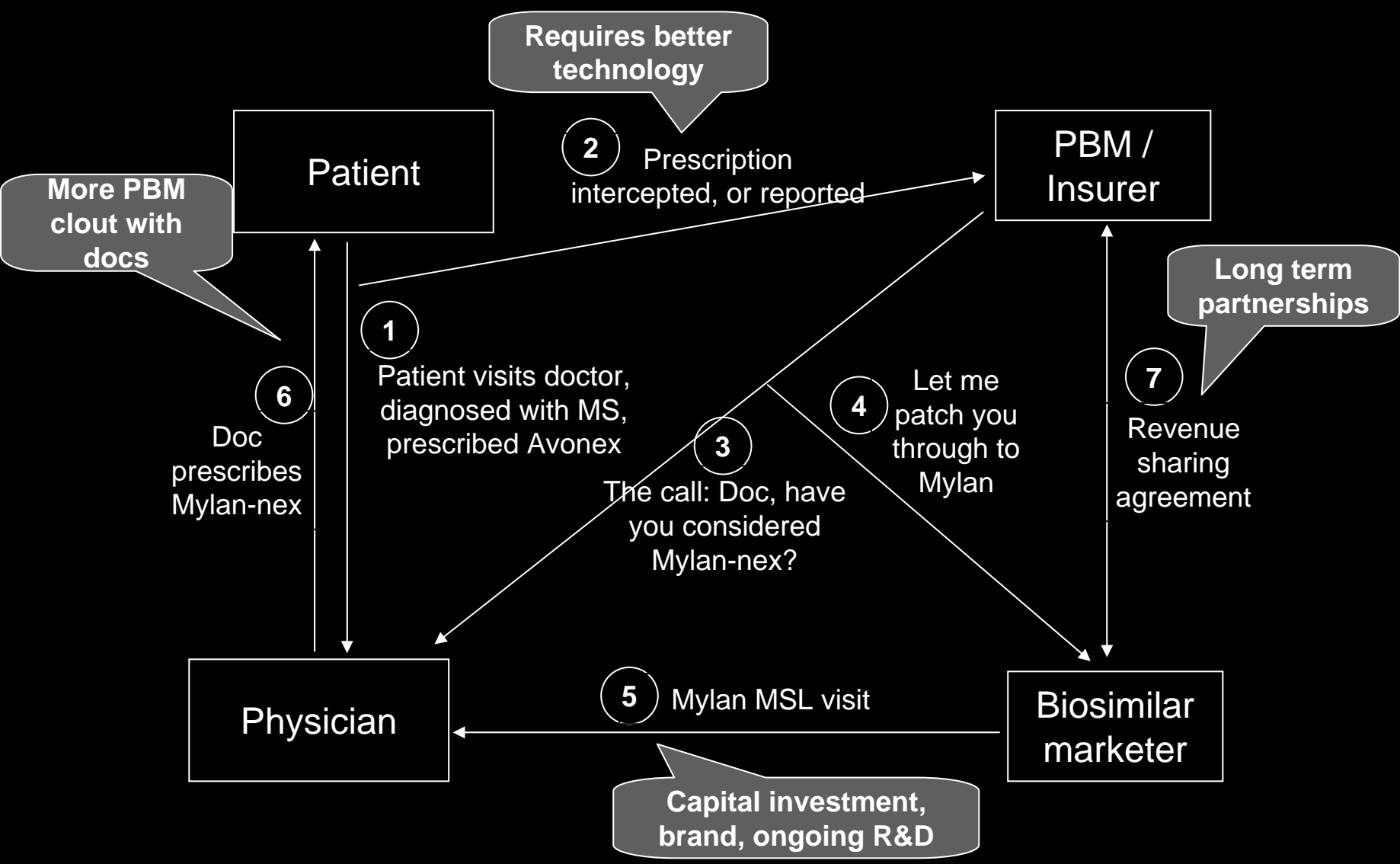
- Involved in debate
- Proactively divided reviewing responsibilities

**hGH**

- Approved under 505j, may have received in



# Market Structure – PBM As The King-Makers? Winner Takes All Markets?



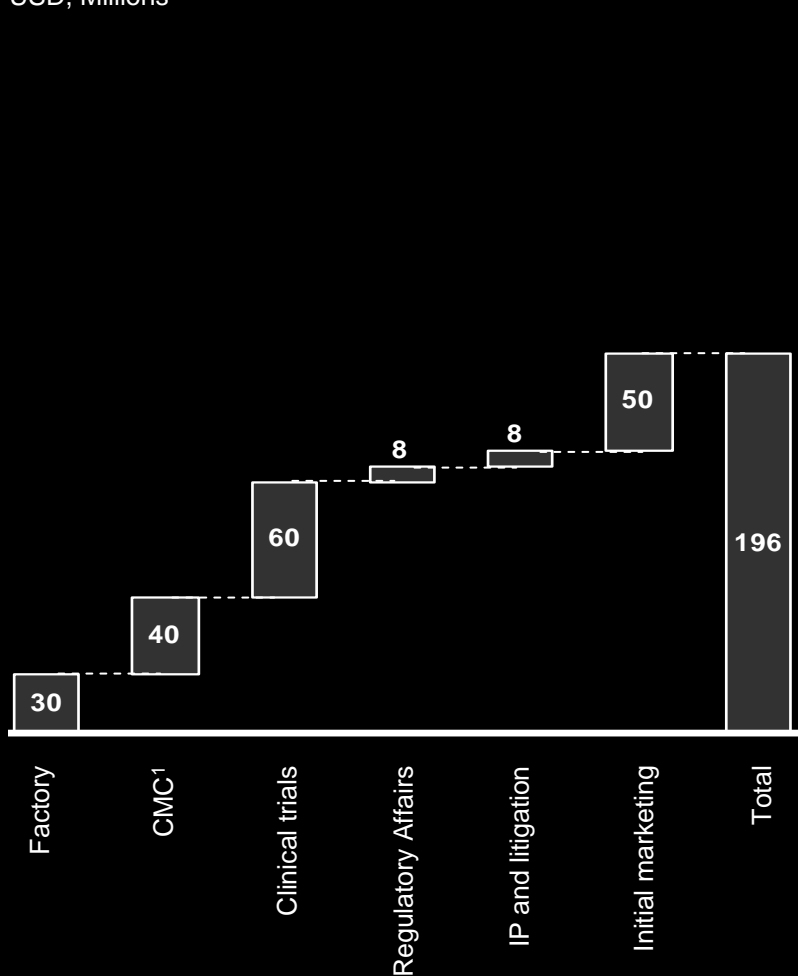
Note: conceptual example. Source: Bernstein estimates and analysis



# Costs (I): Not A Low Cost Proposition

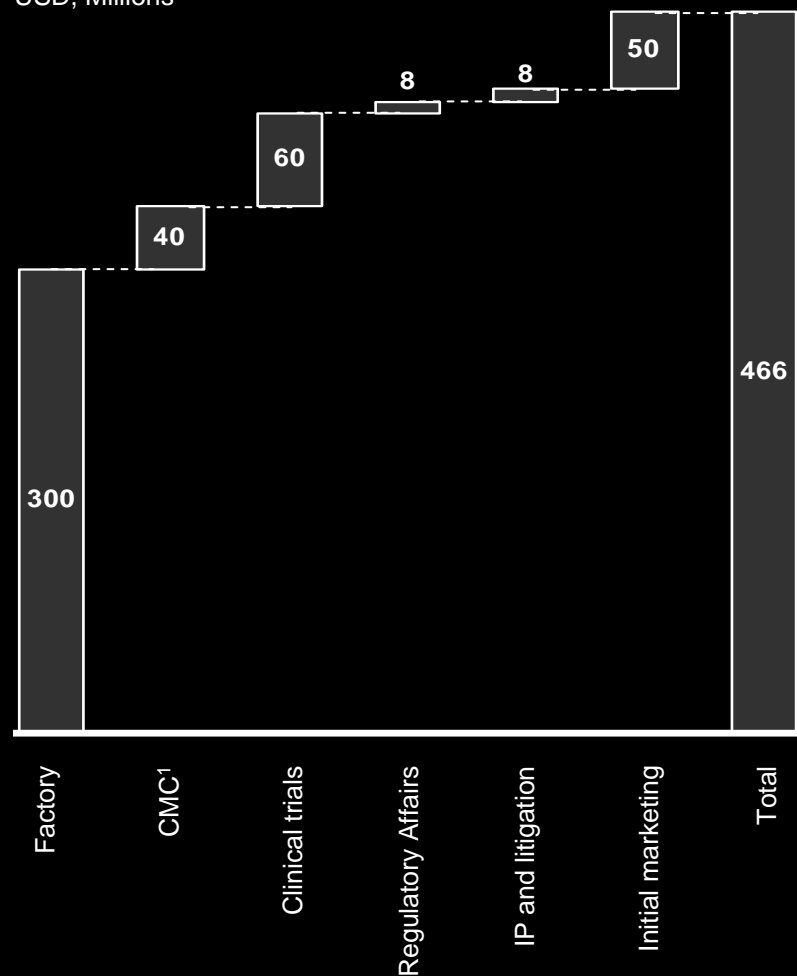
## Bacterial facility

USD, Millions



## Mammalian facility

USD, Millions



## Costs (II): The CapEx Dilemma

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Building mammalian capacity makes CFO uneasy

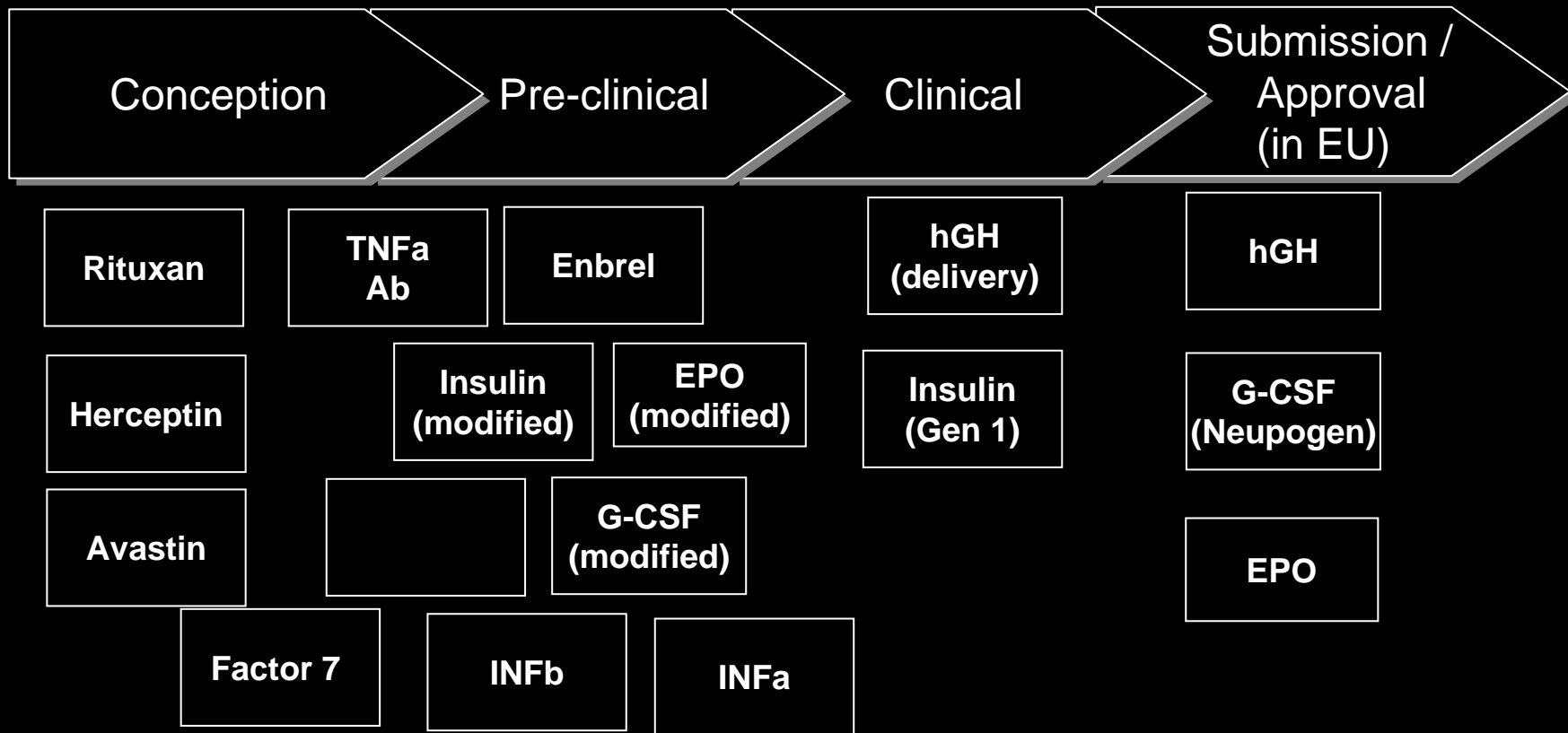
- \$420M upfront: \$300M to build, \$30M/yr while in trials \* 4 years  
X (risk of approval)  
+ (risk of FDA or court delay\*\$30M/yr)

Outsourcing or sharing capacity is relatively attractive

- Global peak demand for Herceptin: 500kg/yr, Enbrel: 400kg/yr
- Can be achieved in ~20,000L production facility
- Modern facilities at 80,000L

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# Targets: Where Are They In Development

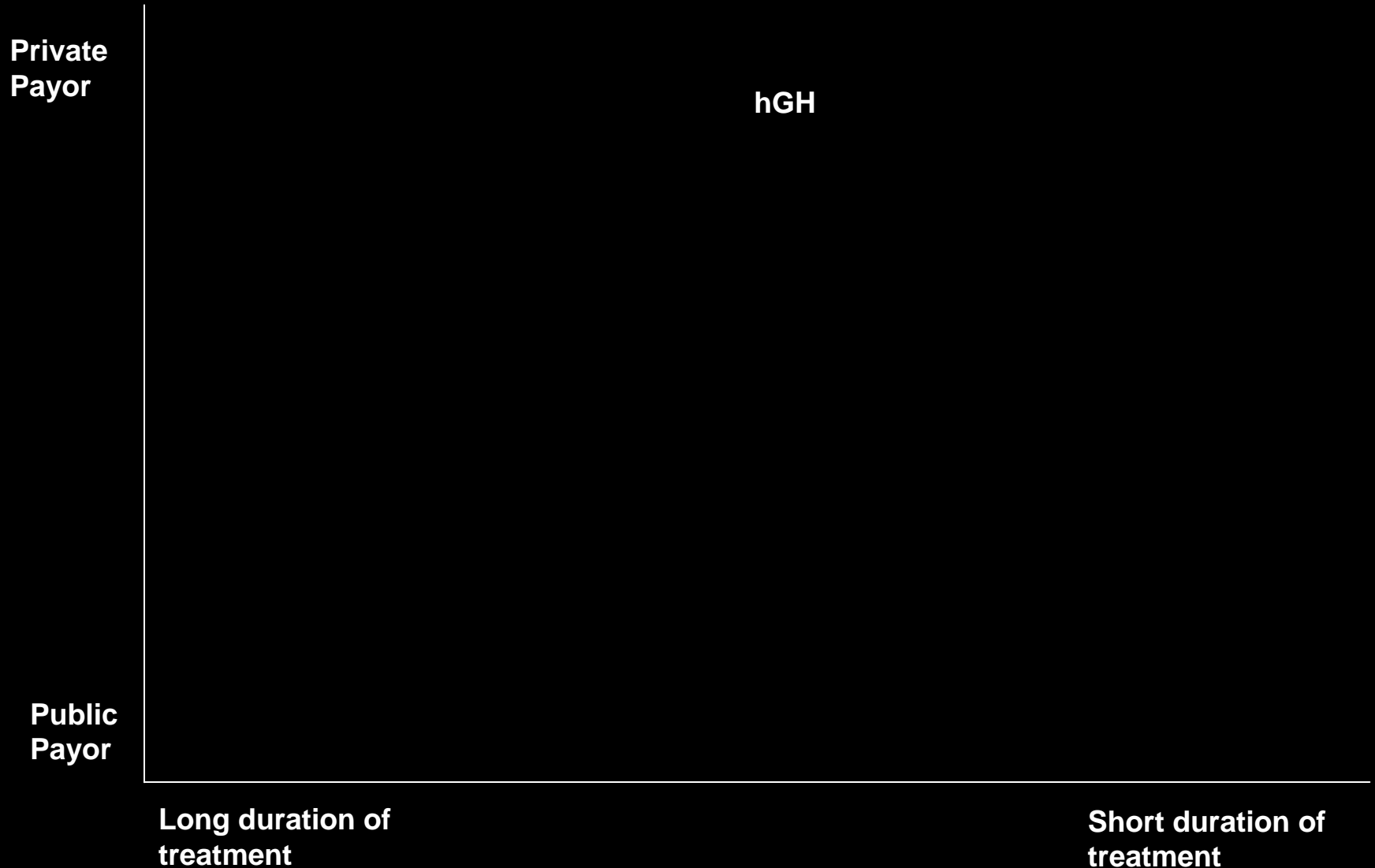






# Market share (II) – There is always a wrinkle

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# Market Participants (II) – The usual Suspects

		Motivation	Disclosed R&D program	Regulated markets Bio-Manufacturing	Innovative regulatory	Innovative marketing	Patent challenges	Capital
<b>Merck</b>	Entry to Biologicals?	●	◐	●	●	●	○	●
<b>Wyeth</b>	Capacity play?	○	●	●	●	●	○	●
<b>Lonza</b>	Compete with clients?	○	●	◐	●	●	○	◐
<b>BIIB</b>	Bio-betters?	○	●	●	●	●	○	●
<b>HGSI</b>	Dual strategy?	○	◐	◐	○	○	○	◐

Bio-betters as tie breakers ?



# Is It All Worth ? (I)

Contribution to generic EBITBA per \$1B branded sales

	Conservative scenario	Moderate scenario	Aggressive scenario
Notional branded sales	\$1B	\$1B	\$1B
Biosimilar share (%)	20%	50%	75%
Biosimilar price (% of BRx)	80%	70%	55%
<b>Biosimilar revenue (\$M)</b>	<b>\$160M</b>	<b>\$350M</b>	<b>\$413M</b>
Biosimilar COGS (% rev)	12.5%	14%	18%
Marginal SG&A/R&D (% rev)	25%	27.5%	30%
<b>Biosimilar EBITDA (\$M)</b>	<b>\$104M</b>	<b>\$205M</b>	<b>\$215M</b>

# Is It All Worth It? (II)

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Contribution to generic EBITBA

Conservative scenario

\$6.64B  
\$3.36B  
\$2.88B  
\$3.74B  
\$5.99B  
\$7.95B

20%

80%

**\$4.89B**

12.5%

25%

**\$3.06B**

**29%**



