



# LEVERAGING OUR BIOLOGICS EXPERTISE IN BIOSIMILARS

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# SAFE HARBOR STATEMENT

This presentation contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including statements about estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of June 15, 2016 and expressly disclaims any duty to update information contained in this presentation.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign) and difficulties or delays in manufacturing our products. In addition, sales of our products are affected by reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Our efforts to integrate the operations of companies we have acquired may not be successful. Cost saving initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our ongoing restructuring plan. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock.

This presentation includes GAAP and non-GAAP financial measures. In accordance with the requirements of SEC Regulation G, reconciliations between these two measures, if these slides are in hard copy, accompany the hard copy presentation or, if these slides are delivered electronically, are available on the Company's website at [www.amgen.com](http://www.amgen.com) within the Investors section.



# WE EXPECT THE BIOSIMILARS BUSINESS TO LOOK MORE LIKE BRANDED BIOLOGICS THAN SMALL MOLECULE GENERICS

		Generics	Biosimilars	Biologics
Development	Scientific Difficulty	Low		High
	Time	Short (3–4 Years)		Long (10+)
	Cost	Low (< \$5M) Bioequivalence		High (> \$800M) Full Clinical Dev
Ops	Manufacturing Process	Simple, Short		Long, Complex
Commercial	Sales and Marketing	Low		High
	Decision Makers	GPOs, MCOs		Prescribers, Patients
	Competitors	Many, Little Differentiation		Few, Well Differentiated

**Deep scientific skills and strong branded commercial capabilities required for success**

GPO = group purchasing organization; MCO = managed care organization

Provided February 6, 2017, as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.

Source(s): Market research on file.

# CHALLENGES AND THE AMGEN SOLUTION

## Challenge

- Scientifically complex and difficult to design and manufacture
- Uncertain and complex regulatory and legal/patent requirements
- Overcoming stakeholder uncertainty
  - Compromise in quality?
  - Biosimilars not all the same and each represents distinct therapeutic choice
- Reliability of supply
- High capital commitment

## Amgen Solution

- ➔ Deep biologics scientific skills and strong biologics manufacturing heritage
- ➔ Core biologics regulatory and legal/patent expertise with strong track record
- ➔ Branded commercial capabilities and Amgen brand equity
- ➔ Amgen heritage = “every patient every time”
- ➔ Return on capital criteria

# FDA STANDARD FOR BIOSIMILARS

The biological product is **highly similar** to the reference product notwithstanding minor differences in clinically inactive components

**AND**

There are **no clinically meaningful differences** between the biological product and the reference product in terms of the safety, purity and potency of the product

# BIOSIMILAR SCIENCE IS COMPLEX, TYPICALLY REQUIRING A MATCH OF ~ 100 CRITICAL ATTRIBUTES NECESSARY TO SHOW BIOSIMILARITY

Product Example

## Amgen Biosimilar Attributes Compared to U.S. and EU Reference Product

	ABP vs. U.S. Reference Product	ABP vs. EU Reference Product
General Properties		
Primary Structure		
High-Order Structure		
Biological		
Product-Related Substances and Impurities		
Process-Related Impurities		
Particles and Aggregates		
Thermal-Forced Degradation		
<b>Attributes Matched</b>	<b>91</b>	<b>93</b>
<b>Attributes Not Matched but Not Critical</b>	<b>4</b>	<b>2</b>
<b>Attributes Not Matched and Critical</b>	<b>0</b>	<b>0</b>

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# SAFE, RELIABLE BIOLOGICS MANUFACTURING

- **Customers want safe, effective and reliable supply of biologic medicines**
- **Our biosimilars will be manufactured with the same high Amgen standards as our originator biologics**
- **Most biosimilars will be manufactured using next-generation technologies**





# STRONG BRANDED COMMERCIAL CAPABILITIES

- **Branded commercial strategies are a key to success in the EU and likely will be needed for success in the U.S.**
- **Amgen has deep, branded biologic commercial capabilities in core therapeutic areas that can be leveraged to sell Amgen biosimilars**
  - Sales and marketing
  - Pricing and reimbursement
  - Patient services
  - Contracting
- **Specific product commercial strategies are being developed**
- **A deep, high-quality portfolio will help international expansion, leveraging Amgen brand equity**



# KEY QUESTIONS YET TO BE ANSWERED IN EVOLVING BIOSIMILARS MARKET

- **Timing of market entry**
- **Number of competitors**
- **Discounts offered by biosimilar competitors and originators**
- **Potential delays caused by patent disputes**
- **Policies that continue to shape the biosimilars environment (reimbursement, naming, labeling, interchangeability and state pharmacy laws)**

# AMGEN'S POSITION ON KEY ISSUES

<b>Biologics Price Competition and Innovation Act (BPCIA)</b>	<b>Amgen supported enactment of BPCIA</b>
<b>Extrapolation of Indications</b>	<b>Supportive, given sufficient pharmacological and clinical evidence</b>
<b>Interchangeability</b>	<b>Manufacturers should demonstrate that patients face no additional risk by alternating or switching products</b>
<b>Naming Convention</b>	<b>Unique nonproprietary names serve to identify manufacturers, promoting traceability and minimizing unwarranted class attribution</b>

# OUR UNIQUE CAPABILITIES POSITION US FOR LEADERSHIP IN BIOSIMILARS

	Status	Originator Worldwide 2016 Sales*
ABP 501	FDA approved	HUMIRA® ~ \$16B
ABP 980	Phase 3 breast cancer completed	Herceptin® ~ \$7B
ABP 215	Filed for approval	Avastin® ~ \$7B
ABP 710	Phase 3	REMICADE® ~ \$8B
ABP 798	Phase 3	RITUXAN® ~ \$8B
ABP 959	Phase 1	Soliris® ~ \$3B
ABP 494	Process development	ERBITUX® ~ \$2B
Molecules #8–#10	Process development	~ \$11B
<b>Total</b>		<b>~ \$60B+</b>

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# AMGEN BIOSIMILARS REPRESENT A COMPELLING GROWTH OPPORTUNITY

- **Biosimilars are more like branded biologics than generics, requiring deep scientific skills and branded commercial capabilities**
- **Amgen has significant competitive advantages and is making good progress**
- **Big opportunity (\$3B+ annual revenue potential)**

Annual revenue guidance as of September 18, 2015, and is not being updated at this time.

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