Biosimilar Drug Formulations

ANMD-MRS9-085 · Advanced Therapeutics & Biomanufacturing

A Global Sustainability Due Diligence & Market Research Study

History 2020–2024 · Base Year 2025 · Forecast 2025–2032 · Outlooks 2035 / 2040 / 2050 · Currency US$

WHY THIS REPORT

Biosimilar drug formulations are the affordability engine of the biologics market — the mAb, insulin/hormone, fusion-protein and growth-factor biosimilars that follow originator patent expiry to expand access and cut healthcare costs. This decision-grade study sizes the global market three ways — value, doses/patients treated and production volume — across biosimilar type, regulatory status and application, across seven regions and four scenarios to 2032, with outlooks to 2050.

SUSTAINABILITY & SDG IMPACT — THE ANMD LENS

Sustainability is this report's backbone, not an afterthought. Biosimilar drug formulations deliver measurable cost reduction and expanded access to biologics, while affordability and treatment-economics improvement across major diseases strengthen the health-equity story.

Mapped Sustainable Development Goals:

SDG 3	SDG 9	SDG 10	SDG 12	SDG 17
Good Health	Industry & Innovation	Reduced Inequalities	Responsible Consumption	Partnerships for Goals

Measurable sustainability outcomes assessed:

- Expanded access and lower treatment cost
- Affordability across oncology and immunology
- Healthcare-system savings as biologics lose exclusivity
- Manufacturing energy, single-use plastics and supply-chain ESG as material risks

Framework alignment: Double materiality mapped to GRI, SASB, ISSB, TCFD, TNFD, CSRD and the EU Taxonomy, with greenwashing and SDG-washing screens applied throughout.

WHAT'S INSIDE AT A GLANCE

53 Chapters	**9** Report Parts	**7** Regions Covered	**40+** Country Markets
2025–32 Forecast Horizon	**4** Forward Scenarios	**25+** Companies Profiled	**5** SDGs Mapped

REPORT COVERAGE

Geographic scope: North America, Europe, Asia Pacific, Latin America, Africa, Middle East and Rest of World — with named country intelligence. North America is the value leader (United States) on pipeline depth and CDMO capacity; Europe is the technology leader (Germany, United Kingdom, Switzerland) on platforms and manufacturing; Asia Pacific is the scale engine; other regions assessed on their own merits.

MARKET OVERVIEW

From patent cliff to access engine — where biologics go biosimilar, interchangeable and lower-cost.

Biosimilars are scaling on a patent-cliff tailwind. Demand is driven by originator expiries, payer pressure for lower-cost biologics, and interchangeability pathways — with manufacturing cost and regulatory navigation central to competitiveness. The market is read three ways — value, doses/patients treated and production volume — and forecast under four scenarios, each region reported separately.

- **North America is the value leader** — United States, on patent-cliff launches and interchangeability
- **Europe is the adoption leader** — Germany, United Kingdom and Nordics, on biosimilar uptake
- **Asia Pacific is the scale engine** — South Korea, China and India, on biosimilar manufacturing
- **Cost and regulation are the differentiators** — interchangeable designations plus manufacturing-cost discipline

REGIONAL OUTLOOK

Across seven reporting regions, the report separates early commercialisation leaders from high-growth and emerging markets — each profiled in full rather than aggregated into Rest of World.

Region	Stage	Lead Markets & Drivers
North America	Value leader	United States — pipeline depth, CDMO capacity, reimbursement
Europe	Technology leader	Germany, United Kingdom, Switzerland — platforms, manufacturing
Asia Pacific	Scale engine	China, Japan, South Korea — biomanufacturing, build-out
Middle East	High-growth	Saudi Arabia, Israel, UAE — biotech investment, access
Latin America	Emerging	Brazil, Mexico — biologics access, manufacturing
Africa	Emerging	South Africa, Egypt — access, local manufacturing

KEY MARKET DRIVERS & RESTRAINTS

Drivers	Restraints
• Patent-cliff + payer-cost-pressure convergence	• Originator-defence & launch-sequencing pressure
• Affordability & access value	• Regulatory navigation & interchangeability burden
• Policy support (interchangeability, biosimilar pathways)	• Manufacturing-cost & pricing competition
• Manufacturing-cost & commercial-reach economics	• Single-use plastics & sustainability scrutiny
• Process, formulation & analytics gains	• Uptake, substitution & reimbursement gaps

SEGMENTATION SNAPSHOT

By Biosimilar Type	mAb biosimilars · insulin & hormone · fusion-protein · filgrastim / growth-factor · interchangeable
By Regulatory Status	Approved · interchangeable · in development
By Application	Oncology · rare / genetic disease · immunology & infectious disease
By End User	Hospitals · pharma / biotech · CDMOs · academia
By Business Model	Product sales · CDMO services · licensing
By Region of Supply	Domestic · imported

TABLE OF CONTENTS — PARTS & CHAPTERS

The full report is organised into nine parts across 53 chapters, listed below. Detailed sub-headings, country tables and directories are provided in the full report.

COMPETITIVE & INVESTMENT SNAPSHOT

The competitive field spans global biopharma majors, specialist biosimilar drug formulations makers, and emerging innovators. Deal activity — M&A, technology acquisition and platform expansion — signals a market consolidating around scalable, scaled, GMP-ready platforms.

Representative players profiled in the full report:

Sandoz Group AG · Pfizer Inc. · Amgen Inc. · Samsung Bioepis Co., Ltd. · Celltrion, Inc. · Biocon Biologics Limited · Teva Pharmaceutical Industries Ltd. · and 20+ further profiled players across specialists, CDMOs and challengers and emerging innovators.

Investment intelligence: venture, infrastructure, development, climate and blended finance, green bonds and sustainability-linked loans — culminating in a bankability assessment and a Go / No-Go / Conditional-Go investment verdict.

KEY QUESTIONS THIS REPORT ANSWERS

? How large is the global biosimilar drug formulations market, and how fast will it grow to 2032?
? Which regions, countries and segments offer the strongest risk-adjusted opportunity?
? How do manufacturing cost, scalability and access change value versus incumbent therapies?
? Who leads, and where is the competitive and patent white space?
? Is the investment case bankable — and under what conditions?
? How does the category align with the SDGs, health-equity and patient-access and disclosure regulation?

WHY ANMD — THE DIFFERENCE

Most market studies stop at units and revenue. This report is built as a sustainability due diligence instrument — fusing market sizing with ESG, SDG, climate, water and natural-capital intelligence and a decision-ready bankability verdict in a single architecture.

- **Triangulated sizing** — every market read three ways so value, volume and production-volume views reconcile rather than conflict.
- **Region-honest forecasting** — Latin America, Africa and the Middle East reported in full, never hidden inside Rest of World, every forecast resolved to the 2025 base year.
- **Integrated evidence base** — company, patent and project databases linked to the analysis, with published-filing patents and FTO treated as an indicator, not a legal conclusion.
- **No-fabrication discipline** — every estimate carries a data-confidence rating and disclosed sources; gaps are flagged for further diligence, never filled with invented numbers.
- **Anti-greenwashing rigour** — SDG-washing and greenwashing screens plus claim-substantiation checks built into the ESG and project analysis.
- **Decision-first structure** — 9 Parts and 53 Chapters culminating in stakeholder playbooks and a clear Go / No-Go / Conditional-Go investment verdict.

WHO SHOULD BUY THIS REPORT

Investors and life-sciences / PE funds, pharma and biotech companies, CDMOs and CROs, hospitals and treatment centers, tools and consumable suppliers, payers and regulators, and corporate strategy and ESG teams, plus strategic corporate planners and decision-makers.

Access the Full Report

The complete report delivers all 53 chapters in full, with every sub-heading, country table, company and patent directory, forecast model and due diligence checklist.

Purchase at **www.anewmarketdynamics.com** · Standard & Premium licences · Single-Site (SSL) and Global-Site (GSL) options at checkout.

Want the Complete Detailed Table of Contents?

This prospectus lists the nine parts and 53 chapters. The complete detailed table of contents — every sub-heading, country table, exhibit, company and patent directory and annex — is available on request to registered users. To receive it, register with your official company email at **www.anewmarketdynamics.com**. The full detailed table of contents will be sent directly to your registered company email address.