

Next Generation Antibody Therapeutics Market Size to Double, Hitting USD 5.28 Billion by 2033 | By DataM Intelligence

Next-Generation Antibody Therapeutics Market: Engineered Antibodies to Power a Multi-Billion Dollar Oncology & Immunotherapy Revolution

AUSTIN, TX, UNITED STATES,
September 19, 2025 /

EINPresswire.com/ -- According to DataM Intelligence: [Next Generation Antibody Therapeutics Market Size](#) reached US\$ 9.09 Billion in 2024 and is expected to reach US\$ 22.88 Billion by

2033, growing at a CAGR of 10.9% during 2025–2033.

Next-generation antibody formats including antibody-drug conjugates (ADCs), bispecific/multispecific antibodies, Fc-engineered constructs, and antibody-mimetic scaffolds are redefining biologics by delivering higher specificity, dual-target engagement, and improved

safety profiles. This rapid market expansion represents a significant opportunity for manufacturers to expand pipelines, scale production, and strengthen strategic partnerships.

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The market is entering a new era engineered antibody formats plus AI-driven discovery are unlocking precision treatments for cancer and rare diseases, making next-gen therapeutics a growth cornerstone”

*Gundreddy Gopinadh |
Research Head*

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Next Generation Antibody Therapeutics Market

Key Growth Drivers

The market is fueled by robust investments and clinical innovation. In March 2025, Callio

Therapeutics launched with a USD 187 million Series A financing to advance HER2-targeted dual-payload ADCs. Oncology remains the largest therapeutic segment, accounting for 41.18% of the market in 2024. For manufacturers, this growth outlook supports stronger R&D investment and enhances their ability to attract capital and licensing deals.

Regulatory Landscape

Collaborations with regulators are accelerating the path to approval. In July 2025, Sutro Biopharma partnered with the U.S. FDA to establish reference standards for ADC development, underscoring the agency's proactive stance on next-gen biologics. Such developments benefit manufacturers by signaling more supportive approval frameworks, provided they invest in advanced safety models, biomarker-driven patient selection, and compliance readiness.

Challenges Ahead

Despite strong momentum, safety concerns such as cytokine release syndrome (CRS), neurotoxicity, and off-target toxicities remain critical hurdles. Manufacturing complexities and regulatory scrutiny also present challenges that manufacturers must address to ensure successful commercialization.

Market Segmentation Insights

By Technology

Antibody-Drug Conjugates (ADCs) led the market in 2024, generating revenues of over US\$ 3.5 billion, fueled by approvals in oncology. ADCs continue to dominate pipelines, with more than 100 candidates in clinical trials worldwide.

Bispecific Antibodies, valued at US\$ 2.2 billion, are witnessing the fastest growth, driven by their ability to engage multiple targets simultaneously, particularly in immuno-oncology.

Fc-engineered / Fc-fusion proteins reached US\$ 1.8 billion in 2024, with extended half-life applications enhancing treatment convenience in chronic diseases.

Antibody Fragments & Scaffolds, though a smaller segment at US\$ 1.1 billion, are gaining relevance for their penetration capabilities in solid tumors and neurological applications.

Other emerging technologies-including trispecifics and engineered antibody formats-represent a collective US\$ 0.5 billion, with strong R&D momentum.

By Therapeutic Area

Oncology dominated the therapeutic landscape in 2024, contributing nearly 55% of total revenues (US\$ 5 billion). High prevalence cancers and accelerated FDA/EMA approvals for ADCs and bispecifics are reinforcing this dominance.

Autoimmune & Inflammatory Diseases generated US\$ 1.8 billion, with monoclonal antibody evolution expanding into biosuperiors and half-life extended therapies.

Infectious Diseases, valued at US\$ 0.9 billion, benefitted from antibody therapeutics against viral infections, including HIV and COVID-19 extensions.

Ophthalmology and Rare Diseases collectively accounted for US\$ 0.7 billion, with pipeline candidates targeting macular degeneration and rare genetic disorders.

By End-User

Hospitals accounted for the largest share in 2024, with revenues of US\$ 4.2 billion, reflecting their dominance in oncology and specialty infusion therapies. Specialty Clinics contributed US\$ 2.1 billion, particularly in autoimmune treatment settings. Ambulatory Surgical Centers (ASCs) and Academic & Research Institutes collectively generated US\$ 1.5 billion, with research-led antibody trials gaining traction.

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Regional Insights

United States

The U.S., valued at US\$ 4.1 billion in 2024, is the largest global market. Growth drivers include:

- Expedited FDA approvals for bispecific antibodies and ADCs in oncology.
- Strategic partnerships between biotech startups and big pharma to accelerate commercialization.
- Expansion of reimbursement frameworks for novel antibody therapies, particularly in oncology and autoimmune conditions.

Recent trends (2025) include Amgen's FDA approval of a bispecific antibody for relapsed multiple myeloma and Roche's U.S. expansion of its ADC portfolio targeting HER2-low breast cancer.

Japan

Japan, with a 2024 market size of US\$ 0.9 billion, represents Asia-Pacific's innovation hub for antibody therapeutics. Key developments include:

- PMDA's accelerated review pathways for next-generation biologics, reducing time-to-market by 20%.
- AstraZeneca and Daiichi Sankyo's continued expansion of their ADC portfolio in the Japanese oncology market.
- Rising collaborations between Japanese academic institutes and multinational pharmaceutical firms for antibody-based rare disease therapies.

Major players include:

F. Hoffmann-La Roche Ltd

Roche remains the global leader in next-generation antibodies, particularly ADCs. In 2024, its oncology antibody portfolio generated over US\$ 6 billion, with Kadcyra and Polivy leading sales. The company continues to expand into bispecific antibodies targeting hematologic malignancies and is investing heavily in trispecific formats.

Amgen Inc.

Amgen reported US\$ 28.2 billion in 2024 revenues, with next-gen antibodies forming a growing share. In 2025, Amgen secured FDA approval for a bispecific antibody in multiple myeloma, strengthening its hematology pipeline. Its strategy emphasizes accelerated clinical development, global licensing partnerships, and lifecycle management of established biologics.

Bristol-Myers Squibb (BMS)

BMS has established itself as a leader in immuno-oncology, with a diversified pipeline of bispecific antibodies and Fc-engineered products. In 2024, BMS invested US\$ 11 billion in R&D, with a significant allocation to antibody therapeutics. Its strategic acquisition of a biotech firm specializing in antibody fragments reinforced its presence in rare disease applications.

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