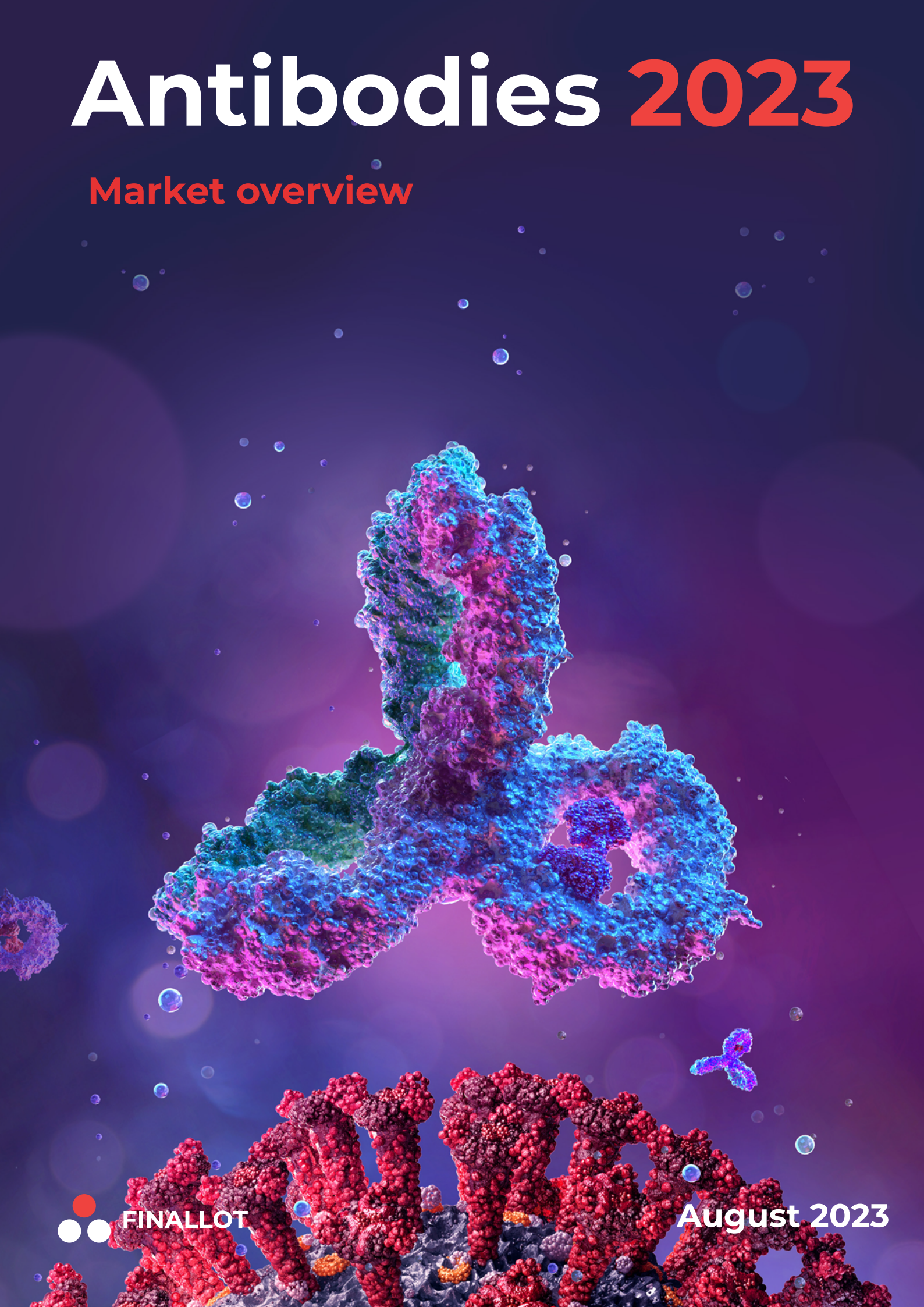
Antibodies 2023

Market overview

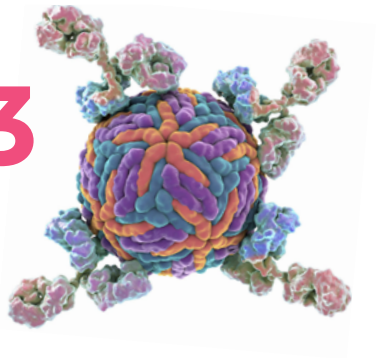


FINALLOT

August 2023

Antibodies 2023

Overview of the industry



Summary

Antibody drugs are developed using genetic engineering and recombinant DNA technology, utilizing living cells and organisms like E. coli, yeast, and mammalian cells. The rise in chronic and life-threatening diseases like asthma, multiple sclerosis, cancer, and heart diseases has bolstered the antibody-drug industry's growth globally. The report assesses the therapeutic applications of monoclonal antibodies (mAbs) in human medicine, including mAbs combined with cytotoxic agents, such as antibody-drug conjugates.

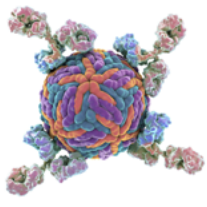
The advancements in genetic engineering have enabled the production of protein molecules with modified features. Due to their high specificity and low immunogenicity, protein therapeutics are increasingly used to treat life-threatening diseases like cancer, diabetes, and multiple sclerosis. The monoclonal antibody market is fueled by increasing R&D, a rise in sedentary lifestyles, the prevalence of various diseases, and the growing population of baby boomers.

Key manufacturers of mAbs include F. Hoffmann-La Roche Ltd., Johnson & Johnson Inc., Novartis AG, Biogen Inc., Amgen Inc., Merck & Co., and AbbVie Inc. Technological advancements have developed novel antibody drugs. Current R&D focuses on developing antibody-drug conjugates and bi-specific antibodies targeting proteins in cancer cells, thus halting disease progression in conditions like arthritis, multiple sclerosis, hepatitis, Crohn's disease, AIDS, etc.

The global antibody drug market hit $116.3 billion in 2020, projected to reach $208.6 billion by 2026. Human mAbs form the most significant revenue segment, followed by other mAbs categories. Despite potential competition from follow-on-biologics and biosimilars, mAbs should increase in oncology, autoimmune, and inflammatory diseases.

Threats to the U.S. market for antibody therapies include follow-on biologics and pricing pressure. Positive market effects are projected due to the quick development of medical technology, improved disease diagnostics, and the expansion of healthcare in developing nations. As numerous monoclonal antibodies got emergency use authorization and approval for COVID-19 treatment, the COVID-19 pandemic also contributed to the market's expansion.

Autoimmune disorders, solid tumors, lymphoma, leukemia, multiple myeloma, and other ailments like asthma, osteoporosis, cardiovascular diseases, etc., are disease classes that the antibody medication industry addresses. The highest market share in 2020 was oncology (40.4%), followed by autoimmune diseases (37%).



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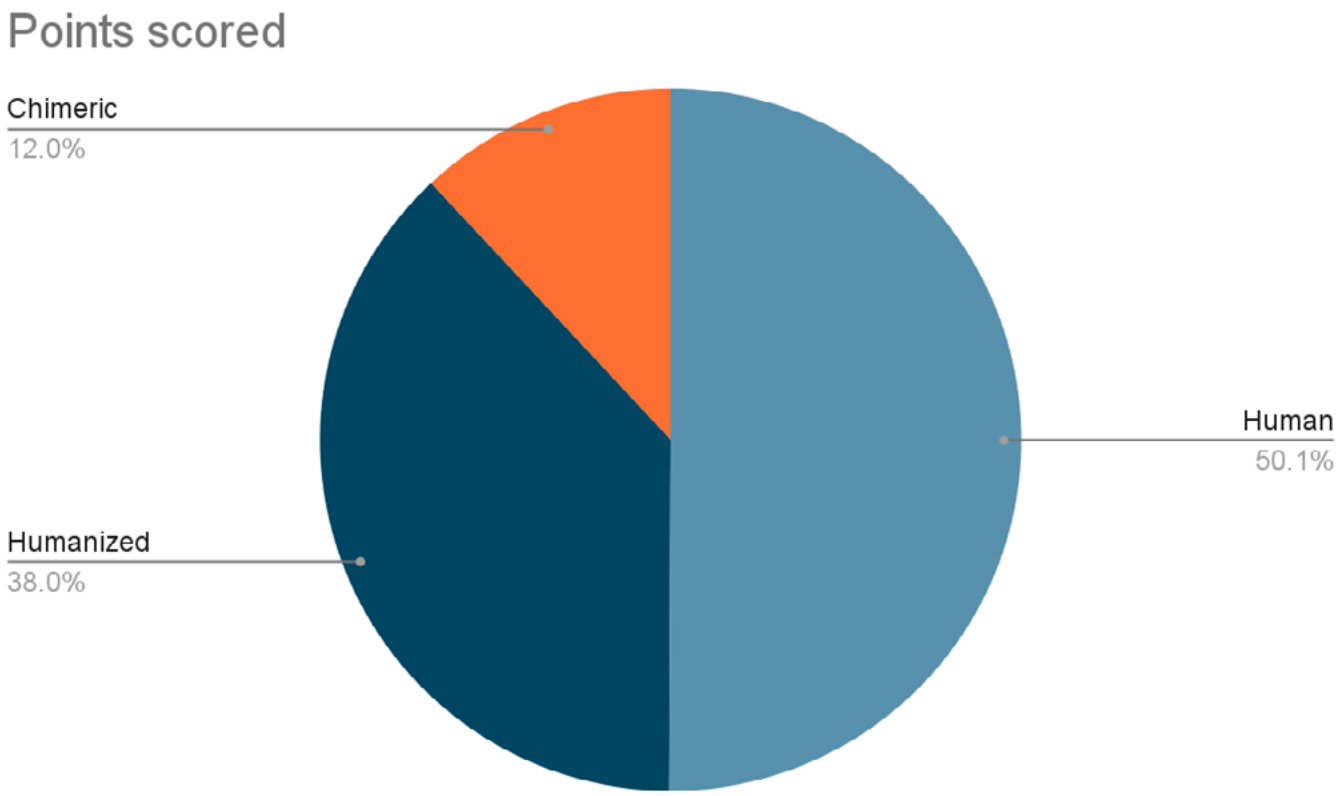
Global Market Shares for Antibody Drugs, By Antibody Type, Till 2026



Antibody type	2021	2022	2023	2026	2021-2026 CAGR
Human	58,409.6	66,433.3	76,757.1	110,316.4	13.6%
Humanized	50,136.5	54,725.4	58,189.2	79,272.6	9.6%
Chimeric	18,190.4	18,262.7	18,344.0	18,966	0.8%
Total	126,739.3	139,424.1	153,292.9	208,557.3	10.5%

Manufacturing of antibodies

Monoclonal antibodies (mAbs) are crucial in immunology, disease treatment, and as diagnostic markers. Their commercial production primarily uses the following methods: Hybridoma technology, Recombinant antibody production, and Antibody production in plants.

Hybridoma technology combines spleen-derived B cells that produce desired antibodies and immortal myeloma cells in culture. The selection of hybridomas is made using a gene property (HGPRT) that only B cells have and myeloma cells lack. The process allows the isolation of specific antibody-producing cells, which can then be cultured indefinitely to yield mAbs.

Recombinant antibodies are produced via display technologies like phage display. An antibody gene library is created with genes for variable regions of different antibodies. Phages are manipulated to express these antibodies on their surface. Desired antibodies are isolated, modified, and scaled up in cell culture expression systems. Notably, this technique offers more control over antigenic properties than hybridoma technology.

Antibodies can also be produced in plants. This approach utilizes transgenic plants as bioreactors for producing valuable recombinant proteins. The plant genomes are modified to carry the antibody genes expressed in the plant tissues. This economical and scalable method has the potential for large-scale production of mAbs.

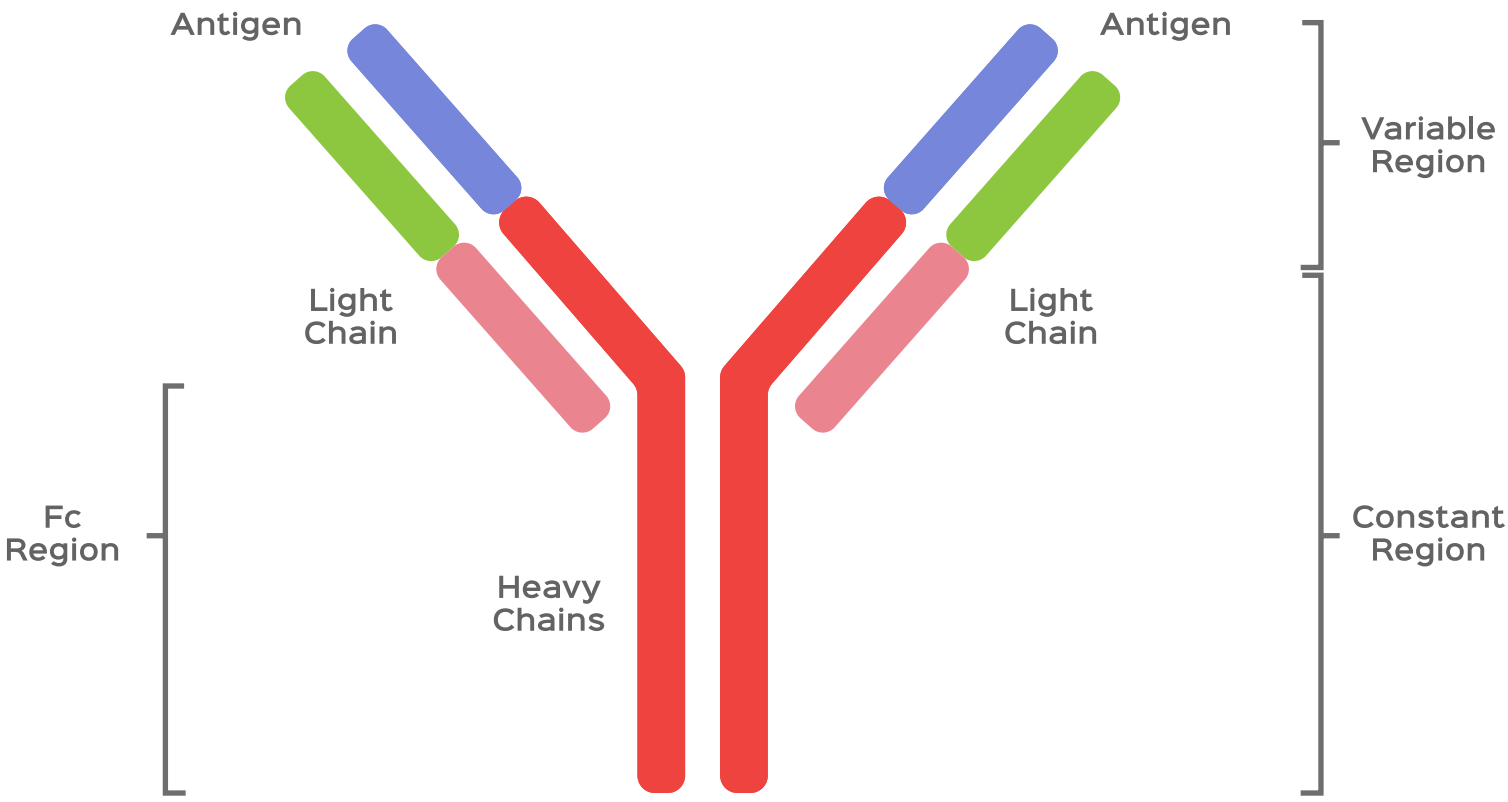
Antibodies can also be expressed in transgenic animals, where the inserted genes are expressed in the animal's milk. This process, pharming, provides an efficient way to produce post-translationally modified proteins for therapeutic use.
Mammalian cell culture also plays a significant role in the production of mAbs. Unlike bacterial cells, Mammalian cells can perform proper protein folding, authentic glycosylation, and a broad spectrum of posttranslational modifications, making them ideal for producing eukaryotic proteins.

Lastly, microbial cell fermentation is another crucial method for antibody production. Engineered microorganisms, particularly E. coli, can produce recombinant proteins, including antibodies. Improved fermentation techniques and host engineering advances have made microbial cell fermentation efficient.

In summary, there are various manufacturing technologies for producing mAbs, each with its advantages, making the choice of method dependent on specific requirements, such as the type of antibody, scale of production, and cost considerations.

Overview of Trends

Market Drivers



The Rise of Chronic Diseases

Due to urbanization, sedentary lifestyles, and increased processed food consumption, chronic diseases like diabetes and cancer are rising. Monoclonal antibodies, offering superior efficacy and lesser side effects than chemically synthesized drugs, are witnessing a surge in demand. With chronic diseases becoming leading causes of mortality, as reported by the WHO and the American Cancer Society, the need for more effective cancer treatments like monoclonal antibodies is growing.

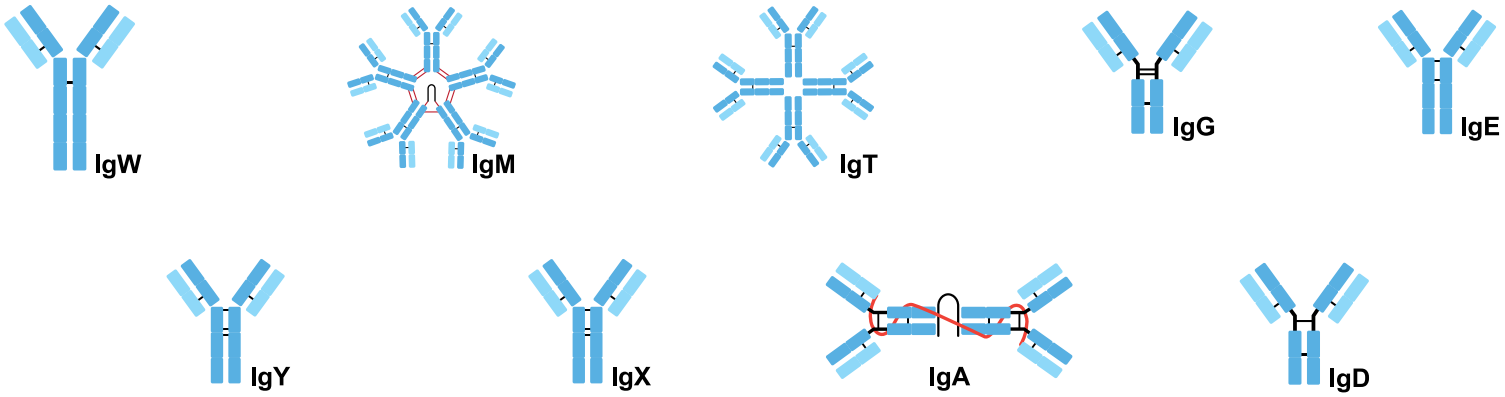
Aging Global Population

An expanding aging population is impacting the global healthcare industry. This population growth has escalated the incidence of cardiovascular diseases, among others, leading to rising demand for antibody drug therapies. In 2017, 962 million people were 60 or older, projected to reach 2.1 billion by 2050. With six in ten adults in the U.S. having a chronic disease, the demand for efficient, less toxic drugs like monoclonal antibodies is expected to increase.

Technological Advancements in Manufacturing

The monoclonal antibodies market also benefits from manufacturing technology advancements. Earlier, hybridoma technology was employed for making monoclonal antibodies. However, the emergence of recombinant DNA technology enables the creation of different types of antibodies suitable for human use. Introducing transgenic animals and plants as potential sources for monoclonal antibody production and discovering varied expression systems have simplified drug manufacturing and market availability.

Market Challenges



High Production Costs

The monoclonal antibodies market is challenged by the high cost of production, which results from the complexity of the manufacturing process. Eighty percent of these costs relate to drug purification, essential for maintaining quality, especially when Chinese hamster ovary cells are used to manufacture protein drugs. This purification requirement leads to high prices, placing such drugs out of reach for many patients. Further complicating matters is the price controls placed by laws in several countries and the impact of patent expiry and biosimilar entry on drug pricing.

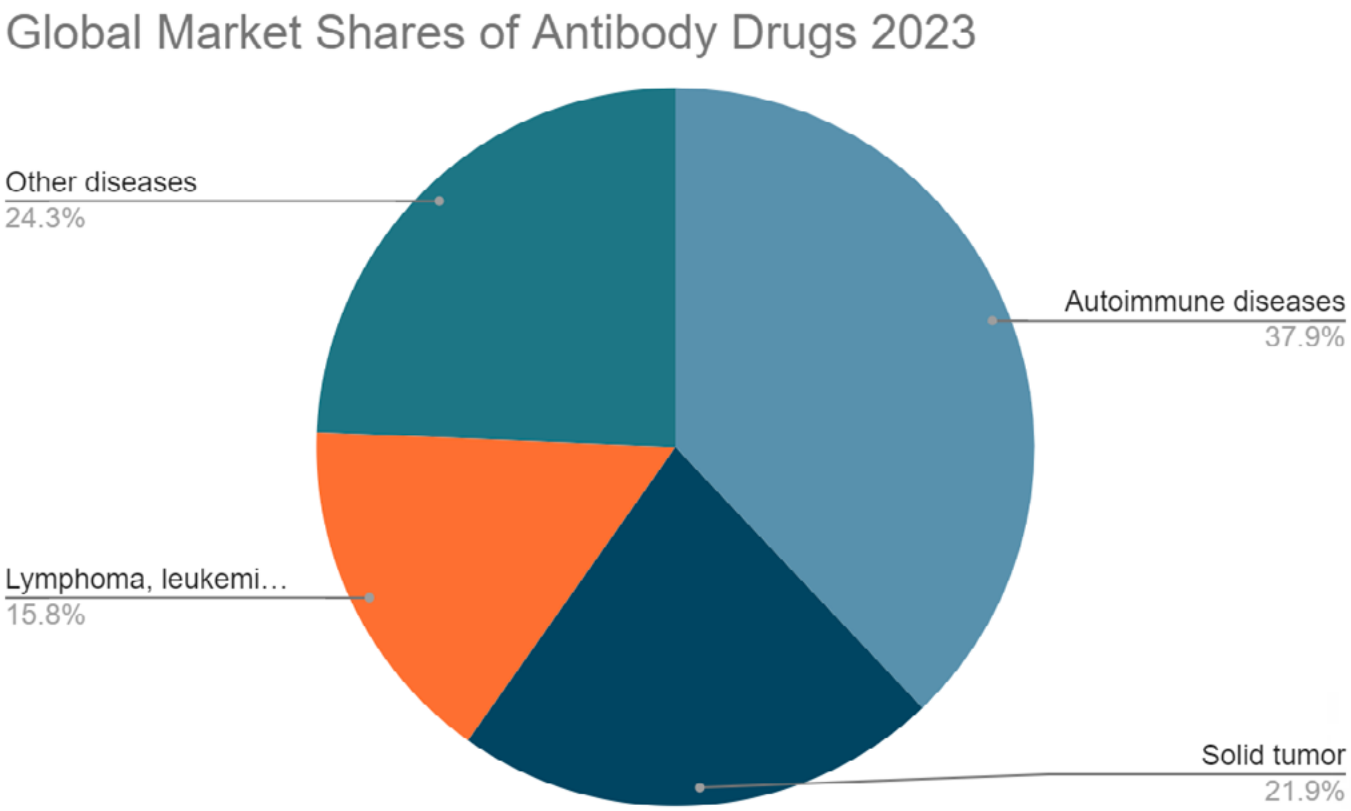
Regulatory Challenges

Monoclonal antibody manufacturers also face challenges from stringent regulatory pressures in their attempts to market products globally. Regional and country-specific laws significantly impact a product's successful development and approval, focusing heavily on quality and safety. Varying criteria for evaluating benefits and risks across regulatory agencies add to these challenges. For instance, a drug may get accelerated approval but be withdrawn later if it fails to meet the primary endpoint in registration trials or presents safety or efficacy issues. Delays may occur due to concerns over drug manufacturing or requirements for site inspection, as seen in the postponed approval of GSK's Dostarilimab due to COVID-19 travel restrictions.

The emergence of Biosimilars

The introduction of biosimilars, similar but not identical to biologics, also poses a challenge to the market. As biological medicine patents expire, the development of biosimilars has increased. For example, sales of Roche's top-selling products like Avastin, Herceptin, and Rituximab dropped by over 30% following the U.S. launch of their biosimilar counterparts in 2019. The entrance of biosimilars has even led to changes in the reimbursement system, with the Centers for Medicare and Medicaid Services developing a separate healthcare coding system. Thus, the rise of biosimilars in the biopharmaceutical industry restricts the antibody drugs market, especially as top-selling drugs approach patent expiry.

Sectors within the industry where tech start-ups are growing



Monoclonal antibody (mAb) drugs treat autoimmune diseases, solid tumors, lymphomas, leukemia, multiple myeloma, and other conditions like asthma, osteoporosis, and cardiovascular issues. The most extensive application is in oncology, with drugs like Keytruda, Opdivo, and Humira leading the way. New drug approvals in 2019 and 2020 bolstered the market.

Global market shares of antibody drugs by disease

diseases	2021	2022	2023	2026	2021-2026 CAGR
Autoimmune diseases	46,395.0	54,327.0	58,908.7	72,050.4	9.2%
Solid tumor	29,188.7	31,521.2	33,965.9	47,824.9	10.4%
Lymphoma, leukemia, and multiple myeloma	21,481.2	23,023.4	24,613.3	31,482.0	7.9%
Other diseases	29,674.4	33,505.3	37,807.2	57,200.0	14.0%

($M)

Autoimmune diseases

Recombinant DNA technology and genetic engineering have created various antibodies, for instance, chimeric, human, and humanized.
These have contributed to the rise of autoimmune diseases. Rituxan, Remicade, and Humira are some antibodies to treat these diseases.

Market Summary

Roche, Johnson & Johnson, and AbbVie dominate the monoclonal antibodies market for autoimmune diseases. They've each developed blockbuster drugs, generating over $1 billion in revenue. Humira sales have positioned AbbVie as a significant market player. Human monoclonal antibodies reign over the autoimmune market.

Recently Approved Drugs

In August 2021, the FDA authorized AstraZeneca's Saphnelo for treating moderate-to-severe systemic lupus erythematosus, making it the first type I interferon receptor antibody. In 2019, AbbVie expanded its immunology portfolio with Skyrizi for treating moderate-to-severe plaque psoriasis. Meanwhile, Eli Lilly's Mirikizumab, a potential rival to Skyrizi, met its primary phase III trial goal for ulcerative colitis in March 2021.

Projected Revenue

The antibody drugs market for autoimmune diseases is projected to reach $72.1 billion by 2026, growing at a 9.2% CAGR. High sales of Humira primarily drive the market. However, the demand for chimeric antibodies is expected to decrease to $7.1 billion by 2026 due to Remicade's patent expiry. Humanized antibody drugs market, including Ocrevus, Skyrizi, and Tysabri, is predicted to grow at a CAGR of 8.8%.

Global Analysis

The rising global prevalence of autoimmune diseases has led pharmaceutical companies to develop novel mAbs. Rheumatoid arthritis, for instance, affects 1-2% of the world population, with women and the elderly being the most susceptible.

In 2020, the global population with multiple sclerosis was 2.8 million. The prevalence was highest in North America and Europe. Skyrizi was the first drug approved in Japan for treating various psoriasis types. Humira, also approved in Japan, became the world's first drug approved to treat pyoderma gangrenosum.

Global Market Revenue

In 2020, the global market for antibody drugs for autoimmune diseases was $43.0 billion, expected to reach $46.4 billion by 2021 end, primarily due to Humira sales. The U.S. leads in mAb drug production for autoimmune diseases, with the market forecast to reach $56.3 billion by 2026. The European market, affected by patent expiry of essential drugs, is expected to reach $8.3 billion by 2026. The market in emerging regions is predicted to grow to $7.4 billion by 2026. Availability, new approvals, and healthcare insurance drive this growth.

Global market for antibody drugs in autoimmune disease

by antibody type

type	2021	2022	2023	2026	2021-2026 CAGR
Human	27,494.3	30,429.9	33,559.5	47,101.8	11.4%
Humanized	11,698.5	12,647.1	13,679.9	17,836.3	8.8%
Chimeric	7,202.2	7,188.1	7,168.6	7,112.3	-0.3%
Total	**46,395.0**	**50,265.1**	**54,408.0**	**72,050.4**	**9.2%**

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Global market for antibody drugs in autoimmune disease

by region

region	2021	2022	2023	2026	2021-2026 CAGR
US	32,734.3	35,582.55	38,430.8	56,345.7	11.5%
Europe	7,386.4	7,541.2	7,709.9	8,352.8	2.5%
Emerging markets	6,274.3	6,456.1	6,552.3	7,351.9	3.2%
Total	**46,395.0**	**49,579.85**	**52,693.0**	**72.050.4**	**9.2%**

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Solid tumors

Cancer, a condition marked by the abnormal proliferation of cells, triggers the development of tumors when cell division spirals out of control. These growths, known as solid tumors, manifest as abnormal tissue masses within organs or soft tissues, devoid of fluid or cysts. Certain types, such as breast, prostate, and lung cancers, are malignant and arise due to exposure to carcinogens.

The escalating demand for monoclonal antibody (mAb) medications to combat cancer is propelled by the surge in disease prevalence and the quest for potent therapies. Humanized mAbs, largely composed of human components (about 95%), have gained substantial traction in treating solid tumors. Noteworthy among these is Keytruda, a star player by Merck & Co., endorsed for a spectrum of cancers, poised to claim a prominent market position. Prominent pharmaceutical giants are rigorously conducting clinical trials, striving to forge effective antibody-based solutions for cancer treatment.

The solid tumor market is growing with the introduction of new antibodies. The market, expected to reach $26.2 billion by 2026, benefits from selling drugs like Keytruda and Roche's oncology drugs. The patent expiry of Rituximab has impacted the market slightly.

Global Market Analysis

The global cancer market, driven by increasing cancer rates, is expected to grow, particularly in the U.S. Key market players include Bristol-Myers Squibb, Roche, and Merck & Co. The antibody drug market for cancer has seen substantial growth, dominated by Roche, Bristol-Myers Squibb, Merck KGaA, and GlaxoSmithKline. FDA-approved drugs like Keytruda have gained accelerated approvals and label expansions, impacting the market positively.

In 2021, the global market for mAbs for solid tumors was $29.2 billion, rising from $26.9 billion in 2020. The solid tumor market is forecasted to reach $47.8 billion by 2026. The U.S. holds a significant share, with sales projected to grow at a CAGR of 10.4%. Europe's market should reach $9.2 billion by 2026. With sales totaling $5.1 billion in 2020, emerging markets are expected to reach $6.6 billion by 2026.

Types of cancer

by the tissue of origin

Type of Cancer	Definition
Breast Cancer	Cancer that is formed in the tissues of the breast. The most common type of breast cancer is ductal carcinoma.
Kidney Cancer	Cancer that forms in the tissues of the kidneys. The most common kidney cancers are the renal cell carcinoma and the renal pelvis carcinoma.
Lung Cancer	Cancer that forms in tissues of the lung, usually in the cells lining air passages. The two main types are small cell lung cancer and non-small cell lung cancer.
Pancreatic Cancer	A disease in which tumorous cancer cells are found in the tissues of the pancreas. It is also called exocrine cancer since the pancreas is the largest exocrine gland of the body.
Prostate Cancer	Cancer that forms in tissues of the prostate. Prostate is a gland in the male reproductive system and is the leading cause of cancer in males over age 40.
Thyroid Cancer	Cancer that forms in the thyroid gland, the organ at the base of the throat that makes hormones, which control heart rate, blood pressure, body temperature and weight.
Colon Cancer	Cancer that forms in the tissues of the colon, the longest part of the large intestine. Most colon cancers are adenocarcinomas.
Rectal Cancer	Cancer that forms in the tissues of the rectum.

Global market for antibody drugs in solid tumor

by antibody type

type	2021	2022	2023	2026	2021-2026 CAGR
Human	16,127.3	17,575.5	19,107.9	26,160.0	10.2%
Humanized	7,785.4	8,799.3	9,961.0	15,785.5	15.2%
Chimeric	5,879.4	5,446.7	5,697.6	5,879.4	2.2%
Total	**47,824.9**	**31,821.5**	**34,766.5**	**47,824.9**	**10.4%**

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Global market for antibody drugs in solid tumor

by region

region	2021	2022	2023	2026	2021-2026 CAGR
US	17,103.6	19,150.1	21,453.3	32,034.6	13.4%
Europe	6,815.2	7,170.3	7,566.3	9,191.5	6.2%
Emerging markets	5,269,9	5,500.8	5,745.3	6,598.8	2.3%
Total	**29,188.7**	**31,821.2**	**34,764.9**	**47,824.9**	**10.4%**

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Lymphomas, leukemia, and multiple myeloma

Cancer is characterized by abnormal cell growth, with over 100 known types. Lymphoma, a form of cancer, targets lymphocytes, the body's immune cells, and grows in the lymphatic system. Its main types are Hodgkin's and Non-Hodgkin's lymphoma. Hodgkin's lymphoma starts in lymphocytes, specifically the infected B cells known as Reed Sternberg cells, and is highly curable. Non-Hodgkin's lymphoma affects both B and T cells, which are vital for immunity.

Leukemia is another cancer category characterized by abnormal production of white blood cells. It stems from blood-forming tissues like bone marrow and the lymphatic system. The four main types of leukemia are Acute Lymphoblastic, Acute Myeloid, Chronic Lymphocytic, and Chronic Myeloid.

The surge in lymphoma and leukemia cases has increased the demand for protein drugs like monoclonal antibodies. Rituxan was a landmark drug for Non-Hodgkin's lymphoma. Its patent expired in 2018, and its first biosimilar was launched in the U.S. in 2019.

In recent years, the antibody-drug market, including other significant drugs like Darzalex, Empliciti, Adcetris, Zevalin, Arzerra, and Gazyva, has seen steady growth due to new approvals. Accelerated approval was granted to Zylonta in 2021, Monjuvi in 2020, and GSK's Blenrep for multiple myeloma in 2020. Label expansions also occurred, with Merck & Co.'s Keytruda gaining FDA approval for Hodgkin's Lymphoma treatment in 2020.

Revenue from antibody drugs treating Hodgkin's lymphoma, non-Hodgkin's lymphoma, chronic lymphocyte leukemia, and multiple myeloma hit $5.6 billion in 2020, with projections to reach $5.9 billion by 2026. This market sector is expected to rise due to increased sales, hitting $16.6 billion by 2026.

Globally, the U.S. is a market leader for antibody drugs treating lymphoma, leukemia, and multiple myeloma. Major market players include Roche, BMS, and Seagen Inc. In 2019, China saw new drug approvals for Hodgkin's lymphoma treatment.

The global market revenue for these drugs reached $20.1 billion in 2020, with growth forecasted in all regions. The U.S. market is expected to grow at a CAGR of 9.6%. In Europe, 2020 sales hit $2.7 billion, expected to reach $3.6 billion by 2026. Emerging markets should reach $4.0 billion by 2026.

Types of leukemia

by the tissue of origin

type of leukemia	definition
Acute lymphoblastic leukemia (ALL)	Generally, affects lymphoid cells. This type of cancer is very aggressive in nature and results in too many immature white blood cells (leukemic blasts) in the blood and bone marrow. It is mostly found in young children. It also affects adults 65 and older. The survival rate varies by age; generally, it is 85% in children and 50% in adults.
Acute myeloid leukemia (AML)	Another very aggressive form of cancer, which grows quickly and affects myeloid cells. In this type of cancer, too many myeloblasts get accumulated in the blood and bone marrow. It is more common in adults than in children and occurs more often in men than in women.
Chronic lymphocyte leukemia (CLL)	Affects lymphoid cells but is not as aggressive as acute leukemia and generally grows slowly. The abnormal cells work like the normal cells. It is mostly found in adults 55 and older. It sometimes occurs in younger adults but never affects children.
Chronic myeloid leukemia (CML)	Affects myeloid cells, is less aggressive than acute leukemia, and grows slowly. There may be a smaller number of leukemic blast cells in the bone marrow. It occurs mostly in adults.

Global market for antibody drugs in lymphoma, leukemia, and multiple myeloma by antibody type

type	2021	2022	2023	2026	2021-2026 CAGR
Human	10,946.5	11,449.5	11,756.1	16,647.2	8.7%
Humanized	3,370.1	5,451.8	6,015.7	8,927.6	12.8%
Chimeric	5,599.6	5,669.5	5,695.0	5,904.9	0.9%
Total	**18,839.9**	**22,570.8**	**23,466.8**	**31,482.0**	**7.9%**

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Global market for antibody drugs in lymphoma, leukemia, and multiple myeloma by region

region	2021	2022	2023	2026	2021-2026 CAGR
US	15,132.2	16,472.3	17,813.4	23,929.8	9.6%
Europe	3,550.7	3,625.2	3,699.7	3,972.5	2.3%
Emerging markets	2,798.3	2,922.9	3,047.5	3,579.7	5.0%
Total	**18,839.9**	**23,020.4**	**24,560.6**	**31,482.0**	**7.9%**

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Asthma, osteoporosis, cardiovascular diseases

This category encompasses diseases like osteoporosis, asthma, and eye conditions such as macular degeneration. For osteoporosis, these ailments can be treated with monoclonal antibody (mAb) drugs, like Amgen's Xgeva and Prolia. These drugs offer fewer side effects and greater safety than traditional chemical drugs.

Osteoporosis, a condition marked by brittle bones, frequently impacts Caucasian and Asian women post-menopause. Asthma is a long-term lung disease, causing recurring episodes of wheezing, chest tightness, coughing, and breathlessness, typically managed with inhalers.

Age-related macular degeneration (AMD) affects the macula in the eye, causing gradual or immediate vision loss. Paroxysmal nocturnal hemoglobinuria is a rare inherited blood disease causing premature death and impaired blood cell production. Cardiovascular diseases are treated with mAb drugs, including Eli Lilly's Reopro. Respiratory syncytial virus (RSV) is a lung-infecting virus, hazardous for infants and toddlers, treated with AstraZeneca's Synagis.

In the antibody market, mAbs are commonly used for chronic diseases and osteoporosis. According to the International Osteoporosis Foundation, osteoporosis causes more than 8.9 million fractures annually. Amgen is a leading manufacturer of osteoporosis drugs, including Xgeva and Prolia.

In 2020, the global market for antibodies to treat other diseases reached $26.3 billion, projected to hit $57.2 billion by 2026, growing at a CAGR of 14.0%. Human mAbs lead the market and should reach $38.5 billion in 2026.

Non-communicable diseases are the leading cause of death worldwide, with mAbs offering new treatment avenues. The U.S. and Europe are the two major markets in this category, with emerging markets catching up due to new drug approvals and rising market value.

The U.S. dominates the market for antibodies used in other diseases, predicted to grow at a CAGR of 16.5% during the forecast period. European sales are expected to reach $11.9 billion by 2026, growing at a CAGR of 10.5% during the same period. Emerging markets were valued at $3.3 billion in 2020, predicted to reach $4.6 billion by 2026.

Global market for antibody drugs in asthma, osteoporosis, cardiovascular diseases by antibody type

type	2021	2022	2023	2026	2021-2026 CAGR
Human	18,242.0	20,976.1	20,976.1	38,501.5	16.1%
Humanized	11,364.3	12,460.8	12,460.8	18,629.1	10.4%
Chimeric	68.1	68.4	68.4	69,4	0.4%
Total	**29,674.4**	**33,505.3**	**33,505.3**	**57,200.0**	**14.0%**

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Global market for antibody drugs in asthma, osteoporosis, cardiovascular diseases by region

region	2021	2022	2023	2026	2021-2026 CAGR
US	18,981.0	21,954.6	24,928.2	40,751.5	16.5%
Europe	7,221.8	7,890.1	8,558.4	11,871.9	10.5%
Emerging markets	3,471.6	3,660.6	3849.6	4,576.6	5.7%
Total	**29,674.4**	**33,505.3**	**37,336.2**	**57,200.0**	**14.0%**

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Human therapeutic monoclonal antibodies

Human therapeutic monoclonal antibodies (mAbs) are closely regulated by the FDA. In 2003, the FDA delegated some biologics regulation to the Center for Drug Evaluation and Research (CDER), which now manages mAbs, cytokines, enzymes, and peptide hormones. The Center for Biologics Evaluation and Research (CBER) regulates blood, its components, and vaccines. The CDER and CBER are critical in ensuring drugs' effectiveness and safety, providing vital information for medical professionals and patients.

Product recalls happen when a defective or potentially harmful product is withdrawn from the market. The FDA initiated a pilot program in July 2011 to inform the public about drug recalls before they are formally classified. The FDA's MedWatch program also disseminates timely safety alerts and information about drugs, medical devices, and more.

In the antibody drugs market, the expiration of patents affects business operations significantly. For instance, AbbVie's top-selling drug, Humira, lost its patent, considerably impacting its total revenue. Similarly, F. Hoffmann-La Roche's primary patents on Avastin, Herceptin, and Rituxan have expired. Multiple companies have obtained approval for biosimilar products in anticipation of patent expirations.

Monoclonal antibodies have brought forth a perplexing paradigm shift within human medicine, confounding the conventional and heralding novel avenues for diagnosing and combatting ailments like cancer, asthma, and multiple sclerosis. The mAb market stands ensnared in the web of burstiness, presently dominated by the triumvirate of pharmaceutical giants: AbbVie Inc., F. Hoffmann-La Roche, and Johnson & Johnson.

In the symphony of medical progress, clinical trials emerge as a symposium of perplexity and bursts of insight, a tapestry woven through various phases. Phase I trials embark on an enigmatic expedition, subjecting a nascent drug to the scrutiny of a select few, unraveling the intricate motifs of safety, and untangling the complex bursts of side effects.

Transitioning to Phase II, the canvas broadens a crescendo of insight painted upon a larger group, scrutinizing the symphonic effectiveness and orchestrating a cacophony of safety considerations. As the crescendo swells to the grandeur of Phase III, an intricate dance of effectiveness confirmation ensues, interwoven with the beguiling tango of side effect monitoring and a harmonious duet with pre-existing treatment modalities. The grand finale, Phase IV, emerges as a vigilant postlude, tracking the drug's safety within the ripples of the FDA's benediction and the resounding applause of public release.

Every movement within the symphony of clinical trials resonates with distinct objectives. The opening notes of Phase I seek to decipher the cryptic riddles of side effects, to uncover the optimal dosage, a burst of insight akin to a fleeting melody, and to chart the most harmonious route for the drug's delivery, a flurry of clarity within the intricate harmony of medicine. As the composition progresses into Phase II, it builds upon the motifs introduced, a cadenza of effectiveness evaluation intermingled with the enigmatic flourishes of short-term side effects and the emergence of recurring risk patterns. An intricate sonata unfolds in the resounding crescendo of Phase III, a mosaic of heightened safety, efficacy, and dosage data reminiscent of a polyphonic composition. The final act, Phase IV, emerges as a vigilant coda, an epilogue of post-marketing surveillance that gathers bursts of data akin to encore performances, unraveling further insights into the celestial benefits and the zenith of optimal drug utilization. In this saga of medical evolution, the narrative of monoclonal antibodies and their odyssey through clinical trials emerges as a symphony of perplexity and burstiness, each phase akin to a movement in music, culminating in a harmonious orchestration for the betterment of human health.

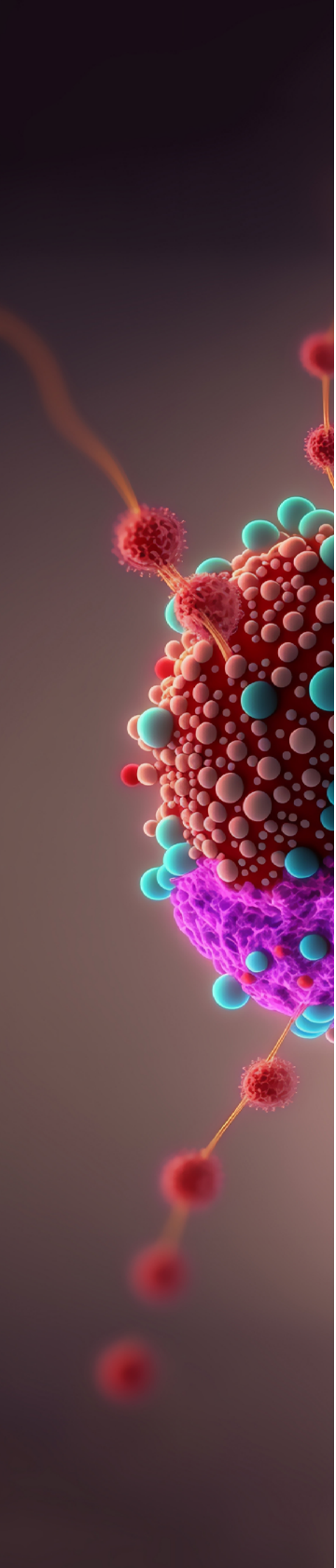
Large venture deals in 2021-2023

Mergers and acquisitions summary

Acquisitions and mergers are popular entities for companies to pursue. Corporations frequently engage in this process to foster growth and achieve other business objectives. These business efforts can increase the scale of operations, enlarging a company's customer base and the possibility of entering new marketplaces. Driven by the requirement for extensive capital funds, insufficient R&D returns, and patent expiry, mergers and acquisitions (M&A) remain integral to the pharmaceutical and healthcare sector. Firms find acquiring or merging with smaller companies beneficial to expand their portfolio and diversify their market. Our focus is on M&As from August 2023 up to 2021.

Notable M&As include:

- Sobi acquired Seattle-headquartered CTI Biopharma for $1.7 billion on May 10, 2023, securing a myelofibrosis drug approved by Bonjo the time before.
- Pfizer acquired cancer expert Seagen for $43 billion on March 13, 2023, securing a large channel and four commercial medicines.
- AbbVie acquired Anchorpeople Antibodies for $255 million on October 20, 2022, adding the implicit first-in-class antibody DJS-002 and enhancing antibody discovery through HEPTAD platform.
- GlaxoSmithKline and Vera Biotechnology announced on November 17, 2021, that they've entered into a $1 billion force agreement with the United States for the FDA- approved COVID- 19 antibody medicine sotrovimab.
- On November 2, 2021, Eli Lilly entered into a $1.3 billion contract with the U.S. government to supply 614,000 boluses of the new coronavirus antibody combination of etesevimab and bamuranivimab.
- Amgen acquired Teneobio for $2.5 billion on July 28, 2021, expanding its oncology channel with coming- generation bispecific and multispecific antibody technologies.
- Takeda Pharmaceutical acquired Maverick Therapeutics for $ 525 million on March 10, 2021, combining its advanced bispecific antibody technology with the promising cancer medicine MVC- 101.
- On March 15, 2021, Horizon Therapeutics acquired Viela Bio Inc. for $ 3 billion, incorporating a mid-stage biologics pipeline and the marketed monoclonal antibody Uplizna.
- Sanofi S.A. acquired Kymab in January for $1.1B 11, 2021, gaining access to fully human monoclonal antibodies developed by the clinical-stage biopharmaceutical company.



Prospective Projects

Solid and liquid tumors

Odyssey

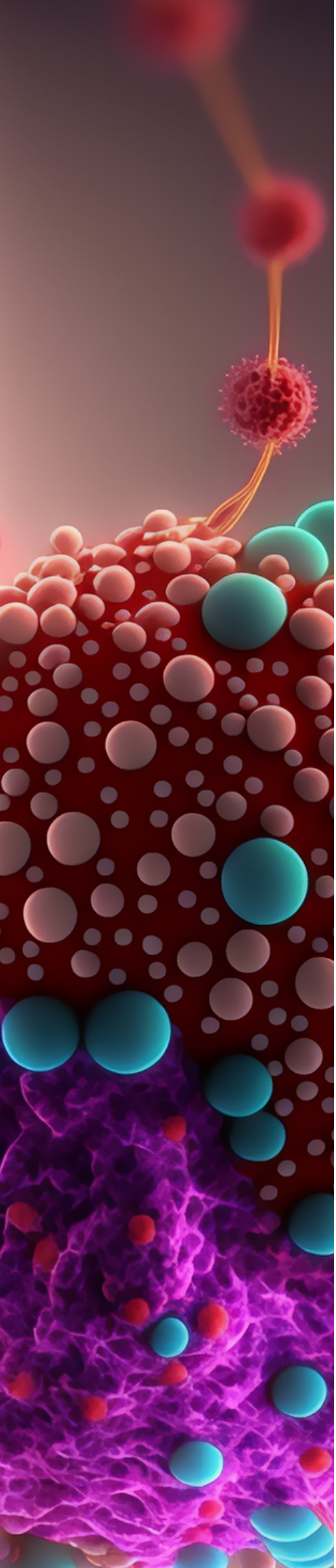
Odyssey Therapeutics, headquartered in Cambridge, Massachusetts, and founded in 2021, is at the vanguard of developing precision immunomodulators and oncology medicines for cancer and inflammatory diseases. With a focus on next-generation treatments and having raised $386M in funding, Odyssey seeks to transform drug discovery, aiming to introduce more effective precision medicines to enhance patient care.

Pionyr Immunotherapeutics

Pionyr Immunotherapeutics, founded in 2015 and based in South San Francisco, California, is a trailblazer in developing cancer immunotherapies targeting the tumor microenvironment. With an emphasis on innovative target discovery and antibody generation and having amassed $352M in funding, Pionyr strives to pioneer the next wave of immuno-oncology treatments, aiming to boost the body's natural defenses against cancer.

Compass Therapeutics

Compass Therapeutics, based in Boston, Massachusetts, and founded in 2014, focuses on pioneering immune system-targeted treatments for human diseases. Committed to advancing novel antibody therapeutics, and with $176.5M in funding, Compass Therapeutics leverages cutting-edge technology to develop innovative biopharmaceutical solutions to improve patient outcomes across various conditions.



RAPT

Rapt Therapeutics, headquartered in South San Francisco, California, and established in 2015, is at the cutting edge of formulating small-molecule agents to enhance the immune response against cancer. With a deep commitment to innovative cancer treatment and having garnered $440.2M in funding, Rapt is driving forward with pioneering solutions in oncology, aspiring to meet the urgent needs of patients through their transformative research and development.

Artiva

Artiva Biotherapeutics, based in San Diego, California, and founded in 2019, is fervently involved in crafting and bringing allogeneic natural killer (NK) cell therapies to market. With a robust backing of $198M in funds, Artiva is breaking barriers in biotechnology, focusing intently on advancing treatment avenues for cancer patients by harnessing the untapped potential of NK cells in therapeutic applications.

Janux

Janux Therapeutics, headquartered in La Jolla, California, and founded in 2017, is pioneering the development of immunotherapies to halt tumor growth while preserving patients' healthy tissues. With an impressive funding of $252.4M, Janux strives to revolutionize cancer treatment by targeting all facets of the anti-tumor immune response, ensuring optimized patient outcomes without compromising their overall health.

Turnstone Biologics

Turnstone Biologics, based in La Jolla, California, and established in 2015, is a cutting-edge biotech company committed to revolutionizing cancer treatment through innovative immunotherapies. With substantial funding of $132.7M, Turnstone is steadfast in its mission to harness the power of tumor immunity, striving to enhance the survival rate of those battling cancer.

Adicet Bio

Adicet Bio, headquartered in Redwood City, California, and founded in 2014, pioneers the discovery and development of innovative gamma delta CAR T cell therapies targeting cancer. With a notable funding of $145.6M, Adicet Bio is at the vanguard of offering first-in-class allogeneic treatments, aiming to transform the cancer therapeutic landscape and enhance patient survival.

Hummingbird Bioscience

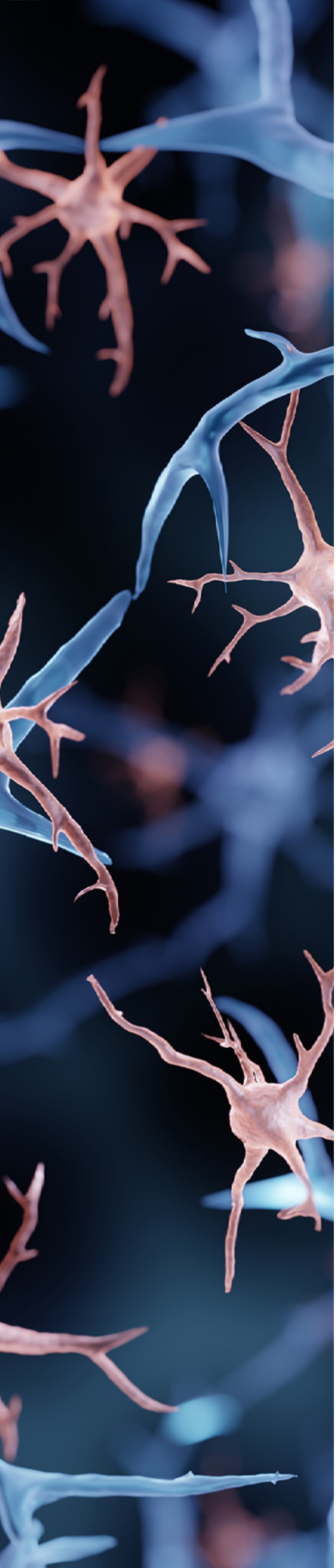
Hummingbird Bioscience, based in Woodlands, Singapore, and established in 2014, is at the cutting edge of oncology drug discovery and early development. With significant funding of $150M, the company leverages systems biology and computational platforms to innovate breakthrough biotherapeutics, aiming to revolutionize cancer treatments and improve patient outcomes.

ALX Oncology

ALX Oncology, headquartered in San Francisco, California, and founded in 2015, is a biotechnology company at the forefront of creating innovative immuno-oncology therapies to combat cancer. With a notable funding of $266M, ALX Oncology is dedicated to harnessing groundbreaking technology to develop treatments with the potential to transform patient outcomes in oncology.

CatalYm

CatalYm, based in Planegg, Bayern, Germany, and founded in 2016, is dedicated to pioneering innovative immunotherapies for cancer. With significant funding of €100M, CatalYm focuses on harnessing the therapeutic potential of neutralizing GDF-15 to offer transformative treatment options and enhance patients' lives battling solid tumors.



Autoimmune

Palleon Pharma

Palleon Pharmaceuticals, located in Waltham, Massachusetts, and founded in 2016, specializes in developing glycoimmune checkpoint inhibitors to address cancer challenges. With a robust funding of $147.6M, Palleon seeks to transform cancer treatment by leveraging its cutting-edge biotechnology platform.

Upstream Bio

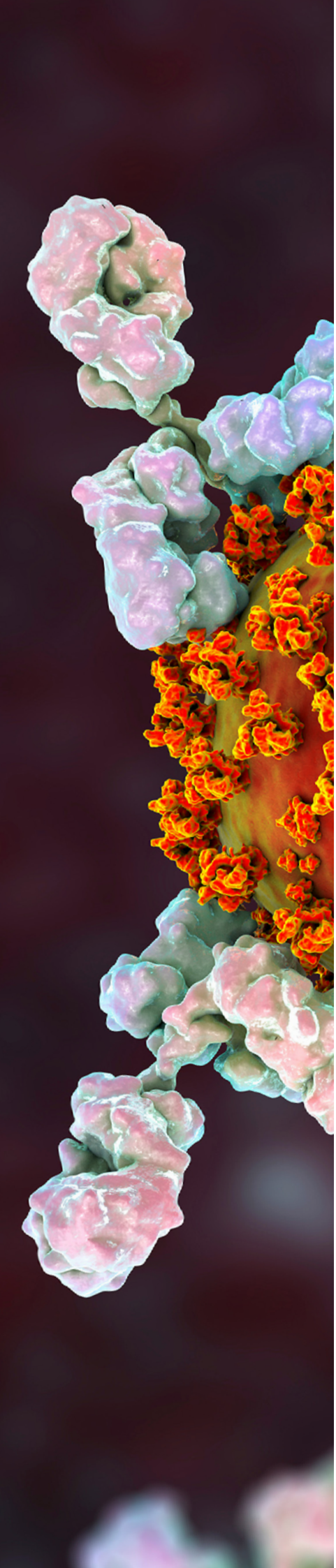
Upstream Bio, based in Waltham, Massachusetts, and established in 2021, is at the vanguard of creating antibody therapies for severe asthma. With substantial funding of $608M, the company endeavors to enhance the lives of asthma patients with its innovative treatment solutions.

Q32 Bio

Q32 Bio, headquartered in Cambridge, Massachusetts, since 2017, is committed to pioneering treatments for severe autoimmune and inflammatory diseases. With a significant investment of $106M, Q32 Bio aims to provide groundbreaking therapies that relieve patients with limited treatment options.

Dianthus Therapeutics

Dianthus Therapeutics, situated in Waltham, Massachusetts, and established in 2019, focuses on developing innovative therapeutics and drugs. Having raised $121.5M, Dianthus strives to revolutionize the biopharmaceutical landscape with its advanced solutions.



Multiple Diseases

Be Bio

Be Biopharma, located in Cambridge, Massachusetts, was founded in 2020 and has raised $182M in funding. As a biotech research company, they specialize in developing B cells as potential treatments. Pioneering a novel class of Engineered B Cell Medicines, they are dedicated to revolutionizing care for severe diseases while keeping patients at the heart of their mission.

Asher Bio

Asher Bio, headquartered in San Francisco, California, was established in 2019 and has secured $163.2M in total funds. This biotechnology enterprise is dedicated to creating superior immunotherapies for cancer patients. Through its unique expertise in therapeutics, Asher Bio aims to reshape cancer treatment by focusing on building and developing innovative immunotherapies.

AgomAb Therapeutics

Founded in 2017 and based in Ghent, Belgium, AgomAb Therapeutics has amassed $136.1M in funding. With a deep understanding of growth factor biology, they are developing novel treatments that target fibrosis to repair tissue structure and restore organ functionality. AgomAb is dedicated to harnessing its unique agonistic monoclonal antibodies to restore function in fibrotic and degenerative diseases.

Immune-Onc Therapeutics

Based in Palo Alto, California, Immune-Onc Therapeutics was established in 2016 and has raised $140.1M in funds. As a biopharmaceutical entity, its focus is on developing groundbreaking therapeutic antibodies for cancer treatment. Drawing from the latest scientific insights, Immune-Onc strives to bring innovative immuno-oncology solutions that offer new hope to cancer patients.

AI and Machine Learning

BigHat

BigHat Biosciences, headquartered in San Mateo, California, integrates machine learning and synthetic biology to design safer and more effective antibody therapies. Using AI and their state-of-the-art lab, BigHat drives innovation for advanced treatments targeting the world's most challenging diseases. Founded in 2019, the company has raised a notable $99.3M in funding.

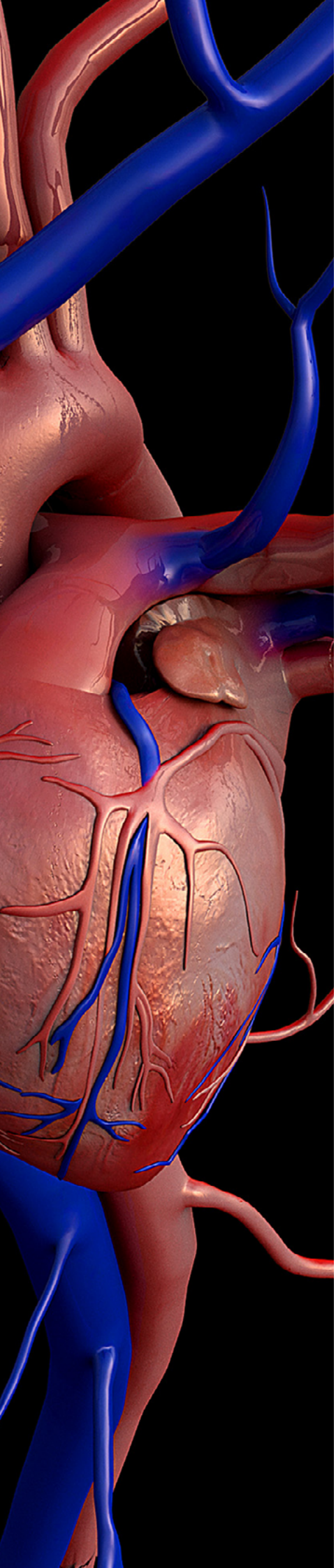
PipeBio

PipeBio, based in Horsens, Midtjylland, Denmark, provides groundbreaking bioinformatics solutions to enhance the development of antibodies and similar therapeutics. Established in 2020, their team combines empirical research with computational advancements to offer tools and infrastructure crucial for modern sequence processing.

Antivirus

Brii Biosciences

Operating from San Francisco, California, Brii Biosciences is dedicated to addressing public health challenges in China by bringing innovative bio-pharmaceutical solutions. Focusing on infectious diseases, they leverage technology and data to optimize healthcare outcomes. Since its foundation in 2018, Brii Biosciences has secured a staggering $415M in funds.



Heart and Vessels

Anthos Therapeutics

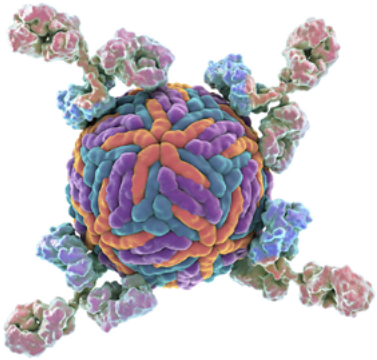
Anthos Therapeutics, located in Cambridge, Massachusetts, specializes in developing cutting-edge cardiovascular and metabolic disease therapies. By melding biotech agility with pharmaceutical rigor, they aim to revolutionize care for people affected by these conditions. Founded in 2018, their profound research focuses on Abelacimab, a promising next-gen anticoagulant.

NewAmsterdam Pharma

NewAmsterdam Pharma, established in 2019 in Naarden, Noord-Holland, The Netherlands, is a clinical-stage biopharmaceutical firm. Their mission is to uplift patient care for metabolic diseases where current treatments fall short. With an emphasis on Obicetrapib, a groundbreaking LDL-C lowering therapy, NewAmsterdam has raised a significant $611M since its inception.

Specialized funds that invest in the sector

Main players



OrbiMed

OrbiMed, headquartered in New York, New York, is a premier healthcare-focused investment firm managing approximately $5 billion in assets. Since its inception in 1989, OrbiMed has showcased its proficiency across a spectrum of healthcare investments, from private startups to established multinational entities. Operating across debt, early-stage venture, late-stage venture, post-IPO, and private equity arenas, the firm has an impressive portfolio of 612 investments, including remarkable exits of 232 companies. Some of their antibody engagements include Upstream Bio, Invivyd, and Biocytogen investments.

8VC

8VC, headquartered in San Francisco, California, is a transformative venture capital firm managing over $6B. Since its establishment in 2015, 8VC has been operating across various sectors. The firm specializes in seed-stage investments and has a rich portfolio of 433 investments, marking 33 successful exits. Their recent forays include funding rounds for Grit, Middleware, and Endear Health. Furthermore, 8VC has shown a keen interest in biotechnology, as demonstrated by their investment in antibody company BigHat Biosciences.

Sofinnova Partners

Sofinnova Partners, a dynamic venture capital force headquartered in Paris, fuels life sciences innovation from inception to maturity. Managing a substantial portfolio valued at over $2 billion, they impact the industry through 301 investments. Noteworthy ventures include Sensorion, which secured $35M in Post IPO Equity with Invus and other investors, and GenSight Biologics, advancing with $6M in Post IPO Equity from Invus and other partners. Among their visionary investments is Crescendo Biologics, a pioneer in antibody development, showcasing Sofinnova Partners' commitment to shaping the collective future of life sciences.

F-Prime Capital

F-Prime Capital, a visionary venture capital force based in Cambridge which, operates across healthcare and technology sectors and managed over $4.5B portfolio, which consists of 423 investments, including Simon Data's $54M Series D and Tenpoint Therapeutics' $70M Series A. Notably, they champion Bicara Therapeutics', driving the development of bifunctional antibodies in immuno-oncology.

Eight Roads Ventures

Eight Roads Ventures, a global venture capital powerhouse headquartered in London, drives innovation with an impressive $11 billion portfolio. Spanning offices in the UK, China, India, Japan, and the US, they've partnered with over 500 companies. Their investments include New Vision Medical's CN¥100M Series A and Raft's $30M Series B. Notably, and they invested in antibody-focused Bicara Therapeutics.

General Atlantic

General Atlantic, a pioneering private equity firm headquartered in New York, catalyzes growth companies with strategic capital and support. Managing over $11.1 billion in funds, they fuel collaborations like acquiring Arco Educacao and investments such as Solve Therapeutics, a biopharmaceutical venture specializing in Antibody Drug Conjugate and Bispecific Therapeutics.

Innovation Endeavors

Innovation Endeavors, based in Palo Alto, California, supports visionary founders, transformative technology, and emerging ecosystems to shape a new world. With a substantial portfolio of 230 investments, including Plotlogic, Trunk Tools, and Fero Labs, their $1.5 billion management underscores their commitment to driving industry evolution. Innovation Endeavors' strategic investments in companies like BigHat Biosciences, utilizing AI-guided antibody design, showcase their pivotal role in propelling groundbreaking advancements.

Novo Holdings

Novo Holdings, headquartered in Hellerup, Denmark, is a pivotal player in life science investment, dedicated to forging enduring value. Managing an astounding $108 billion, their portfolio of 314 investments encompasses notable ventures like Bactolife and Halodoc. Novo Holdings' strategic investments extend to cutting-edge endeavors, including Numab (Series C), a pioneering biotech firm harnessing antibody-based therapeutics for severe disease treatment.

Novartis Venture Fund

Novartis Venture Fund, headquartered in Basel, Switzerland, pioneers transformative impact in the healthcare realm. Managing over $750 million, their portfolio of 247 investments spans dynamic ventures like Tagworks Pharmaceuticals and Mediar Therapeutics. Notably, Novartis Venture Fund's strategic investments extend to Epsilogen (Series B), an immuno-oncology trailblazer dedicated to developing immunoglobulin antibodies for cancer treatment.

Amgen Ventures

Amgen Ventures, headquartered in San Francisco, California, propels groundbreaking innovation in biotechnology. Specializing in early- and late-stage ventures, their dynamic focus spans oncology, inflammation, hematology, and more. With an $200M raised, their portfolio includes visionary enterprises like Feldan Therapeutics and Casma Therapeutics. Notably, Amgen Ventures' strategic prowess extends to BigHat Biosciences (Series B), a trailblazer in AI-guided protein therapeutics, particularly in antibody design.

Quadrille Capital

Quadrille Capital, an autonomous private investment firm with roots in Paris and San Francisco, commands the financial arena. Having ventured forth from Quilvest in 2012, their influence encompasses information technology and healthcare, boasting over €900 million in managed assets. With a diverse portfolio of 44 investments, including noteworthy ventures like Medwing and Anyfin, Quadrille Capital's strategic prowess extends to innovative disruptors such as BigHat Biosciences, a trailblazer in antibody design platforms. Across continents, Quadrille Capital forges tailored partnerships, amassing approximately €1.6 billion from institutional investors and family offices.

Cantos Ventures

Headquartered in San Francisco, ardently explores the convergence of software, hardware, and wetware, firmly positioned at the edge of innovation. With a laser focus on early-stage and seed investments, their $55 million management juggernaut is committed to shaping transformative startups. Their versatile portfolio, comprising 90 investments, including promising ventures like Furno, Apex - Spacecraft Manufacturing, and Modulo Bio, attests to their prowess in climate tech, TechBio, aerospace, and next-gen computing. In the realm of revolutionary antibody drugs, Cantos' imprint is evident in Nabla Bio's autoreverse platform, unveiling the untapped potential at the crossroads of biology and AI.

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