

Forecast Report

Biopharmaceutical Industry Maintains Dynamic Growth

Strong, long-term trends drive growth in the pharmaceutical industry, which is almost entirely independent of business cycles. EvaluatePharma estimates that the global pharmaceutical market will grow by around 6% annually for the period up to 2026. Within the pharmaceutical market, the biopharma segment has been enjoying particularly strong performance for years and will continue to outperform the market according to various forecasts. For the period up to 2026, the compound annual growth rate is projected at about 8% to 11%. This would equate to an increase in market volume to more than €520 billion. The share of biological medications and vaccines in the total revenue generated by the global pharmaceutical market is forecasted to rise from 34% to 37% in this period.

Revenues from the currently approved coronavirus vaccines and Covid-19 therapeutics are likely to reach approximately the prior year's level in 2022 and then fall in subsequent years according to one data analytics company. For 2022, the leading manufacturers of bioprocessing technology also expect pandemic-related business at approximately the same level as in the prior year. Due to the exceptionally strong growth in the reporting period and the resulting high basis for comparison, the rates of increase are, however, likely to be lower. Delayed approval of new drugs as a result of the interruption of clinical trials as well as possible normalization of the inventory coverage of some biopharma companies could have a dampening effect on further growth in the next few years.

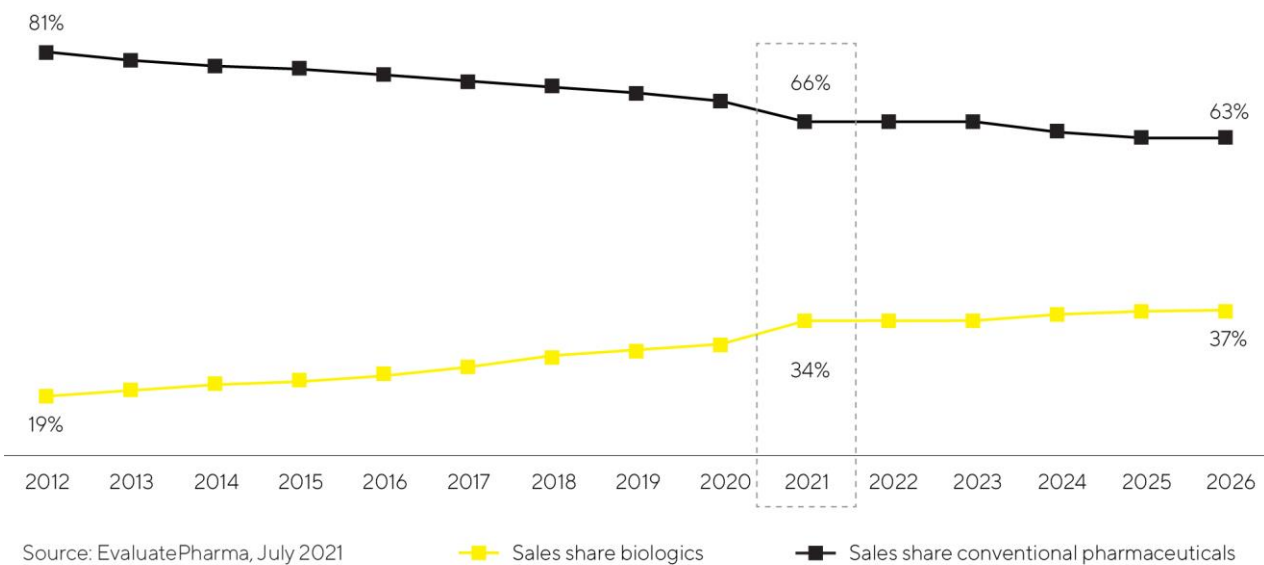
Regionally, the most dynamic market will likely continue to be China. Positive regulatory and political conditions, a constantly rising number of local biotech companies and increasing demand for advanced biopharmaceuticals have been fueling above-average growth for several years now. This trend could continue as a result of the huge amount of catch-up potential in the market and the improved availability of biotech medications. Considerable growth in the United States and Europe is also anticipated, driven in particular by a growing need for medications for aging societies as well as the rising number of patients. In addition, more and more medications are being approved. For example, biopharmaceuticals are increasingly being used in yet-to-be fully explored therapeutic areas and in the treatment of rare diseases that have so far been incurable. The pharma industry is increasingly concentrating on advanced therapies such as cell and gene therapeutics or biotechnologically processed tissue products. At the end of 2021, approximately 1,000 such compounds were in clinical development, so this area offers significant growth potential over the mid to long term. Innovative types of therapy for regenerative medicine and new substance classes, such as antibody-drug conjugates (ADCs) or mRNA-based drugs, are increasing the number and range of approved biopharmaceuticals in the long term and necessitating investments in innovative production technologies. As a result, they are key growth drivers.

This relatively young biopharmaceuticals segment is driving sector growth with its high innovative power, as reflected in the strong research and development pipelines. Of the estimated 10,000+ medications in R&D pipelines, over 40% are based on biological manufacturing processes. These include more than 1,700 biosimilars and biobetters, which are generic versions of reference biologics with comparable or better efficacy or fewer side effects than the original compounds.

Biosimilars are contributing increasingly to the growth of the biotechnology market. Current estimates indicate that by 2025, the market could grow by an annual average of 32% and reach a volume of around €41 billion. The significantly lower prices of biosimilars, particularly in emerging and developing countries, are creating new, affordable therapy options and are projected to result in increased demand and rising production volume. The development of national production capacities to meet the growing demand for medications is receiving political support in these countries and is fueling the establishment of local biotech

companies. The biosimilars market in industrialized countries is also likely to expand considerably in the coming years due to the expiration of patents for high-selling biopharmaceuticals and an increasing number of approved biosimilars. While such generic medications have been widely used in Europe for many years and have been able to gain significant market share in some areas, progress in the USA has been rather slow until now due to regulatory, patent-law-related, and marketing hurdles. In the next few years, however, the development of increasing usage of biosimilars is likely to accelerate. Further market penetration of biosimilars could thus more than triple sales volume by 2025.

Biopharmaceuticals Are Gaining Importance - Growing Share of Sales in the Global Pharmaceutical Market



The biopharmaceutical industry must meet growing demand for medications while producing an increasing number of approved medications and ensuring new types of therapy. For these reasons, industry observers expect that worldwide bioreactor capacities will continue to expand in the years to come. At the same time, the industry faces rising cost pressure. This increases the significance of innovations for boosting flexibility and efficiency in biopharmaceutical research and production. In the future, the biopharmaceutical market will shift away from a low number of especially high-selling medications that account for a majority of total production volume towards an expanding range of products for smaller groups of patients. Technological progress leads to ongoing improvements in the productivity of biopharmaceutical production processes. Therefore, according to the research and consulting institute BioPlan, many manufacturers will likely rely increasingly on flexibly usable single-use technologies for the commercial production of many new medications. Particularly in the case of relatively small batches, single-use equipment and technologies already ensure more cost-effective production than conventional stainless-steel units and have a better environmental footprint. To master these challenges, more and more pharmaceutical companies are relying on digitalization and automation as well as innovative software solutions for controlling and optimizing their processes. A further trend is process intensification in which several process steps, called unit operations, are interconnected and a smooth transition is created, among other things, enabling greater product quantities to be manufactured faster while achieving higher quality.

Further Growth Expected in the Laboratory Market

Various market observers expect the market for laboratory instruments and consumables to grow by about 4% to 5% annually in the next few years and to reach a volume of around €71 billion in 2024. The sector is also expected to grow in the current year, but at a lower rate of increase than in 2021 due to high prior-year comparables. The demand for certain product groups, which was particularly high in the reporting year in connection with coronavirus test kits, is expected to decline in 2022.

Regarding end markets, the greatest dynamics will probably continue to be generated by the pharmaceutical and biopharma industries, in particular, as a result of continuous research into and approval of new medications, the high momentum of scientific and technological innovations, and strong growth in China. For instance, EvaluatePharma expects sector-specific research spending to climb annually by 4.2% during the period from 2021 to 2026. According to market studies, the product area of bioanalytical instruments should particularly benefit from this and further grow at an above-average rate within the laboratory market.

Budget increases for academic and public-sector research institutions are also expected to act as growth drivers in some countries. On the other hand, the pandemic and potential lockdowns or temporary production shutdowns and any unexpected slowdown in global economic growth still pose risks to demand from industrial end markets. Market observers continue to expect Asian countries, such as China and India, to generate the highest growth rates. Stricter regulatory requirements in a range of industries are also stimulating increased demand for instruments used in sample analysis and quality control. In addition, investments in laboratory infrastructure are becoming more attractive, especially in China, as a result of government-supported efforts to promote innovativeness in several key industries. The country invested more in research and development than the USA for the first time in 2021, as a result of which its share of R&D spending further increased.

Sources: BioPlan: 18th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production; IQVIA Institute: Global Medicine Spending and Usage Trends, April 2021; EvaluatePharma: World Preview 2021, Outlook to 2026, July 2021; SDI: Global Assessment Report 2020, June 2021; www.fda.gov

Future Business Development

Sartorius Stedim Biotech expects dynamic performance for the full year of 2022 as well. Consolidated sales revenue is thus projected to increase by about 15% to 19%. The acquisitions closed or agreed upon in 2021 are forecasted to contribute about 2 percentage points of non-organic growth to this increase. Following the jump in profitability in 2021, the company expects its underlying EBITDA margin to stay at a similarly high level and to reach more than 35%.

Regarding pandemic-related business, management projects sales revenue for 2022 at the previous year's level of around €500 million.

The margin targets already include expenses for measures to reduce the company's CO₂ emission intensity; these expenses will account for about 0.5% of consolidated sales revenue in 2022.

Against the backdrop of strong organic growth, Sartorius Stedim Biotech is currently expanding its capacities considerably in all regions. Accordingly, capital expenditures in relation to sales revenue, the CAPEX ratio, is estimated to be around 14.5%.

The ratio of net debt to underlying EBITDA is expected to be around 0.2 at year-end, without taking any potential further acquisitions into account. All forecasts are based on constant currencies, as in the past years, and assume that the global economy as well as supply chains will remain stable.