

Forecast Report

Biopharmaceutical Industry Maintains Dynamic Growth

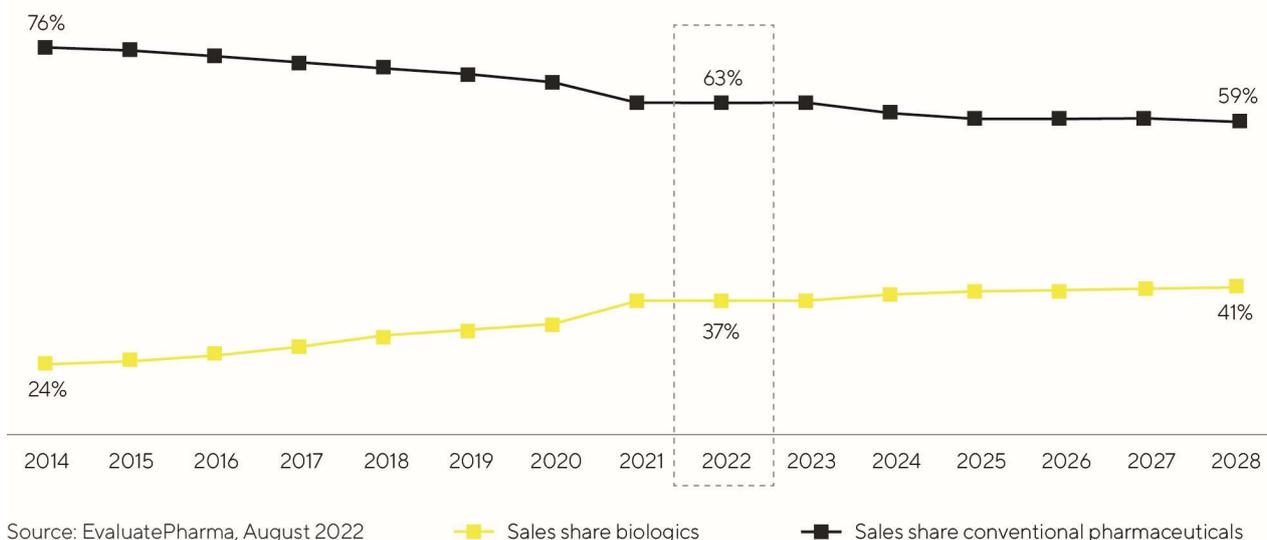
Strong, long-term trends drive growth in the pharmaceutical industry, which is almost entirely independent of business cycles. EvaluatePharma estimates that the global pharmaceutical market will grow by around 6% annually for the period up to 2028. Within the pharmaceutical market, the biopharma segment has been enjoying particularly strong performance for years and will continue to outperform the market according to various forecasts. Average annual growth is expected to range between 8% and 11% in the coming years. The market is expected to have a total value of around €575 billion in 2028, which means that the share of biological medications and vaccines as a percentage of total revenue in the global pharmaceutical market could rise from the current 37% to 41%.

From a regional perspective, China is still expected to be the most dynamic market. 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, the number of approved biopharmaceutical medications is steadily increasing. Of the estimated 10,000+ medications in R&D pipelines, over 40% are based on biological manufacturing processes. 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. In 2022, more than 2,000 clinical trials with such treatment approaches were conducted, meaning that this area offers significant growth potential over the medium 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.

Biosimilars, i.e., generic versions of reference biologics with comparable or better efficacy or fewer side effects than the original compounds, are also playing an increasingly important role in the growth of the biotechnology market. Current estimates indicate that by 2026, the market could grow by an annual average of 20% to 30% and reach a total value of approximately €42 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.

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. Therefore, 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 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, which, among other things, enables 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 total value of around €85 billion in 2026.

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 3.0% during the period from 2022 to 2028. 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 should also act as a growth driver in some countries. On the other hand, the pandemic and potential lockdowns or temporary production

shutdowns, as well as the projected slowdown in global economic growth, pose risks to demand from industrial end markets. Market observers continue to expect 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: 19th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, April 2022; Evaluate Pharma: World Preview 2022, Outlook to 2028, October 2022; SDI: Global Assessment Report 2022, June 2022; www.fda.gov

Future Business Development

Following the exceptionally strong previous years, Sartorius Stedim Biotech expects further growth in 2023 despite demand normalization and anticipated further declines in the Covid-19-related business. Consolidated sales revenue is expected to increase by an amount in the low single-digit percentage range. Excluding the Covid-19-related business, the increase would be in the mid to high single-digit percentage range. Acquisitions are anticipated to contribute around 1 percentage point to growth. The Group's underlying EBITDA margin should be around the level of the prior year (35.0%).

The company will continue its comprehensive capacity expansion program in 2023. The CAPEX ratio should be at roughly 12.5% and the ratio of net debt to underlying EBITDA at about 0.5. Possible acquisitions are not included in this projection.

All forecasts are based on constant currencies, as in the past years. In addition, management points out that the dynamics and volatilities in the life science and biopharma sectors have increased over the past years and the coronavirus pandemic has further amplified these trends. Moreover, the forecasts are based on the assumption of no deterioration in the geopolitical and global economic situation, supply chains, inflation and energy supply, and no new relevant restrictions in connection with the coronavirus pandemic. Accordingly, current forecasts show higher uncertainties than usual.