INDEPENDENT MARKET RESEARCH ON THE GLOBAL AND INDIAN CRO AND CDMO MARKET

Frost & Sullivan

Report Prepared for Anthem Biosciences

12/27/24

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The market research process for this study has been undertaken through secondary/desktop research and primary research, which involves discussing the market status with leading participants and experts.

The research methodology used is the Expert Opinion Method. Quantitative market information was sourced from interviews, primary research, and trusted portals. Therefore, the information is subject to fluctuations due to possible business and market climate changes. Frost & Sullivan's estimates and assumptions are based on varying levels of quantitative and qualitative analyses, including industry journals, company reports, and information in the public domain.

The data has been collated from publicly available sources such as the Ministry of Corporate Affairs (MCA) database.

Forecasts, estimates, predictions, and other forward-looking statements contained in this report are inherently uncertain because of changes in factors underlying their assumptions, events, or combinations of circumstances that cannot be reasonably foreseen. Actual results and future events could differ materially from forecasts, estimates, predictions, or such statements. All financial and operational details for Anthem Biosciences Private Limited are for continuing operations and are provided by the company.

Frost & Sullivan has prepared this study independently and objectively and has taken adequate care to ensure its accuracy and completeness. We believe that this study presents an accurate and fair view of the Pharmaceutical Contract Services Market in selected geographies within the limitations of, among others, secondary statistics and primary research, varying scenarios created due to the COVID-19 pandemic, and it does not purport to be exhaustive. Our research has been conducted with an "overall industry" perspective, and it may not necessarily reflect the performance of individual companies in the industry. Frost & Sullivan shall not be liable for any loss suffered because of reliance on the information contained in this study. This study should also not be considered a recommendation to buy or not to buy the shares of any company or companies as mentioned in it or otherwise.

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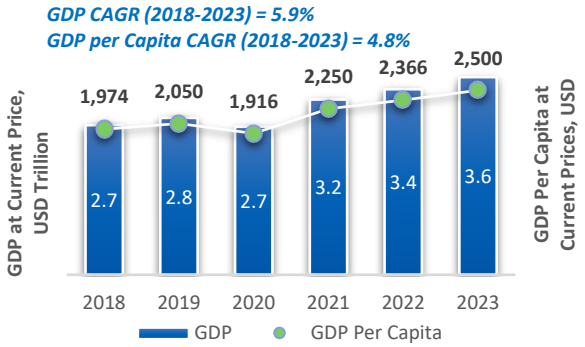
Fiscal Year (FY) refers to the twelve months starting 1st April and ending 31st March. Accordingly, Fiscal Year (FY24) refers to the period starting 1st April 2023 and ending 31st March 2024. Unless otherwise specified, all referenced time periods pertain to the calendar year (CY).

1 MACROECONOMIC OVERVIEW

1.1 OVERVIEW OF INDIAN GDP AND GDP PER CAPITA TREND

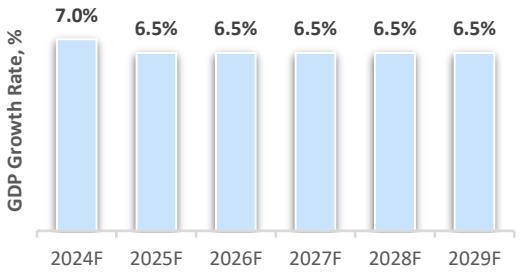
The Indian economy is the fifth largest in the world with a GDP (at current prices) of USD 3.6 trillion in 2023. It is expected to become the world's third-largest economy by 2027, surpassing Japan and Germany, with a GDP exceeding USD 5.0 trillion. The Indian Government aims to achieve the status of a developed economy by 2047.[1] This growth spurt is fueled by increasing domestic demand, significant domestic and international investments, enhanced global relationships, reforms based on Atmanirbhar Bharat[2], and a thriving micro, small, and medium-sized enterprise (MSME) sector.

Exhibit 1.1A: India's GDP at Current Prices and GDP Per Capita, India, 2018-2023



Source: World Economic Outlook - April 2024, Frost & Sullivan

Exhibit 1.1B: India's GDP Growth, 2024F-2029F



Source: World Economic Outlook - April 2024, Frost & Sullivan

1.1.1 INDIA'S GDP GROWTH DRIVERS

The Indian government's push to transform the manufacturing sector, India's unique demographic advantage, favorable Government policies to attract investments, and the China + 1 strategy have collectively laid a robust foundation for India's manufacturing sector.

- **Commendatory government reforms for the manufacturing sector:** The Indian manufacturing industry generated 16-17% of India's GDP pre-pandemic and is projected to be one of the fastest growing sectors[3]. By prioritizing manufacturing across various sectors and implementing initiatives such as "Make in India," the Production-Linked Incentive (PLI) scheme, PM Gati Shakti - National Master Plan (NMP), and industrial development schemes in states with underdeveloped industrial infrastructure, the government aims to increase the manufacturing sector's contribution to 25.0% of GDP by 2025[4].
- **Demographic dividend:** India is not just the world's most populous nation (as of 2023) but also has a rapidly growing working-age population. A large pool of young, English-speaking graduates, especially in STEM (Science, Technology, Engineering, and Mathematics) fields, gives the country a competitive advantage, particularly in skill-intensive industries such as pharmaceutical R&D and manufacturing. Rapid urbanization and rising affluence amongst the masses are expected to continue to drive demand for goods and services and thereby contribute to India's growth.
- **Indian Manufacturing Purchasing Managers' Index ("PMI") is at its highest level in 2024:** Steady expansion in manufacturing activities has led to an increase in manufacturing PMI to 57.3 in November 2024 from 56.0 in November 2023, and the India's manufacturing PMI is higher than the global average of 49.4 (as of

[1] Invest India
[2] Atmanirbhar Bharat, or "Self-reliant India," is a vision and initiative introduced by the Indian government. It aims to make India a self-reliant and economically strong nation. This concept emphasizes the importance of reducing dependence on imports and promoting domestic production and manufacturing.
[3] https://www.ibef.org/industry/manufacturing-sector-india
[4] India Brand Equity Foundation (IBEF)

November 2024).[5] Output growth was at a 28-month high (from December 2021 to March 2024), new orders expanded for the 23rd month running (from April 2022 to March 2024), with the steepest rate of increase since January 2021, and overseas orders and employment increased the most in six months. India is also benefiting from the changes in the global supply chain, which are geared towards diversification.

- **Factors boosting the Indian Pharma industry include:**

  - **Development of "Make in India" programs for pharmaceuticals with PLI scheme:** PLI Schemes targeted specifically to promote the development of Bulk Drug Parks are expected to boost the manufacturing of drug intermediates and API. This provides a large potential for India to emerge as a global manufacturing hub, driven by the pharmaceutical industry, and an expected increase in outsourcing to Contract Research Development and Manufacturing Organizations (CRDMOs).
  - **Favorable FDI Policies:** The Indian government allows up to 100% FDI in the pharmaceutical sector, allowing the investor to enjoy the sole rights to its establishment. Under the automatic approval route, up to 100% FDI is allowed in greenfield projects and up to 74.0% FDI is allowed in brownfield projects. This improves the infrastructure and capabilities in the Indian pharmaceutical ecosystem needed to cater to the global demand. FDI in the Indian pharmaceutical sector grew at a CAGR of 31.6% from USD 18 billion in FY2019 to USD 54 billion in FY2023[6].
  - **Strong Development and Manufacturing base:** The Indian pharma industry is highly developed, with approximately 3,000 drug companies, 10,500 manufacturing units, and the largest number of US FDA-approved plants outside of the US as of 2023.
  - **Lower manufacturing costs:** India provides substantial cost advantages in terms of labor and operational expenses compared to the US and Western markets. Drug development and manufacturing costs in India are approximately 30-40% lower than in the US or Europe[7], making it an appealing outsourcing destination for pharmaceutical companies aiming to decrease R&D and production costs without sacrificing quality.
  - **China +1 strategy:** Companies are seeking to reduce dependence on any single country to mitigate risks associated with geopolitical uncertainties. The pandemic exposed weaknesses in worldwide supply chains, particularly the heavy dependence on China. As a result, companies are now exploring alternative manufacturing locations in countries like India to strengthen their resilience.

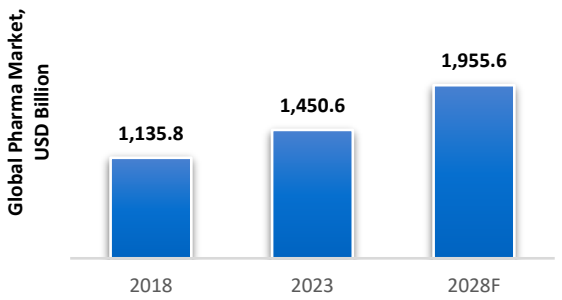
[5] S&P Global
[6] https://www.india-briefing.com/news/foreign-investment-prospects-in-indias-pharmaceutical-industry-29938.html/
[7] Invest India.

2 GLOBAL PHARMACEUTICAL (PHARMA) MARKET OVERVIEW

2.1 GLOBAL PHARMA MARKET

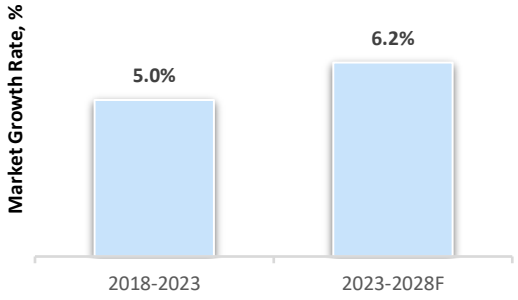
The global pharmaceutical industry is rapidly transforming across all value chains from manufacturers, providers, and patients. It was valued at USD 1,450.6 billion in 2023 and is expected to grow at a CAGR of 6.2% to reach USD 1,955.6 billion by 2028, driven mainly by factors such as the growth of the elderly population, rising incidence of chronic diseases, sedentary lifestyles, and increasing health awareness.

Exhibit 2.1A: Global Pharma Market, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

Exhibit 2.1B: Global Pharma Market Growth Rate, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

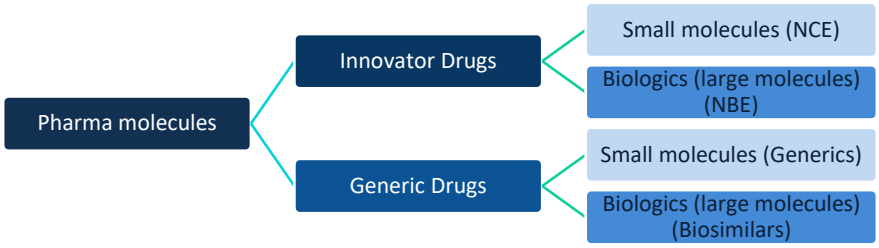
Exhibit 2.2: Global Pharma Market Growth Drivers

Source: Frost & Sullivan

2.1.1 Global Pharma Market by Innovation Type

The pharmaceutical market can be divided into two types of drugs: innovators (comprising of new chemical entities (NCEs)[8], and new biological entities (NBEs)[9]) and generics (including biosimilars[10]).

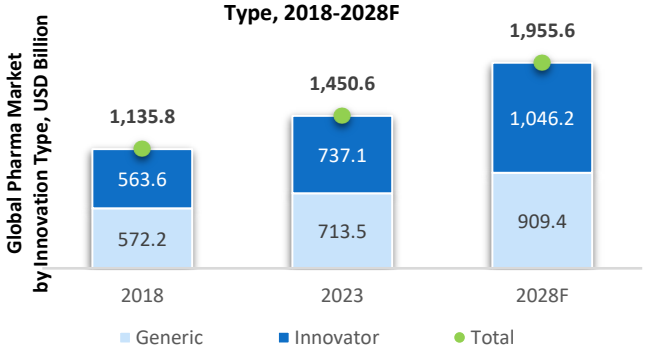
Exhibit 2.3: Global Pharma Market by Type of Molecule



Source: Frost & Sullivan

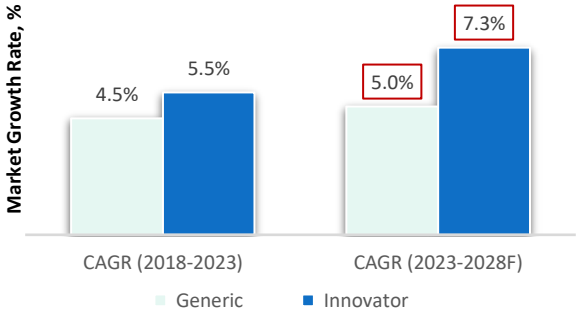
Innovator Drugs Market: Innovator drugs are the first version of NCE or NBE to be developed, approved, and marketed, that usually contain a new active ingredient and require extensive clinical development and a patent approval process for use. **The innovator drug market, valued at USD 737.1 billion in 2023, had historically grown at a CAGR of 5.5% (2018-2023) and is projected to reach USD 1,046.2 billion by 2028 at a CAGR of 7.3%, faster than the overall pharmaceutical market growth**. The share of the innovator revenue is expected to grow from 50.8% in 2023 to 53.5% of the global pharmaceutical market in 2028. This growth is driven by an increasing focus on R&D by pharmaceutical companies, leading to continued demand for novel, high-value curative therapies especially those targeting complex and rare diseases.

Exhibit 2.4A: Global Pharma Market by Innovation Type, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: Innovators are Orginal Branded products, F - Forecast

Exhibit 2.4B: Growth Rate of Global Pharma Market by Innovation Type, 2018-2028F



Source: IQVIA, Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

Generic Drugs Market: Once the patent of an innovator drug expires, other companies can make and sell the same composition drugs, known as generic drugs. Generic drugs are equally safe and effective as innovator drugs and are usually cheaper. **The generic drug segment accounts for 49.2% of the total pharmaceutical market by revenue in 2023, has grown at a CAGR of 4.5% (2018-2023), and is projected to grow at a CAGR of 5.0% between 2023 and 2028, reaching a value of USD 909 billion by 2028**. The upcoming patent cliff (expiry of patents for innovator drugs) represents a significant opportunity estimated at USD 130 billion (in the developed markets alone) over the next five

[8] A NCE (New Chemical Entity) is a novel, small, chemical molecule drug that is undergoing clinical trials or has received a first approval
[9] A NBE (New Biological Entity) is a biological compound or vaccine not previously approved for human use by the Center for Biologics Evaluation and Research (CBER).
[10] Biologic medical products that are highly similar to an already approved reference biologic, with no clinically meaningful differences in terms of safety, purity, and potency, and are used to treat various diseases by providing more affordable treatment options

years[11]. The introduction of cost-effective generics and biosimilars is expected to enhance accessibility and health equity by offering more affordable alternatives to high-cost originator drugs.

2.1.2 Global Pharma Market by Companies

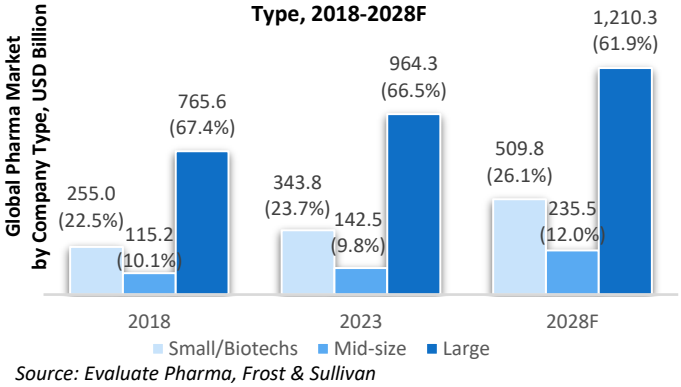
The global pharmaceutical market is categorized into three segments by company type:

- small pharmaceutical and biotechnology ("biotech") companies (revenues less than USD 500 million) with biotech largely being startups in the pharmaceutical sector focusing on innovative drug development technologies to address unmet medical needs,
- mid-size pharmaceutical companies (revenues between USD 500 million and USD 10 billion), and
- large pharmaceutical companies (revenues more than USD 10 billion).

Large multinational pharmaceutical companies currently dominate the global pharmaceutical market. They leverage extensive R&D capabilities, vast global reach, and significant financial resources to command high market share. However, the trend is gradually reversing as the aggregate market share of large pharmaceutical companies is expected to decline from 66.5% in 2023 to 61.9% in 2028, whereas the share of small pharmaceutical and biotech companies is expected to increase from 23.7% in 2023 to 26.1% in 2028.

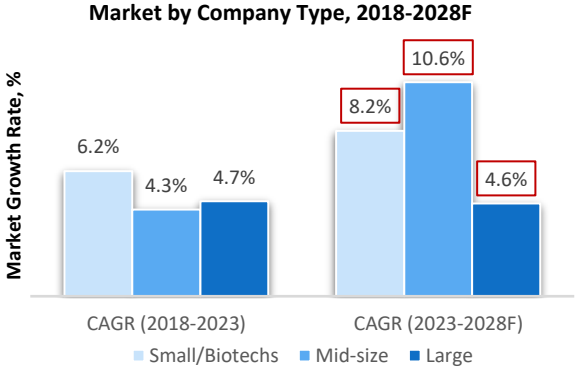
Small pharmaceutical and biotech companies are typically characterized by their innovative approach to drug development and have witnessed faster growth in the 2018-2023 period, a CAGR of 6.2% as compared to mid-size (4.3%) and large pharmaceutical companies (4.7%). Going forward, between 2023 to 2028, the growth is expected to increase to a CAGR of 8.2% for small pharmaceutical and biotech companies versus 4.6% for large pharmaceutical companies. The growth is largely enabled by substantial venture capital funding in these companies.

Exhibit 2.5A: Global Pharma Market by Company Type, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: Large = Revenue >10 Billion, Mid-Size = 500 Million - 10 Billion, Small - <500 Million, Biotech = startups in the pharmaceutical sector which typically focus on developing innovative drugs and drug development technologies. (%) represents market share.

Exhibit 2.5B: Growth Rate of Global Pharma Market by Company Type, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

Unlike large pharmaceutical companies, which have diversified interest across therapeutic areas, small pharmaceutical and biotech firms as well as mid-size pharmaceutical companies often concentrate on novel niche therapies, making them more agile and responsive to new scientific developments. Mid-size pharmaceutical companies are projected to grow at a CAGR of 10.6% between 2023 and 2028, making them the fastest-growing segment by company size.

[11] Evaluate Pharma

The growing prominence of small pharmaceutical and biotech companies reflects a broader shift in the pharmaceutical industry towards novel therapies and innovation-driven growth.

2.1.3 Global Pharma Market by Modality

The global pharmaceutical market comprises primarily two key types of drugs by modality[12]: Small Molecule and Biologics (large molecule) drugs.

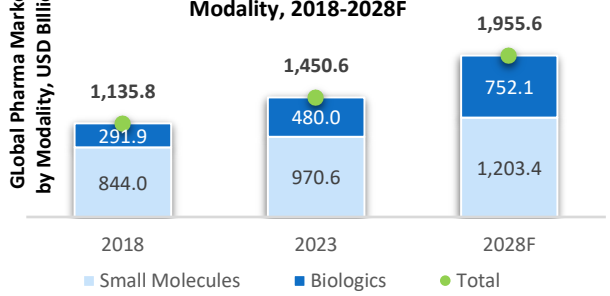
Small Molecules

Small molecule drugs (including NCEs and Generics) have been the mainstay of the pharmaceutical industry, accounting for 66.9% of the market revenue in 2023. Defined as any organic compound with low molecular weight, they are known for their affordability, ease of administration (largely orally), and broad therapeutic coverage. Small-molecule drug substances are typically manufactured using synthetic chemistry processes.

Biologics (Large Molecules)

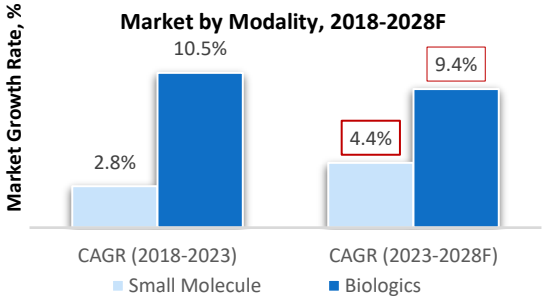
Biologics or large molecules (including NBE and Biosimilars) are defined as complex, high-molecular-weight compounds, made of proteins, manufactured from living organisms through biological methods. Biologics (large molecules) are costly to manufacture and, in most cases, can only be administered by injection or infusion. Biologic drug substances are typically manufactured biologically, i.e. extracted from living organisms, but often include certain synthetic chemistry processes. Antibody Drug Conjugate (ADC) is one such example, which is an emerging class of anti-cancer targeted therapeutic drugs that can deliver highly cytotoxic molecules directly to tumor cells while sparing healthy cells. ADCs are a hybrid construct that combines a biologic (monoclonal antibody) with a small molecule (Drug-Linker) via chemical conjugation. Over the past few decades, the biologics (large molecules) market has expanded rapidly, buoyed by innovations in gene and cell therapies and advanced drug delivery systems. Due to their complexity, high technological capabilities required, and higher development and approval timelines, there is

Exhibit 2.6A: Global Pharma Market by Modality, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

Exhibit 2.6B: Growth Rate of Global Pharma Market by Modality, 2018-2028F



Source: IQVIA, Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

limited competition in the biologics (large molecules) space as compared to small molecules.

The market share of biologics (large molecules) has increased at a 10.5% CAGR, from 2018 to 2023, and is projected to grow at a CAGR of 9.4% to reach a market size of USD 752.1 billion by 2028. The blockbuster[13] nature of many biologics (large molecules) and their dominance in revenue generation underpins the growing salience of biologics (large molecules). For instance, there were over 90 blockbuster biologic drugs sold in 2023, and the top 10 biologics accounted for nearly USD 127 billion in sales[14]. In comparison to most traditional small molecules, biologics (large molecules) offer superior efficacy and specificity, often targeting complex diseases more precisely, which has elevated them to blockbuster status with significant commercial potential. These therapies involve intricate

[12] Method of treatment
[13] Blockbuster status of drugs refers to those with annual sales over USD 1billion.
[14] Evaluate Pharma

manufacturing processes and longer development timelines, but their extended market exclusivity post-approval allows for substantial revenue generation, distinguishing their lifecycle from that of small molecules.

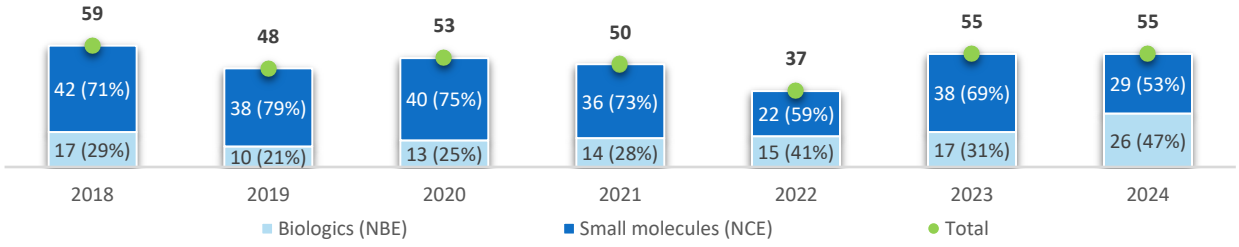
Exhibit 2.7: Factors Contributing to the Growth of Biologics (Large Molecules)

Commercial factors	Technology factors	Operational factors
• **Growing R&D investments in biological therapies** driving the share of the Biologics drug pipeline volume to 45% in 2023 with a growth of 12.2% from 2018 to 2023 • **Expanding access and availability to new markets** and a broader patient population through sponsorships and company programs • **Regulatory support and fast-track approvals** for new biologics (large molecules) • **Acceptance of experimental therapies** (e.g. combination immunotherapies) • **Emergence of value-based care reimbursement** models driving faster adoption of expensive therapies	• **Biologics (large molecules) offer targeted action**, precision, and efficacy with fewer side effects • **Highly effective in complex therapeutic areas** such as oncology and autoimmune diseases • **Technology advancements in bi-specific and multi-specific antibodies, innovations in mRNA[15] and in CGT** are creating higher curative potential of biologics (large molecules) • **Introduction of novel action mechanisms**, offering promising solutions for previously untreatable and rare diseases	• **Investments in global bio-manufacturing infrastructure**, including modular facilities and single-use technologies, are supporting the scalability and accessibility of biologics (large molecules), contributing to market growth • **Improvements in discovery and manufacturing technologies** (enhancing production efficiency, scalability, and reducing costs) such as CRISPR, high-throughput screening, and single-use bioreactors, are accelerating the development and production of biologics (large molecules), improving accessibility.

Source: Frost & Sullivan

Between 2018 and September 2024, the FDA approved 357 new drugs (NCE + NBE), out of which 112 (31.4%) were NBEs and 245 (68.6%) were NCEs. The share of NBE approvals increased from 29.0% in 2018 to 47.0% in 2024 highlighting the increasing importance of biologics (large molecules) alongside traditional small molecules.

Exhibit 2.8: US NBE and NCE Approval Trends (Number of approvals and Percentage), 2018-2024



Source: US FDA , Frost & Sullivan
Note: Data as of September, 2024

The total market size of small molecules, which grown at a slower pace of 2.8% CAGR over 2018-2023, is projected to grow at 4.4% CAGR over 2023-2028, to reach a market size of USD 1,203 billion by 2028. While biologics (large molecules) will outpace small molecules, they will continue to remain a mainstay of the overall pharmaceutical market, accounting for 61.5% of the market revenue in 2028.

[15] mRNA, or messenger RNA, is a type of RNA that carries genetic information from DNA to the ribosome, where it serves as a template for protein synthesis. mRNA is transcribed from a DNA sequence and then translated into a specific protein sequence during the process of translation, playing a crucial role in the expression of genes.

3 GLOBAL PHARMA MARKET DYNAMICS

3.1 PHARMA R&D DYNAMICS

In pharmaceuticals, a new drug must undergo a thorough testing and regulatory assessment to confirm its safety and efficacy before it can be introduced to the market. This process usually lasts over ten years and involves R&D expenditures exceeding USD 1 billion from the initial stages of drug discovery to the final commercialization. The success rate for bringing a new drug from discovery to approval is relatively minimal.

3.1.1 GLOBAL PHARMA R&D PROCESS AND AVERAGE SPEND

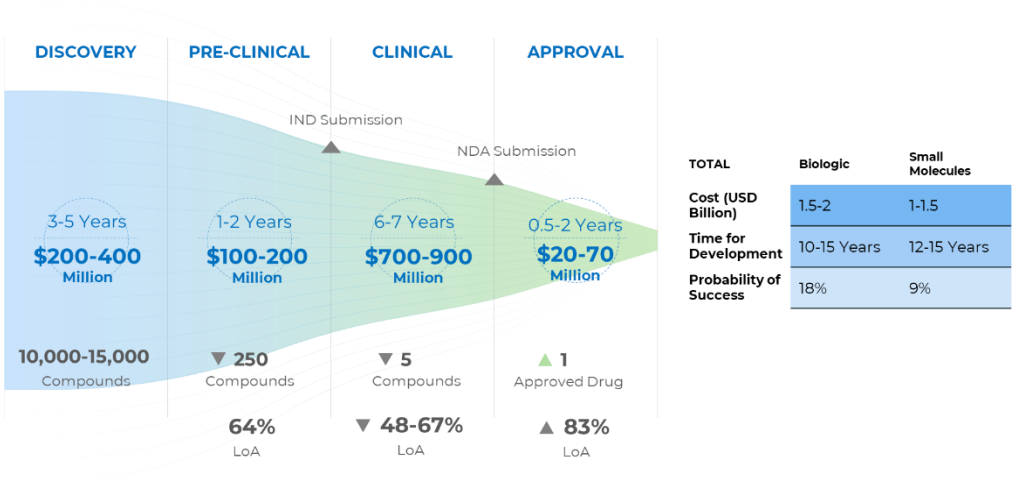
The pharmaceutical R&D value chain has four stages: discovery, followed by development (pre-clinical and clinical – Phase 1,2 and 3), and finally, approval of the new drug.

Exhibit 3.1: Global Pharma R&D Value Chain

Phase	Stages	Description
Drug Discovery		Processes from target identification to target validation to lead generation and lead optimization. During this stage, thousands of compounds are narrowed down to a few hundred with promising potential. Researchers collaborate to identify and optimize potential leads to a specific target. Essentially, the leads must elicit a desirable effect on a specific biological target implicated in a disease, in the hopes of treating it and potentially becoming a medicine.
Development	Pre-clinical Phase	The substances identified during Drug Discovery are refined, and optimized, and exhaustive laboratory and animal experimentation of the preclinical drug candidates are performed for safety and therapeutic effect to determine whether a compound is suitable for human testing. The process may take several years, and the data generated during this stage is a critical part of the dossier to regulatory bodies to receive approvals for conducting clinical trials.
	Clinical Trials	Promising drug candidates are presented to regulatory authorities for permission to conduct human clinical trials via "Investigational New Drug Applications". Once approved, these drug candidates are referred to as an IND ("Investigational New Drugs"). INDs proceed to clinical trials which are studies in humans to determine the safety, efficacy, and suitable drug dosage of potential drug candidates. Clinical Trials are composed of four phases: Phase I, II, III, and IV. In the first stage, the tolerance and safety of the drug candidate are tested in a very small group of healthy subjects. After tolerance and effectiveness have been tested, phases IIa and IIb are started to examine the effectiveness, tolerability, and dosage in a larger group. In phase IIa studies, the therapy concept is primarily checked (proof of concept); in phase IIb studies, the aim is to find the right dose. In the last phase (phase III) before a possible approval as a drug, the effectiveness and safety are checked in a larger pool of patients. Phase IV studies (also known as Post-Marketing Surveillance Trials) take place after receiving marketing authorization from the authorities, these studies are designed to assess the long-term effects of a drug.
	Drug Substance Development	Covers early-stage and late-stage process development and optimization. Small quantities of drug substances are manufactured under non-GMP conditions for toxicology evaluation and GMP conditions for initial clinical studies. Depending on the outcome of these studies, larger quantities of drug substances are manufactured for late-stage clinical programs. Since the quantity requirements move up as the drug moves across clinical phases, drug substance production now must be adapted through a scalable, robust, safe, and efficient manufacturing process to meet higher drug substance demand in the Clinical Trials phase.
	Clinical Supplies / Drug Product Development	Covers early-stage and late-stage formulation development and manufacture. As the molecule moves further along the development cycle, the formulation becomes increasingly nuanced in line with the data being generated through the trials.
Commercial Manufacturing		Large-scale commercial production of the approved drug with the highest level of quality. Companies must adhere to the FDA or all other relevant regulations for Drug Substance and Drug Product manufacturing.

Source: Frost & Sullivan

Exhibit 3.2: Global Pharma R&D Process (Illustrative)



TOTAL	Biologic	Small Molecules
Cost (USD Billion)	1.5-2	1-1.5
Time for Development	10-15 Years	12-15 Years
Probability of Success	18%	9%

Note: LoA – Likelihood of Approval; LoA for Phase 1 – 48%; LoA for Phase 2 – 25%, LoA for Phase 3 – 67%.

Source: Frost & Sullivan; Note: IND = Investigational New Drug, NDA = New Drug Approval

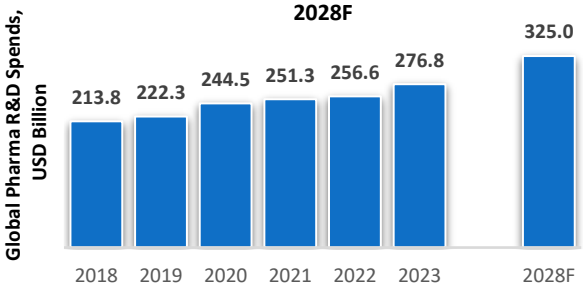
3.1.2 Global Pharma R&D Spending

R&D spending by global pharmaceutical and biotechnology companies ("Pharma Innovators") is projected to grow at a CAGR of 3.3% from 2023 to 2028.

Pharmaceutical R&D spending has increased significantly from USD 213.8 billion in 2018 to USD 276.8 billion in 2023. This surge is linked to the increasing intricacy of drug discovery and development processes, necessitating substantial investments in research infrastructure and sophisticated technologies. The average investment required to develop and bring a new drug to market now surpasses USD 1 billion per drug. Given the intensifying market competition and evolving market dynamics, along with patent expirations and generic erosion, R&D is vital for pharmaceutical companies to maintain a competitive edge and spur future growth.

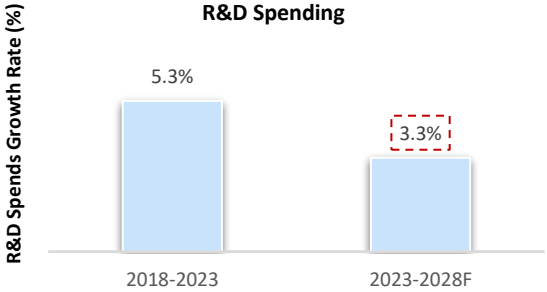
R&D Spending by large pharma companies contributes a larger share of the global R&D spending; however, small pharma and biotech companies' R&D spending is expected to register the fastest growth over 2023-28F.

Exhibit 3.3A: Global Pharma R&D Spending, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

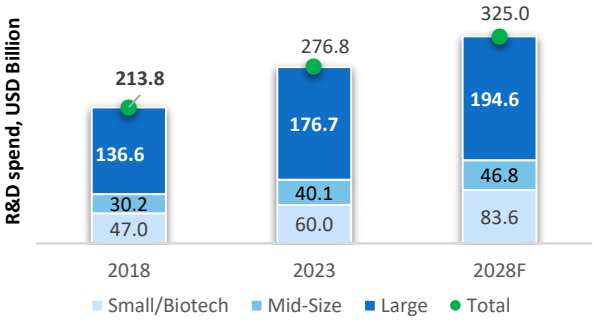
Exhibit 3.3B: Growth rate of Global Pharma R&D Spending



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

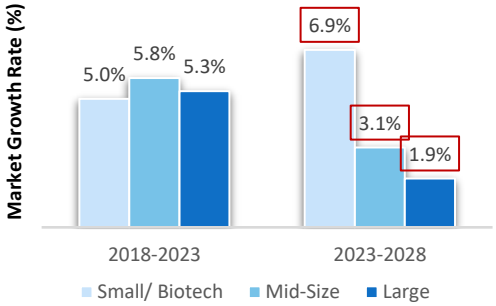
In 2023, large pharmaceutical companies made up 63.9% of R&D spending, growing at 5.3% annually from 2018 to 2023. Smaller pharmaceutical and biotech companies are expected to increase their combined share from 21.7% in 2023 to 25.8% by 2028, with a CAGR of 6.9%. The allocation of R&D funds to biotech firms is rising, driven by increased venture capital (VC) funding and greater accessibility to technology and drug discovery.

Exhibit 3.4A: Global R&D Spending by Company Type, 2018- 2028F



Source: Pharmaprojects, Evaluate Pharma
Note: F - Forecast, Large pharma: Pharma companies with revenues > USD 10 Bn, Mid-size pharma: Revenues in range of USD 500 Mn to USD 10 Bn, Small pharma: Revenue lower than USD 500 Bn

Exhibit 3.4B: Growth rate of Global R&D Spending by Company Type, 2018- 2028F

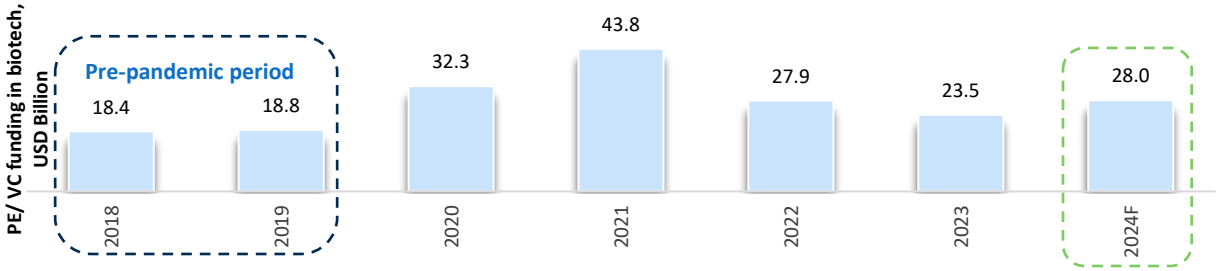


Source: Pharmaprojects, Evaluate Pharma
Note: F - Forecast

The global VC/PE funding in Biotech is higher than the pre-COVID levels.

The level of private capital funding (PE/VC) in the biotech industry has surpassed the pre-pandemic funding levels in 2022 (USD 28 billion) and 2023 (USD 24 billion), and it is estimated to reach USD 28 billion in 2024 (1.5X higher). The recent increase in biotech funding is expected to lead to increased R&D spending by these companies, contributing to overall growth in pharmaceutical R&D.

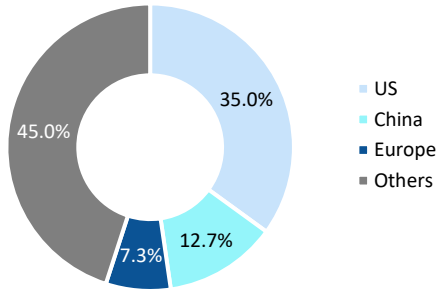
Exhibit 3.5: PE/VC Funding in Biotech, 2018-2024 (USD Bn)



Source: DealForma Database, Frost & Sullivan

The US has many well-funded Biotech companies in innovation hubs such as Cambridge, San Francisco, Boston, New York, and San Diego. These leading innovation hubs in the US are home to over 1,000 Biotech and Pharma companies and drive a significant share of the global R&D spending in CY2023. These emerging biotech companies also focus on collaborating with CRDMO companies in cost-competitive geographies (like India), with the collaboration offering a competitive edge for drug development and large-scale commercial production.

Exhibit 3.6: Share of Biotech Funding, 2023

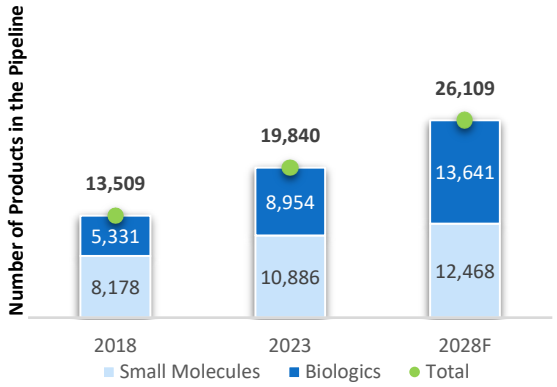


Source: Drug Development & Outsourcing, Frost & Sullivan

3.1.3 Global Pharma R&D Pipeline

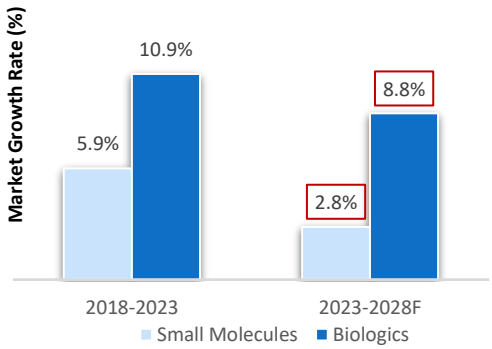
The number of molecules in the R&D stage is on the rise; small molecules will continue to have a significant share. In the year 2023, nearly 20,000 molecules were in different stages of development (from preclinical to launch). Small molecules currently comprise a large proportion (54.9% in 2023) of the molecules under development. The biologics (large molecules) R&D pipeline is expected to grow faster and is expected to comprise 52.2% of the R&D pipeline in 2028F.

Exhibit 3.7A: Global Number of R&D Products in Pipeline by Modality, 2018- 2028



Source: Pharmaprojects, Evaluate Pharma
Note: F - Forecast

Exhibit 3.7B: Growth rate of Global R&D Pipeline by Modality, 2018- 2028F

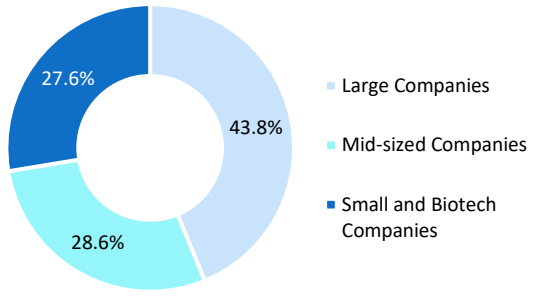


Source: Pharmaprojects, Evaluate Pharma
Note: F - Forecast

3.1.3.1 GLOBAL PHARMA R&D PIPELINE BY COMPANY TYPE

Large pharma companies constitute a larger share (43.8%) of the drug pipeline, followed by mid-sized pharma companies (28.6%) and small pharma and biotech companies (27.6%) in 2023. Loss of exclusivity (patent expiry), pricing pressure, and technological advancements are major factors driving R&D investments for large pharma companies.

Exhibit 3.8: R&D Pipeline by Pharma Company Size, 2023



Source: Pharma Projects, Frost & Sullivan

3.2 PHARMA MANUFACTURING DYNAMICS

3.2.1 Manufacturing Technologies and Platform Trends

The pharmaceutical industry is transitioning from traditional drug manufacturing to cutting-edge methods like Biotransformation, Flow Chemistry, and Recombinant DNA. Traditional chemical synthesis often requires stringent conditions such as high temperatures, high pressures, and toxic reagents, making it more costly due to the need for multi-step catalytic reactions, expensive chemical catalysts, and organic reagents, resulting in low yield rates. These innovations in manufacturing technologies and platforms are streamlining drug development, minimizing

environmental impact, and enabling the production of high-value molecules like peptides, oligonucleotides, and monoclonal antibodies at scale. This shift represents a game-changing opportunity for the industry.

Exhibit 3.9: Manufacturing Technology Platforms

Platform	Description	Benefits/ Drivers	Select Applications	Examples of Top-Selling Products, 2023, USD
Biotransformation	Biosynthesis/ biotransformation is a process that uses enzymes[16] as catalysts to replace heavy metals or other chemical catalysts when synthesizing drugs.	Biosynthesis/biotransformation provides a faster, cost-efficient, and more environmentally friendly CRDMO solution as compared to the traditional chemical synthesis process, resulting in a milder reaction process that is more environment-friendly, safer, and cost-efficient as it combines multi-step catalytic reactions into one, significantly reducing manufacturing waste and costs. The molecules produced by biosynthesis/biotransformation are considered natural and safe. The reactions are typically carried out in a milder temperature range (4–60 °C), leading to a lower amount of energy required for the reactions compared to traditional chemical synthesis. Hence sustainable and more eco-friendly.	• Green Chemistry • Organic Synthesis • Asymmetric Synthesis • Drug Modification	• Sitagliptin (Januvia): **2,400 million** • Atorvastatin (Lipitor): **1,600 million** • Montelukast (Singulair): **452 million**
Flow Chemistry/ Continuous Manufacturing	Flow Chemistry or Continuous Manufacturing is a technique where chemical reactions are carried out in a continuous flow system (uninterrupted production line), rather than in batches.	This method offers several advantages, including improved control, efficiency, and safety. Flow processes can produce higher yields, and be safer, cleaner, and cheaper to set up and operate leading to higher operational efficiency. Flow chemistry solutions offer precise control over four critical reaction parameters, namely stoichiometry[17], mixing, temperature, and reaction time.	• Peptide and oligonucleotide synthesis • API Production • Drug Formulation	• Ribociclib (Kisqali): **2,100 million** • Celecoxib (Celebrex): **364 million**
Fermentation	Fermentation is a biological process that involves the conversion of organic compounds into other products by the action of microorganisms.	This method allows the production of large quantities of specific compounds in a relatively short time, making it a cost-effective method to produce specific drugs with better operational efficiency.	• Monoclonal Antibodies • Recombinant proteins • Microbial vaccines	• Ceftriaxone (Rocephin): **443 million** • Minocycline (Arestin, Monocin, Minocycline): **156 million**
Metal-Mediated Chemistry	Metal-mediated chemistry is an important tool in organic synthesis, involving the use of metal catalysts to facilitate chemical reactions.	Metal ions can enhance the toxicity of coordinated drugs by producing Fenton reactions These drugs can be used to treat a variety of ailments, including diabetes, ulcers, rheumatoid arthritis, and inflammatory diseases.	• Chiral Catalysis • Catalytic hydrogenation • Oxidation and Reduction • Carbon bond formation	• Valsartan (Diovan): **674 million** • Oseltamivir (KeWei, Tamiflu): **370 million** • Sertraline (Zoloft): **292 million** • Losartan (Cozaar): **368 million**
Recombinant DNA	Recombinant DNA technology involves using enzymes and various laboratory techniques to	Recombinant DNA technology can produce proteins and antibodies with a high degree of uniformity and specificity.	• Production of Insulin, Recombinant Proteins, Human Growth Hormone	• Adalimumab (Humira): **14,000 million** • Etanercept: **4,500 million**

[16] Proteins or RNAs that catalyze chemical changes to other molecules
[17] Stoichiometry is a branch of chemistry, which is used to determine the exact quantities of reactants needed to produce a specific drug.

	manipulate and isolate DNA segments of interest		• Gene therapy	• Trastuzumab (Herceptin): **1,800 million** • Insulin Glargine (Lantus): **1,500 million**
Electrochemistry	Electrochemistry is a technique that uses electricity to perform chemical reactions like oxidation and reduction. It has applications in medicinal chemistry labs, early development for the synthesis of intermediates, and synthesis of impurities.	Electrochemistry can make the process of synthesizing small molecules more sustainable and efficient. Electrochemistry can be used to create molecules that are difficult or impossible to make using traditional chemistry. It can also replace hazardous or waste-generating reagents in the synthesis of active pharmaceutical ingredients	• APIs and intermediates	• NA
Photochemistry	Photochemistry utilizes light, often in the visible or ultraviolet spectrum, to activate a substrate or catalyst, which then facilitates a chemical reaction.	Light as a reagent aligns with the principles of green and sustainable chemistry, reducing reliance on hazardous traditional reagents and minimizing the use of hazardous substances.	• APIs and intermediates	• NA

Source: Evaluate Pharma, Frost & Sullivan

3.2.2 Global Pharmaceutical Market by Molecule Type

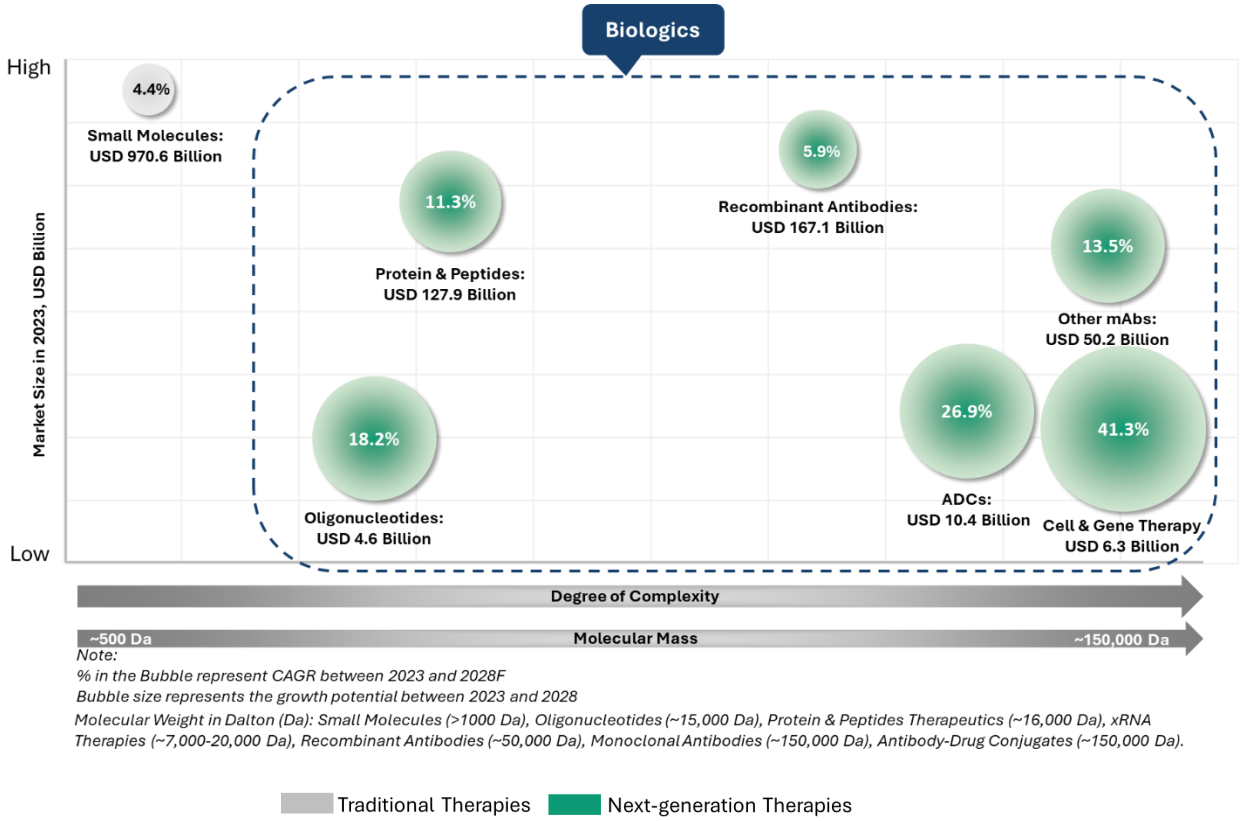
Evolution of the Pharma market and introduction of new-age modalities

Small molecules are easily synthesized through chemical processes and have been vital in medicine since the early 20th century. However, their broad action can lead to off-target effects[18]. In contrast, biologics (large molecules) like monoclonal antibodies (mAbs), Antibody Drug Conjugates (ADCs), and Cell and Gene Therapies (CGTs) offer specificity but are costly and challenging to produce consistently due to intricate manufacturing processes involving living cells and sterile environments.

As pharmaceutical modalities (small molecules and biologics) evolve, each step offers more targeted, potent, and personalized treatment options, but also requires increasingly complex development, manufacturing, and regulatory strategies. Innovations within each category, such as ADCs in biologics (large molecules) or Lipid Nanoparticle (LNP) systems for genetic therapies, reflect the industry's push for precision and efficacy, accompanied by innovation in manufacturing technologies.

[18] Non-targeted action of drug

Exhibit 3.10: Market Potential by Type of Molecules, Market Size (2023) and Growth (2023 – 2028F)



Source: Evaluate Pharma, Frost & Sullivan

- **Monoclonal Antibodies (mAbs)** are a type of protein that is made in the laboratory and can bind to certain targets in the body, such as antigens on the surface of cancer cells. mAbs comprises molecules such as Antibody Drug Conjugates (ADC), Recombinant antibodies, and other mAbs.

    - **Recombinant Antibody:** Recombinant antibodies are generated outside the immune system using synthetic genes and, therefore, do not require animal immunization for their production. The market for Recombinant Antibodies, valued at USD 167.1 billion in 2023, is anticipated to grow to USD 222.8 billion in 2028 at a CAGR of 5.9%.

    - **Antibody-drug conjugates:** ADCs, which link antibodies to cytotoxic drugs, provide targeted delivery of potent therapies to cancer cells and have the potential to replace conventional chemotherapies. Manufacturing ADCs is particularly complex, requiring precision in conjugating toxic payloads to antibodies while maintaining stability and activity, necessitating highly controlled production environments. The ADC market, valued at USD 10.4 billion in 2023, is one of the fastest-growing biologic segments and is anticipated to grow to USD 34.4 billion by 2028 at a CAGR of 26.9%.

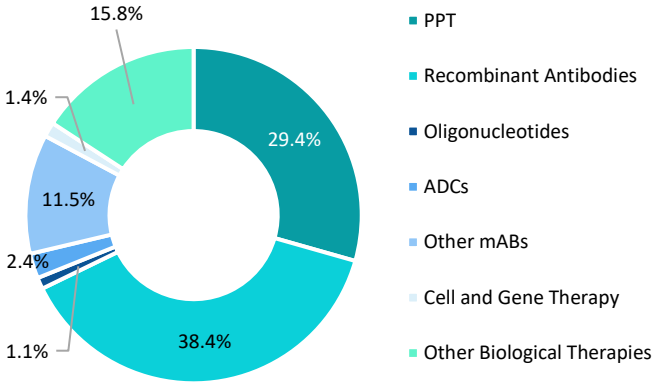
- **Proteins and peptides**, like enzymes and GLP-1 agonists provide focused actions with less systemic exposure. The protein and peptide market, valued at USD 127.9 billion in 2023, is projected to grow to USD 218.3 billion by 2028 at a CAGR of 11.3%.
    - GLP-1 agonists, specifically, have gained prominence due to their effectiveness in managing metabolic disorders, with a market size of USD 36.8 billion in 2023, expected to reach USD 105.3 billion by 2028, growing at 23.4%.

However, these therapies require sophisticated delivery systems like encapsulation (combining with polymer-nanoparticles to offer a stable environment and reduce degradation) or chemical modification to improve stability and half-life) to prevent degradation and enhance bioavailability, complicating their development and manufacturing.

- **Oligonucleotides**, such as antisense and small interfering RNA (siRNA) therapies, represent a leap into genetic modulation, directly targeting RNA[19] to alter protein production. Oligonucleotides are short, single- or double-stranded DNA or RNA molecules which forms a part of xRNA[20] therapies. The oligonucleotide market, estimated at USD 4.6 billion in 2023, is forecasted to grow to USD 10.6 billion by 2028, at a CAGR of 18.2%. Approved therapies such as Spinraza and Onpattro demonstrate their potential but involve complex synthesis, purification, and delivery systems to achieve cellular uptake and avoid degradation. Advanced delivery technologies, such as Lipid Nanoparticles (LNP), are crucial yet challenging to produce consistently.

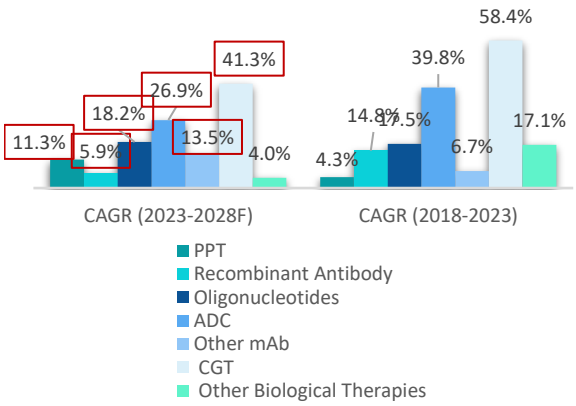
- **Cell and gene therapies (CGT)**, including CAR-T cell therapies and gene-editing techniques like CRISPR offer potentially curative treatments by altering or correcting genetic material. The CGT market was valued at USD 6.3 billion in 2023 and is projected to surge to USD 35.8 billion by 2028, with a CAGR of 41.3%. These therapies require advanced bio-manufacturing involving viral vectors or plasmid DNA and must adhere to rigorous quality control and regulatory standards, further increasing their complexity and cost.

Exhibit 3.11A: Share of Biologics by Technology, 2023



Source: Evaluate Pharma, Frost & Sullivan
Note: PPT = Protein & Peptide Therapy, mAB - Monoclonal Antibody, CGT = Cell & Gene Therapy; Other Biological Therapies include Vaccine, Oncolytic Products e.t.c.

Exhibit 3.11B: Growth Rate of Select Biologic Technologies, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan

[19] Ribonucleic Acid, a single-stranded molecule essential in various biological roles, including coding, decoding, regulation, and expression of genes
[20] xRNA, or exogenous RNA, typically refers to RNA molecules that originate outside of an organism or cell.

Exhibit 3.12: Benefits of Key Emerging Technologies

Technology	Description	Key therapeutic areas	Top Selling Drugs (in USD Million)	Market Size (2023); Projected CAGR (2023-2028F)
Antibody Drug Conjugate (ADC)*	ADCs are innovative biopharmaceutical products in which a monoclonal antibody is linked to a small molecule cytotoxic drug with a stable linker. Used for targeted therapy, ADCs target and kill tumor cells without harming the healthy cells by integrating the antigen specificity of monoclonal antibodies (mAbs) with antibody fragments.	Mostly for treating cancer, but there is enormous potential for using ADCs to treat other diseases such as hemophilia and inflammatory diseases	▪ Enhertu (Oncology) - 3,003 ▪ Kadcyla (Oncology) - 2,190 ▪ Adcetris (Oncology) - 1,755 ▪ Trodelvy (Oncology) - 1,063 ▪ Polivy (Oncology) - 932	▪ USD 10.4 billion ▪ 26.9% CAGR
Peptides*	Peptides are strings of molecules called amino acids, which are the "building blocks" of proteins. Peptides include GLP-1, and non-GLP-1 such as GLP-2, Calcitonin. Peptides function as hormones and growth factors, and they act as antioxidants, scavenging free radicals. Additionally, they possess antibacterial properties	Peptides are used in a wide range of therapeutic areas, such Gastro-intestinal and metabolic disorders.	Some of the top-selling peptides (non-GLP-1) drugs are listed below: ▪ Gattex – 826 (Gastro-intestinal disorder)	**Total Peptide** ▪ USD 40.0 billion ▪ 23.0% CAGR **Non-GLP-1** ▪ USD 3.0 billion ▪ 17.3% CAGR
GLP-1*	Glucagon-like peptide 1 (GLP-1) is a hormone and neurotransmitter peptide that plays a role in lowering serum glucose levels and thereby managing metabolism in affected patients	Reduces body weight, glycemia, blood pressure, postprandial lipemia, and inflammation — actions that could contribute to reducing cardiovascular events	▪ Ozempic (Metabolic disorder) - 13,897 ▪ Trulicity (Metabolic disorder) - 7,133 ▪ Mounjaro (Metabolic disorder) - 5,163 ▪ Wegovy (Metabolic disorder) - 4,551 ▪ Rybelsus (Metabolic disorder) - 2,722	▪ USD 36.8 billion ▪ 23.4% CAGR
Oligonucleotides#*	Oligonucleotide drugs are short strands of DNA or RNA, they work by binding to DNA or RNA to either increase or decrease the expression of target RNA. They are more targeted and can alter gene expression, thereby effectively treating genetic disorders	They are used to treat Neurodegenerative disorders, cancer, auto-immune disorder	▪ Spinraza (Auto-immune disorder) - 1,741 ▪ Amvuttra (Auto-immune disorder) – 558 ▪ Exondys (Auto-immune disorder) – 540 ▪ Leqvio (Cardiovascular) - 355 ▪ Onpattro (Auto-immune disorder) – 354 ▪ Givlaari (acute hepatic porphyria - hepatic disorder) - 219 ▪ Oxlumo, (Genito-Urinary) - 110	▪ USD 4.6 billion ▪ 18.2% CAGR
RNAi[21]*	RNAi (RNA interference) is gaining more salience in its key therapeutic areas such as liver-related disorders, cardiovascular disorders, and urinary disorders since it can effectively suppress the	RNAi drugs are used to treat liver-related disorders, cardiovascular disorders, and urinary disorders.		

[21] RNA interference, which is a biological process to inhibit gene expression or translation by neutralizing the targeted mRNA molecules

	growth of advanced-stage tumors, has relatively low cost, and offers high specificity. RNAi can simultaneously inhibit multiple genes of various pathways, which may help in reducing drug resistance.			
Lipids*	Lipid-based drug delivery systems include various formulations aimed at presenting poorly water-soluble drugs in a solubilized form, thereby eliminating dissolution as the rate-limiting step for absorption.	Lipids[22] are used in the field of oncology.	▪ Taxol (Oncology): 22 ▪ Gemzar (Oncology): 18	▪ USD 0.8 billion ▪ 12.9% CAGR
Recombinant Monoclonal Antibodies (mAbs)	Monoclonal antibodies (mAbs) are laboratory-made proteins that can bind to specific antigens in the body, such as those on cancer cells. They mimic, enhance, or restore the immune system's attack on unwanted cells. Their specificity, ease of production and conjugation, and generally low toxicity make them advantageous compared to small molecules	Mostly oncology and immunology/ infectious diseases, but expanding into other therapeutic areas	▪ Keytruda (Oncology) - 25,011 ▪ Humira (Anti-inflammatory) - 14,497 ▪ Dupixent (Anti-inflammatory) - 11,590 ▪ Stelara (Anti-inflammatory) -11,323 ▪ Darzalex (Oncology) - 9,744	▪ USD 217.4 billion (excluding ADCs) 5.9% CAGR
Cell & Gene Therapies	Gene therapy involves the transfer of genetic material, usually in a carrier or vector, and the uptake of the gene into the appropriate cells of the body.	CGTs are used to treat genetic disorders, immune disorders, and cancer to name a few	▪ Yescarta (Oncology): 1,498 ▪ Zolgensma (Auto-immune disorder): 1,214 ▪ Kymriah (Oncology): 508 ▪ Carvykti (Oncology): 500 ▪ Abecma (Oncology): 472	▪ USD 6.3 billion ▪ 41.3% CAGR

Source: Evaluate Pharma; Frost & Sullivan
Note: Sales for branded products only, do not include sales for the entire active ingredient family
#Oligonucleotides is a part of xRNA therapy and make up the majority share in xRNA therapies.
**Modalities offered by Anthem (i.e. ADCs, xRNAs, Oligonucleotides, peptides) have high growth in the pharma industry (based on CAGR values)*

3.3 EVOLUTION OF THE PHARMA OUTSOURCING MODEL

Even as pharma companies experience significant growth, they encounter various obstacles, prompting them to pursue outside collaborations with experts such as CROs and CDMOs.

In the past, these companies mainly focused on outsourcing large volumes and forming partnerships with contract service providers to improve their late-stage clinical trials and carry out large-scale manufacturing of established drugs at low cost. However, outsourcing is no longer about cost or manufacturing. Pharmaceutical companies are building closer relationships with contract service providers to get help in R&D, access new markets, share the risk

[22] Lipids are a diverse group of organic compounds, including fats, oils, and waxes, that are insoluble in water but soluble in nonpolar solvents, and play essential roles in energy storage, cell membrane structure, and signaling. Lipids are essential biomolecules used in various applications, such as drug delivery systems, the creation of lipid nanoparticles for mRNA vaccines, and the development of cell membrane models for research and therapeutic purposes

of drug development such as regulatory hurdles, and clinical trials, speed up timelines, and ensure the best quality output at lower costs.

Key challenges faced by pharmaceutical companies across the drug lifecycle

The pharmaceutical sector faces significant challenges, underpinned by rising profitability and pricing pressures from both payors (insurance companies) and governments. Some of the key challenges faced by pharma companies are highlighted below.

- **Cost pressures and shift towards asset-light model:** The pharmaceutical industry has seen significant progress since the late 1990s with around 23,000 active molecules in the R&D pipeline (Discovery and Development phase) as of September 2024, compared to just 6,000 in 2001. However, the cost per NBE or NCE has risen significantly, surpassing USD 1.0 billion per drug. The drug development time has doubled from 6 years in the 1970s to 13.5 years in the 2000s, highlighting the need for innovation and efficiency in the industry. Clinical trials have become more intricate, demanding new endpoints and advanced subject profiling methods for participant recruitment. Additionally, using potent and toxic raw materials often necessitates costly manufacturing technologies.

Exhibit 3.13: Increasing Cost and Time Per Drug Approved

	1970s	2020s
Active Molecules in R&D Pipeline	5,000	23,000
Cost per NME or NCE	USD 100 Million per Drug	USD 1 Billion per Drug
Time for Drug Development	6 Years	13.5 Years
Studies indicate that R&D expenses range from USD 1 billion to USD 3 billion, potentially reaching USD 6 billion when accounting for capital and attrition costs.		

Source: Frost & Sullivan
Note: Active molecules in the R&D pipeline signify the cumulative number of drugs that are in the R&D stage in that period.

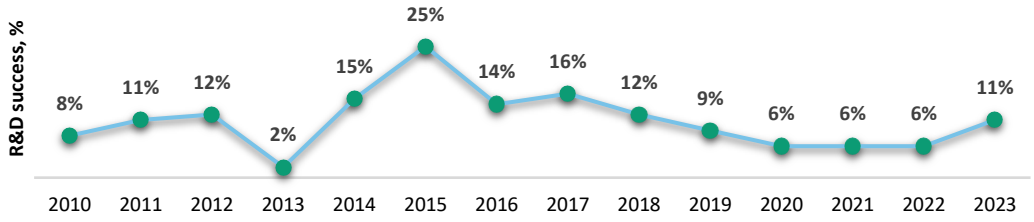
This increasing cost pressure is driving companies to opt for an asset-light model which allows a seamless focus on core innovation activities.

- **R&D efficiency concerning ROIs and success rate:** In 2022, the FDA approved 12 new personalized medicines[23], representing 32% of total approvals. It is widely recognized that only a small percentage of experimental compounds, roughly one in 10,000 to 15,000, move from preclinical trials to regulatory approval and commercialization as of 2023.[24] R&D for new drugs faces increasing difficulties, leading to a decrease in the overall success rate. From a peak of 25% in 2015, the composite success[25] from phase 1 to regulatory approval reduced to 11% in 2023 globally.

  The uncertainty on the drug approval process has further dissuaded pharmaceutical companies from investing in their in-house manufacturing capabilities.

[23] Personalized medicine is an emerging practice of medicine that uses an individual's genetic profile to guide decisions made regarding the prevention, diagnosis, and treatment of disease.
[24] American Journal of Public Health
[25] Cumulative success from phase 1 to approval.

Exhibit 3.14: Global R&D Success Rate (Composite) across all Phases



Source: Frost & Sullivan, IQVIA

[26]

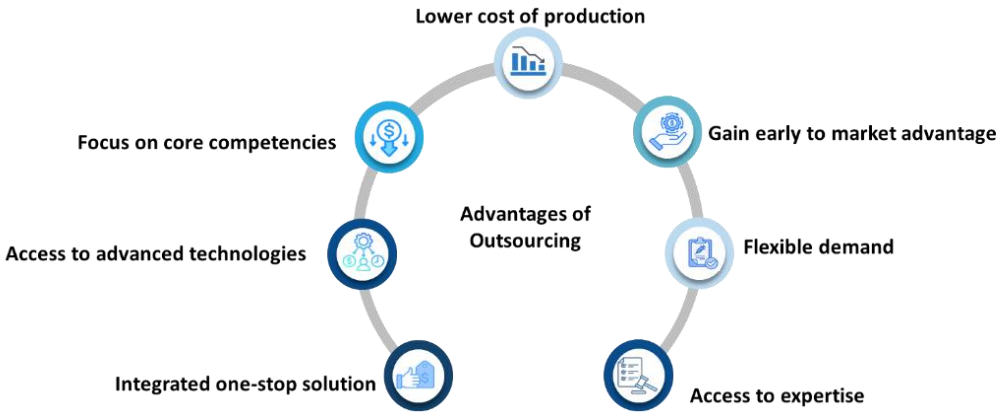
- **Resource constraint of small pharmaceutical and biotech companies:** Biotech and small pharmaceutical companies, who typically depend on funding and are often funded by PE and VC, are growing at a higher rate since 2018 and will continue the trend between 2023 and 2028. Most of them are virtual companies with lean resources and minimal physical infrastructure and rely on third-party providers like CRDMOs. Small pharmaceutical and emerging biotech companies have to overcome several challenges during the drug discovery and development process. The usual challenges faced by them include securing PE and VC funding (the challenge of which is heightened in challenging economic climates), navigating evolving regulatory requirements that necessitate expertise to navigate complex standards, approval processes and compliance demands, scientific and technical obstacles, and scaling up manufacturing while maintaining quality and cost-efficiency. Collaboration with external partners allows access to required expertise and technologies without the financial burden of establishing the capabilities in-house.
- **Increased regulatory oversight:** The pharmaceutical industry is subject to stringent regulatory and compliance requirements, thus facing stricter access and pricing regulations. In the United States, the government has initiated drug price negotiations to decrease the price for the first 10 prescription products bought by the US national health insurance providers under the Inflation Reduction Act (IRA), resulting in reduced pricing power for pharmaceutical companies. BIOSECURE Act, introduced in the United States in recent times, reduces the accessibility of Chinese manufacturers accessing US federal funding, thus resulting in the diversion of business that was earlier going to China to other lower-cost economies, like India.

3.4 ADVANTAGES OF OUTSOURCING

Pharma outsourcing offers multifold advantages to innovators and the need for and importance of CRDMOs is well recognized due to the benefits offered such as reducing operational cost, access to technical expertise and technology capabilities, integrated offering, and improved speed to market. Outsourcing R&D and manufacturing to CROs and CDMOs has proven successful in overcoming the above challenges faced by pharma companies.

[26] Composite success rate refers to the combined success rate of drugs from phase 1 to approval.

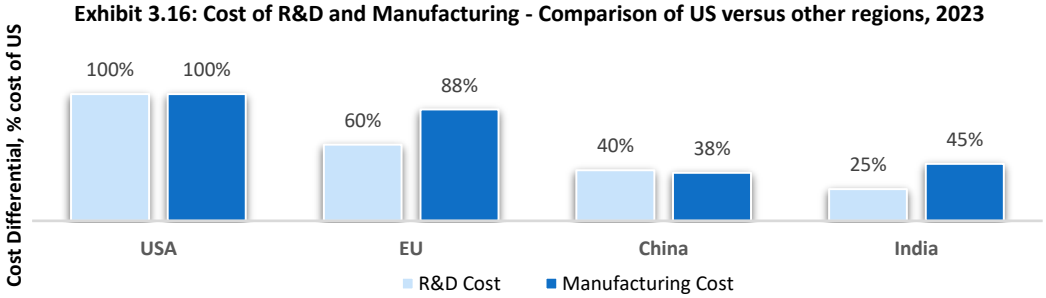
Exhibit 3.15: Benefits for Pharma Companies Due to Outsourcing



Source: Frost & Sullivan

1. **Cost advantage***:* Outsourcing R&D and manufacturing tasks to service providers in India can result in an estimated cost reduction of nearly 75% and 55% for R&D activities and manufacturing respectively as compared to performing those activities in the US. The reason for the cost savings can be attributed to the providers' specialized knowledge, economies of scale in R&D and manufacturing, and availability of low-cost skilled manpower.

Exhibit 3.16: Cost of R&D and Manufacturing - Comparison of US versus other regions, 2023



Source: Frost & Sullivan
Note: Relative numbers indexed against the USA, based on Industry KOL estimates

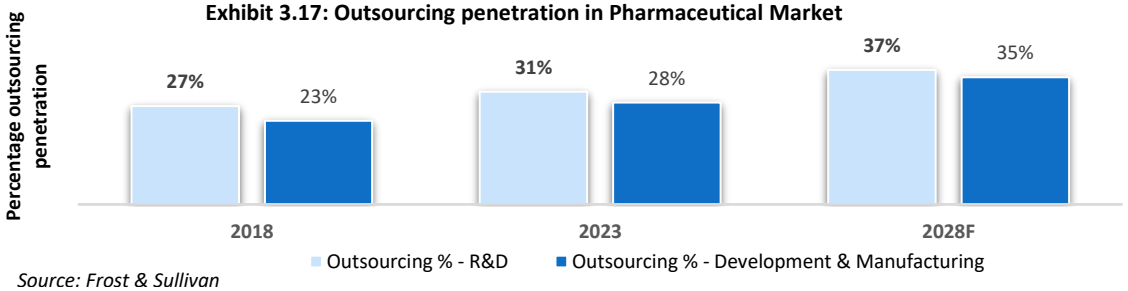
2. **Time savings necessary for early-to-market advantage:** CRDMOs are skilled in accelerating drug discovery, development, and manufacturing timelines by leveraging advanced technologies and specialized expertise to identify promising leads more effectively. CRDMOs expedite drug development and manufacturing through large-scale production capabilities, optimized processes, and regulatory proficiency. As a result, up to an estimated 30% reduction in project timelines for drug discovery and a 20% to 30%[27] reduction in manufacturing timelines can be achieved through outsourcing to low-cost geographies such as India.
3. **Flexibility and scalability:** Contract service providers offer flexible and scalable solutions, providing access to research labs and clinical trial sites for diverse projects[28]. They also enable companies to adjust production levels to manage market fluctuations caused by unforeseen events like pandemics, wars, or inflation.
4. **Access to specialized and global expertise:** A deep understanding of chemistry, biology, data science, and regulatory requirements is essential for drug discovery and development. CRDMOs employ highly skilled professionals with diverse backgrounds and extensive industry experience. They offer valuable insights and

[27] KOL interviews
[28] Projects are Unique program(s) commissioned by customers, under each of such program multiple work orders are received from the customer

knowledge across therapeutic areas and disciplines. Additionally, CRDMOs in India and other countries leverage global networks and collaborations for access to cutting-edge technologies, regulatory intelligence, and market insights worldwide. International expertise allows pharmaceutical companies to take advantage of new-age technologies.

5. **One-stop shop solution:** CROs and CDMOs are consolidating and becoming one-stop shops with end-to-end service offerings as CRDMOs. CRDMOs today are positioned as valuable long-term partners to pharma companies, reducing project management costs, sharing risks of product success, mitigating supply chain risks, and eliminating scalability challenges. Opportunities for new partnerships are also on the rise. The global R&D outsourcing penetration is projected to increase from 27% in 2018 to 37% in 2028 in terms of value. The development and manufacturing outsourcing penetration value is expected to increase from 23% to 35% during the same period.

Exhibit 3.17: Outsourcing penetration in Pharmaceutical Market



Source: Frost & Sullivan

6. **Access to Advanced Technologies:** Contract service providers invest significantly in developing a suite of high-end technology, including proprietary platforms, which may not be available to pharmaceutical companies in-house. With the rapidly evolving landscape of technologies and processes, pharmaceutical companies may not be able to keep up with the pace, on the other hand, contract service providers can invest with more agility in new-age processes and state-of-the-art manufacturing technologies, to name a few areas of investment. This allows them to offer pharmaceutical sponsors high-quality output and process efficiency.
7. **Ability to Concentrate on Core Competencies and Move from Capex to Opex Model:** The increasingly resource-constrained environment with onerous regulatory and reimbursement requirements [29] And globally spread-out R&D processes have made it critical for pharma companies to outsource. Similarly, building and maintaining manufacturing facilities and infrastructure can be capital-intensive. Outsourcing non-core functions drives concentrated focus on core competencies, such as brand building, marketing, and strategic planning. Hence, pharma companies are drifting from Capex to Opex models and, in the process, find co-owners for their assets through co-invention and co-commercialization deals with contract service providers.

Overall, outsourcing benefits pharma innovators by decreasing operational costs, improving the lead time from innovation to commercialization, and accessing the capabilities of contract service providers. These lead to competitive pricing while maintaining healthy margins and good quality of drugs.

[29] Reimbursement refers to the process by which healthcare providers or patients receive compensation for the cost of the drug which are covered under insurance or any Government linked Medicare aid.

4 CONTRACT SERVICES (CRO AND CDMO) INDUSTRY OVERVIEW

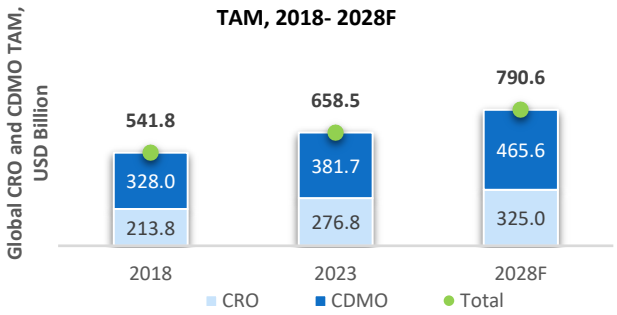
Contract Research Organizations (CROs) and Contract Development and Manufacturing Organizations (CDMOs) are crucial players in the pharmaceutical and biotechnology industries, providing outsourced services across various stages of drug development and manufacturing. While CROs specialize in research services, including preclinical and clinical trial support, CDMOs focus on development and manufacturing activities, such as formulation development, process optimization, and large-scale production of pharmaceutical products.

By leveraging the expertise, infrastructure, and resources of CROs and CDMOs, pharmaceutical companies can accelerate the drug development process, reduce costs, and access specialized capabilities that may not be available in-house. In an environment of moderating sales, increasing rebates, declining margins, and increasingly stringent regulatory requirements, CROs and CDMOs' value proposition has been strengthening as they address critical and increasingly prevalent business challenges.

4.1 GLOBAL CRO AND CDMO TOTAL ADDRESSABLE MARKET

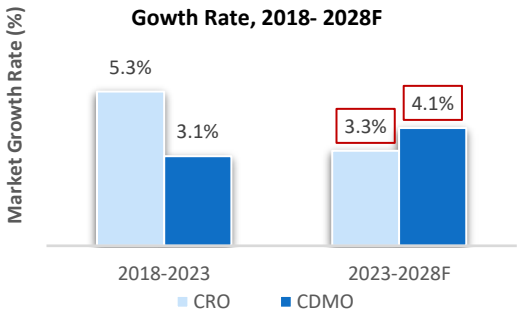
The Total Addressable Market (TAM) refers to overall potential market opportunity for CRO or CDMO (as the case may be). The TAM for CRO comprises of entire R&D spending by pharmaceutical companies that can be entirely outsourced, while TAM for CDMO covers manufacturing costs incurred by pharma companies. The TAM for CRO

Exhibit 4.1A: Global CRO and CDMO TAM, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.1B: Global CRO and CDMO TAM Gowth Rate, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

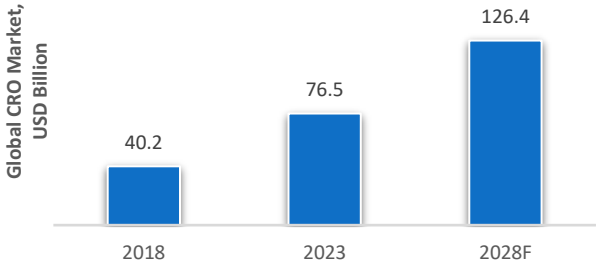
services stood at USD 276.8 billion in 2023 and is estimated to grow at a CAGR of 3.3% between 2023 and 2028 to reach USD 325.0 billion while TAM for CDMO was USD 381.7 billion and is forecasted to grow at a CAGR of 4.1% between 2023 and 2028 to reach USD 465.6 billion in 2028.

4.1.1 GLOBAL CRO MARKET

Integrated CROs are adept at managing drug discovery to pre-clinical and clinical trial activities rapidly and seamlessly by facilitating the transfer of samples, data, knowledge, and technical feedback between scientists of diverse disciplines resulting in estimated cost reductions of nearly 30%[30] compared to in-house, timely entry into new markets and helping pharmaceutical sponsors to focus on their core skills while proactively mitigating development risks. The global CRO market revenue has increased from USD 40.2 billion in 2018 to USD 76.5 billion in 2023, growing at a CAGR of 13.7%. It is forecasted to reach USD 126.4 billion in 2028, driven primarily by increasing outsourcing, improving technological capabilities, and global expertise.

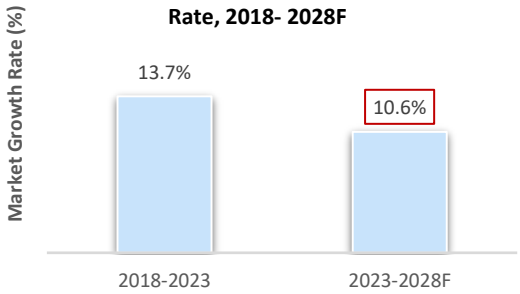
[30] Frost & Sullivan estimate.

Exhibit 4.2A: Global CRO Market, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.2B: Global CRO Market Gowth Rate, 2018- 2028F

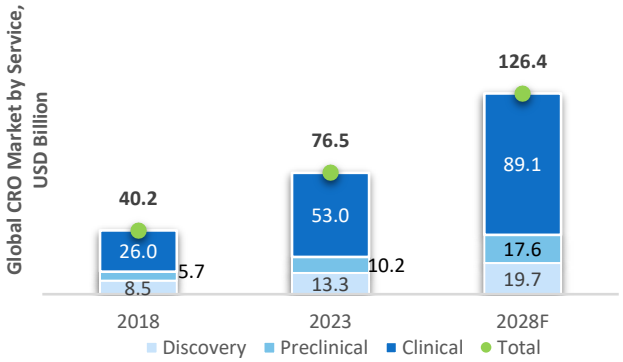


Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.1.1.1 GLOBAL CRO INDUSTRY BY SERVICES TYPE

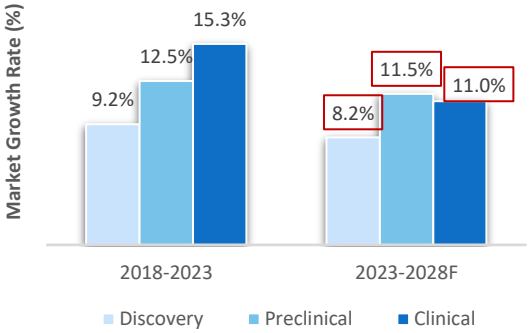
The CRO industry includes non-clinical (such as discovery and preclinical services) and clinical services. In drug discovery, non-clinical CROs identify potential drug candidates, design and conduct lab tests, analyze resulting data, and ensure drug safety for human trials. Clinical CROs focus on later stages, testing drugs on human subjects from phase I to phase III or IV trials. Strengthened IP protection laws have increased reliance on CROs for early discovery and preclinical studies, coupled with the rise of smaller pharmaceutical companies and biotech, the outsourcing of non-clinical services has increased and is expected to reach a combined value of USD 37.3 billion by 2028, growing at a CAGR of approximately 9.7% from 2023 to 2028.

Exhibit 4.3A: Global CRO Market by Service, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.3B: Global CRO Market by Service Gowth Rate, 2018- 2028F

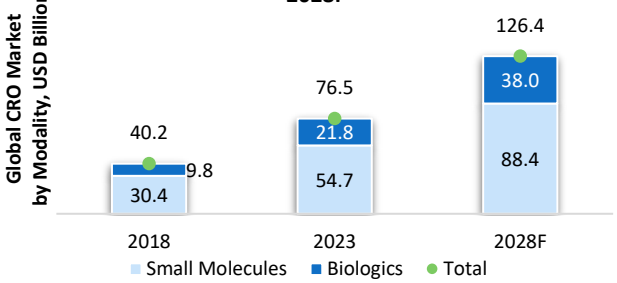


Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.1.1.2 GLOBAL CRO BY MODALITY

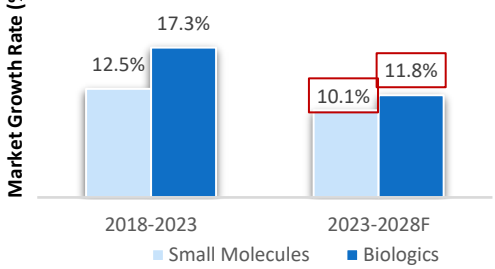
In line with the overall pharma industry, small molecules dominate the CRO industry by modality. However, biologics (large molecules) demand for CRO has been increasing from 25% in 2018 to 28% in 2023 and is estimated to capture nearly 31% of the CRO market by 2028. Biologics (large molecules) demand for CRO services is expected to reach USD 38.0 billion by 2028, growing at a CAGR of 11.9% from 2023 to 2028, with small molecules share of the CRO services expected to grow at a CAGR of 10.1% during the same period, to reach USD 88.4 billion by 2028.

Exhibit 4.4A: Global CRO Market by Modality, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.4B: Gowth Rate of Global CRO Market by Modality, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.1.1.3 GLOBAL CRO INDUSTRY BY REGION

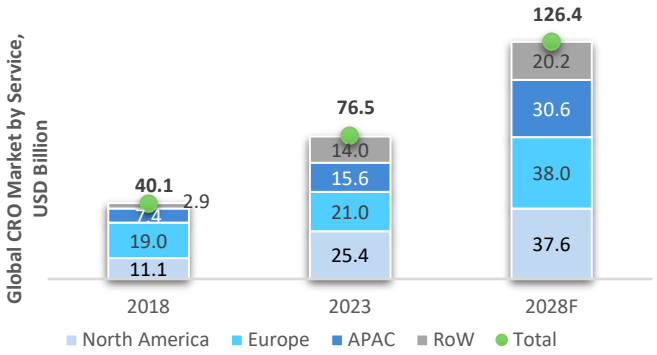
The global CRO market is divided into five major regions: North America, Europe, APAC, and the Rest of the World (RoW). In 2023, North America held the largest market share at 32.9% but is expected to reduce to 30.2% in 2028. North America region has a strong presence of existing CROs, a robust healthcare infrastructure that supports clinical trials, and is home to some of the largest pharmaceutical companies globally. The region is projected to experience a CAGR of 8.2% from 2023 to 2028, with the market value reaching USD 37.6 billion in 2028, up from USD 25.4 billion in 2023.

The Europe region is the second-largest CRO market, holding a market share of 27.6% in 2023. The region has a robust foundation for R&D with established research institutes, medical centers, centers of excellence, and leading pharmaceutical companies. It also serves as a strong manufacturing hub for pharmaceutical companies. The Europe market is expected to grow from USD 21.0 billion in 2023 to USD 38.0 billion in 2028, at a CAGR of 12.6%.

APAC region is expected to demonstrate the highest CAGR of 14.4% from 2023 to 2028, outpacing the large market peers, North America and Europe. The CRO market in the region is expected to reach USD 30.6 billion in 2028 from USD 15.6 billion in 2023. A major reason for increased outsourcing in APAC regions is owing to countries like India, China, and Indonesia offering several advantages, like reduced costs (compared to North America and Europe), availability of skilled labor, strong infrastructure for pharma manufacturing, higher population densities facilitating easier patient recruitment, and offering patient population diversity.

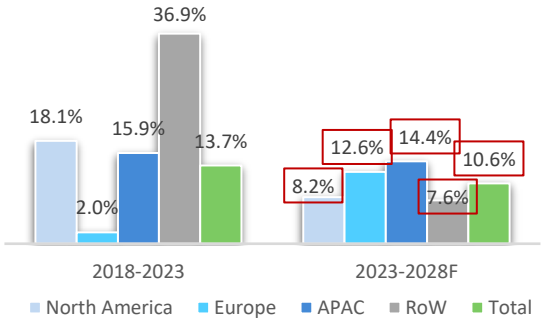
The RoW region, comprising geographies such as Africa, Latin America, and others, is expected to grow from USD 14.0 billion in 2023 to USD 20.2 billion in 2028 at a CAGR of 7.6%.

Exhibit 4.5A: Global CRO Market by Region, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.5B: Growth rate of Global CRO Market by Region, 2018- 2028F

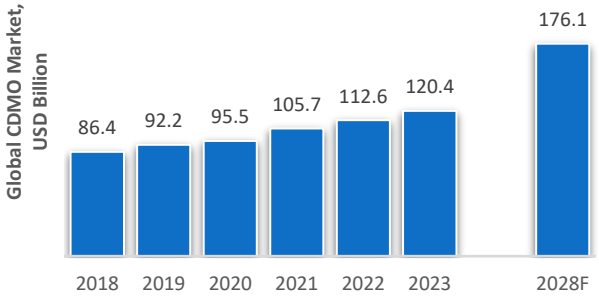


Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.1.2 GLOBAL CDMO MARKET

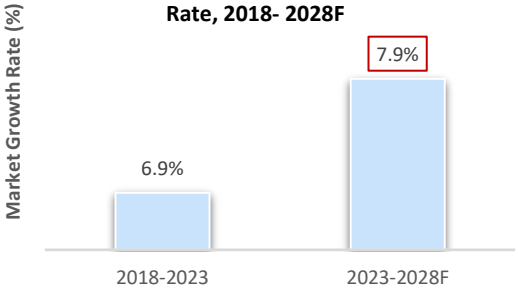
The CDMO industry is vital for drug development and manufacturing. With the shift to precision medicine, pharmaceutical companies now see CDMOs as strategic partners. Their reliance is expected to increase due to their consistent delivery of commercially feasible solutions. Key factors contributing to their success include technical capabilities, R&D infrastructure, access to skilled talent, and a history of quality manufacturing with regulatory compliance. The global CDMO industry has experienced significant growth, expanding from USD 86.4 billion in 2018 to USD 120.4 billion in 2023 at a CAGR of 6.9%. Projections indicate that it will reach USD 176.1 billion in 2028, reflecting a CAGR of 7.9% from 2023 to 2028.

Exhibit 4.6A: Global CDMO Market, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.6B: Global CDMO Market Gowth Rate, 2018- 2028F

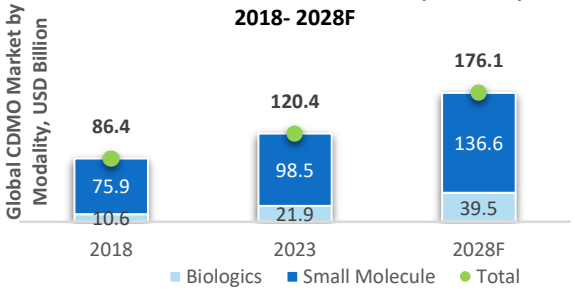


Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.1.2.1 GLOBAL CDMO MARKET BY MODALITY

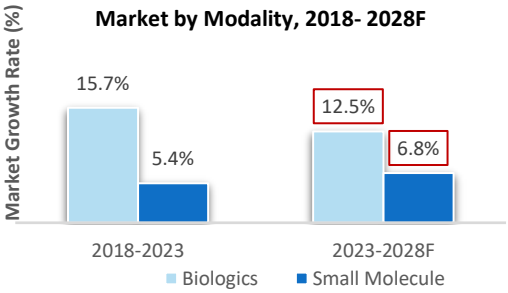
The CDMO market is primarily led by small molecules, which is estimated to grow at a CAGR of 6.8% from 2023 to 2028, reaching USD 136.6 billion by 2028. While biologics (large molecules) accounted for only 12.2% of the CDMO market in 2018, they experienced a faster growth rate of 15.7% to reach USD 21.9 billion in 2023. By 2028, biologics (large molecules) is projected to represent 22.4% of the CDMO market. The biologics (large molecules) CDMO market is experiencing higher growth due to an increased number of approvals for biologics (large molecules) drugs, a growing demand for innovative treatments, and significant financial investments by pharma companies, particularly in oncology.

Exhibit 4.7A: Global CDMO Market by Modality, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.7B: Growth Rate of Global CDMO Market by Modality, 2018- 2028F



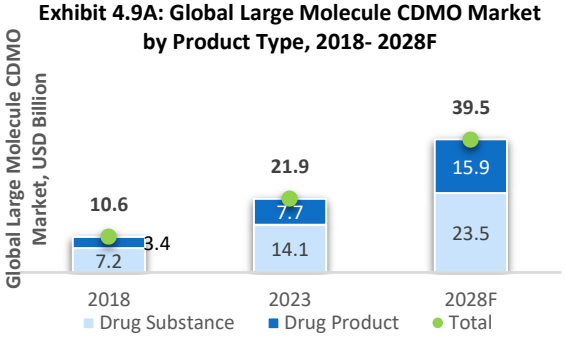
Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.1.2.2 GLOBAL CDMO MARKET BY PRODUCT TYPE

Due to significant economic advantages, the outsourcing of Active Pharma Ingredients (API)[31] manufacturing has led to a substantial dependence on CDMOs, with many APIs being produced in countries such as China, India, and Italy. Notably, China is the world's largest supplier of raw materials for the CDMO market and caters to about 30 to 35% of the global raw material/key starting material (KSM) demand as of 2023. Due to the increasing complexity and potency of APIs, there is an anticipated rise in outsourcing for their production. It is expected that API and intermediates will continue to be the dominant force in the small molecule CDMO market from 2023 to 2028. The revenue for API in the small molecule CDMO market in 2023 was USD 72.9 billion and is projected to reach USD 101 billion by 2028, with a growth rate of 6.7% between 2023 and 2028 while the finished dosage formulation (FDF)[32], referred to as the actual finalized drug product that is meant for consumption, is expected to grow at a CAGR of 6.9% during the forecast period and reach USD 35.7 billion by 2028.

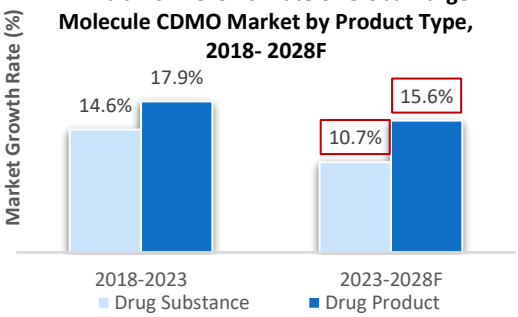
Like small molecules, large-molecule drug substances[33] play a significant role in the CDMO market. The market for large-molecule drug substances is projected to reach USD 23.5 billion by 2028, at a CAGR of 10.7% between 2023 and 2028. In comparison, the market for drug products[34] is expected to grow at a faster rate of 15.6% over the same period, reaching USD 15.9 billion in 2028.

Exhibit 4.9A: Global Large Molecule CDMO Market by Product Type, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.9B: Growth rate of Global Large Molecule CDMO Market by Product Type, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.1.2.3 GLOBAL API CDMO MARKET BY INNOVATION TYPE

The outsourcing of generic manufacturing has historically been a significant part of API CDMO outsourcing, as it involves replicating existing manufacturing processes once patents expire, which is relatively straightforward. In

[31] API is the biologically active component of a drug product (tablet, capsule, cream, injectable) that produces the intended effects.

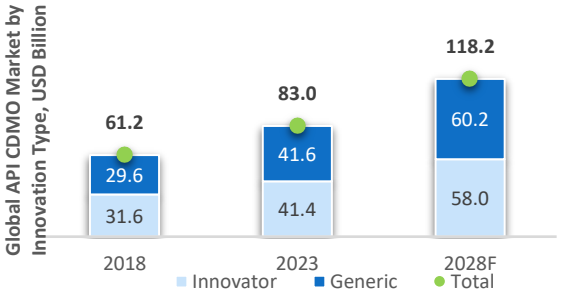
[32] FDF describes the consumable, finalized drug product - tablets, pills, liquid solutions, and other forms of FDFs all come under this category.

[33] The main ingredient in a medicine that causes the desired effect of the medicine.

[34] Refers to the finished drug.

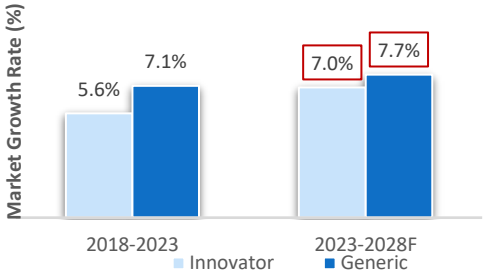
recent years, there has been a noticeable shift towards outsourcing the production of innovative drugs as well. This change is driven by factors such as the increasing complexity of innovative drugs, the necessity of using advanced machinery, technologies, and know-how for their manufacturing, and the importance of resource optimization for small and mid-sized businesses that are driving innovation. The innovator drug API and drug substance CDMO industry experienced a 5.6% growth from 2018 to 2023 and is expected to grow at 7.0% CAGR from 2023 to 2028 while during the same forecast period, generics is expected to grow at 7.7% CAGR to reach USD 60.2 billion in 2028.

Exhibit 4.10A: Global API CDMO Market by Innovation Type, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: Excludes FDF; F- Forecast

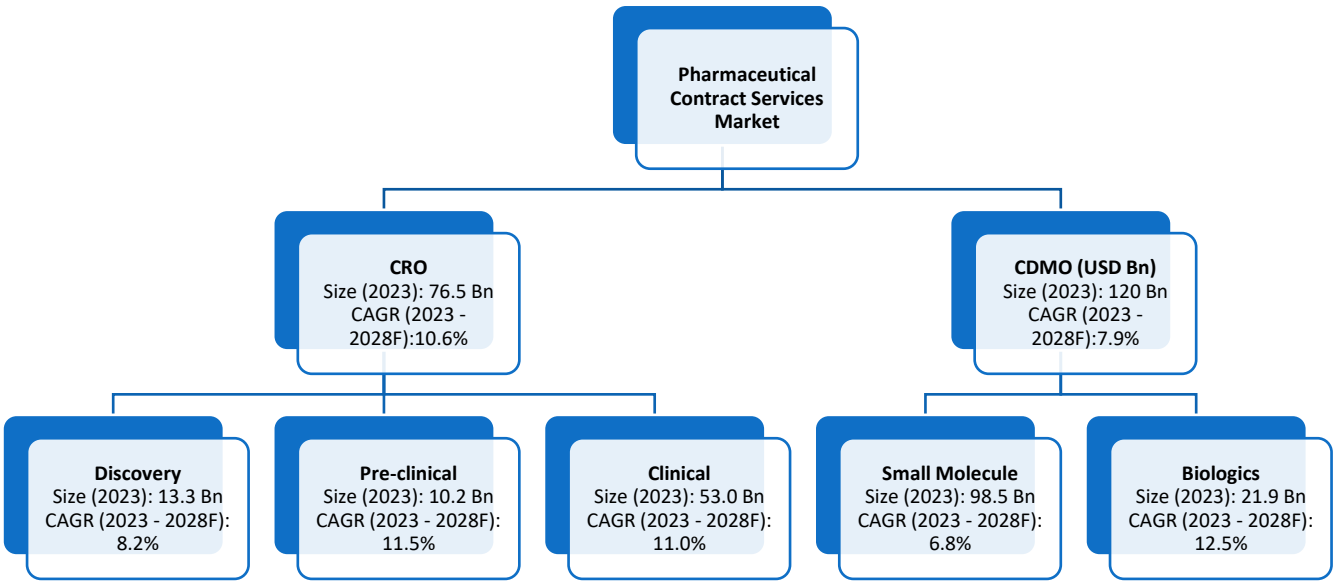
Exhibit 4.10B: Growth rate of Global API CDMO Market by Innovation Type, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: Excludes FDF; F- Forecast

4.2 SUMMARIZING THE GLOBAL PHARMA CONTRACT SERVICES MARKET

Exhibit 4.11: Global Pharmaceutical Contract Services Segmentation



Source: Evaluate Pharma, Frost & Sullivan

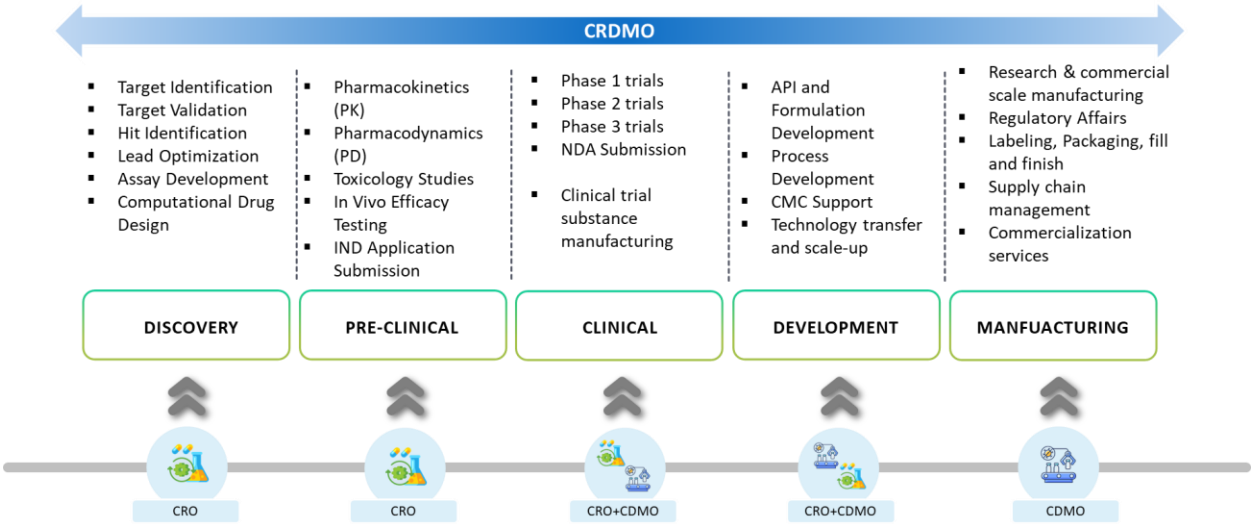
4.3 THE SHIFT TO INTEGRATED CRDMO MODEL

Traditionally, pharmaceutical companies have relied on CROs for early-stage drug discovery and CDMOs for drug development and production, with some overlapping services such as API and formulation development. However, there is now a clear trend towards collaborating with integrated CRDMOs that offer a comprehensive suite of services covering the entire pharmaceutical value chain. This shift towards integrated CRDMO is notable among small pharmaceutical innovators and biotech firms with limited resources and lean organizational structures. Collaborating with a CRDMO in an integrated manner offers numerous advantages, including a seamless transition from laboratory to market, access to integrated services, enhanced collaboration, cost savings, improved success rates, and expedited time-to-market for pharmaceutical products.

Additionally, working with CRDMOs eliminates the need and associated risks of transferring molecules between multiple service providers, leading to increased efficiency and reduced complexities. As a result, companies work with the same partner throughout the entire drug lifecycle. CRDMOs also benefit from competitive differentiation, diversified revenue streams, operational efficiency, long-term partnerships, and opportunities for innovation and expertise. It also provides CRDMOs multiple entry points for client engagement, leading to higher customer win rates, increased share of wallet, and enhanced customer retention. Under an integrated approach, CRDMOs are incentivized to engage in new drug development programs with existing or new customers and to extend their involvement in these programs from inception to commercialization.

By embracing the integrated CRDMO model, pharmaceutical companies and CRDMOs stand to gain a competitive edge in the drug development and manufacturing landscape.

Exhibit 4.12: CRDMO Industry Operating Model



Source: Frost & Sullivan

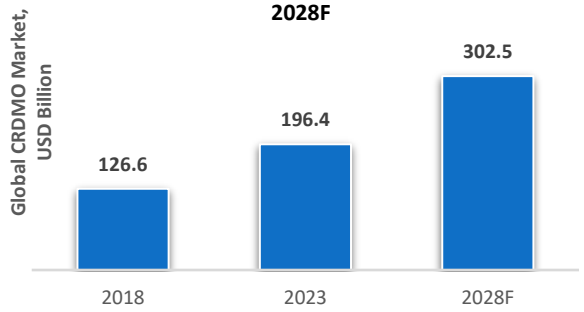
Note: PK[35], PD[36], In Vivo Efficacy[37]

[35] PK is a term that describes the four stages of absorption, distribution, metabolism, and excretion of drugs.
[36] PD refers to the effects of drugs in the body and the mechanism of their action.
[37] Drugs tested is done with or within an entire, living organism.

4.3.1 Global CRDMO Industry

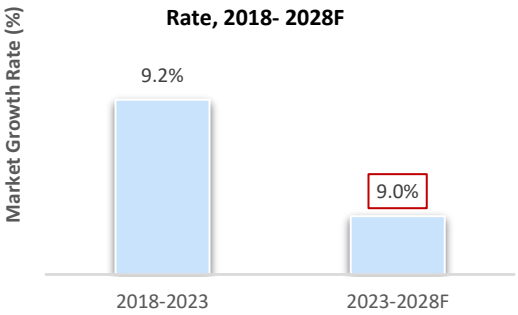
In 2023, the global CRDMO industry was assessed at an estimated value of USD 196.4 billion. The industry is anticipated to expand at a CAGR of 9.0% over the forecast period between 2023 and 2028, to reach USD 302.5 billion by 2028.

Exhibit 4.13A: Global CRDMO Market, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

Exhibit 4.13B: Global CRDMO Market Gowth Rate, 2018- 2028F



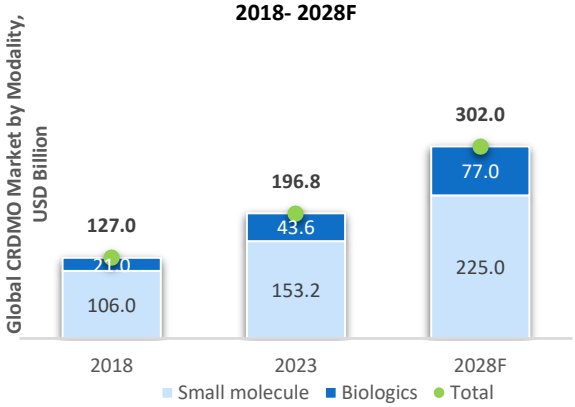
Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.3.2 Global CRDMO Industry by Modality

The global large molecule CRDMO industry size was estimated at USD 43.6 billion in 2023 and is expected to expand at a CAGR of 12.2% from 2023 to 2028. The global large molecule CRDMO industry is expected to reach USD 77.0 billion by 2028, comprising 25.6% of the overall CRDMO industry globally. Key drivers for this growth are increasing pharmaceutical and biotech R&D outsourcing, continued demand for biologics (large molecules), and growing demand for precision and targeted drugs.

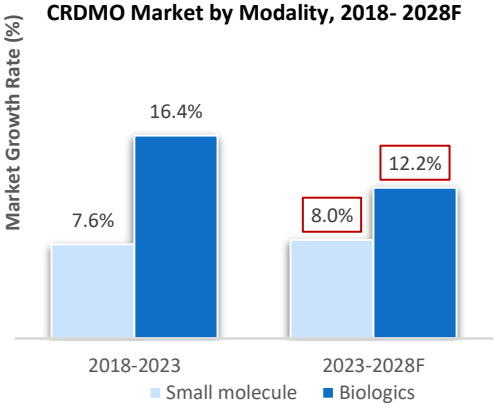
The small molecule CRDMO industry continues to be the mainstay of the overall CRDMO industry, comprising 77.8% of the overall CRDMO market in 2023, and is expected to grow at a CAGR of 8.0% over 2023 to 2028.

Exhibit 4.14A: Global CRDMO Market by Modality, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.14B: Growth Rate of Global CRDMO Market by Modality, 2018- 2028F



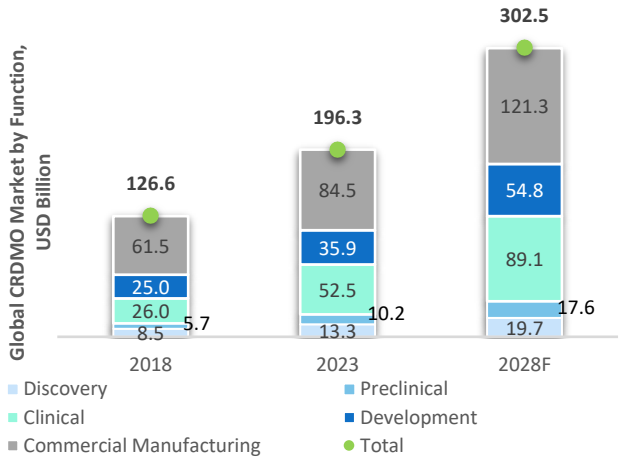
Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.3.3 Global CRDMO Industry by Function

The CRDMO industry offers discovery, preclinical, development, and commercial manufacturing services. In 2023, development and commercial manufacturing captured about 61.3% of the global CRDMO market. Between 2023 and 2028, both discovery and commercial manufacturing are expected to grow at a faster rate compared to the period between 2018 and 2023. It is estimated that development will grow at a CAGR of 8.8% between 2023 and

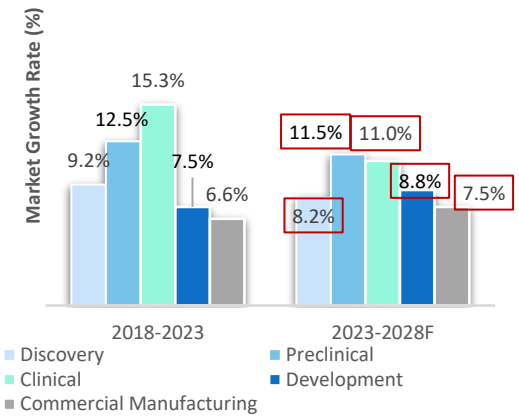
2028, reaching USD 54.8 billion, while manufacturing is projected to grow at 7.5% during the same period, reaching USD 121.3 billion.

Exhibit 4.15A: Global CRDMO Market by Function, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.15B: Growth rate of Global CRDMO Market by Function, 2018- 2028F



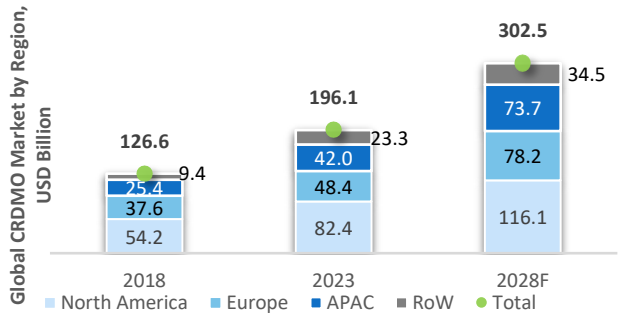
Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.3.4 Global CRDMO Industry by Region

North America is the key market for CRDMOs. Being the largest pharmaceutical consumer market as well as the global innovation hub, many large global CROs and CDMOs have established bases in North America to serve local needs. North America will continue to account for the largest share of the global industry for CRDMOs due to strong R&D infrastructure, booming pharmaceutical industry, and conducive regulatory regime.

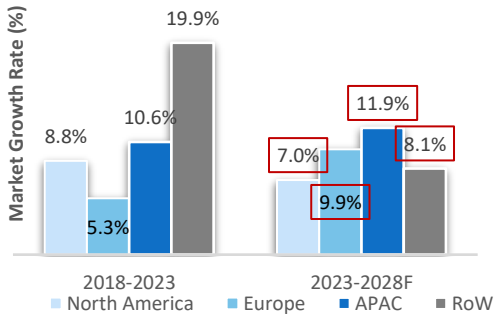
The APAC region is the fastest-growing region for CRDMOs. The region is expected to grow at a faster rate of 11.9% during 2023-28 driven by cost-effective manufacturing capabilities, availability of skilled manpower, and regulatory compliance capabilities. The key APAC countries serving the CRDMO market include China, India, South Korea, and Singapore, driven by strong technical know-how, trained manpower, and affordable prices.

Exhibit 4.16A: Global CRDMO Market by Region, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.16B: Growth rate of Global CRDMO Market by Region, 2018- 2028F

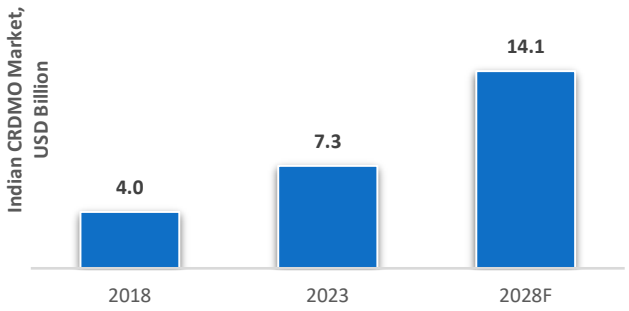


Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.4 INDIAN CRDMO INDUSTRY

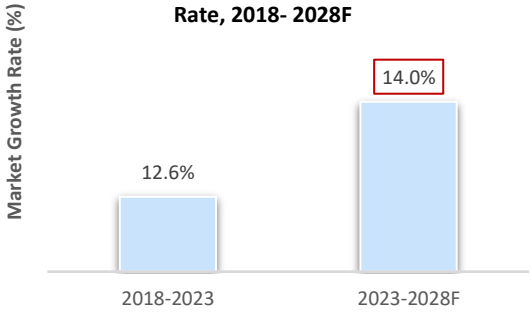
The Indian CRDMO industry is one of the fastest-growing globally, having grown at a CAGR of 12.6% between 2018 and 2023. India is an emerging hub for pharma innovators and is gaining significant prominence due to multiple growth tailwinds in the APAC region. The Indian CRDMO is poised to grow at 14.0% CAGR between 2023 and 2028to reach an estimated value of USD 14.1 billion in 2028 outpacing the global industry rate of 9.0% (2023 to 2028) and other markets such as the PRC due to the implementation of the US BIOSECURE Act, which makes India a front runner in the CRDMO outsourcing business. With multiple structural tailwinds in place and supported by the strong credentials of Indian CRO and CDMO players, India will likely garner a higher share of the global pharma outsourcing industry.

Exhibit 4.17A: Indian CRDMO Market, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

Exhibit 4.17B: Indian CRDMO Market Gowth Rate, 2018- 2028F

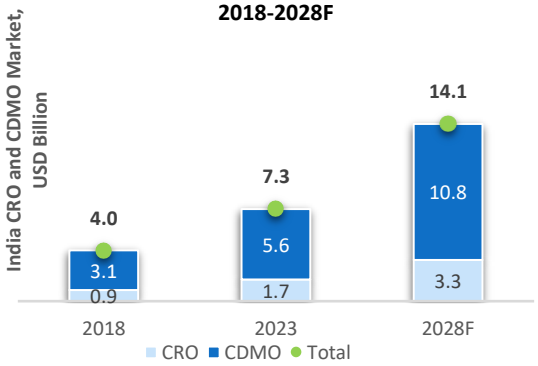


Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.4.1 INDIAN CRO AND CDMO MARKET FORECAST

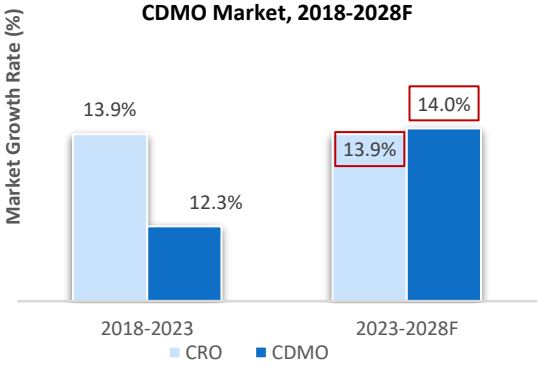
The Indian CRO market grew 13.9% from USD 0.9 billion in 2018 to USD 1.7 billion in 2023, while the CDMO market grew at a CAGR of 12.3% to USD 5.6 billion in 2023. The Indian CRO market is forecasted to reach USD 3.3 billion in 2028, while the CDMO is estimated to be USD 10.8 billion during the same period.

Exhibit 4.18A: India CRO and CDMO Market, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.18B: Growth rate of India CRO and CDMO Market, 2018-2028F

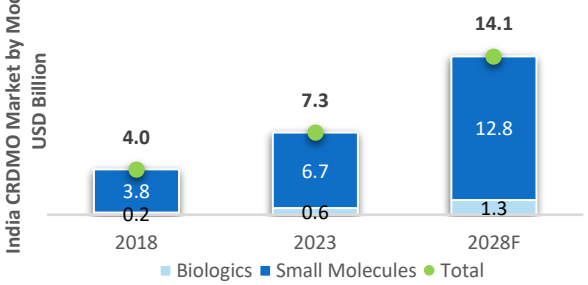


Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.4.2 INDIAN CRDMO INDUSTRY BY MODALITY

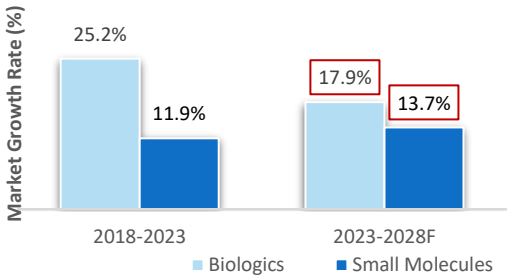
Indian CRDMO industry has largely been dominated by small molecules with their proportion constituting more than 90% of the total industry in 2023. However, the salience of biologics (large molecules) in Indian CRDMOs is expected to continue to improve given higher growth rates relative to small molecules. The biologics (large molecules) segment in India grew rapidly between 2018 and 2023 at a CAGR of 25.2% to reach USD 0.6 billion in 2023 and is estimated to grow at 17.9% CAGR from 2023 to 2028.

Exhibit 4.19A: India CRDMO Market by Modality, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.19B: Growth Rate of India CRDMO Market by Modality, 2018- 2028F

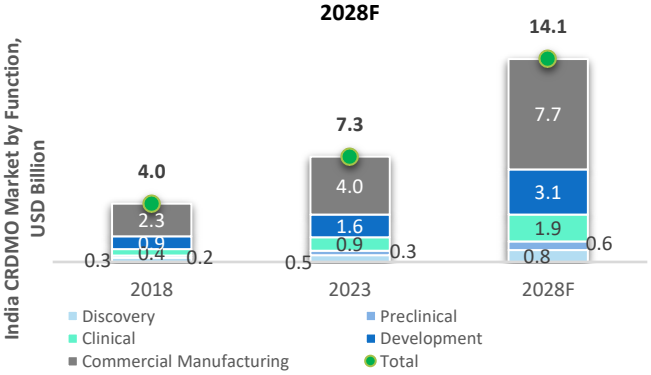


Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

4.4.3 Indian CRDMO Industry by Function

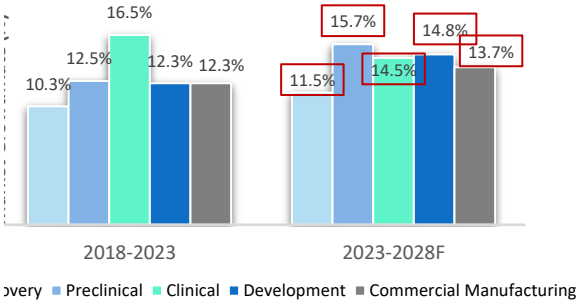
In the value chain functions, development and commercial manufacturing contribute to 76.6% of the Indian CRDMO market in 2023 and are expected to grow at 14.8% and 13.7% between 2023 and 2028F, respectively. The growth can be attributed to significant improvements in the technical capabilities of Indian companies, which attract manufacturing outsourcing demand from global pharma companies. Indian companies are also growing their integrated offerings with an increased focus on various therapeutic segments, including biologics (large molecules).

Exhibit 4.20A: India CRDMO Market by Function, 2018- 2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F- Forecast

Exhibit 4.20B: Growth rate of India CRDMO Market by Function, 2018- 2028F



ce: Evaluate Pharma, Frost & Sullivan
: F- Forecast

4.4.4 Growth Drivers for Indian CRDMOs

India is fast emerging as the preferred destination for pharma outsourcing; from cost efficiency to quality assurance, Indian CRDMOs are increasingly becoming the preferred partners for Indian and global pharma sponsors.

India-based CRDMOs have traditionally been recognized for their cost advantage. However, in recent years, they have made significant investments in advanced technologies and built a broad suite of technical capabilities across various services. Today, Indian CRDMOs are best positioned to take up complex chemistries for global pharma and are now being benchmarked against leading global firms. Some of the key factors contributing to the growth of Indian CRDMOs include:

Exhibit 4.21: Growth Enablers for Indian CRDMOs

Source: Frost & Sullivan

Demographic Advantage:

- **Young working-age population to support research and manufacturing activities:** India is a relatively young country with 65% of the population below 35 years of age as of 2022[38]. According to the World Bank, India's working-age population is also rising from 65% in 2012 to 68% in 2022[39].
- **Skilled English-speaking workforce capable of delivering high-tech global needs:** India produces an average of 24,000 post-doctoral graduates annually and has a strong base of STEM graduates, crucial for science-intensive drug discovery work. India has a bigger pool of STEM graduates than the US and UK.
- **Large disease burdened population and patient pool to participate in clinical trials:** With 1.4 billion of population (as of 2023), India offers a significant patient pool for clinical trials. As one of the leading nations for lifestyle diseases, including Diabetes (77 million cases in 2019) and Hypertension (230 million+ cases in 2019), as well as chronic conditions such as Cancer (23 million new cases in 2019), India offers a diverse treatment patient group which has not received any treatment for a particular condition and with a wide-ranging gene pool.

Infrastructure Advantage:

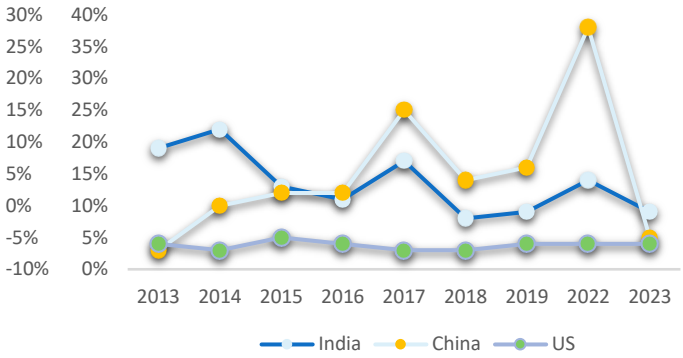
- **Strong Development and Manufacturing base:** The Indian facilities have a lower percentage of OAI (Official Action Indicated) flags compared to China. Indian companies also have deep experience working with the FDA and the European Medicines Agency (EMA) and are fully equipped to work at scale and in line with global standards. Notably, India is the world's largest provider of generic drugs with ~60% share of global vaccine supply (as of 2023)[40]. India has the second-highest number of cataloged sites as per the FDA, next to the US, and saw an increase of 16% between 2019 and 2023.

[38] World Population Prospects, United Nations Department of Economic and Social Affairs,
[39] World Bank Database
[40] Invest India

Exhibit 4.22A: US FDA reviewed sites

Source: FDA, Frost & Sullivan

Exhibit 4.22B: FDAs percentage OAI classification



Source: FDA, Frost & Sullivan
Note: 2020 and 2021 not considered due to Covid-19 pandemic

Favorable Policy Advantage:

- **Government's FDI Policy:** Supportive FDI policies have particularly benefited the pharma sector, which was ranked 8th for FDI in 2024. Under the automatic approval route, up to 100% FDI is allowed in greenfield projects and up to 74% FDI is allowed in brownfield projects.
- **Robust IP Protection laws have boosted confidence in outsourcing novel drug development and manufacturing**: With India's transition to embrace complete product patents, patent infringement concerns have been alleviated. Supportive IP laws position India as a compelling hub for pharmaceutical innovation and growth. India ranked sixth globally for patents applications[41].
- **Financial incentives for pharma manufacturing and R&D:** The pharmaceutical sector benefits significantly from the Government's fiscal and policy support. There is a 100% tax deduction on R&D expenditure and policy initiatives such as Biotechnology Industry Research Assistance Council (BIRAC), Bio-NEST, and Biotech Science Clusters fortify pharmaceutical R&D and support biotech startups. Besides, the Production-Linked Incentive (PLI) scheme and the establishment of bulk drug parks have created a supportive environment for pharma manufacturing and exports in India. The PLI scheme, with an allocation of USD 2.0 billion in 2023, incentivizes domestic manufacturing of key pharmaceutical products, while bulk drug parks reduce operational costs by providing infrastructure for API production.[42] These policies are accelerating the growth of Indian CRDMOs by attracting foreign investments and enabling cost competitiveness in manufacturing.
- **Policy changes to make processes efficient and transparent:** Revamped R&D regulations, which are now aligned with global standards, have improved process transparency. Key reforms include the 2019 New Drugs and Clinical Trial Rules, the 2017 National Ethical Guidelines for Human Research, and the SUGAM online submission portal. Streamlined clinical trial applications, shorter approval times, and higher participant compensation for adverse events are the building blocks for a predictable and efficient clinical trial environment in India.

Cost Advantage:

India continues to offer significant cost advantages in both labor and operational expenses compared to Western markets as drug development and manufacturing costs in India are approximately 30-40% lower than in the US or Europe.[43], making it an attractive outsourcing destination for pharmaceutical companies seeking to reduce R&D and production costs without compromising quality.

[41] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2073890
[42] Invest India, PIB (Ministry of Chemicals and Fertilizers), IBEF
[43] Invest India

Transition of Growth from China to other emerging markets, particularly India

China's advantages in the CDMO market are now diminishing, which has initiated a shift of growth away from China to other developing geographies such as India. Biopharmaceutical corporations are minimizing their supply chain vulnerabilities by expanding geographically, and India is becoming an attractive choice for outsourcing. The shift in pharmaceutical manufacturing from China to other destinations is a significant trend influenced by various factors such as:

1. **Trade Wars and Tariffs:** Increasing trade conflicts, particularly between the US and China, have increased emphasis on the 'China +1'[44] strategy. which aims to explore alternative manufacturing locations in countries like India to strengthen their resilience against geographical concentration risk. For instance, the US-China trade war saw tariffs on pharmaceutical raw materials, prompting multinational corporations to seek alternative suppliers. India, with its well-established pharmaceutical base, is a key beneficiary of this strategy.
2. **Supply chain Diversification:** Companies are seeking to reduce dependence on any single country to mitigate risks associated with geopolitical uncertainties. The pandemic highlighted vulnerabilities in global supply chains, including over-reliance on China, and companies are now looking to diversify their manufacturing locations to other geographies, such as India, to enhance resilience.
3. **Regulatory and Compliance Issues in China:** The Chinese government has taken steps in recent years to crackdown on industrial pollution which has impacted pharmaceutical manufacturing sites as well.[45] There have been also concerns about the quality and regulatory compliance of products manufactured in China, leading to increased scrutiny and a push towards alternative manufacturing sites such as India.
4. **Cost Considerations:** The increase in labor costs has diminished China's cost advantages, and India has benefitted significantly from this trend. Between 2010 and 2020, China's labor costs increased by 120%, while that of India's grew only by 80%. This cost differential incentivized companies to partner with Indian CRDMOs.
5. **Impact of the BIOSECURE Act:** The proposed US BIOSECURE Act (pending Senate approval), which seeks to block US-based companies from using biotechnology equipment or services from select Chinese firms, potentially reduces demand for Chinese CDMO services (particularly the demand generated by the largest pharma market in the world - US). This legislative shift is prompting global pharmaceutical companies to seek alternative markets for contract services if the purview of the BIOSECURE Act expands to other Chinese firms as well. Pharma companies are already seeking partners in destinations that offer similar cost and competency advantages, and India is emerging as the preferred choice. Leading CRDMO companies such as Anthem Biosciences, Syngene, Suven Pharma, and Aragen are likely to benefit from the impending shift.

4.4.5 Key Success Factors for Indian CRDMOs, CROs, and CDMOs

To grow to even larger scales and compete with global CRDMOs, Indian CRDMOs will have to focus on quality, offer scalability-flexibility-competency, and be able to serve across larger parts of the pharma value chain.

Pharma companies seek reliability, specialization, and quality of services to select the right partner in this highly fragmented market with more than 1,000 CROs and CDMOs as of September 30, 2024. To stand out and win global market share, Indian CRDMOs need to emerge as true, long-term partners for pharmaceutical sponsors.

[44] Avoiding reliance only on China and diversifying the supply chain.
[45] FiercePharma

Exhibit 4.23: Key Success Factors for Indian CRDMOs

Source: Frost & Sullivan

Full-Service Offerings: While sponsors highly value expertise and specialization across various therapy areas, drug development stages, and geographic regions, the convenience of working with a single vendor will always be preferred as it helps to streamline processes, shorten time to market, reduce project management complexities, optimize cost and technology transfer, and invest in building future capabilities with their partners.

CRDMOs, thus need to offer comprehensive end-to-end services spanning non-clinical to clinical to post-marketing activities, including regulatory affairs, medical communication and writing, pharmacovigilance, post-approval services, Health Economic Outcomes Research (HEOR), and small to large-scale manufacturing.

Investments For Continuous Improvement: CRDMOs must strive to enhance and expand their capabilities, infrastructure, and suite of expertise on a constant basis. Investments are necessary to build scale for serving multiple sponsors simultaneously.

CRDMOs must also embrace manufacturing technology upgrades and transition to green and sustainable manufacturing practices to enhance profitability for partners and to comply with environmental regulations. Together, these factors drive a preference for partnerships with sponsors.

Strong Delivery Track Record: A proven track record of successfully commercializing pharmaceutical products is crucial for building trust securing long-term partnerships and expanding the client base. Since efficiency and cost-effectiveness are primary drivers for outsourcing clinical research & development, CRDMOs must adhere to pharma sponsors' budgets while ensuring timely delivery. Implementation of an effective risk mitigation framework by leveraging technology to protect delivery timelines and budgetary slippages is critical for success.

Indian CRDMOs have an increasingly strengthening record of successful projects. For example, Anthem Biosciences has a history of commercializing 10 molecules, of which top 5 commercialized molecules have an end-market value of USD 9.0 billion in 2023 and expected capture USD 20.0 billion by 2028. This helps the company build a pipeline of 196 ongoing projects with 100+ projects in early-phase development and 10+ projects in late-phase development of the NCE/NBE lifecycle for the six months ended September 30, 2024.

Full Suite of Operational Capabilities

- **Broad range of Therapeutic expertise:** CRDMOs need to build multi-specialty expertise to cater to a diverse set of pharma sponsors. Each product is unique and requires varied forms of knowledge and

experience. As experts, CRDMOs offer insights relevant to the therapeutic area and accelerate the clinical development of the product.

- **R&D expertise to drive innovation and adopt new technologies:** Robust R&D capabilities within a CRDMO are indispensable. These capabilities empower the development of proprietary platforms, novel formulations, and improvements to existing drugs, resulting in a positive impact on drug development and the manufacturing process. CRDMO's R&D function should be digitized and equipped with robust IT infrastructure for lab data management and analytics.
- **Ability to offer scale flexibility, diverse drug types, delivery models, and dosage forms:** CRDMOs must be agile in responding to different volume needs and be proficient in handling multiple drug modalities, including complex active ingredients, formulations, routes of delivery, and dosage forms.
- **Technological sophistication.** Advanced technologies such as custom synthesis, flow chemistry, fermentation, and biotransformation allow CRDMOs to improve efficiency, reduce waste, and enhance scalability in pharmaceutical manufacturing. Furthermore, CRDMOs that specialize in biologics (large molecules) are leveraging advanced techniques like recombinant DNA technology, fermentation, and metal-mediated chemistry to develop complex molecules. CRDMOs that can integrate a slew of sophisticated technologies can offer faster development and higher quality, making them indispensable partners for pharmaceutical companies.
- **Regulatory Expertise:** Deep familiarity with global regulatory frameworks is critical for streamlining product approvals. Indian CRDMOs, such as Anthem Biosciences, have built deep regulatory expertise, by working closely with the most stringent regulatory agencies such as the US FDA, EMA, and Japan's PMDA. The ability to navigate complex regulatory environments ensures that the final product is not only compliant but also clears the approval process swiftly, reducing time to market.

Global Delivery Model

CRDMOs can leverage the global delivery model with offshore operations and onshore sales presence through captive offices (owned) or through partnership models, like Anthem Biosciences' partnership with Davos Pharma. Having an international presence provides added advantages such as access to local insights and market knowledge, which assists in acquiring new clients and scaling up CRDMO operations.

4.4.6 Challenges and Risks for CRDMOs

CRDMOs are required to adapt to this changing environment through investments in newer technologies, and better infrastructure. They also need to tackle the complex and ever-changing regulatory environment to remain compliant and competitive. The following are some of the key challenges and risks for the CRDMOs:

Excess Production Capacity and Associated Costs: Excess production capacity can lead to CRDMO facilities not operating at optimal levels. This underutilization of resources can result in increased fixed costs per unit of production, driving up the overall cost structure.

Need of Experienced and Skilled Workforce: Limited availability of experienced and skilled talent pool can impact the quality and timeliness of services provided, potentially leading to delays in drug development and manufacturing. This challenge is further exacerbated by the increasing demand for specialized expertise in emerging areas. To address the challenge of shortage of experienced and skilled workforce, CRDMOs must focus on attracting and retaining top talent, investing in training and development programs, and creating a positive work culture that fosters innovation and collaboration.

Regulatory Compliance Risks: The increasing decentralization of the supply chain poses additional challenges for CRDMOs. One of the key regulatory standards for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (CGMP)[46] regulations, as well as global practice standards such as the International

[46] Current Good Manufacturing Practices, a quality system enforced by relevant regulatory authorities, such as the USFDA, to ensure that the products produced meet specific requirements for identity, strength, quality and purity

Organization for Standardization, European Union Good Manufacturing Practice, the World Health Organization Good Manufacturing Practice, and the standards prescribed by the United States National Sanitation Foundation. These provides for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to these regulations is also critical for receiving approvals from USFDA, PMDA Japan, and other such regulatory bodies. Moreover, regulations keep changing and are increasingly becoming increasingly stringent, the compliance with which poses challenges to CRDMOs. In addition, sustainable manufacturing, which was largely good-to-have earlier, has now become imperative for CDRMOs. It is thus crucial for CRDMOs to stay updated on current compliance standards and ESG policies while maintaining their commitments to their partnerships. In order to ensure that CRDMOs are prepared to pass regulatory audits, pharmaceutical companies routinely conduct strict GMP, Safety and Sustainability audits or inspections, either directly or receive access to audits conducted by the Pharmaceutical Supply Chain initiative (The Pharmaceutical Supply Chain Initiative (PSCI) is a group of pharmaceutical and healthcare companies who share a vision of excellence in safety, environmental, and social outcomes) or Ecovadis (EcoVadis is one of the world's largest and most trusted provider of business sustainability rating), of their current and prospective CRDMO partners. The ability to face and pass such customer audits is a critical risk for CRDMOs.

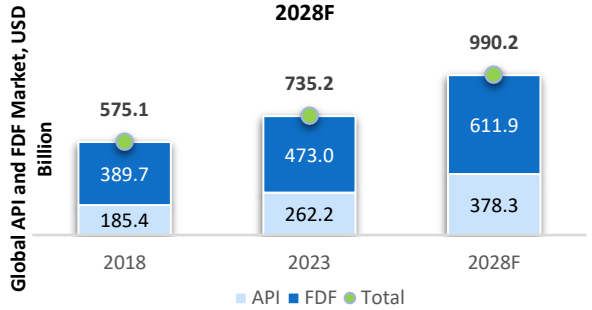
5 GLOBAL API AND SPECIALTY INGREDIENTS MARKET OVERVIEW

5.1 GLOBAL API MARKET

Active Pharmaceutical Ingredient (API) is any substance or combination of substances used in a finished pharmaceutical product (either small molecules or biologics (large molecules)), which is intended to furnish pharmacological activity or to otherwise have a direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

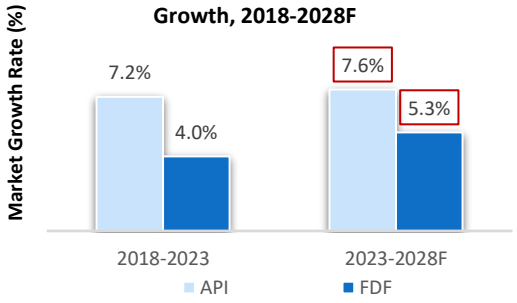
The effectiveness and safety of a drug are closely linked to its precise API. As pharmaceutical demand rises, so does the need for APIs. The global API market was valued at USD 262.2 billion in 2023 and is projected to reach USD 378.3 billion by 2028, driven by increased drug consumption, including biologics (large molecules) and small molecules.

Exhibit 5.1A: Global API and FDF Market, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan

Exhibit 5.1B: Global API and FDF Market Growth, 2018-2028F



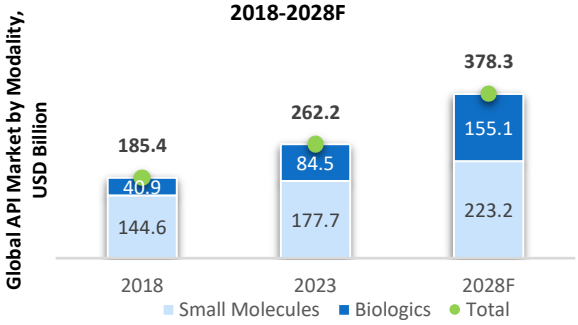
Source: Evaluate Pharma, Frost & Sullivan

The pharma industry is seeing a rise in demand for complex APIs like Highly Potent Active Pharmaceutical Ingredients (HPAPIs) and those derived from fermentation processes. These APIs offer enhanced drug efficacy but have higher production costs and technical complexity. Fermentation-derived APIs, produced through microbial or cell line fermentation, are integral to a wide range of pharmaceutical products. Fermentation technology provides economic advantages and a faster route to market, especially for protein, peptide, and antibody drugs.

5.1.1 GLOBAL API MARKET BY MODALITY

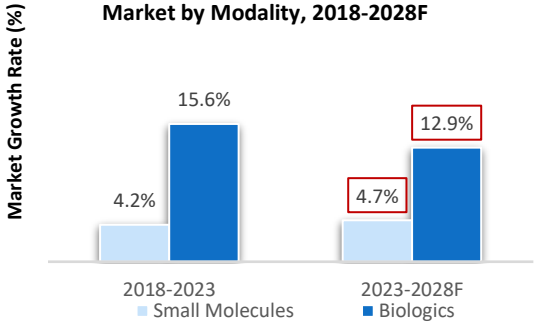
The small molecule API dominates the overall API market value representing 67.9% in 2023. However, the share of biologics (large molecules) demand for API is seeing a steady increase from 22.2% in 2018 to 32.4% in 2023, and by 2028 it is expected to capture 41.0% of the market. This increase can be attributed to the growing demand for biologics (large molecules) drugs that are more targeted.

Exhibit 5.2A: Global API Market by Modality, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

Exhibit 5.2B: Growth rate of Global API Market by Modality, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan
Note: F - Forecast

5.1.2 Global API Market for Select Molecules

5.1.2.1 Select Specialty Ingredients

Specialty APIs are innovative ingredients with unique properties and a sub-set of APIs. Specialty ingredients such as fermentation-based APIs, probiotics, and enzymes have high barriers to entry as they are difficult to manufacture and require specialized technical capabilities in development as well as manufacturing and often use green chemistry.

Exhibit 5.3: Select Specialty Ingredients Growth Drivers and Use Case

Specialty Ingredients	Growth Drivers	Use Case	Market Size, (2023); Projected CAGR (2023-2028F)
Biosimilars	The biosimilars market, which includes microbial and mammalian, is poised for high growth of 14.9% between 2023 and 2028F due to the patent expiry of several biologic drugs and the increasing demand for affordable biologics (large molecules) therapeutics. Approximately 200 biosimilars are currently under development (as of 2023) in India due to advantages such as lower time taken for biosimilar development which is estimated to be between 3 to 5 years in India, compared to 7 years in western countries, and the average cost of biosimilar development in India is estimated to be ten-times lower in certain cases.	Therapeutic categories include oncology, immunology, musculoskeletal, endocrine (anti-diabetes), ophthalmology, and hematology.	USD 25.0 billion, 14.9%
Fermentation Products	**Vitamin K2**: The rising prominence of Vitamin K2 offerings in blended form owing to their bone and cardiovascular health claims. **Serratiopeptidase[47]:** With an increase in chronic diseases, Serratiopeptidase demand is growing as an alternative to non-opioid pain relief and inflammation management drugs.	**Vitamin K2**: Dietary supplements, F&B such as adult and infant nutrition, and childcare products, cosmetics, pharma **Serratiopeptidase:** Pain management and inflammation drugs	USD 0.2 billion, 8.9%
Probiotics[48] & Enzymes	**Probiotics:** Rising awareness, regulatory support on new strains & product approvals **Enzymes:** Growing focus on sustainable production technologies	**Probiotics:** Functional F&B, dietary supplement, infant formula **Enzymes:** Pharma, home care, paper & pulp processing, textiles	USD 7.2 billion, 5.5%
Peptides	The increased prevalence of chronic diseases such as cancer, diabetes, and cardiovascular disorders drives the demand for peptides as they provide targeted treatment with minimal side effects. Significant opportunity with GLP-1 across diabetes and weight loss treatment (approximately 92.5% of peptides market in 2023)	Peptide drugs are used in a wide range of therapeutic areas, such as Gastro-intestinal and metabolic disorders.	USD 39.8 billion, 23.0%

[47] Serratiopeptidase is a proteolytic enzyme produced by the Serratia bacteria, commonly used for its anti-inflammatory, analgesic, and anti-edemic properties in the treatment of conditions involving inflammation and pain

[48] Live micro-organisms which when administered in adequate amounts confer a health benefit on the host

Protease[49]	Protease represents one of the three largest groups of industrial enzymes, accounting for approximately 44.8% of the worldwide sales of enzymes in 2023. The shift towards eco-friendly processes has increased the demand for enzymes such as protease in various industrial applications including pharma (used as therapeutic agents, an alternative to chemicals).	Pharma, leather, industrial waste management, brewing industry, food industry.	USD 2.1 billion, 5.4%
Nutritional Actives[50] and Vitamin Analogues[51]	The expanding geriatric population and the rising incidence of lifestyle diseases have urged consumers to become health conscious, resulting in the growing demand for nutritional active ingredients and vitamin analogs. Further, the increasing demand for supplements to meet specific health needs beyond immunity will positively influence the vitamin market.	Nutritional Actives use case: Dietary supplements, functional food, functional beverages. Vitamin Analogues use case: Dietary supplements, F&B, personal care, pharma grade vitamins, specialized nutrition such as infant formula and medical food.	USD 29.7 billion, 6.7%

Source: Frost & Sullivan

5.1.2.2 GLP-1

Glucagon-like peptide-1 (GLP-1) agonists are a class of medications utilized to treat type 2 diabetes mellitus (T2DM) and obesity and are recommended for mitigating cardiovascular risk. GLP-1 drugs also demonstrate the potential to decrease the progression of chronic kidney disease. GLP-1, originally approved in 2005 as an anti-diabetic class of drugs, found clinical use as anti-obesity drug in 2014, significantly amplifying the market potential. As the class of drugs continue be used for managing other disorders such as cardiovascular, liver, and kidney diseases, market for GLP-1 drugs is expected to reach USD 105.9 billion by 2028. The high demand of the drugs has even created shortage in the market as companies are not able to keep up demand.

As several of the innovator GLP-1 lose exclusivity, paving way for more cost effective biosimilars, the market is expected to soar further, particularly benefiting the very few contract manufacturers which have GLP-1 manufacturing capability.

Exhibit 5.4: Top GLP-1 Drugs and Patent Expiry

GLP-1 drug	Brand Name	Company	2023 Sales (USD billion)	2028F Sales (USD billion)	CAGR 2023-2028F	Patent Expiry
Semaglutide	Ozempic, Wegovy, Rybelsus	Novo Nordisk	21.0	61.0	23.7%	2026
Dulaglutide	Trulicity	Eli Lilly	7.0	3.0	-15.6%	2027
Tirzepatide	Mounjara, Zepbound	Eli Lilly	5.0	41	52.3%	2036
Liraglutide	Victoza, Saxenda, Xultophy	Novo Nordisk	3.0	1.0	-19.7%	2024
Linaclotide	Linzess	AbbVie	1.2	1	-4.6%	2026
Plecanatide	Trulance	Bausch Health	0.1	0.2	14.9%	2032

Source: Evaluate Pharma, Frost & Sullivan

The top 3 GLP-1 branded drugs in 2023 based on the revenue were Ozempic (USD 14.0 billion), Trulicity (USD .0 billion) and Mounjaro (USD 5 billion). In terms of molecules, semaglutide, which is sold under the brand names Ozempic, Wegovy, and Rybelsus, is the top-selling GLP-1 molecule, which was valued at USD 21 billion in 2023 and

[49] Protease is an enzyme that catalyzes the breakdown of proteins into smaller peptides or amino acids by cleaving the peptide bonds within proteins
[50] Bioactive compounds in foods or supplements that provide health benefits beyond basic nutrition, such as vitamins, minerals, antioxidants, probiotics, and phytochemicals, which support various bodily functions and overall well-being
[51] Vitamin analogues are compounds structurally similar to vitamins that can mimic or interfere with the biological activity of the original vitamin, often used in medical treatments, research, or as dietary supplements to address specific health conditions or deficiencies

is expected to grow at a CAGR of 23.7% between 2023 and 2028 to reach USD 61.0 billion by 2028. Tirzepatide, which is sold as Mounjaro and Zepbound is valued at USD 5.0 billion in 2023 and is expected to grow at a CAGR of 52.3% between 2023 and 2028 to reach USD 41.0 billion by 2028. Other molecules such as Dulaglutide (sold as Trulicity) and Liraglutide (sold as Saxenda, Victoza, Xultophy) which are valued at USD 7.0 billion and USD 3.0 billion in 2023, are seeing a declining growth.

In India, very few CRDMO companies such as Anthem Biosciences have GLP-1 manufacturing capabilities, which could enable them to capitalize on the upcoming GLP-1 opportunity following the expiry of the existing patents in 2026.

5.1.2.3 INSULIN ANALOGUES – A REVOLUTION IN DIABETES MANAGEMENT

In recent years, the advent of insulin analogs has markedly enhanced treatment options for individuals with diabetes. These modified forms of human insulin are engineered to optimize efficacy and patient convenience through alterations in the amino acid sequence or the incorporation of fatty acid chains. Insulin analogs are categorized into two primary types: rapid-acting and long-acting.

Rapid-acting insulin analogs, such as Lispro, Aspart, and Glulisine, have a quicker onset of action, making them ideal for managing blood glucose levels around mealtime. Conversely, long-acting analogs, including Glargine and Detemir, provide stable insulin baselines, essential for maintaining glycemic control between meals and overnight.

The overall market for insulin and insulin analog is projected to experience a negative growth rate of 0.1% from 2023 to 2028, with a market size estimated to reach USD 14.5 billion in 2028 from USD 14.6 billion in 2023[52].

5.1.3 MARKET GROWTH DRIVERS FOR INDIAN API COMPANIES

India is the third-largest producer of APIs, commanding a 6% share of the Global API Industry in 2023. With over 500 distinct APIs manufactured within its borders, India emerges as a pivotal contributor, supplying 57% of APIs listed on the prequalified World Health Organization (WHO) roster in 2023[53]. Factors such as increasing global demand, cost advantage, high-quality standards, government support, strong manufacturing infrastructure, R&D capabilities, and strategic partnerships/collaborations drive the Indian API market.

Exhibit 5.5: Growth Drivers for Indian API Companies

Source: Frost & Sullivan

[52] Source: Evaluate Pharma; Frost & Sullivan

[53] Invest India: Harnessing India's API Potential. WHO' prequalified API roster list contains sources of APIs that have been assessed by WHO and found to be acceptable, in principle, for use in finished pharmaceutical products procured by United Nations agencies.

6 COMPETITIVE LANDSCAPE

6.1 COMPETITIVE LANDSCAPE

The CRDMO market is marked by high fragmentation, with over 1,000 global CROs and CDMOs competing for market share as of September 30, 2024. This landscape encompasses a diverse range of players, including full-service CRDMOs, large to small unintegrated pure-play CROs and CDMOs, and in-house departments of pharmaceutical companies and academic institutions. Functioning as full-service CRDMOs with global capabilities presents a distinctive advantage, viz: barriers to entry such as technology capabilities, high capex required for setting up manufacturing and research infrastructure, and long-standing relationships with sponsor networks. While limited-service CROs and CDMOs may find ingress into niche service segments relatively attainable due to fewer barriers, the full-service CRDMO model offering a comprehensive, robust, and sophisticated infrastructure, catering to a wide spectrum of therapeutic areas and scientific disciplines poses significant entry barriers to new emerging competitors.

The need for integrated CRDMO services is thus high, driven both by big pharmaceutical companies with a large portfolio of products across multiple geographies and by small pharmaceutical and emerging biotech companies due to resource constraints, the need for clinical development, and regulatory support.

6.1.1 KEY CROS AND CDMOS IN THE MARKET

For the study, the global CRDMO/ CRO / CDMO landscape has been narrowed down to a short list of domestic and global peers for benchmarking against Anthem Biosciences' capabilities and business model. The companies that were benchmarked include five (5) Indian (Syngene International Limited, Sai Life Sciences Limited, Suven Pharma Limited, Divi's Laboratories Limited, Aragen Life Sciences Limited), three (3) Chinese (Wuxi AppTec Co. Ltd., Asymchem Laboratories (Tianjin) Co. Ltd., Pharmaron Beijing Co. Ltd), and five (5) other global (Lonza Group AG, Catalent Inc. Siegfried Holding AG, PolyPeptide Group AG, Bachem Holding AG) peers.

6.1.1.1 OPERATIONAL COMPARISON

Among the assessed peers, Anthem Biosciences is one of the few companies with integrated capabilities for small molecules and biologics (large molecules). It is one of the few companies in India, which focuses on new biologics (large molecules) platforms and offers the broadest range of technology capabilities for drug development relative to its peers. Moreover, Anthem is one of the few Indian CRDMOs with specialty ingredients offering which are sold in both regulated and semi-regulated markets[54], which enhances its manufacturing credentials with global customers. Anthem Biosciences is also one of the leading enzymes solutions providers in India catering to global markets. The company is among the first few players in India to utilize flow chemistry, biotransformation (such as bio-catalysis and enzymatic processes), micellar technology, and other innovative manufacturing techniques and the only company in India that has a strong presence across small molecules and biologics (large molecules). Anthem Biosciences is one of three CRDMOs that possess technological capabilities in India across ADCs, RNAi, peptides, and oligonucleotides, which are among the fastest growing in the pharmaceutical industry.

Anthem Biosciences is one of the first in India to venture into ADC development with the first Linker.[55] being worked in 2016, and the first payload[56] being worked in 2019, and one of the pioneers in India to introduce biotransformation as a manufacturing capability in 2014 and flow chemistry in 2019. Anthem started working on glycolipids[57] as an RNAi delivery platform as a modality in 2016 which represents a significant step forward in the field of gene expression amongst Indian CRDMOs, and the commercialized molecule has achieved more than USD 500 million in end-market global sales for the nine months ended September 30, 2024. In RNAi therapeutics,

[54] Regulated markets as defined by WHO as 'Stringent Regulatory Authority (SRA)' and include countries such as Australia, Canada, Japan, South Korea, the US, and SRA classified countries in Europe. All other countries are classified as emerging markets and include semi-regulated and unregulated markets. Semi-regulated markets have less-stringent regulations and offer low entry barriers in terms of regulatory requirements and intellectual property rights.

[55] Linker in ADCs provides a specific bridge between the monoclonal antibody and the cytotoxic drug, thus helping the antibody to selectively deliver and accurately release the cytotoxic drug at the tumor cells. In addition to conjugation, the Linker maintains ADC's stability during the preparation and storage stages of the ADCs and during the systemic circulation period.

[56] Payload is the highly active and toxic drug attached to the monoclonal antibody via the chemical Linker.

[57] An essential component of cell membranes, consisting of a lipid and a sugar group, which plays crucial roles in a variety of biological processes, including cell-cell recognition, signal transduction, and maintaining membrane stability

glycolipids have garnered attention for their potential to facilitate the delivery of RNA molecules, such as siRNA into cells, thus having significant potential for the treatment of a wide range of diseases.

Anthem Biosciences' bio-catalysis and biosynthesis capabilities provide differentiated solutions for custom synthesis and chemical manufacturing using enzymes and their advanced capabilities for high-potency compounds position them as one of the preferred knowledge partners for large pharma companies and emerging biotech companies.

Anthem Biosciences cater to small pharmaceutical and emerging biotech companies that are typically underserved segments in the market due to their unique needs and requirements for cost-effective and integrated solutions with a high potential for success in the drug discovery space. Anthem Biosciences' customers include both small pharmaceutical and emerging biotech companies and large pharmaceutical companies, of which some of its small pharmaceutical and emerging biotech customers were subsequently acquired by large pharmaceutical companies. Over the last 5 calendar years, six of Anthem's biotech customers were acquired by large pharmaceutical companies with an aggregate deal value of USD 28.5 billion. For one of these large pharmaceutical companies, Anthem has provided CDMO for three commercialized molecules which have blockbuster status and have achieved annual sales of over USD 1 billion.

Exhibit 6.1: Biologics (Large Molecules) Platforms Focus of Anthem Biosciences and its Peers

Company/ Technology Capabilities	Flow Chemistry	Enzymatic Processes	Bio-catalysis	Fermentation based manufacturing	ADC Development and Manufacturing	Peptide Development and Manufacturing	RNAi & Lipids Platform	Oligonucleotide Development and Manufacturing
Anthem Biosciences								
Indian Peers								
Competitor 1								
Competitor 2								
Competitor 3								
Competitor 4								
Competitor 5								
Global Peers								
Competitor 6								
Competitor 7								
Competitor 8								
Competitor 9								
Competitor 10								
Competitor 11								
Competitor 12								
Competitor 13								

Legend: Dark Green – Strong Presence; Light Green – Limited Presence; Orange – No Presence

Source: Company filings/ websites/ new articles/ presentations, Frost & Sullivan analysis
Note:
1. The information above is as of September 2024.
2. Presence refers to the utilization of the specified technologies.

Anthem Biosciences is an innovation-driven and technology-focused CRDMO with fully integrated operations spanning drug discovery, development, and manufacturing, and it is the only CRDMO in India with a strong capability in both small molecules and biologics (large molecules). It is one of the few Indian companies with integrated New Chemical Entity ("NCE") and New Biological Entity ("NBE") capabilities across all three segments of drug discovery, development, and commercial manufacturing, and is also among the pioneers in introducing biologic capabilities in India. R&D Services comprised 13.1% of their revenues, with Development and Manufacturing revenues contributing 72.7% and 63.2% for the 6M Fiscal 2025 and Fiscal 2024 respectively, which is amongst the highest of the assessed Indian peers. This provides a comparatively stable revenue base with high visibility for future growth as

developmental and commercial manufacturing generally relate to projects which are at a more advanced stage of their drug development lifecycle (as compared to discovery/research) and which require larger quantities produced.

In Anthem Biosciences' portfolio of commercialized molecules, the top five (in terms of revenue contribution in FY2024), manufactured for three large pharmaceutical companies (including after acquisitions or consolidations), had an end-market value of USD 9.0 billion in 2023. These molecules accounted for 1.1% of global drug sales and are projected to reach USD 20.0 billion in value and a 1.8% market share by 2028 growing at a CAGR of 17.4.[58]. Its CRDMO business caters to customers in regulated markets and semi-regulated markets, which are jurisdictions where products are subject to strict regulatory standards and are required to be manufactured in facilities that meet certain standards.

Exhibit 6.2: CRDMO Capability Mapping and Client Partnerships of Anthem Biosciences and its Indian Peers

Company	Discovery	Development & Manufacturing	Revenue share from Development and Manufacturing	Commercial Small Molecule Production	Biologics Biomanufacturing	Clients
Anthem Biosciences	●	●	> 60 %	●	●	500+
Competitor 1	●	◑	< 40%	●	●	450+
Competitor 2	●	●	< 65%	●	○	280+
Competitor 3	◔	●	> 60%	●	○	100+
Competitor 4	◔	●	> 60%	●	○	NA
Competitor 5	●	◔	< 35 %	◑	◔	400+

● Strong Presence ◑ Limited Presence ◔ Negligible Presence ○ No Presence

Source: Company filings/ websites/ new articles/ presentations, Frost & Sullivan analysis

Note:

1. The information above is as of September 2024.

2. Presence refers to the service capability pertaining to the company. The magnitude of presence is evaluated based on the disclosure of capabilities by the company in publicly available sources such as company website, annual report and investor presentations.

Among the assessed companies, very few global CRDMOs have sizeable fermentation capacities. Anthem Biosciences has the largest fermentation capacity among all assessed Indian CRDMOs, with 142 kL capacity as of September 30, 2024, and following completion of its expansion activities by first half of 2025, the capacity will increase to 182 KL and it is expected to be more than six times that of the second-largest assessed player. Anthem Biosciences is the only Indian company that has nearly 90% of energy sourced from renewable energy as of September 2024, which is the highest in the industry, and it has the lowest GHG emission intensity (scope 1+scope 2) and GHG emission/total revenue in USD compared to its assessed Indian CRDMO peers as of Fiscal 2024 based on company reports. The company has also focused on adopting sustainable manufacturing practices and is one of the first to utilize green chemistry techniques such as biotransformation, micellar technology, pincer catalysis, and other innovative manufacturing techniques, including flow chemistry, in India.

Exhibit 6.3: Operational Benchmarking of Anthem Biosciences and its Peers

Company	Number of R&D and Manufacturing Sites	Fermentation Capacity	FTE focus	FFS focus	GHG emission intensity, tCO2e/ USD million (tCO2e/INR Million)	Renewable Energy
Anthem Biosciences	3	142,000 L		✓	104 (1.24)	89%
Domestic Peers						
Competitor 1	3	500 L*	✓		223 (2.68)	76%
Competitor 2	4	NA	✓		172 (2.06)	45%
Competitor 3	4	NA	✓		509 (6.10)	2.5%
Competitor 4	2	NA	✓		732 (8.79)	0.1%
Competitor 5	6	5L**	✓		237 (2.84)	22%
Global Peers						

[58] Source: Evaluate Pharma

Competitor 6	32	NA			94 (1.13)	1%
Competitor 7	8	NA			101 (1.21)	
Competitor 8	21	NA			155 (1.85)	
Competitor 9	30	23,000 L			100 (1.20)	38%
Competitor 10	10	300 L**			34 (0.41)	80%
Competitor 11	11	NA			48 (0.58)	73%
Competitor 12	6	NA			29 (0.34)	54%
Competitor 13	6	NA			NA	

*Competitor 1 has acquired a company with a potential expansion of fermentation capacity to 20 Kl, which is expected to be operational by first half of 2025.
**Capacity is only for clinical development and not focused on commercial manufacturing.

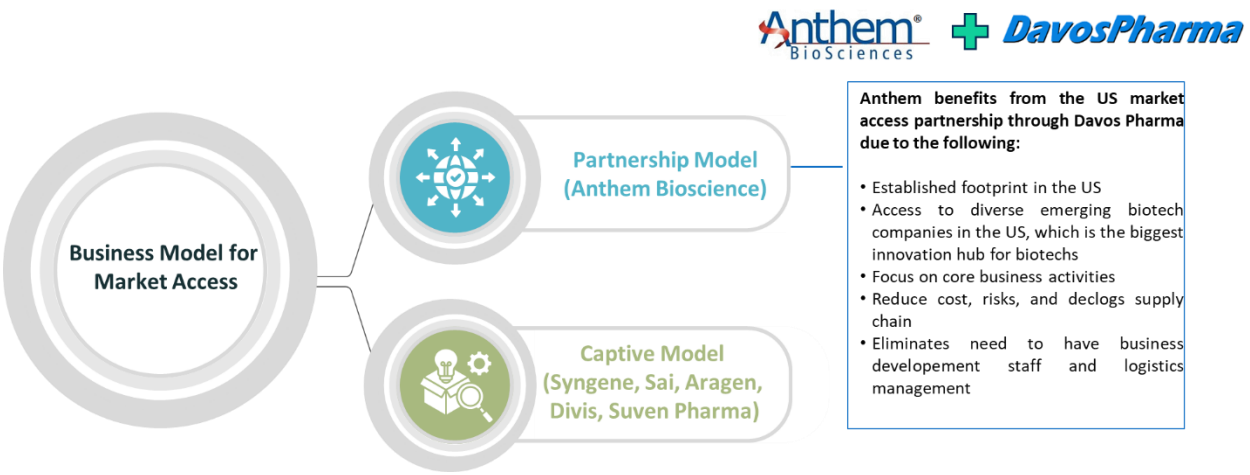
Focus refers to main contract model adopted

Source: Company filings/ websites/ new articles/ presentations, Frost & Sullivan analysis

Business Model Comparison

The US, a global innovation hub, hosts over 1,000 pharmaceutical and biotech companies and accounted for a substantial share of global R&D spending in CY2023. To penetrate this pivotal market, Anthem Biosciences leverages a partnership-driven model. Through a strategic alliance with Davos Pharma, a leading provider of discovery services and custom cGMP manufacturing of APIs, NCEs, and biologics (large molecules), Anthem is engaging with several biotech and pharmaceutical companies in the US.

Exhibit 6.4: Business Models for Market Access for CRDMO



Service Model

There are two major operating models in the CRDMO industry for discovery and development: Fee-For-Service (FFS) and Full-Time-Equivalent (FTE). In the FFS model, fees are payable based on specific services or deliverables as opposed to FTE contracts, where payments are paid based on time, cost, and number of employees engaged in the contract. Small pharmaceutical and emerging biotech companies generally prefer the FFS model due to its cost-effectiveness and their limited capacity and budget to repeat a workstream. The FFS model aims to streamline the drug discovery process. It benefits emerging biotech companies because of its transparent cost (allowing pharmaceutical companies to manage their budgets effectively) and improved productivity, speed, flexibility, quality, and reliability. Further, FFS model contracts generally have a better pricing model and higher margins than the FTE model if the project is successfully delivered. Using an FFS model contract allows a 20-30% cost reduction compared to in-house operations.[59]. In the case of large pharma companies, there is a preference for FTE contracts due to the scale of the projects, long-term commitment, dedicated R&D team, ring-fenced infrastructure, and ease of administration. An FFS model is suitable for well-defined, discrete tasks across all phases, particularly when cost control and task-specific transparency are priorities and are preferred by small pharmaceutical and emerging biotech companies as compared to the FTE model. Owing to the marked benefits of the FFS model, Anthem Biosciences has

[59] Based on KOL interviews

predominantly adopted this model, which they expect to follow through the same molecules since such molecules' discovery or development stage and would make forward-looking investments in resource allocation accordingly

Exhibit 6.5: CRDMO Industry Service Model

	FTE Model	FFS Model
Definition	The FTE model is a service arrangement where a client hires a dedicated team of scientists, researchers, or technical personnel from the CRDMO on a full-time basis for a defined period. The client pays for the time and effort invested in the project, rather than a fixed outcome or deliverable. This model offers flexibility in projects with evolving scope and for high-risk projects.	A service agreement, where a CRDMO is contracted to deliver a specific outcome or service for a predetermined price. Unlike the FTE model, which is based on time and resources, the FFS model emphasizes the achievement of a defined outcome. The scope of work, timelines, and endpoints are precisely defined at the outset, positioning the CRDMO not just as a service provider, but as a strategic partner, co-innovator, and risk sharer in the process.
Advantages for Sponsor	• Direct access to dedicated, skilled resources • Flexibility to adjust project scope and priorities • Cost efficiency for long-term, iterative projects • Enhanced control over project execution and timelines	• Outcome-based service • Reduced management oversight compared to FTE • Clear deliverables and project timelines • Flexibility to select specific services as needed • Risk sharing as the contract are set at a predetermined price thereby, avoids any wastages due to better resources utilization
Advantages for Service Provider	• Stable, predictable revenue streams from ongoing projects • Increased capacity utilization of in-house resources • Flexibility to participate in multiple service areas	• Enables specialization and expertise-driven service delivery • Faster project turnover and multiple client engagements • Reduced dependency on long-term resource allocation • Opportunity for higher margins on specialized services

Source: Frost & Sullivan

6.1.1.2 FINANCIAL COMPARISON

Anthem is one of the youngest Indian CRDMO companies and the fastest to achieve INR 10,000 million in revenue within 14 years of operations, reaching this milestone in FY21. It recorded the highest revenue growth among Indian and global peers between FY23 and FY24. The company demonstrated rapid growth from 2020 to 2024, with sales, EBITDA, and net profit growing at CAGRs of 22.1%, 29.5%, and 41.0%, respectively. In FY24, Anthem achieved the highest RoCE, RoE, and gross fixed asset turnover among assessed Indian peers, underscoring its operational efficiency and optimized manufacturing practices. Additionally, Anthem also reported the second-highest employee productivity, with an average revenue per employee of USD 93,151 (INR 7.78 million) in FY24. Anthem's metrics reflect industry-leading profitability and capital efficiency, positioning it as a benchmark in the CRDMO sector.

Exhibit 6.6: Anthem Biosciences Financial Comparison with Indian Peers

		Indian Peers				
Company/ Parameter	Anthem Biosciences	Syngene	Sai Lifesciences	Suven Pharma	Divi's	Aragen
Time taken to reach INR 10,000 million mark (Year incorporated)	14 years (2006)	23 (1993)	24 (1999)	32* (1999)	18 (1990)	20 (2001)
Revenue from Operations (FY24), USD million, (INR million)	170 (14,194)	418 (34,886)	176 (14,652)	126 (10,514)	941 (78,450)	199 (16,576)
Rank	5	2	4	6	1	3
Revenue Y-o-Y Growth (FY23-FY24)	34.3%	9.3%	20.4%	-21.6%	1.0%	-4.5%
Rank	1	3	2	6	4	5
Revenue CAGR (FY20 – FY24)	22.1%	14.8%	19.2%	6.0%	10.2%	14.9%
Rank	1	4	2	6	5	3
EBITDA (FY24) USD million (INR million)	62 (5,200)	122 (10,144)	34 (2,855)	49 (4,058)	268 (22,350)	52 (4,326)
Rank	3	2	6	5	1	4
EBITDA Margin (%) (FY24)	36.3%	29.1%	19.5%	38.6%	28.4%	26.1%
Rank	2	3	6	1	4	5
EBITDA (Y-o-Y) Growth (FY23-FY24)	16.6%	8.6%	73.1%	-29.3%	-10.5%	-13.0%

Rank	2	3	1	6	4	5
EBITDA CAGR (FY20 - FY24)	29.5%	13.2%	14.7%	1.3%	1.7%	16.2%
Rank	1	4	3	6	5	2
PAT, (FY24) USD million (INR million)	44 (3,673)	61 (5,100)	10 (828)	36 (3,003)	192 (16,000)	19 (1,601)
Rank	3	2	6	4	1	5
PAT Margin (FY24)	24.8%	14.2%	5.5%	27.0%	19.6%	9.6%
Rank	2	4	6	1	3	5
PAT CAGR (FY20 – FY24)	41.0%	5.5%	2.1%	2.7%	3.9%	12.6%
Rank	1	3	6	5	4	2
Post-Tax ROCE (FY24)	25.7%	11.3%	7.1%	19.5%	15.2%	10.5%
Rank	1	4	6	2	3	5
ROE	20.0%	13.0%	8.9%	15.9%	12.1%	12.4%
Rank	1	3	6	2	5	4
Revenue per employee (FY24) (in USD) (INR million)	93,151 (7.78)	60,067 (5.01)	61,770 (5.15)	119,868 (9.99)	53,768 (4.48)	47,336 (3.95)
Rank	2	4	3	1	5	6
Gross fixed assets turnover	1.51	0.74	0.87	1.25	1.20	0.87
Rank	1	6	5	2	3	4

Source: Annual Reports, Frost & Sullivan, MCA

*Note: * Suven Lifesciences; Suven Pharma carved out in 2018*

While Anthem Biosciences stands-out amongst its Indian peers, it is also outperforming relative to its global peers. It has achieved a remarkable 34.3% year-over-year revenue growth, and an EBITDA margin of 36.3% in FY2024, a high gross fixed assets turnover of 1.51x outperforming its global peers and is ranked first in terms of post-tax ROCE of 25.7%.

Detailed benchmarking of performance summary relative to Anthem Biosciences' global peers is as under.

Exhibit 6.7: Anthem Biosciences Financial Comparison with Global Peers

		Chinese Peers			Other Global Peers				
Company/ Parameter	Anthem Biosciences	Wuxi Apptec	Asymchem Labs	Pharmaron	Lonza	Catalent	Siegfried	PolyPeptide	Bachem
Revenue from Operations (FY24), USD million, (INR million)	170 (14,194)	5,690 (474,390)	1,098 (91,506)	1,627 (135,682)	7484 (623,998)	4,263 (355,423)	1,417 (118,120)	347 (28,891)	643 (53,632)
Revenue Y-o-Y Growth (FY23-FY24)	34.3%	2.5%	-23.9%	12.4%	7.9%	-11.2%	3.4%	14.0%	8.6%
Rank	1	7	9	3	5	8	6	2	4
Revenue CAGR (FY20 – FY24)	22.1%	33.1%	25.4%	22.4%	10.5%	8.3%	10.8%	12.1%	9.5%
Rank	4	1	2	3	7	9	6	5	8
EBITDA (FY24) USD million (INR million)	62 (5,200)	2,070 (172,542)	372 (31,046)	374 (31,218)	1,714 (142,878)	258 (21,510)	263 (21,893)	-11 (-945)	201 (16,731)
Rank	8	1	4	3	2	6	5	9	7
EBITDA Margin (%) (FY24)	36.3%	36.4%	33.9%	23.0%	22.9%	6.1%	18.5%	-3.3%	31.2%
Rank	1	2	3	5	6	8	7	9	4
EBITDA (Y-o-Y) Growth (FY23-FY24)	16.6%	21.8%	-23.3%	22.1%	-20.7%	-75.9%	-22.5%	-129.0%	11.4%
Rank	3	2	7	1	5	8	6	9	4
EBITDA CAGR (FY20 - FY24)	29.5%	42.3%	28.3%	11.5%	2.8%	-20.3%	15.6%	NA	8.8%
Rank	2	1	3	5	7	8	4		6
PAT, (FY24) USD million (INR million)	44 (3,673)	1,523 (126,978)	317 (26,469)	223 (18,601)	730 (60,848)	-256 (-21,344)	126 (10,469)	-56 (-4,639)	125 (10,392)
Rank	7	1	3	4	2	9	5	8	6
PAT Margin (FY24)	24.8%	26.1%	27.5%	13.3%	9.8%	-6.0%	8.8%	-15.8%	19.3%
Rank	3	2	1	5	6	8	7	9	4
PAT CAGR (FY20 – FY24)	41.0%	54.2%	32.9%	7.8%	-2.7%	NA	16.6%	NA	9.4%
Rank	2	1	3	6	7		4		5
Post-Tax ROCE (FY24)	25.7%	26.4%	25.3%	14.0%	8.6%	-1.9%	12.7%	-10.2%	14.0%
Rank	2	1	3	4	7	8	6	9	5
Revenue per employee (FY24) (in USD) (INR million)	93,151 (7.78)	138,387 (11.54)	112,131 (9.35)	80,187 (6.69)	415,796 (34.67)	239,494 (19.97)	372,828 (31.08)	272,213 (22.70)	320,671 (26.74)
Rank	8	6	7	9	1	5	2	4	3
ROE	20.0%	21.1%	13.6%	13.1%	6.5%	-6.2%	13.8%	-12.8%	9.0%

Rank	2	1	4	5	7	8	3	9	6
Gross fixed assets turnover	1.51	1.12	1.43	1.41	0.42	0.66	0.64	0.64	0.54
Rank	1	4	2	3	9	5	6	7	8

Source: Annual Reports, Frost & Sullivan

Notes:

- EBITDA = Sum of profit/(loss) before tax, plus depreciation and amortization expense and finance costs less other non-operating income (calculated as other income less forex gain (net), RoDTEP/MEIS duty credit incentives, electricity grid cross subsidiary received and freight and forwarding charges collected).
- EBITDA Margin= EBITDA divided by revenue from operations along with other operating income.
- PAT Margin= Restated profit after tax divided by total income
- Return on Equity = PAT / Average Total Equity (incl non-controlling interest (NCI)). Total Equity has been considered incorporating minority interest/ NCI
- Post-tax Return on Capital Employed (RoCE) = Earnings before interest and taxes times (1 - tax rate), divided by average capital employed. Average capital employed is the sum of average net worth, average net debt, average lease liability and average deferred tax liability for the current period/ Fiscal and the previous period/ Fiscal.
- Revenue per Employee = Revenue from Operations divided by the number of Employees at the end of the year.
- Gross fixed assets turnover = Operating Revenue/ Average Gross fixed assets (property, plant, and equipment, rights of use, and intangible assets) for FY24and FY23.
- All restated consolidated figures are considered in the above table
- For Catalent: The restated figures for FY21, FY22 are considered from the Annual Report of FY23. Other Income is considered from other income/ expenses net note no 15 of the Annual Report of FY23. For Net Profit, the total net earnings are considered. Total Debt also includes Non-current & Current operating leases (please refer to note 16 of the Annual Report of FY23)
- For Siegfried: Other Income= Financial Income + Other operating income. The depreciation amount is taken as the depreciation & impairment for PPE and intangible assets from the cash flow statement.
- For Bachem: Profit before tax is taken without considering the impact of extraordinary gain/ loss. The depreciation amount is taken as the depreciation, amortization, and impairment from the cash flow statement. Total Debt is taken as a total of Current & Non-Current Financial Liabilities
- For Polypeptide: Other Income= Financial Income + Other operating income.
- For Asymchem Laboratories, the amount due to related parties is considered while calculating total debt as it is an unsecured current borrowing.
- Currency Conversion Rates:

Conversion rates	Average INR_USD	Average RMB_USD	Average CHF_USD	Average USD_EURO
FY24	83.37	7.089892	0.897475	1.081642

Source: RBI, Investing.com

7 CONCLUSION

The pharma industry, poised to grow at a CAGR of 6.2% between 2023 and 2028F to reach USD 1,956 billion, will bring more significant opportunities for contract service providers. With the increasing complexities of drugs and technologies, pharma companies increasingly turn to contract service providers. Pharma companies are increasingly looking for one-stop-shop solution providers, particularly among small pharmaceutical and biotech companies with limited resources and streamlined organizational structures. Hence, CROs and CDMOs are increasingly combining their services to establish integrated CRDMO business models.

As outsourcing activities to CRDMOs brings multifold benefits to pharma companies, such as reduction in cost, reduced time taken to market, access to broader expertise, and advanced technologies, to name a few, will drive growth for CRMDOs which is expected to grow at a CAGR of 9.0% between 2023 and 2028F while during the same period Indian CRDMO is poised to outpace the global growth rate at 14.0% due to the opportunities arising from growing competence of Indian CRDMOs, US BIOSECURE Act, and pharma companies increasingly adopting China+1 strategy.

Further, while small molecules currently dominate the pharma market, due to the growing importance of biologic therapies, which have higher specificity and effectiveness compared to small molecules, CRDMOs with expertise in biologics (large molecules) manufacturing capabilities are better positioned to benefit from the emerging biologics (large molecules) opportunity (e.g., ADC, CGT, XRNA, Peptides) from pharmaceutical innovators.

8 ABBREVIATIONS

Term	Description
“AB-PMJAY”	Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana
“ADC”	Antibody–Drug Conjugates
“ANDA”	Abbreviated New Drug Application
“ANVISA”	The Brazilian National Health Surveillance Agency
“APAC”	Asia Pacific
“API”	Active Pharmaceutical Ingredient
“ASEAN”	Association of Southeast Asian Nations
“AT&M”	Alimentary Tract and Metabolism
“biotech”	Biotechnology
“Bn”	Billion
“BER”	Business Environment Rankings
“BLA”	Biologics License Application
“BRICS”	Brazil, Russia, India, China, and South Africa
“CRISPR”	Clustered Regularly Interspaced Short Palindromic Repeats
“CAGR”	Compound Annual Growth Rate
“CDMO”	Contract Development Manufacturing Organization
“CDSCO”	Central Drug Standard Control Organization
“cGMP”	Current Good Manufacturing Practices
“CGT”	Cell and Gene Therapy
“CHE”	Current Healthcare Expenditure
“CMO”	Contract Manufacturing Organization
“CNS”	Central Nervous System
“CRDMO”	Contract Research Development and Manufacturing Organization, which is an integration of CRO and CDMO
“CRO”	Contract Research Organization
“CVS”	Cardiovascular
“CY”	Calendar Year
“DGFT”	Directorate General of Foreign Trade

Term	Description
“DNA”	Deoxyribonucleic Acid
“DPIIT”	Department for Promotion of Industry & Internal Trade
“EBITDA”	Earnings Before Interest, Taxes, Depreciation, and Amortization
“EIU”	Economist Intelligence Unit
“EMA”	European Medicine Agency
“ESG”	Environmental, Social, and Governance
“ETP”	Effluent Treatment Plant
“EU GMP”	European Union Good Manufacturing Practice
“FDA” or “USFDA” or “US FDA”	United States Food and Drug Administration
“FDF”	Finished Dosage Form
“FDI”	Foreign Direct Investment
“FFS”	Fee for Service
“FTE”	Full-Time Equivalent
“FY”	Fiscal Year
“GATT”	General Agreement on Trade and Tariffs
“GDP”	Gross Domestic Product
“GDUFA”	Generic Drug User Fee Amendments
“GI”	Gastro-intestinal
“GLP -1”	Glucagon-like Peptide -1
“glycolipids”	An essential component of cell membranes, consisting of a lipid and a sugar group, which plays crucial roles in a variety of biological processes, including cell-cell recognition, signal transduction, and maintaining membrane stability
“GMP”	Good Manufacturing Practices
“HPAPI”	Highly Potent Active Pharmaceutical Ingredients
“kg”	Kilogram(s)
“IP”	Intellectual Property
“IPFC”	Investment Promotion & Facilitation Centre
“IPM”	India Pharma Market
“ISO”	International Standardization Organization

Term	Description
"kL"	Kiloliter(s)
"KSM"	Key Starting Materials
"L"	Litre(s)
"mAbs"	Monoclonal Antibodies
"MCC"	Multiple Chronic Conditions
"Mn"	Million
"MNC"	Multinational Company
"mRNA"	messenger RNA (Ribonucliec Acid)
"MSME"	Micro, Small, and Medium-sized Enterprise
"MT"	Metric Ton(s)
"MW"	Mega-watt
"NBE"	New Biological Entity
"NCE"	New Chemical Entity
"NDA"	New Drug Application
"NDDS"	New Drug Delivery Systems
"Net Cash"	Net Cash is calculated as the sum of cash and cash equivalents, bank balance and investment in mutual funds and corporate bonds, less gross debt.
"NME"	New Molecular Entity
"NMP"	National Master Plan
"OAI"	Official Action Indicated
"OEL"	Occupational Exposure Limit
"OEB"	Occupational Exposure Band
"PAT"	Profit after tax or total comprehensive income for the period
"PAT margin"	PAT divided by our revenue from operations
"Payload"	A highly active and toxic drug, which is attached to the monoclonal antibody via the chemical Linker
"PE"	Private Equity
"PLI"	Production-Linked Incentive
"PMBJP"	Pradhan Mantri Bhartiya Janaushadi Pariyojana

Term	Description
“PMDA”	The Pharmaceuticals and Medical Devices Agency of Japan
“PNG”	Piped natural gas
“R&D”	Research and Development
“RNA”	Ribonucleic Acid
“RNAi”	RNA interference
“RoCE”	Return on Capital Employed
“ROE”	Return on Equity.
“RoW”	Rest of the World
“siRNA”	small interfering RNA
“SAI”	Systemic Anti-Infectives
“sq. m”	Square metre(s)
“STEM”	Science, Technology, Engineering, and Mathematics
“TAM”	Total Addressable Market
“tCO2e/million”	tonnes of CO_2 equivalent per million
“TGA”	The Therapeutic Goods Administration in Australia
“UK”	United Kingdom
“US”	United States
“WHO”	World Health Organization