Management Discussion & Analysis

GLOBAL PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is critical to patient care and community development as it not only provides numerous life-saving treatments but also generates employment and contributes to the world economy. Amidst the challenging global landscape of inflation, pandemic, and escalating geopolitical tensions in 2023, international health systems exhibited remarkable resilience. The industry witnessed a continued focus on adopting novel therapies and a sustained increase in overall usage. On 5 May 2023, the World Health Organization (WHO) declared the end of the COVID-19 public health emergency. This changed the dynamics of the pharmaceutical world, shifting it back to the prevention and treatment of other communicable and non-communicable diseases. Antibacterials, which witnessed significant disruption during the pandemic, saw modest growth in 2022 and 2023. Older populations in developed markets and China are driving demand for over-the-counter (OTC) medicines, generics and medicines for treating chronic diseases.

While high inflation and interest rates were impacting household spending in 2022, leading to lower demand for OTC products, demand witnessed robust growth in 2023 as inflation is witnessing a downward trend. Public healthcare spending also supports growth for pharmaceutical products. However, some markets, including the EU, US and UK, are imposing new or revised drug pricing regulations in a bid to lower state healthcare costs. The volume use of medicines globally plateaued in 2023 and will witness gradual growth up to 2028, led by Asian markets, especially India and China. Novel therapies and accelerated use of technology are expected to boost future market growth.

The use of artificial intelligence (AI) is accelerating drug discovery, clinical trials, development processes, marketing strategies and enhancing efficiency. Analytics enables pharmaceutical companies to use available historical and real-time data for predictive, diagnostic, prescriptive, and descriptive analytics. Blockchain technology acts as a critical tool in drug production and distribution to tackle the use of counterfeit medicines and substandard drugs and for enhancing the tracking and safety of the pharmaceutical transaction landscape. There has been a growing prevalence of e-commerce and e-Pharmacy globally mainly led by the pandemic, telemedicine, remote patient monitoring, and digital health solutions. However, retail pharmacy continues to hold ground, with advice and consultation still being highly valued.

Top 10 Pharmaceutical Industry Trends in 2024 | StartUs Insights (startus-insights.com)

Specific therapies, particularly immunology, endocrinology, and oncology, have been key drivers of medicine use since 2018. Medicine use in terms of volume plateaued globally in 2023. While the global medicine market – using invoice price levels stood at US$ 1.6 trillion, up from US$ 1.5 trillion in 2022. It is expected to grow to about US$ 2.3 trillion, at a 6-9% CAGR through 2028, driven by robust growth in existing branded medicines in the leading ten developed markets and accelerated growth in Asian countries, especially India and China. In these regions, the use of medicines is expected to grow faster than 3%. In contrast, North America, Western Europe, and Japan are expected to witness slower medicine usage growth, partly due to their already higher per capita use. In addition to the contribution of new products, the impact of patent expiries, including the growing impact of biosimilars, is expected to further accelerate market growth.

(Source: IQVIA - Global Use of Medicines 2024, January 2024)

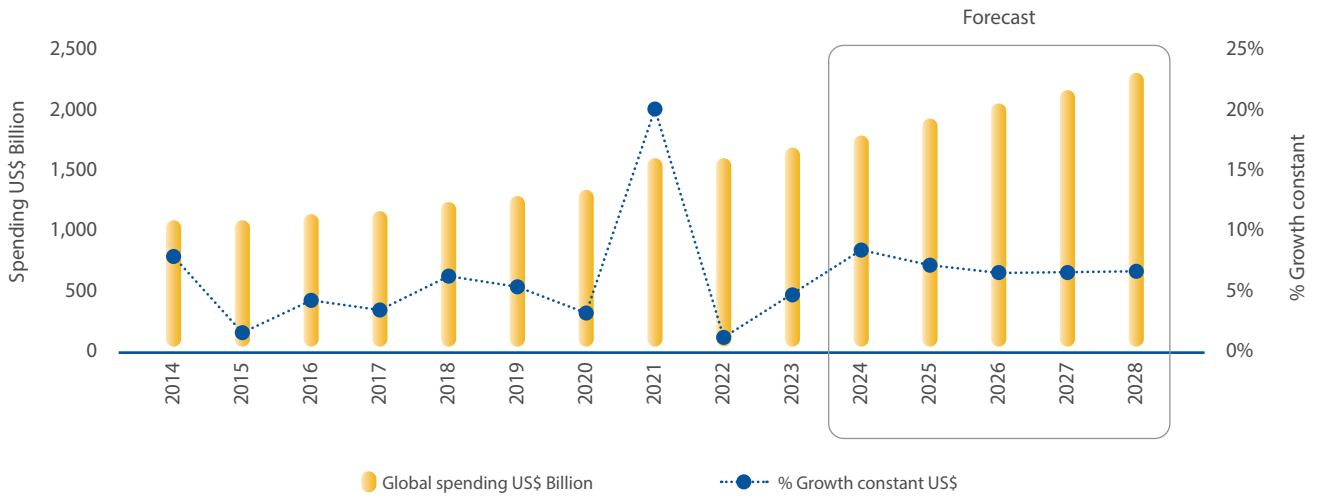
Climate-related events have led to some notable localized disruptions in medicine usage. This is expected to become commonplace and more severe in the coming years. Demand for specific medicines tends to spike in regions hit by calamities like wildfires, floods and hurricanes. To deal with such scenarios, it is imperative to build resilient health systems and supply chains.

Global medicine spending and growth by product type

	Year ended 31 March 2023	ORIGINAL BRANDS	NON-ORIGINAL BRANDS	UNBRANDED GENERICS	OTHER	TOTAL
Spending 2023 US$ Billion	**Global**	**1,057.2**	**248.1**	**158.5**	**143.0**	**1,606.8**
	Developed	967.4	128.7	113.4	65.9	1,275.5
	10 Developed	858.9	81.0	98.1	43.5	1,081.6
	Other developed	108.4	47.8	15.3	22.4	193.9
	Pharmerging	81.0	105.7	43.3	73.7	303.7
	Lower-income countries	8.8	13.6	1.7	3.4	27.6
Constant dollar CAGR 2019-2023	**Global**	**8.0%**	**6.9%**	**4.6%**	**5.8%**	**7.3%**
	Developed	7.9%	7.6%	2.8%	4.5%	7.2%
	10 Developed	7.9%	6.4%	2.1%	3.1%	7.0%
	Other developed	8.1%	9.8%	8.4%	7.5%	8.5%
	Pharmerging	9.7%	6.2%	10.3%	7.0%	7.8%
	Lower-income countries	3.2%	6.6%	7.2%	7.1%	5.6%
Spending 2028 US$ Billion	**Global**	**US$ 1,520-1,552**	**US$ 315-345**	**US$ 185-205**	**US$ 165-185**	**US$ 2,225-2,255**
	Developed	US$1,390-1,420	US$ 165-185	US$ 125-145	US$ 68-88	US$ 1,775-1,805
	10 Developed	US$ 1,230-1,260	US$ 105-125	US$ 100-120	US$ 47-51	US$ 1,505-1,535
	Other developed	US$ 150-170	US$ 58-62	US$ 18-22	$27–31	US$ 255-285
	Pharmerging	US$ 110-130	US$ 130-150	US$ 53-73	US$ 84-104	US$ 400-430
	Lower-income countries	US$ 9-13	US$ 15-19	US$ 1.5-2.5	US$ 3.5-4.5	US$ 33-37
Constant dollar CAGR 2024-2028	**Global**	**6-9%**	**8-11%**	**3-6%**	**3-6%**	**6-9%**
	Developed	6-9%	4-7%	1-4%	1-4%	5-8%
	10 Developed	6-9%	4-7%	0-3%	0-3%	5-8%
	Other developed	6-9%	4-7%	4-7%	4-7%	5-8%
	Pharmerging	10-13%	12-15%	9-12%	5–8%	10-13%
	Lower-income countries	3-6%	4-7%	3-6%	4-7%	3-6%

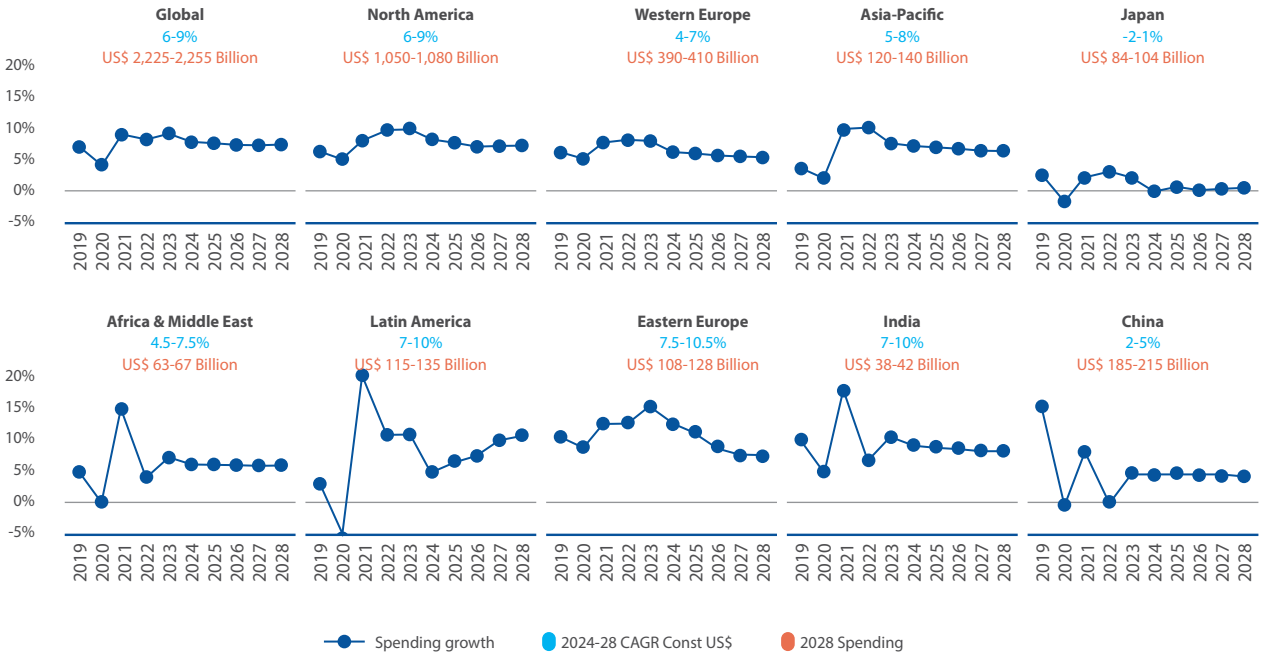
Source: IQVIA Market Prognosis, Sep 2023; IQVIA Institute, Dec 2023

Global medicine market size and growth 2014-2028



Source: IQVIA Market Prognosis, Sep 2023; IQVIA Institute, Dec 2023.

Spending growth globally and in 9 regions, total market, const US$ 2019-2028



Source: IQVIA Market Prognosis, Sep 2023; IQVIA Institute, Dec 2023.

The global pharmaceutical market can broadly be divided into developed and pharmerging markets. With a market share of ~70%, the developed markets dominate the global pharmaceutical market. The developed market group mainly comprises the United States, the top five European markets (namely Germany, France, Italy, the United Kingdom, and Spain), Japan, Canada, and Australia. The pharmerging group mainly comprises China, India, Brazil, Russia, and South Africa, where consumption of medications is relatively low but rapidly increasing.

Market Trends in Developed and Pharmerging Markets

The developed markets, primarily the larger world economies, have well-structured healthcare systems. These regions are mainly characterized by high levels of healthcare spending amidst highly regulated markets. These markets typically have high per capita medicine use. Drug approval, pricing and reimbursement are highly regulated and thus, the market is controlled by large multinational pharmaceutical companies with a focus on high-margin speciality drugs and biologics. These markets being more mature, offer a stable revenue stream. The United States (US) remains the largest spender in the world, followed by Japan and Western Europe.

Growth rate: The growth in these developed markets is expected to be moderate, at 5-8% CAGR over 2024- 2028 driven by new and existing branded products. However, growth in these markets is expected to be offset by generics and biosimilars to some extent. In the near future, players are expected to face budget pressures and act to curb drug spending growth, partly motivated by the costs of managing the pandemic and to moderate the impact of increased spending on novel therapies.

The pharmerging markets are typically characterized by lower levels of healthcare spending compared to developed markets with low per capita medicine use and lower pricing. Hence, they hold immense growth potential led by increased per capita incomes and improved access to healthcare. These less regulated markets find a mix of local and multinational companies offering various low-cost generic drugs, branded generics and biosimilars. China, a pharmerging market, has become the second-largest spender on healthcare in the world, led by its huge population and increasing focus on streamlining healthcare infrastructure.

Growth rate: Pharmaceutical sales in the pharmerging market are expected to grow at a higher rate than in developed markets at 10-13% CAGR over 2024-2028, driven by factors such as increasing demand for healthcare products and services, rising incomes, and expanding access to healthcare.

Overall, although the developed markets will continue to constitute the lion's share of global pharmaceutical sales, the pharmerging markets will drive future growth.

KEY MARKETS

United States Pharmaceutical Market

The world's largest pharmaceutical market, the United States, was estimated at US$ 711 billion (medicine spending on invoice price) and is projected to increase by US$ 299 billion through 2028 to reach US$ 1,010 billion, growing at 6-9% CAGR. The largest driver of growth will be increased usage of existing protected branded products. Brand spending is expected to continue to be robust on an invoice basis, and off-invoice discounts and rebates are expected to be amplified by the provisions of the Inflation Reduction Act (IRA).

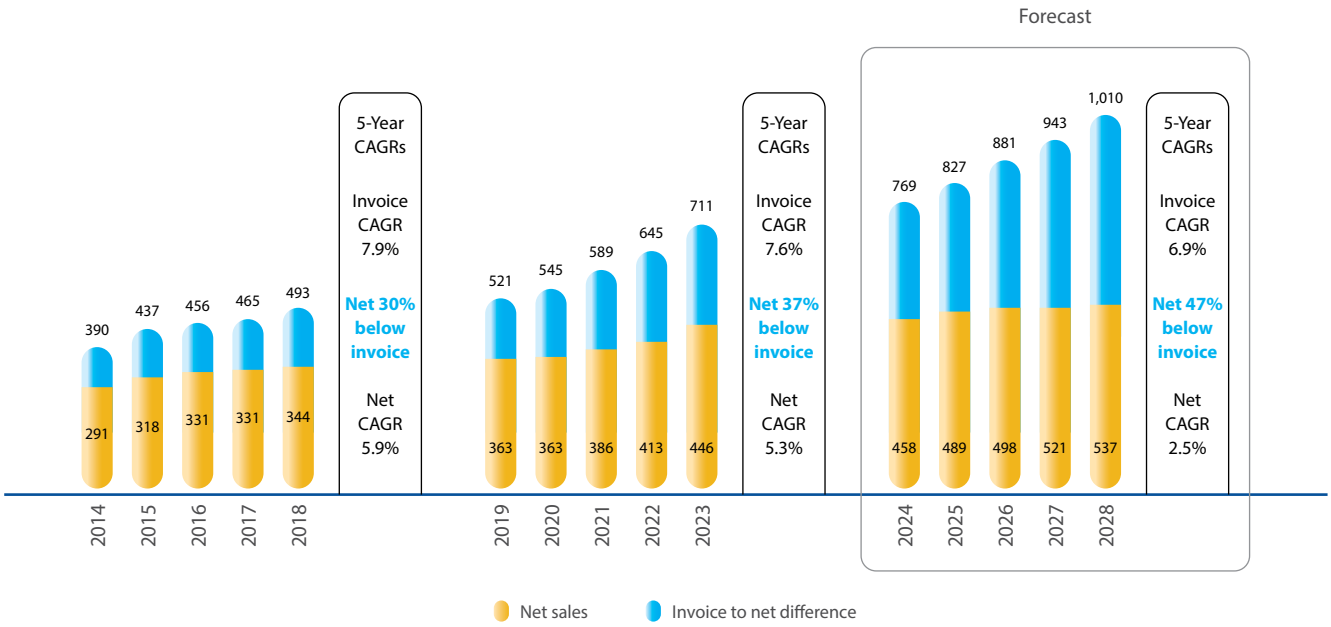
The contribution from new brands is expected to increase to US$ 119 billion over five years as more than 250 new active substances (NASs) are expected to be launched. This presents a significant opportunity for Indian pharmaceutical companies to launch their own innovative products in the US market. India caters to ~40% of the total demand in the US's generic drug market.

During the January-September 2023 period, the US FDA approved a total of 618 ANDAs, of which Indian companies and their subsidiaries secured 46% of the total approvals amounting to 284 ANDA approvals. The continued dominance of Indian players in the US market is the result of the Indian pharmaceutical industry's unwavering focus on research and development (R&D) activities. Indian players exhibit a stronghold across therapeutic areas, including cardiovascular, anti-diabetes, and anti-cancer.

THE ANDA BOOST (pharmabiz.com)

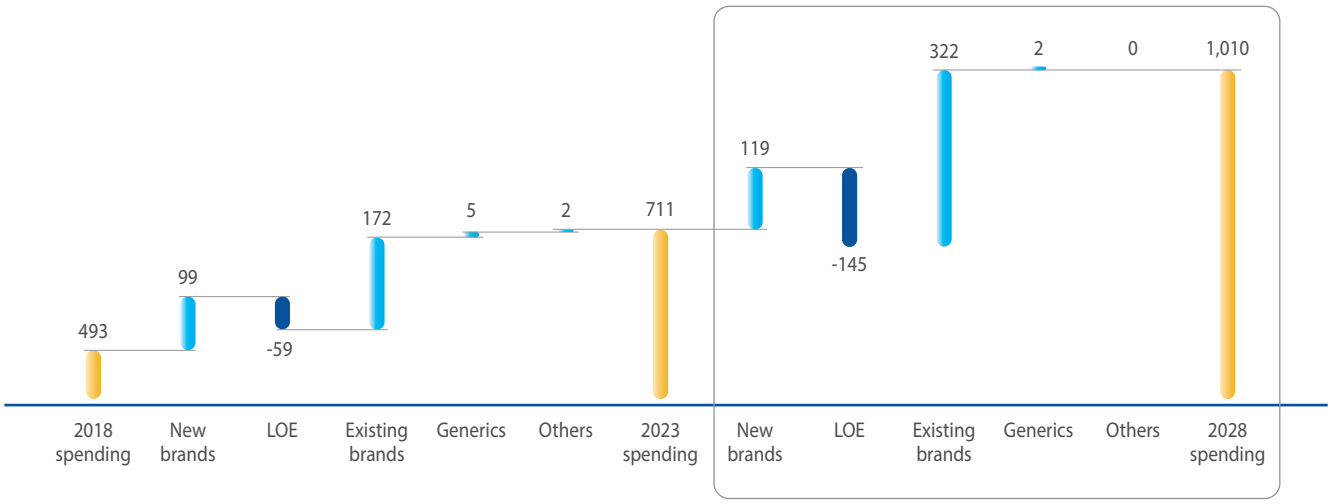
The impact of Loss of Exclusivity (LoE) is expected to be US$ 145 billion as compared to US$ 59 billion in the prior five years, as both small molecule and biologic product exposure to LOE has increased substantially. This presents a humungous growth opportunity for Indian pharmaceutical companies to launch generic versions of these drugs.

Exhibit 24: U.S. medicine spending and growth at invoice-level and estimated net 2014-2028 excluding COVID-19 vaccines and therapeutics



Source: IQVIA Institute, Dec 2023.

Exhibit 25: Spending and growth drivers in US 2018-2028, constant US$ Billion



Source: IQVIA Market Prognosis, Sep 2023; IQVIA Institute, Dec 2023.

Being a developed market, the US pharmaceutical market presents unique challenges which include high competitive intensity, stringent regulation, and complex pricing and reimbursement systems. Indian pharmaceutical companies are well aware of these nuances, and with their experience in the global pharmaceutical market, are in a good position to grow their business in the US market.

INDIAN PHARMACEUTICAL MARKET

The Indian pharmaceutical market is a global powerhouse, being the third-largest in terms of volume. It is renowned for its extensive production of generic medicines and cost-effective vaccines. As the largest supplier of generic medicines worldwide, India manufactures approximately 60,000 different generic brands across 60 therapeutic categories, contributing 20% to the global supply of generics.

A significant segment of the pharmaceutical industry is the production of Active Pharmaceutical Ingredients (APIs), which make up around 35% of the market. APIs are the biologically active components of drugs responsible for their intended medical effects. India's API production is not only significant in volume but also in variety as it ranks as the third-largest producer of APIs, holding an 8% share of the global API market. India produces over 500 different APIs, contributing to 57% of the World Health Organization's (WHO) prequalified list.

India boasts the second-highest number of pharmaceutical factories outside the United States that comply with US-FDA regulations. Additionally, it has a considerable number of WHO Good Manufacturing Practices (GMP)-compliant plants and facilities approved by regulatory authorities from various countries. This makes India a pivotal player in the global pharmaceutical landscape, supplying affordable, high-quality generic drugs to over 200 countries.

Access to affordable HIV treatment from India is one of the greatest success stories in medicine. Because of the low price and high quality, Indian medicines are preferred worldwide, making it the pharmacy of the world.

According to CARE Ratings, in FY 2022-23, the Indian pharmaceutical industry was valued at US$ 49.8 billion, up 5% YoY. The domestic growth was healthy at 7%, but the muted export growth at 3% suppressed overall market growth. Within exports, the emerging markets were largely flat, while the developed market registered a robust 8% growth. The slower growth in emerging markets was attributed to the Russia-Ukraine war, foreign currency shortages in several African countries, and significant depreciation of local currencies.

Post-pandemic, there has been a notable shift in the Indian consumer mindset, reflected in the growing demand for vitamins, minerals, and supplements (VMS). According to IMARC, the Indian pharmaceutical market is expected to reach to US$ 163.1 billion by 2032, at 12.3% CAGR. The growing incidences of diseases, rising healthcare needs, favorable government initiatives prioritizing healthcare, development of healthcare infrastructure, and improving health consciousness will provide a boost to future market growth.

(₹ in Crore)

Therapy Area	Sales in FY 2023-24	Therapy Contribution	YoY growth in FY 2023-24
Cardiac	26,947	12.5	10.0
Anti-Infectives	24,328	11.3	4.7
Gastro Intestinal	22,857	10.6	7.2
Anti Diabetic	19,128	8.9	6.0
Respiratory	17,817	8.2	2.7
Pain / Analgesics	17,226	8.0	8.1
Vitamins / Minerals / Nutrients	16,897	7.8	7.3
Derma	14,859	6.9	6.2
Neuro / CNS	12,946	6.0	8.5
Gynecology	10,858	5.0	6.3
Others	32,228	14.9	12.8

Source: IQVIA data, March 2024

India's Pharma Exports by Country (US$ Million)

Rank	Country	FY 2022-23 (US$ Million)	FY 2021-22 (US$ Million)	YoY Growth	Contribution
1	USA	7,547.5	7,108.2	6.2%	29.7%
2	Belgium	714.9	449.1	59.2%	2.8%
3	South Africa	657.0	612.3	7.2%	2.6%
4	United Kingdom	647.7	706.0	-8.3%	2.6%
5	Brazil	642.7	583.8	10.1%	2.5%
6	Netherlands	594.3	460.6	29.0%	2.3%
7	Russia	573.2	598.3	-4.2%	2.3%
8	France	569.8	513.7	10.9%	2.2%
9	Germany	523.0	529.3	-1.2%	2.1%
10	Nigeria	516.0	588.3	-12.3%	2.0%
11	Canada	506.6	419.0	21.0%	2.0%
12	Australia	422.3	386.8	9.2%	1.7%
13	Kenya	362.5	342.6	5.8%	1.4%
14	China	348.1	343.6	1.3%	1.4%
15	UAE	342.5	331.9	3.2%	1.4%
	Others	10,426.0	10,620.8	-1.8%	41%
	Grand Total	**25,394.1**	**24,594.3**	**3.2%**	**100.0%**

Pharmexcil Annual Report - 12-09-2023.cdr

India's healthy demographic profile with an expanding population, increasing life expectancy, and growing incidences of chronic diseases, provides growth opportunities for the pharma market. The availability of a skilled workforce at affordable prices enables India to supply low-cost medicine worldwide. A talented pool of scientists and unwavering focus on R&D, ensure quality products are manufactured and supplied at competitive prices. The government has prioritized the healthcare sector and has launched several schemes to promote the pharmaceutical industry. In the interim budget 2024-25, the government laid unparalleled focus on healthcare. Total expenditure on healthcare has been increased from ₹ 79,221 crore in 2023-24 to ₹ 90,171 crore in 2024-25. With a strong focus on affordable healthcare and sustainable development, allocations for PMABHIM (~2x), Ayushman Bharat-PMJAY (0.5%) and the PLI scheme (50%) were enhanced. In addition, allocation towards Biotechnology Research and Development has been doubled to ₹ 1,100 crore in 2024-25. The government also emphasized the need to promote investment in Research and Development.

The players in the industry realize the humongous growth opportunity and are investing in future growth with a strong focus on digital technologies. The growing adoption of analytics and artificial intelligence across the value chain is helping the players not only improve the quality of products but also optimize production processes and enhancing efficiency.

Strong economic growth, government support for the pharmaceutical sector and private investment in R&D, are the key drivers of robust market growth. Indian generic medicines are 30-90% less expensive than branded counterparts. Complex generic drugs such as biosimilars and oncology drugs are manufactured in India at highly competitive rates without any compromise on quality. The Indian generic drug industry has been able to compete with other global players by leveraging its expertise in chemistry, manufacturing and innovation.

With a strong focus on affordable healthcare and sustainable development, allocations for PMABHIM (~2x), Ayushman Bharat-PMJAY (0.5%) and the PLI scheme (50%) were enhanced. In addition, allocation towards Biotechnology Research and Development has been doubled to ₹ 1,100 crore in 2024-25. The government also emphasized the need to promote investment in research and development.

Biosimilars and biologics

Biosimilars are biological products highly similar to existing FDA-approved reference products with no clinically meaningful differences. Developed to have the same mechanism of action, route of administration, dosage form and strength, comparable to the original product, they act as a more affordable alternative to high-cost reference biologics. The development and commercialization of biosimilars thus intensifies competition by making complex and often expensive treatments more accessible for more patients.

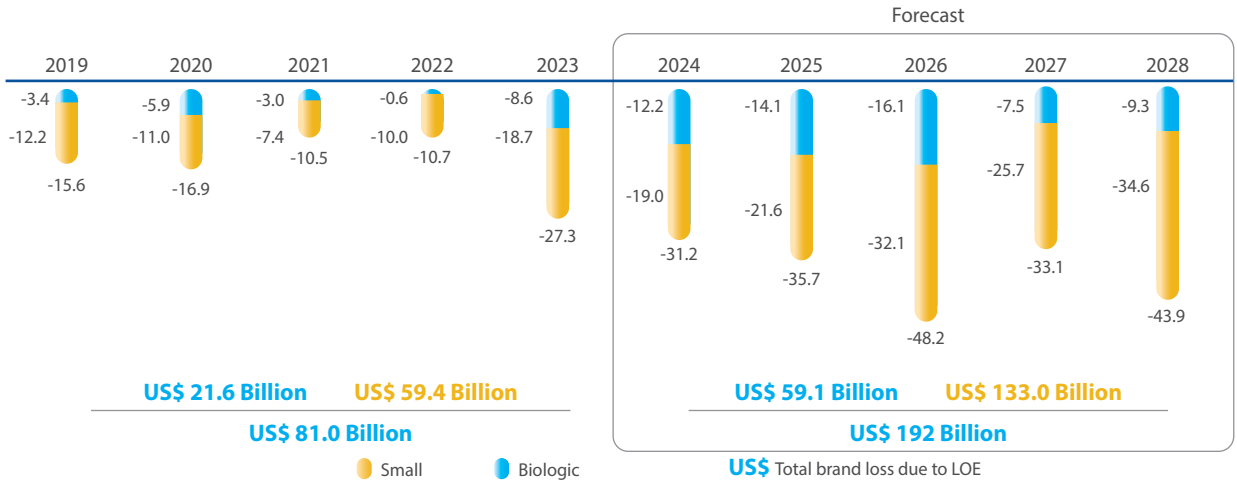
Substantial investments in research and development, clinical trials and manufacturing capabilities are key to the development of biosimilars and biologics. Given their cost competitiveness, the global market for biosimilars presents significant opportunities for pharmaceutical companies to grow their businesses. The global biosimilar market size reached US$ 21.2 billion in 2023, up from US$ 16.8 billion in 2022. The growth is primarily driven by the expiry of patents on blockbuster biologic drugs, rising awareness about efficacy, and cost-effectiveness increased incidences of chronic diseases and technological advancements. The biosimilars market is likely to reach US$ 164.5 billion, growing at a 25.1% CAGR over 2024-2032.

In the coming five-year period, the impact of brand losses of exclusivity (LoE) is expected to reach to US$ 192 billion across the leading 10 developed markets, with US$ 133 billion coming from small molecules and US$ 59 billion from biologics. The growth is primarily attributable to the U.S. patent expiries, including the autoimmune drug adalimumab (Humira) in 2023, lisdexamfetamine (Vyvanse) for ADHD in 2024, and blood thinner rivaroxaban (Xarelto) and autoimmune ustekinumab (Stelara) in 2025.

(Source: IQVIA - Global Use of Medicines 2024, January 2024)

The impact of exclusivity losses will reach US$ 192 billion over the next 5 years, with around 30% due to the availability of biosimilars

10 developed countries impact of brand losses of exclusivity 2019-2028, US$ Billion



Source: IQVIA Market Prognosis, Sep 2023; IQVIA Institute, Nov 2023.
Global Use of Medicines, 2024: Outlook to 2028. Report by the IQVIA Institute for Human Data Science. Copyright ©2024 IQVIA. All rights reserved.

In the five decades of global presence, Alkem Laboratories (the Company / Alkem) has solidified its footing as a global Indian generic pharmaceutical company offering innovative, best-in-class products. For over two decades, Alkem has maintained its position among the top 10 domestic pharmaceutical companies, with a presence panning the entire value chain from product development to manufacturing and sales

While the significant price gap between the original product and biosimilars provides a strong case for the quick acceptance and popularity of these products, the actions of originators, payers and providers to switch patients from brands to equivalent generics or biosimilars have a high degree of variability. A case in point is that adalimumab in the U.S., facing biosimilars since January 2023, saw an increase in brand spending on an invoice basis as biosimilar uptake reached only 1.4% of prescriptions as of November 2023.

Over the next five years, expiring patents will create important revenue opportunities for generic and biosimilar manufacturers to sustain their businesses. This is especially crucial considering the relatively low number of expirations in the past five years. Governments worldwide are seeking to reduce healthcare spending, leading to growing interest in biosimilars as a way to improve access to biologics. With the increasing number of approved biosimilars and the development of more complex versions, regulatory frameworks for biosimilars are becoming more established.

Significant progress in Research and Development has led to substantial advancements in the development of innovative biologic therapies to cure diseases that were previously untreatable, particularly in the areas of gene therapy and cell therapy. The USFDA and the European Medicines Agency (EMA) have established specific guidelines for the approval of interchangeable biosimilars. This has led to a significant increase in the use of biosimilars in recent years in these regions.

Company Overview

In the five decades of its global presence, Alkem Laboratories (the Company/Alkem) has solidified its footing as a global Indian generic pharmaceutical company offering innovative, best-in-class products. For over two decades, Alkem has maintained its position among the top 10 domestic pharmaceutical companies, with a presence spanning the entire value chain from product development to manufacturing and sales. International business is spread across 40 countries, with the United States being its primary export market. The Company's strong brand equity across Indian and international markets is a result of its extensive distribution network of over 8,400 stockists, diversified portfolio of over 800 brands, veteran management team, commitment to superior quality, and strong company ethos and culture.

With 19 advanced manufacturing facilities, 18 in India and 1 in the United States, the Company boasts of having filed 176 ANDAs and 2 new drug applications (NDAs) with the US FDA and has approvals for 145 ANDAs (including 13 tentative approvals), 2 NDAs and 1,100+ product registrations in various international markets. All its facilities undergo regular audits and have approvals from various regulatory agencies, such as the US FDA, WHO, MHRA (UK), TGA (Australia), ANVISA (Brazil), MCC (South Africa) and regulatory agencies from other countries. The Company's four technologically advanced R&D centers are supported by over 500 scientists striving relentlessly to innovate new products in keeping with the dynamic market environment. The Company's investment in biotechnology through its subsidiary, Enzene Biosciences, is witnessing good traction in the market, with 7 biosimilar products in the domestic market.

Alkem is the category leader in several Indian acute therapy areas such as Anti-infective, Gastro-intestinal, Pain management, and Vitamins/ Minerals/Nutrients (VMN). Among the top 50 pharmaceutical brands in India, many Alkem mega brands, such as Clavam, Pan, Pan-D, and Taxim-O, enjoy a unique dominance. Alkem has been the market leader in the anti-infective segment for over a decade and is also one of the leading companies in the Indian trade generic segment. Alkem has been expanding its presence in chronic therapy areas such as Neuro/CNS, Cardiac, Anti-diabetes, and Dermatology.

Revenue from key markets

Business segment	Revenue in FY 2023-24 (₹ million)	Contribution to total revenue (%)	% YoY growth in total revenues
Domestic business	₹ 86,620.2	68.4%	6.2%
US business	₹ 27,709.3	21.9%	10.2%
Other International markets business	₹ 12,346.3	9.7%	33.3%

The Indian domestic business continues to hold the lion's share of Alkem's revenue with around 68% share in FY 2023-24. The Company is well-cemented to leverage its dominance in the pharmaceutical market and benefit from the humungous market growth potential.

Financial overview (₹ in million)

Key profit and loss statement highlights

Particulars	FY 2023-24	FY 2022-23	YoY Change	Comments
Revenue from operations	126,675.8	115,992.6	9.2%	Domestic business grew by 6.2% which was largely impacted due to sporadic season. US business grew by 10.2% on account of single digit price erosion. Other International market registered robust growth of 33.3% led by Latam and Europe market.
Gross Profit	77,300.0	66,924.2	15.5%	Improvement in gross margin is attributable to better product mix and softening of API prices.
Gross Profit margin	61.0%	57.7%		
EBITDA	22,454.9	16,094.5	39.5%	Mainly driven by gross margin improvement and optimization in manpower cost
EBITDA margin	17.7%	13.9%		
PBT before exceptional item	21,446.2	14,077.5	52.3%	Led by improvement in EBITDA and Treasury income.
Exceptional item	(1,214.9)	(1,029.8)		
PBT after exceptional item	20,231.3	13,047.7	55.1%	
PBT margin	16.0%	11.2%		
PAT (After minority interest)	17,957.7	9,841.7	82.5%	PAT for FY 2022-23 was impacted on account of derecognition of Deferred tax assets of ₹ 1,197.2 million adjusted for the said item PAT growth for FY 2023-24 would have been 62.7%.
PAT margin	14.2%	8.5%		

Key ratios

Ratio	Formula used	FY 2023-24	FY 2022-23	Comments
Debtors turnover	Sale of products / Trade Receivable	5.52	5.37	
Inventory turnover	COGS / Inventory	1.86	1.88	
Interest coverage ratio	EBIT / Finance cost	17.31	12.10	The Company reported a higher EBITDA margin YoY on account of increase in sale of products and better gross margins
Return on net worth	PAT / Net worth (attributable to owners of the company)	17.4%	10.9%	
Current Ratio	Current Assets / Current Liabilities	2.61	2.35	
Debt to Equity ratio	Net debt / Total equity	0.07	0.11	The Company generated healthy cash flows from operations during the year, which aided in the net debt reduction.
Operating Profit Margin %	EBITDA / Revenue from operation	17.7%	13.9%	The Company reported higher EBITDA and Net Profit margin YoY mainly on account of better gross margins.
Net Profit Margin %	Net profit / Revenue from operation	14.2%	8.5%	

Domestic Business

During FY 2023-24, the Company clocked secondary sales growth of 6.2% YoY to ₹ 8,684 crore (IQVIA MAT March 2024), marginally lower than the overall Indian Pharmaceutical Market (IPM) growth of 7.6%. The slightly lower-than-market growth can be attributed to therapeutic areas where the Company is a market leader but which grew slower than the overall IPM. For example, the anti-infective therapeutic area in IPM grew at only 4.7% during FY 2023-24.

Key highlights:

- ₹ 86,620.2 Million Revenue from Domestic Business
- 6.2% Y-o-Y Growth in the Domestic Business
- 18 No. of Brands in IPM Top 300 Brands
- 68.4% Revenue Contribution
- No. 5 Rank in the Indian Pharma Market
- No. 1 Anti-infective Company in India for over 15 years

The Company continues to be ranked among the top-five players in the IPM overall, with a market share of 4.02%. In therapeutic areas where the Company has had historical strength, the Company has maintained its rank among the top three players. These therapeutic areas include anti-infectives (leader for more than fifteen years), gastro-intestinal (rank 3), pain and analgesics (rank 3) and vitamins/minerals/nutrients (rank 2). The Company owes this exceptional achievement to the relentless dedication to excellence and steadfast commitment of a strong team of more than 12,000 marketing representatives.

The Company continues its rich legacy of building market-leading brands across therapies. During FY 2023-24, nineteen of Alkem's brands are having sales of more than ₹ 100 crore each. These brands constitute more than half of Alkem's sales and are key drivers of growth. Three of Alkem's brands are featured among the top 15 brands in the IPM: Pan (rank 7), Clavam (rank 9) and Pan-D (rank 15). These brands continue to surpass expectations in their respective markets, reflecting the strong trust and confidence healthcare professionals have in them, their safety, efficacy and quality, and the deep connect developed by the strong sales and marketing team through science-driven engagement.

Performance of some of the new product launches

Brand	Molecule	Rank MAT March 2024
A TO Z Amino	Amino+Vitamin+Lycopene+ Folic+Mineral	5
Dapanorm-L	Dapagliflozin+Linagliptin	4
Cetuxa	Cetuximab	2
Alsita-MP	Metformin+Pioglitazone+ Sitagliptin	1
Denuril	Denosumab	4 (+4)
Dapanorm Trio	Dapagli.+Metfor.+Sitagli.	1
Glycoquic	Glycopyrronium	3 (+2)
Alsita-M	Metformin + Sitagliptin	4
Alsita	Sitagliptin	5
Carilift	Cariprazine	2
Romiset	Romiplotism	3
Topiroxo	Topiroxostat	1
Clavam ES	Amoxicillin + Clavulanic acid	2

Rank in their respective molecule as reported by IQVIA data

Alkem's performance in key therapeutic segments

Therapy Area	Company Rank	Contribution (%)	Market share (%)	Company growth (% YoY)	Industry growth (% YoY)
Anti-Infectives	1	36.1	12.9	2.0	4.7
Gastro Intestinal	3	19.0	7.2	9.0	7.2
Pain / Analgesics	3	10.8	5.4	5.3	8.1
Vitamins / Minerals / Nutrients	2	10.7	5.5	9.3	7.3
Anti Diabetic	15	4.6	2.1	21.6	6.0
Neuro / Cns	7	3.9	2.6	8.5	8.5
Gynecolog	11	3.9	3.1	3.4	6.3
Respiratory	15	3.1	1.5	0.0	2.7
Derma	19	2.9	1.7	10.6	6.2
Cardiac	27	2.4	0.8	8.6	10

Performance of Alkem's Top 10 Brands

Brand	Molecule	Rank in molecule category	Brand sales ₹ crore in FY 2023-24	Market share
PAN	Pantoprazole	1	608.4	34.2
Clavam	Amoxicillin+Clavulanic Acid	2	592.4	15.0
PAN-D	Domperidone+Pantoprazole	1	523.9	32.3
Taxim-O	Cefixime	2	311.8	23.0
A To Z Ns	Ascorbic Acid+Copper+Manganese+Nicotinamide+Pantothenic Acid+Pyridoxine+Retinol+Riboflavin+Vitamin E+Zinc	2	283.6	13.9
Xone	Ceftriaxone	2	265.2	16.4
Pipzo	Piperacillin+Tazobactam	1	197.1	22.8
Gemcal	Calcitriol+Calcium & Comb	1	180.9	19.2
Uprise-D3	Colecalciferol	1	177.4	16.9
Taxim	Cefotaxime	1	176.6	80.8

Source : IQVIA MAT March 2024

> UCPMP will help level the playing field for pharmaceutical companies in prescribing practices as companies will have to compete based on the quality, efficacy, and affordability of their products rather than the extent of promotional activities.

Furthermore, the Company expanded its presence in chronic therapy areas, including anti-diabetes, neurology/CNS, and dermatology, surpassing market growth rates, where it gained market share. The Company also made recent inroads into erstwhile white spaces such as respiratory and ophthalmology. The Company has been consistently ranked among the top three players in IPM in terms of sales from new introductions. For example, in at least two instances of blockbuster diabetes products that faced patent expiries, the Company's new introductions are market leaders among generics.

With steadfast commitment to Research and Development, operational excellence, strategic supply chain management and a proficient management team, the Company is well-positioned to scale new heights as a leader in the pharmaceutical sector in India.

Outlook for Domestic Business

The domestic pharmaceutical market is poised to grow at 7-10% CAGR over the medium term, with chronic therapeutic segments growing marginally higher than acute ones. While growth drivers are robust, several key trends are likely to shape the domestic business going forward.

Healthcare expenditure is increasing, most significantly due to governmental efforts to improve healthcare infrastructure and make healthcare accessible through schemes like Ayushman Bharat insurance coverage. Private sector spending on healthcare is also increasing, through rising income levels, increasing prevalence of lifestyle and chronic diseases, greater awareness, and access to insurance. This, in turn, is driving demand for pharmaceutical products.

The Uniform Code of Pharmaceutical Marketing Practices (UCPMP) will have a significant impact on the formulation landscape of Indian domestic formulations. UCPMP will help level the playing field for pharmaceutical companies in prescribing practices as companies will have to compete based on the quality, efficacy, and affordability of their products rather than the extent of promotional activities. The Company is very well placed to enhance the trust and credibility among prescribers, healthcare professionals, patients and regulatory authorities and further build on the Company's brand reputation. The Company is already focusing on educational initiatives and scientific evidence for promotion and is in the process of implementing internal monitoring systems and training to ensure adherence to the code.

Pharmaceutical manufacturing in India is set for an overhaul of quality systems and risk management, with increased stringency to ensure mandatory compliance with good manufacturing practices. Major changes as per notification of rules have led to introduction of a Pharmaceutical Quality System (PQS), Quality Risk Management (QRM), Product Quality Review (PQR), Qualification and Validation of equipment, change control management, self-inspection and quality audit team, supplier audit and approval, among others. All pharma companies are required to follow the revised good manufacturing practices and comply with the rules over 6-12 months. The Company already has such systems in place, and is well placed to further enhance quality in the domestic business.

Efforts by the Indian Government on self-reliance in APIs, initiated during the pandemic through Production Linked Incentives (PLIs), are beginning to bear fruit. Dependence on China for APIs for domestic formulations will reduce significantly. API prices have been on a downward trend, with a substantial reduction in the latter half of FY 2023-24. This bodes well for the profitability of the domestic business, thereby encouraging sizeable Indian pharmaceutical companies to refocus on the Indian market. With increasing domestic manufacturing of APIs, the industry will gradually be insulated from fluctuating raw material prices and risks of shortages.

The government's price control measures for essential medicines will be critical in ensuring access and affordability. Currently, price controls cover more than nine hundred medications. However, given the low WPI inflationary factor in FY 2023-24, the price increase for our NLEM portfolio will be insignificant. This will exert margin pressure on pharmaceutical companies, to an extent offsetting the benefit from lower raw material prices.

The Company is poised to build on its strengths and aspires to improve on its leadership position in the domestic market. The Company is focusing on plugging portfolio white spaces through strategic new product launches, and enhancing effectiveness within its robust field force, and addressing operational efficiencies across manufacturing, supply chain and distribution, enabled by robust information technology systems and processes. The company is also well-placed to leverage its leadership position in the trade generic segment with an enhanced generic portfolio.

While recent changes, mainly regulatory and compliance, are likely to create new and unique challenges for pharmaceutical companies, with its marquee brands, large and well-equipped field force, resilient supply chain and expansive distribution network, the Company sees a unique opportunity to outperform peers in the domestic business. The Company, therefore, maintains a very positive outlook in the medium to long term for the domestic market and looks forward to fulfilling its commitments towards the medical fraternity and healthcare providers, patients and

caregivers, and channel stakeholders as a manufacturer and marketer of high-quality medication.

US Business

The US business remains a key revenue driver, contributing a substantial portion of the Company's total income. In FY 2023-24, the Company reported a revenue of ₹ 27,709.3 million from the US market, reflecting an 10.2% increase over the previous year. This growth was fueled by market share expansion in existing products.

Key highlights:

- ₹ 27,709.3 Million Revenue from US Business
- 21.9% Revenue Contribution
- 10.2% Y-o-Y Growth in the US Business
- 176 Cumulative ANDAs filed
- 145 Cumulative ANDAs approved, including tentative approvals

During this period, the Company made significant strides in regulatory matters, filing a total of 176 abbreviated new drug applications (ANDAs) and 2 new drug applications (NDAs). The Company's presence in the US market is strengthened with 132 ANDAs approved, 13 tentative approvals received and 2 NDAs approved.

Alkem's ANDA filings and approval (chart)

Year	Total filed (cumulative) *	Total approved (cumulative)*#
2013-14	49	15
2014-15	63	19
2015-16	77	31
2016-17	91	39
2017-18	108	50
2018-19	127	70
2019-20	144	89
2020-21	152	110
2021-22	163	123
2022-23	175	134
2023-24	178	147

*includes NDA

#includes tentative approvals

The international business has grown substantially, making the US pharmaceutical market the second-largest market for the Company. Despite previously faced COVID-19 challenges, heightened price erosion, and fierce competition, the US business has maintained its resilience.

Update on USFDA Inspections

During the year, the USFDA inspected company's manufacturing facilities at Ankleshwar, Mandva, and Baddi. Post-inspection outcomes are as below:

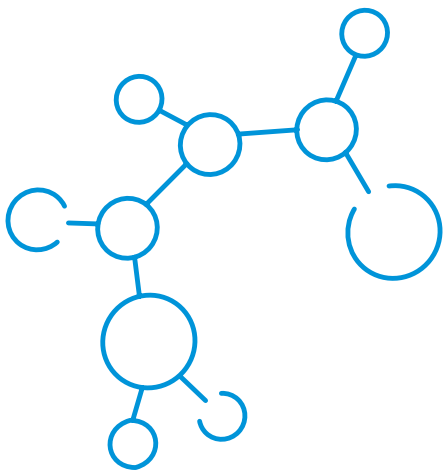
- **April 2023 -** USFDA inspected the Company's manufacturing facility located at Ankleshwar. The inspection was closed successfully without any observations. Establishment Investigation Report (EIR) was received in June 2023.
- **December 2023 -** USFDA had inspected the Company's manufacturing facility located at Mandva. At the end of the inspection, the Company received Form 483 with three (3) observations. Subsequently, the Company received an EIR in March 2024, thereby closing the inspection successfully.
- **March 2024 -** US FDA had inspected at the manufacturing facility located at Baddi. At the end of the inspection, the Company received Form 483 with ten (10) observations. There was no data integrity related observations and the Company has submitted a detailed corrective and prevention action plan to get a closure of the inspection.

The Company places a strong emphasis on delivering high-quality products and adhering to regulatory compliance. The Company invests in its people, processes and technology to remain compliant with the evolving cGMP norms. This strategic approach positions Alkem for continued growth and success.

Status of USFDA inspections

Facility	Inspection Date	Regulatory Status
Baddi (India)	Mar-24	Received Form 483 with ten observations for USFDA inspection done between 19-27 March 2024. Response submitted to USFDA.
Daman (India)	Aug-19	EIR received in October 2019
Taloja R&D (India)	Oct-22	No observation
Ankleshwar (India)	Apr-23	EIR received in July 2023
Mandva (India)	Dec-23	EIR received in March 2024
California (USA)	Aug-18	EIR received in October 2018

Note: USFDA conducted Virtual Inspection at our manufacturing facilities located at Daman from 5 October to 7 October 2020.



About 70-75% of products are manufactured in-house in the Daman and Baddi plants as dedicated manufacturing facilities. To cater to international market needs, the Company also has a dedicated state-of-the-art R&D facility with an in-house CRO unit and Formulation R&D at Taloja and API R&D at Mandva.

Outlook for the US Business

The US pharmaceutical market is essential for global pharmaceutical companies due to its size and purchasing power. Despite heightened competitive intensity and price erosion, there are ample attractive growth opportunities. To maintain competitiveness, the Company prioritizes profitability through cost-efficient measures, enhanced quality filing procedures, and investment in research and development to expand the product portfolio.

The Company is steadfast in its commitment to fortify its market presence by strategically concentrating on key therapeutic domains Neuro/CNS, anti-infective, anti-inflammatory, Oncology and anti-epileptic therapies, ensuring a robust foothold in the healthcare industry.

Our key product portfolio includes 44 products ranked in the Top 3 by market share, with 13 products having a market share greater than 30%. Alkem sells through its subsidiaries and partners to wholesalers, pharmacies, stockists and hospital / institutional customers. About 70-75% of our products are self-manufactured within the Daman and Baddi facilities, which are specialized plants dedicated to our production needs for catering to international markets.

To meet the demands of the global market, the Company maintains a state-of-the-art R&D facility equipped with an in-house CRO unit, alongside Formulation R&D at Taloja and API R&D at Mandva, reflecting our dedication to innovation and quality. The Company has a robust regulatory track record for all its manufacturing facilities.

Competitive intensity is at an all-time high with an efficient FDA approval process resulting in increased competition for almost all products. Amidst a strong competitive market, the Company exhibited resilience.

The US has been a crucial growth driver for generics, with an average of 8-10 ANDA filings per year. New launches averaged at 6-8 per year.

The increasing demand for affordable biologic treatments presents significant growth opportunities in the biosimilar market. Alkem is investing in R&D in biologics through its subsidiary, Enzene Biosciences.

Outlook for Other International Market Business

The Company is endeavoring to enhance its reach in the 40 international markets it is currently present in, apart from India and the US. Its key markets include LatAm, Australia, Europe (UK, Germany) and RoW markets (Philippines, Kazakhstan, South Africa, East Africa, etc.).

In FY 2023-24, the Company's revenues from Other International Markets business grew by 33.3% YoY to ₹ 12,346.3 million, with healthy growth in key markets such as LatAm, and Europe.

The international business is a crucial growth factor. The Company is committed to growing its presence in newer markets and also deepening its reach within existing markets. China and Mexico are the focus markets where Alkem is looking to invest. The Company is looking to introduce tailored products suiting local requirements.

Key international markets	Growth strategies
Australia and New Zealand	Supplement with some dedicated development
LatAm	Fastest growing market in past 3 years
	In-licensing is a key strategy for having a healthy and dynamic portfolio.
	Entering Mexico market as a part of our key strategic initiative for Latam.
Europe	Focus on portfolio creation
	Building relationships with chains in the UK
	Commercial and distribution infrastructure in DE
China	We are looking to enter these markets, which need R&D investments with gestations upwards of 3-5 years.
	The portfolio needs to evolve, robust pipeline is required.

Enzene Biosciences

Enzene is an innovation-driven biotech company and subsidiary of Alkem Laboratories. Enzene's focus lies in developing and producing biosimilars, novel biologics, synthetic peptides and phytopharmaceuticals. Enzene also offers a range of biologics contract development and manufacturing (CDMO) and contract manufacturing organization (CMO) services with capabilities from clone development up to GMP manufacturing supported by bio-reactor capacities ranging from 20 liters to 2,000 liters.

Enzene has established fully integrated biotech process development and manufacturing capabilities across multiple modalities and platforms by deploying disruptive and innovative cutting-edge technologies. Enzene has successfully leveraged its platform to develop a captive pipeline of biosimilars that have been out-licensed to pharmaceutical companies across global markets while also offering end-to-end CDMO services to biotechnology companies.

Enzene is amongst the first movers globally, to have set up an end-to-end continuous manufacturing platform for biologics. The world-class facility in India is equipped with the most advanced equipment in the field of monoclonal antibodies (MABs) and therapeutic protein manufacturing, single-use technology for drug substance manufacturing, and a fully automated fill and finish machine for drug product manufacturing. The facility is capable of higher production versus a traditional biologic manufacturing facility at a lower cost of manufacturing and enables rapid movement of pre-clinical assets to the later stage of development or the commercial stage. This is expected to facilitate the entry of biologics into price-sensitive markets.

Presently, Enzene, through its USA subsidiary, Enzene INC, is setting up a CDMO facility in New Jersey, US, helping Enzene to expand its global footprint. The facility is expected to be commissioned in FY 2024-25. Enzene is looking to become a CDMO partner for US biotech firms and help them bring promising molecules to markets.

Biologic drugs have seen rapid growth across therapeutic areas leading to a US$ 300 billion market. The significant increase in biologic drugs being developed has outpaced worldwide supply capabilities, creating immense opportunities for high-quality contract manufacturers. In addition, the wave of patent expiries within the segment has also led to a significant opportunity for biosimilar products. Enzene has commercialized seven biosimilars in India and has another eleven products in the pipeline at various stages of development. Many of its in-market and pipeline products have already been partnered for commercial rights in emerging and regulated markets.

Key highlights of FY 2023-24

- Enzene generated robust growth in revenue from product sales and CDMO
- For all products, Enzene was able to see an increased offtake due to market growth and the addition of commercialization Partners. Enzene was able to tap and penetrate a significant portion of the market
- In the CDMO space, Enzene has been able to sign deals with multiple companies to develop novel biologics
- Enzene inaugurated its new cutting-edge R&D facility spanning over 75,000 square feet and equipped with an open lab set-up that promotes cross-departmental collaboration, efficient communication, and knowledge sharing. This facility will significantly enhance Enzene's capabilities to serve its valued CDMO partners with greater efficiency and excellence
- Enzene received marketing authorization to commercialize three biosimilar products in India, namely, Cetuximab, Bevacizumab and Ranibizumab
- Enzene has been active in the product development space and has a few molecules that are in the development/ clinical trial stage
- Global clinical trials have progressed from last year, and Enzene, with its robust partner selection strategy, have signed out-licensing & supply partnerships with market leaders across regulated and semi-regulated markets to commercialize these products in the near future. These deals will generate revenue in the near term
- Enzene also established its biologics CDMO business using a novel and disruptive continuous bio-manufacturing platform from pre-IND to the clinical stage and executed agreements with companies across the US, Europe and India which helped in generating revenues from this segment. Enzene, thus established itself as a one-stop shop with "clone to vial" capabilities. It is capable of fully integrated process development capabilities across cell line development, upstream & downstream processes, advanced analytical & bioanalytical characterization and drug product development

Research and Development (R&D)

The Company's clinical research facility is currently focused on bioequivalence and bioavailability studies aimed at proving the bioequivalence of dosage forms. Various Indian and international regulatory agencies, such as DCGI, USFDA, UK MHRA, and NPRA-Malaysia inspect the facility. The Company's clinical division has successfully faced several audits and regulatory inspections, with many products being approved and marketed based on the acceptance of the submitted data by the regulatory agencies. The Company is dedicated to conducting scientifically robust and ethical clinical trials to address unmet healthcare needs and generate quality data for the development of effective and safe novel molecules.

The Company has significant experience in conducting local and global clinical trials from Phase 1 through Phase 4 clinical studies across multiple therapies in accordance with ICH GCP and several other international guidelines and regulations. The R&D team has gained extensive experience and expertise in conducting clinical studies on small and large molecules, including monoclonal antibodies and biosimilars, as well as stem cell-based products for domestic and global regulatory submissions like CDSCO, USFDA, and EMEA.

The Company's clinical team uses complex, innovative and robust clinical designs such as double-blind, double-dummy, differential ratio design, integrated Phase 1 and 3 studies, interchangeability studies, and adaptive design. These studies involve complex molecules, including peptides, MABs and stem cells. The molecules find applications across different therapy areas but are not limited to, as specified. Enlisted below are examples, including regenerative medicine

1. Infectious disease – Invasive fungal disease, Methicillin Resistant Staphylococcus Aureus (MRSA)
2. Oncology – Metastatic breast cancer, colorectal cancer, head and neck cancer (locally advanced as well as metastatic setting)
3. Endocrinology – Type 2 diabetes mellitus, osteoporosis and obesity
4. Cardiology – Secondary prevention of thrombotic cerebrovascular or cardiovascular disease
5. Hematology – Chronic immune thrombocytopenia
6. Rheumatology – Ankylozing spondylitis, osteoarthritis, rheumatoid arthritis
7. Dermatology – Acne vulgaris, psoriasis, vitiligo
8. Ophthalmology – Neovascular age-related macular degeneration, diabetic macular degeneration
9. Gastroenterology – Gastro-esophageal reflux disease, acid peptic disease
10. Surgical – 3D printing for diabetic foot ulcers

Alkem is developing some cutting-edge innovative products in collaboration with worldwide leading academia and research organizations like Harvard, Johns Hopkins University, NIH (USA), Syracuse University, Biosergen (Sweden) and others. These collaborations are to enable drug development and approvals in leading global markets through company's development capabilities in biotechnology and complex products.

Products filings in key international markets (as on 31 March 2024) –

Markets	Filed	Approved
US (ANDA)	176	145#
US (NDA)	2	2
Australia	79	74
Europe	50	34
UK	39	29
Chile*	238	238
China	5	0
South Africa*	175	115
Kazakhstan*	33	31
Philippines*	31	31
Brazil	2	2
Mexico	47	8

*Includes dossier for each strength

#Includes tentative approval

The Company has a well-established pharmacovigilance system to monitor and review the safety of medicines in patients throughout clinical development and post-approval phases. The Company continuously evaluates the benefit/risk profile of the marketed products and is committed to transparency in communicating these benefits and risks with patients, healthcare professionals, and regulators.

Quality Assurance

The Company's commitment to manufacturing and delivering superior quality products is further strengthened by its quality systems. The Company strictly follows the concept of 'Quality by Design' (QbD) to ensure consistent quality of products developed. This approach is embedded in the Company's R&D, manufacturing units, and quality control laboratories, where employees strive to meet and exceed global standards with respect to safety, quality and efficacy.

In addition to its well-established supply chain network, the Company's robust and mature Quality Management System (QMS) ensures that every product it develops, manufactures

The Company fosters a strong quality-conscious culture to ensure that products meet the highest quality standards. It firmly believes in continuous and sustainable improvement in the overall process to build, simplify and establish a sustainable product supply chain.

and distributes, complies with the applicable laws and statutes of the target country. The Company recognizes the importance of developing its employees' skills through internal and external training to ensure that it continues to meet global standards.

The Company fosters a strong quality-conscious culture to ensure that products meet the highest quality standards. It firmly believes in continuous and sustainable improvement in the overall process to build, simplify and establish a sustainable product supply chain.

The Company's stringent Code of Conduct policy is adhered by all stakeholders, including employees, vendors and partners. This policy is in accordance with national and international regulatory and business standards and guidance. All of the Company's manufacturing facilities comply with the regulatory norms of their respective countries, such as Schedule M for India, various sections of Chapter 21 of the Code of Federal Regulations (21CFR) for the USA, GMP requirements for the European Union (EU) as defined in Eudralex, World Health Organization guidance for GMP compliance (WHO-GMP), Orange Book guidance of UK MHRA, TGA guidance for Australia, and other relevant applicable guidance for rest of world countries.

In accordance with the relevant Current Good Manufacturing Practice (cGMP) guidelines, various regulatory agencies of different countries periodically inspect the Company's manufacturing facilities. The Company constantly upgrades its Quality Management System (QMS) with the current advanced technology to keep in line with compliance with the current regulatory guidance of multiple countries, allowing it to meet stringent quality requirements to be the best and beyond the best.

Overall, the Company's commitment to quality is unwavering, and it strives to provide superior-quality products to consumers and patients while ensuring compliance with all relevant laws and regulations. The Company's adherence to high-quality standards and its culture of continuous improvement enables it to remain competitive and exceed customer expectations.

Risk Management

The Company has implemented a robust Enterprise Risk Management (ERM) framework to proactively identify, evaluate and address risks across its operations in various geographic regions. The Board of Directors has formed a Risk Management Committee responsible for overseeing strategic, operational and financial risk management and ensuring the implementation of effective mitigation plans.

Collaborating closely with department heads, the ERM team identifies both internal and external factors that could potentially hinder the Company's objectives. Moreover, the team consistently monitors shifts in the internal and external landscape to detect emerging threats and risks. The key identified risks, along with the proposed mitigation strategies, have been listed below:

Risk	Impact	Mitigation
Competition Risk	Stiff competition from multiple competitors poses a threat to revenue from that particular product and impacts the Company's competitive advantage position.	The Company's robust emphasis on R&D empowers it to innovate and create products with unique characteristics that are difficult for competitors to replicate. The Company keeps a close watch on the prevailing market trends through its Business Development Team, enabling it to strategically plan the launch of new drug/ molecules in accordance with market demand.
Quality Risk	Inadequate control on internal processes, people and systems may impact product quality and adversely impact the Company's brand equity and attract undesired liabilities, fines or penalties.	Strong adherence to CGMP guidelines enforced by leading regulatory agencies for manufacturing processes leads to quality assurance. Timely and regular quality control checks across manufacturing facilities for all machinery and equipment reduces quality risk significantly.
Pricing Risk	The Company's revenue stream and earnings could suffer negative repercussions in the event of adverse pricing regulations affecting essential products.	Operating leverage is achieved through a diversified portfolio and focus on high-volume growth. Robust cost control measures are in place to ensure high operational efficiency, thereby mitigating any adverse impact on earnings.
R&D Risk	The Company invests significantly in R&D to develop molecules/drugs ahead of competition, keeping in line with current market trends. New drug development costs are susceptible to changes in science and technology, shifts in the types of drugs under development, and changes in the regulatory environment. They also have a direct impact on the Company's revenues and earnings prospects.	Astute business planning with clear objectives in mind ensures that R&D budgets are realistic and profitable. Adoption of cost-effective processes and methodologies enables the Company to achieve cost optimization of both existing products and new launches.
Manufacturing Facility Risk	Most of the domestic production is done at Sikkim Facility. Any disruption in production or supply chain at the facility poses a significant threat to business continuity.	To ensure steady and uninterrupted production, the Company is looking to set up alternative in-house manufacturing facilities and use contract manufacturing.
Regulatory Risk	The Company is governed by several rules and regulations enforced by various governing bodies. Non-compliance or misinterpretation may lead to inadequate adherence.	Compliance and integrity are the cornerstones of the Company's organizational values. Strict adherence to all applicable rules and regulations is ensured through various policies and review mechanisms. The Company's strong internal control framework has bolstered its brand equity, particularly in terms of CGMP compliance with respect to various global regulatory guidelines.

Risk	Impact	Mitigation
Information Technology Risk	Redundancy in technology used, lack of proper technological support or lack of awareness of information security among employees may result in breach/theft of confidential data, posing a risk to business growth.	To avoid breaches related to the Company's or stakeholders' data, the vulnerability of technology and IT systems is evaluated on a regular basis through VAPT and IT audits. Further, Microsoft Active Directory enables the Company to enforce Information Security Policy.
People Risk	Human capital is a crucial resource for the Company's growth. Thus, making it imperative to attract and retain quality talent.	Multiple initiatives help to attract and retain talent through development programs, encompassing global talent management, competitive remuneration, inclusive work culture and other employee benefit programs. Specialized pharmaceutical courses are designed and offered by the Company via strategic tie-ups with reputable institutions, enabling skill development and also motivate the employee and increase loyalty.
Climate Change	Lack of energy efficiency consciousness can pose a negative impact on sustainability and result in increased operational costs due to the high energy usage in chemical processes, extensive refrigeration, air conditioning, steam generation, power transmission, and various system operations.	Multiple initiatives have been adopted for energy management. Further, a science-aligned decarbonization roadmap is under development to help the Company manage its emissions and energy usage.
Environment Impact Management	Managing of water and waste are critical issues for the Company to create a positive environmental footprint. Focused efforts for efficient water usage, reduced waste generation and proper disposal are imperative to demonstrate the Company's commitment to a healthy planet.	The Company has identified opportunities to manage its environmental impact. It has established targets for water conservation and waste management. It is focusing on efficient water consumption, reducing water withdrawal and increasing water recovery. For waste management, it is focusing on increasing the share of recycling and reuse within its operations.

Internal Control System

The Company has established a robust global internal control framework fostering a culture of ethics and integrity while ensuring efficient business operations, protection of assets, prevention of fraud, reduction in errors, and compliance with regulatory standards. This framework includes financial, operational and regulatory controls commensurate with the size and complexity of the business.

To further fortify these measures, the Company has engaged a leading Big4 audit firm. Additionally, an autonomous global Internal Audit Function operates at the corporate level, conducting risk-based audits to assess the adequacy and effectiveness of controls. The Audit Committee, which manages oversight of this process, is responsible for endorsing the annual audit plan and reviewing key findings to evaluate the Internal Audit Function's performance.

Compliance with laws, regulations and industry standards is deeply ingrained in the organizational culture through ongoing training and awareness programs. Investment in state-of-the-art information systems security is prioritized to safeguard sensitive data and prevent cybersecurity threats. Continuous improvement is fundamental to the Company's approach, with an aim to enhance internal controls based on both internal and external audit findings, as well as industry best practices.

Human Resources

Human capital is a vital resource for organizational growth and continuity. The Company considers its workforce to be the cornerstone of its achievements at the global level. The Company maintains a safe, conducive and productive work environment across its plants and offices. Our HR team continues to invest in strategic training and skill development programs for its employees to ensure employee goals are aligned with organizational goals. Robust HR practices act as effective tools to attract and retain talent. The Company fosters a learning culture and motivates employees to maintain a healthy work-life balance. Various employee benefits and reward & recognition programs enable the Company to boost employee morale and enhance job satisfaction. In keeping with changing times, various technological advancements have been incorporated within HR team functioning.

During the year, as the Company completed 50 years of successfully serving the pharmaceutical industry, employee contributions were duly acknowledged with the spectacular Golden event. Along with unveiling the Alkem Credo, "Inspiring Healthier Lives," to reinforce its steadfast commitment to global health improvement, the Company unveiled the Alkem anthem and the Alkem Coffee Table Book. In the process of building a culture of learning and development and enhancing capabilities to be future-ready, Alkem Learning Academy hosted multiple capability development initiatives at various levels including classroom, experiential and digital interventions. This was supplemented with multiple initiatives including regular hygiene trainings for medical representatives and line managers in the field, culture building program – "Culture We Wish to Nurture" with senior leadership team in the field, LEAD workshops, Pathshala workshops, outbound training workshops, etc. For the fourth consecutive year, the Company has been certified as 'Great Place to Work For'.

Cautionary Statement

The information provided in the 'Management Discussion and Analysis' regarding the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events are referred to as 'forward-looking statements'. They are subject to applicable securities laws and regulations. Several factors, including but not limited to global and domestic economic conditions, successful execution of strategies, research and development, growth and expansion plans, technological advancements, changes in laws and regulations that apply to the Company, increasing competition, and the conditions of customers, suppliers and the overall pharmaceutical industry, are likely to impact the Company's performance and may cause the actual results to vary materially from those expressed or implied. Any subsequent development, new information or future events or otherwise that may impact any forward-looking statements, need not be publicly updated, amended, modified or revised by the Company except as required by applicable law.