# IPO Note

August 03 2023

## Concord Biotech Limited


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**Issue Snapshot:**
Issue Open: Aug 04 – Aug 08, 2023

Price Band: Rs. 705 – 741 (Discount of Rs 70 for all eligible employees)

*Issue Size: 20,925,652 eq sh (Entirely Offer for sale including Employee reservation of 10,000 eq sh)

Reservation for:

| | | |
|---|---|---|
| QIB | upto | 50% eq sh |
| Non-Institutional | atleast | 15% eq sh |

((including 1/3rd for applications between Rs.2 lakhs to Rs.10 lakhs))

| | | |
|---|---|---|
| Retail | atleast | 35% eq sh |

Face Value: Rs 1

Book value: Rs 123.31 (March 31, 2023)

Bid size: - 20 equity shares and in multiples thereof

100% Book built Issue

**Capital Structure**:

| | | |
|---|---|---|
| Pre Issue Equity: | Rs. | 10.46 cr |
| *Post issue Equity: | Rs. | 10.46 cr |

Listing: BSE & NSE

Book Running Lead Managers: Kotak Mahindra Capital Company Limited, Citigroup Global Markets India Private Limited, Jefferies India Private Limited

Sponsor Bank: Axis Bank Ltd & ICICI Bank Ltd

Registrar to issue: Link Intime India Private Limited

**Shareholding Pattern**

| Shareholding Pattern | Pre issue % | Post issue % |
|---|---|---|
| Promoter and Promoter Group | 44.08 | 44.08 |
| Public & Employees | 55.92 | 55.92 |
| **Total** | 100.0 | 100.0 |

*=assuming issue subscribed at higher band
Source for this Note: RHP

## Background & Operations:

Concord Biotech Limited (CBL) is an India-based biopharma company and one of the leading global developers and manufacturers of select fermentation-based APIs across immunosuppressants and oncology in terms of market share, based on volume in 2022, supplying to over 70 countries including regulated markets, such as the United States, Europe and Japan, and India. It commanded a market share of over 20% by volume in 2022 across identified fermentation-based API products, including mupirocin, sirolimus, tacrolimus, mycophenolate sodium and cyclosporine. As of March 31, 2023, CBL had a total installed fermentation capacity of 1,250 m3. In 2016, it launched its formulation business in India as well as emerging markets, including Nepal, Mexico, Indonesia, Thailand, Ecuador, Kenya, Singapore and Paraguay, and have further expanded to the United States.

CBL manufacture (i) bio-pharmaceutical APIs through fermentation and semi-synthetic processes, across the therapeutic areas of immunosuppressants, oncology and anti-infectives; and (ii) formulations, which are used in the therapeutic areas of immunosuppressants, nephrology drugs and anti-infective drugs for critical care. It is amongst the few companies globally that have successfully and sustainably established and scaled up fermentation-based API manufacturing capabilities. As of March 31, 2023, it had six fermentation-based immunosuppressant APIs, including tacrolimus, mycophenolate mofetil, mycophenolate sodium, cyclosporine, sirolimus and pimecrolimus. It aims to continue to grow its immunosuppressant API portfolio, which will remain one of the key contributors to its API business in the near future.

CBL has invested significantly in capacity expansion in recent years. With its increased capacities, it is in the process of scaling up its API production to serve more customers. As of March 31, 2023, it had 23 API products. It had filed 128 Drug Master Files ("DMFs") across several countries for its APIs, including 20, 65 and four, respectively, in the United States, Europe and Japan, as of June 30, 2023. In India, it markets a portfolio of 27 brands across immunosuppressants, nephrology drugs and anti-infective drugs for critical care. It has a presence across 20 states and five union territories in India, through its sales team. It also has a B2B contract development manufacturing organization ("CDMO") business where it supplies immunosuppressants to the Indian market. Its immunosuppressant formulations are manufactured in facilities inspected or accredited by overseas regulators, such as the USFDA, and distributed to the United States and countries in Asia, Africa and Latin America on a B2B basis, primarily through arrangements with distributors.

The Company's return on capital employed, defined as restated profit before tax and finance costs (excluding interest expense on lease liabilities) divided by the aggregate of tangible net worth (closing net worth less intangible assets), total borrowings and deferred tax liabilities, was 28.54%, 20.55% and 24.27% for the Financial Years 2021, 2022 and 2023, respectively. Its return on equity, was 26.55%, 16.64% and 20.06% for the Financial Years 2021, 2022 and 2023, respectively.

## Objects of Issue:

The objects of the Offer are to (i) achieve the benefits of listing the Equity Shares on the Stock Exchanges; and (ii) carry out the Offer for Sale of up to 20,925,652 Equity Shares by the Selling Shareholder. Further, CBL expects that the proposed listing of its Equity Shares will enhance its visibility and brand image as well as provide a public market for the Equity Shares in India. The Company will not receive any proceeds from the Offer.

### Competitive Strengths

**Established presence across the complex fermentation value chain:** CBL has established capabilities across the fermentation value chain. The fermentation value chain encompasses aspects such as R&D, patents, key starting materials, API and formulation manufacturing, as well as marketing and distribution of fermentation-based products. In addition, it has honed its capabilities across the fermentation value chain, which it leveraged to build a track record across multiple products in various therapeutic areas. Over the last two decades since 2001, CBL has been able to build difficult-to-replicate technical expertise in the fermentation process, which has enabled it to develop and commercialize a wide spectrum of fermentation-based APIs. It has a large portfolio of fermentation-based APIs across a wide range of therapeutic areas, including immunosuppressants, anti-infectives, anti-fungals and oncology with backward integration up to the key starting material level for some of its key APIs. CBL's total annual installed fermentation capacity for APIs was 1,250 m3, as of March 31, 2023. Its business model aims to capture opportunities within the fermentation segment across APIs, formulations and other adjacencies, by combining its R&D and production capabilities. Its integration of R&D, patents, key starting materials, API and formulations manufacturing and marketing and distribution allows it to cater to its customers' specific requirements and provide them with customized solutions. Its ability to do so further enhances its business profile and strengthens its customer relationships.

**Global leadership in immunosuppressant APIs along with a wide spectrum of complex fermentation-based APIs across multiple therapeutic areas:** CBL is one of the leading global developers and manufacturers of select fermentation-based APIs across immunosuppressants and oncology in terms of market share, based on volume in 2022. It commanded a market share of over 20% by volume in 2022 across identified fermentation-based API products, including mupirocin, sirolimus, tacrolimus, mycophenolate sodium and cyclosporine. As of March 31, 2023, it had six fermentation-based immunosuppressant APIs. The global demand for immunosuppressant APIs is expected to increase, driven by the growth of the immunosuppressant formulation markets. In particular, the growth is expected to be driven by organ transplantation becoming more common, where patients would need to take immunosuppressants for the rest of their lives. As an established fermentation-based immunosuppressant API manufacturer, CBL is well-positioned to benefit from the growth potential in the immunosuppressant drug market.

In addition to immunosuppressants, CBL manufacture fermentation-based APIs for the therapeutic areas of anti-bacterials, anti-fungals and oncology. As of March 31, 2023, it had a portfolio of five, three and six commercialized fermentation-based anti-bacterial, anti-fungal and oncology drug APIs, respectively. The oncology drug market is expected to be the fastest growing among the therapeutic areas, with a CAGR of 14.3% from 2022 to 2026 in terms of revenue. Its growth in the near future will be primarily driven by the anti-infective and oncology drug markets.

**Scaled manufacturing facilities with a consistent regulatory compliance track record and supported by strong R&D capabilities:** CBL have three manufacturing facilities in the state of Gujarat, India. Its API manufacturing facilities in Dholka and Limbasi are divided into a total of 41 manufacturing blocks to process different classes of APIs, which provides flexible plant configuration and allows it to scale up production volume to meet increased demand, such as through running parallel processes across different classes of APIs. It also have a formulation manufacturing facility in Valthera, which had an annual installed production capacity of 801.64 million units, with an average dosage capability of 0.45 million tablets, 0.36 million capsules and 646.46 bottles of dry syrup per shift, which is defined as eight hours of production. It has the ability to expand its installed capacity at the existing manufacturing facilities, which may help it reduce the need for significant capital expenditure on capacity expansion in the near term, as compared to setting up new manufacturing facilities. It's focus on undertaking measured capacity expansion in line with its plans of product launches and increase in product sales. All its manufacturing facilities possess effluent treatment processes, including facilities aimed towards zero liquid discharge.

CBL's manufacturing of APIs and formulations have been supported by its R&D capabilities. It has dedicated R&D units for both APIs and formulations. Each of them is approved by DSIR, India. Its R&D team, comprising 148 members, including members having doctoral qualifications, had commercialized 23 fermentation-based APIs, as of March 31, 2023. It is experienced in diverse strains, including actinomycetes, streptomycetes, bacterial, fungi and E. coli. In addition to developing a generic portfolio of complex and niche APIs, its R&D initiatives had created 23 non-infringing processes of developing APIs and approaches to invalidate existing patents in the market, as of March 31, 2023. As on June 30, 2023, it has registered two patents, obtained four ANDA approvals for six products from the USFDA for formulations and had 77 approved products for formulations. It filed 128 DMFs for APIs, as of June 30, 2023. In addition, it assisted its customers with four Paragraph IV filings with its APIs. CBL improves its analytical processes through physical, chemical and microbiological instrument analyses, developing and validating stability-indicating methods and material compatibility studies. With its R&D capabilities, it offers contract research and manufacturing services, where it collaborates with third-party pharmaceutical companies to develop fermentation-based and semi-synthetic NCEs and small molecules.

**Diversified global customer base with long-standing relationships with key customers:** Over the years, CBL has established long-standing relationships with certain key customers, including leading global generic pharmaceutical companies. As of March 31, 2023, it

had over 200 customers in over 70 countries for both its API and formulation products. For its APIs, it had filed 128 DMFs across several countries, including 20, 65 and four, respectively, in the United States, Europe and Japan, as of June 30, 2023. It supplies APIs to customers such as Intas Pharmaceuticals Limited and Glenmark Pharmaceuticals Limited, which has been its long-term customers. As of March 31, 2023, it had relationships with Intas Pharmaceuticals Limited and Glenmark Pharmaceuticals Limited, two of its ten largest customers by revenue for each of the Financial Years 2021, 2022 and 2023, for around 11 years and 18 years, respectively. A majority of its customers are from regulated markets. In addition, it has developed relationships with 48, 47 and 60 new customers during the Financial Years 2021, 2022 and 2023, respectively. Its APIs are provided under a B2B model to pharmaceutical companies globally.

For CBL's formulations business as well, it operates through a B2B model across United States and emerging markets under arrangements with distributors. Its ability to build and strengthen its relationships with its key customers stems from various factors, such as the high quality of its products, its R&D and manufacturing capabilities, its track record of compliance with the various regulatory standards of jurisdictions in which it supplies its products, the consistency of its supply and its competitive pricing. In India, CBL market immunosuppressant, nephrology and anti-infectives drugs for critical care, which it market under its own brands and through its sales force model. As of March 31, 2023, the Company offered formulations across 20 states and five union territories in India, covering over 1,500 government and corporate hospitals.

**Experienced Promoters, management team supported by marquee investors:** CBL is managed by a Promoter-led management team, including Mr. Sudhir Vaid, one of its Promoters and the Chairman and Managing Director on its Board. He has previously been associated with Ranbaxy Laboratories Limited and as a part of M/s. Sudman Consultants acted as a consultant for companies such as Plus Chemicals S.A., Lek Pharmaceuticals & Chemicals Co. and Biocon India Limited, he has been playing a crucial role in building technology capabilities, scaling up manufacturing facilities and developing R&D division. CBL's professional management team is supported by over 1,200 employees, including strong R&D, production, quality and regulatory compliance and marketing teams. As of March 31, 2023, it had 148, 290 and 144 employees in its R&D, quality and regulatory, and marketing teams, respectively. It is also backed by RARE Enterprises (through RARE Trusts), which is an Indian asset management firm with investments across biotechnology, healthcare and other sectors. The Company benefit from the capital sponsorship and professional expertise of its investors.

**Financial track record of rapid growth and consistent profitability with healthy cash flows and shareholder returns:** For the Financial Years 2021, 2022 and 2023, CBL's total revenue from operations was ₹6,169.43 million, ₹7,129.33 million and ₹8,531.68 million, respectively, representing a CAGR of 17.60% from the Financial Years 2021 to 2023; and its EBITDA was ₹3,271.02 million, ₹2,696.36 million and ₹3,452.47 million, respectively. It has been able to maintain a high profit margin because of its niche and complex product portfolio. While it has been funding its continuous investments with internal accruals and limited external financings, it has consistently distributed dividends of more than 30% of its net income to its equity shareholders over the last eight years.

**Business Strategy:**

**Continue to increase API market share and further develop portfolio of complex and niche APIs with high growth potential:** CBL strives to capitalize its leadership position in the field of fermentation-based APIs across these therapeutic areas and continue to grow its API business by:

*Increasing the wallet share from its existing API customers*. CBL not only intends to increase the sales of API products to existing customers, but also focus on cross-selling other API products to these customers. Its significant investment into new manufacturing capacity has enabled it to be well-positioned to grow its wallet share from existing customers. Additionally, it maintains the ability to further expand manufacturing capacity at the existing manufacturing facilities to cater to customer demands.

*Marketing existing APIs to new customers.* With increased manufacturing capacities, CBL has the ability to serve additional customers with its existing API portfolio. Given it has significantly expanded its manufacturing capacities, it intends to achieve optimal potential from the APIs that it commercialized in recent years. It also intends to acquire new customers globally and expand its international customer base, through increasing worldwide marketing activities for its APIs. In addition, it endeavors to increase the global market share of its APIs through additional regulatory filings.

*Expanding API portfolio*. Leveraging the technical expertise CBL has accumulated over the years, it will continue to focus on developing niche and complex fermentation-based products with high growth potential to ensure profitability and strengthen market leadership. It also intends to leverage its expertise in fermentation technology and capture the opportunities to manufacture the low-volume high value fermentation-based APIs which will go off-patent.

Several global pharmaceutical companies have been increasingly seeking to consolidate their supplier base and strengthen existing supply chains. With CBL's reputation in fermentation and its track record of developing and commercializing fermentation-based APIs to meet customer needs, it is well-positioned to leverage this trend to further strengthen its long-standing relationships with these pharmaceutical companies and increase the market share of its API portfolio.

**Increase the presence of existing formulations and expand into new formulations:** CBL intends to pursue growth opportunities for its formulations in India, emerging markets, and the United States. Launched in 2016, its revenue from contracts with customers based on products in its formulation business amounted to ₹1,100.65 million for the Financial Year 2021, ₹1,380.26 million for the Financial Year 2022, and ₹918.54 million for the Financial Year 2023, representing 17.84%, 19.36% and 10.77%, respectively, of its total revenue from operations for the respective years. It plans to grow its business by expanding geographic reach, launching newer dosage forms, and expanding its formulation portfolio with a focus on improving its profitability as well as utilizing its formulation manufacturing capacity more efficiently.

**Improve cost management and operational efficiencies:** CBL plans to enhance its profitability by continuing to improve its cost management and operational efficiencies, including:

*Process efficiency.* The Company strive to improve the production process to optimize its processes and achieve higher yields, with the support of its R&D team.

*Scale efficiency*. CBL seeks to leverage economies of scale through capacity expansion. It incurs certain fixed overheads, including utilities, salaries and depreciation of assets in its operations. It aims to increase capacity utilization, which can reduce fixed overheads per product, increase its profitability and improve operating leverage.

*Product mix.* CBL intends to focus on high-value, low-volume products within its product portfolio. It also seeks to benefit from optimizing its product selection strategy.

## Industry:

**Global API Market**

An API is the biologically-active ingredient of a drug product that is intended to have a specific effect. These effects can range from a pharmacological action to a direct impact on the diagnosis or prevention of disease to altering the physiological functions of humans. A well-formulated API is essential for manufacturing safe and efficacious drugs. The strength of the drug depends on the amount of API present in the formulation.

There are different types of API with different manufacturing needs. For example, synthetic APIs are manufactured using chemical processes such as crystallization. Biotech APIs are produced using fermentation of bacteria or fungus or can be manufactured in bioreactors using cell lines.

API market can also be segmented depending on the manufacturer type-merchant and captive markets. Captive API is API produced internally by pharmaceutical companies for formulation use and accounts for approximately 60% of the market. APIs sold by third-party manufacturers either in the open market or directly to formulation manufacturers is called the Merchant API. According to various industry sources, the merchant API segment accounts for approximately 40% of the market share. However, the Merchant API market is expected to grow at a much higher rate with the increasing outsourcing trend. As formulation companies focus on improving speed-to-market, improving API and resultantly formulation quality, accomplishing cost effectiveness, leveraging external technical expertise, and offsetting internal capacity constraints, they will increasingly rely on quality-focused API suppliers.

**Global API Market Size: High Drug Demand Will Continue to Drive Growth in the API Market**

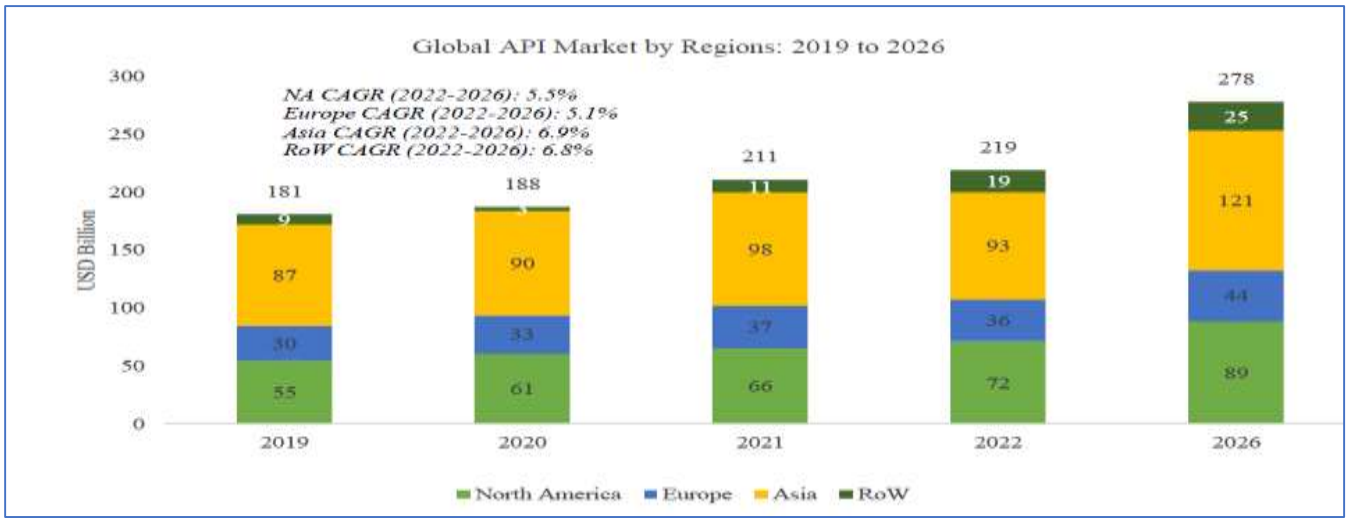
The global API market was valued at approximately USD 219 billion (INR 18,157 billion) in 2022, which constitutes about 16% of the total pharmaceutical formulations market and is expected to reach approximately USD 278 billion (INR 23,051 billion) by the year 2026, at a projected CAGR of 6.1% over the forecast period of 2022 to 2026. Of the total market, biological APIs accounted for 37% of the share in 2022, and small molecule drug APIs accounted for the remainder of 63% share.

The slow growth of the market during the year 2020 can be attributed to the postponement of new drug approvals and launches, disruptions in supply chains due to COVID-19, and a drastic reduction in the number of patient visits to hospitals and clinics resulting in a decline in new prescriptions.

However, the scenario changed in 2021, when the market witnessed a growth spike with the healthcare systems adapting to the new normal (e.g., the proliferation of telemedicine) and supply issues resolved (at least partially). In 2021, the COVID-19 pandemic had a dual impact on the API market, driving volume as well as value (price) increases. On the one hand, the outbreak of COVID-19 increased the demand for various COVID-19 therapeutics, such as antiviral drugs during the peak of infection waves, as well as increased demand for drugs to manage critical comorbidities such as hypertension, chronic obstructive pulmonary disorder ("**COPD**"), and diabetes. The treatment of these comorbidities also led to the positive demand shift towards APIs used in formulations for these therapy areas. The growth rate rationalized in 2022 as some of the APIs' prices regressed to pre-pandemic levels. However, the overall growth in the pharmaceuticals market and drug consumption is expected to sustain long-term growth momentum in the API market.

**Global API Market by Regional Consumption: Asian Markets Will Remain Dominant API Suppliers, As Well As API Consumers, with the Increased Volume of Pharmaceutical Consumption and Adoption of High-Value Innovator Products**

Asia had the highest sales value contribution in APIs, approximately USD 93 billion (INR 7,667 billion) in 2022, and is expected to grow by a CAGR of 6.9% between 2022 and 2026 to reach a value of USD 121 billion (INR 9,995 billion) in 2026. A large part of this growth will be derived from the increasing consumption of pharmaceutical drugs in countries such as India and China and a gradual shift to high-cost innovator drugs. North America was the second largest region, with a market value of USD 72 billion (INR 5,925 billion) in 2022. It is expected to reach USD 89 billion (INR 7,354 billion) by the end of 2026, with a CAGR of about 5.5% between 2022 and 2026. Approximately 16% of the market share was taken up by Europe and is expected to grow at a CAGR of 5.1% between 2022 and 2026, reaching a market size of about USD 44 billion (INR 3,656 billion) by 2026. Western Europe and North America will remain lucrative regions for the supply of innovative APIs as well as APIs for specialty generics. Asia and emerging economies in the Rest of World will continue to offer growth opportunities in the supply of generic drug APIs.




**Market Drivers**

Multiple factors drive the volume and value growth of APIs, resulting in the cumulative growth of the total API market. Some of these factors include:

*Volume Growth*

The increasing prevalence of chronic diseases and improving diagnosis rates are driving volume growth. Furthermore, there has been substantial improvement in diagnosis rates of common diseases globally. Early diagnosis enables early intervention and translates to a more significant number of dosages per patient per lifetime. Secondly, increased volume consumption is also attributable to the fast-growing pharmaceutical sector in emerging markets with advancing healthcare infrastructure and economic prosperity. Lastly, there is growth in pharmaceuticals from the increasing availability of low-cost generic drugs in both developed and emerging markets as expensive innovator drugs lose exclusivity.

*Value Growth*

FDA approved 227 new chemical entities and 88 new biological entities between 2016 and December 2022, of which a measurable chunk of these approvals constitutes complex products such as peptides and SiRNA. The APIs for these formulations are also complex and thus expensive. Likewise, the new generation pipeline drugs also require sophisticated APIs. For instance, 25% of all NCEs under development today are highly potent. The increasing adoption of these complex drugs will drive the growth of high-value APIs.

**Global Fermentation-Based API Market**

Fermentation-derived APIs are active ingredients or intermediates made using microbial or cell line host fermentation. Fermentation products can be naturally derived as well as semi-synthetically processed with a combination of fermentation and chemical synthesis. These APIs are used in a wide range of pharmaceutical products ranging from vaccines to anti-cancer cytotoxic drugs, antibiotics and antifungals, hormonal products, immunosuppressants, and vitamins. A wide array of microorganisms such as bacteria, yeast, fungi, and streptomycetes have been used in fermentation to produce small and low-weight molecules such as peptides, organic molecules, and large molecules such as proteins, nucleic acids (DNA and RNA), and macromolecules such as lipids and carbohydrates, along with a combination of products such as lipopolysaccharides, lipopeptides, and peptidoglycans. These molecules now constitute a large section of the APIs used by the pharmaceutical industry for the treatment of rare and chronic diseases such as cancer, autoimmune diseases, and central nervous system disorders.

**Global Fermentation API Market by Regional Consumption**

Asia is the largest consumer of fermentation-derived small molecule APIs, driven by the high use of antibiotics and the increasing use of oncology and immunology drugs. Asia, including countries such as India, China, and Japan, accounted for 51% market share by volume (Source: IQVIA MIDAS Dataset) (and approximately 25% by value) of the fermentation API market in 2022. In addition to holding a dominant share, the Asian region is forecasted to grow at the fastest rate owing to the increase in healthcare expenditures, cases of chronic diseases, and effective government policies supporting the booming pharmaceutical market. This dominance in some parts is attributable to the higher use of anti-infective drugs (which account for the largest share of fermentation-derived APIs) in Asia and Rest of World markets, given the higher vulnerability to infectious diseases. Additionally, the Asian markets are dominated by older generation of affordable generic drugs, compared to western regions, which adopt a new generation of specialty products more readily. Europe is the second largest market, accounting for a 19% share by volume (Source: IQVIA MIDAS Dataset) (and approximately 22% by value) in 2022. The Rest of World and North American markets accounted for 17% and 13% by volume (Source: IQVIA MIDAS Dataset), and approximately 10% and 43% by value, respectively.

In line with the global trend of greater dispensing of generic prescription drugs in North America, the highest proportion of generic API use within these markets was observed in North America, followed by Rest of World and Europe. Additionally, across North America and Rest of World the proportion of generic drugs has been on the rise in the past 3 years.

**India API Market**

India's growth trajectory of the API market is well-cemented for domestic API consumption as well as exports. The Indian API market, valued at USD 17 billion (INR 1,377 billion) in 2022, comprises APIs manufactured for export and APIs consumed in formulation manufacturing. These formulations are domestically consumed as well as exported to the global market. While API exports accounted for USD 5 billion (INR 356 billion) in 2022, APIs required for formulation manufacturing amounted to USD 12 billion (INR 1,035 billion) in 2022.

The total domestic India API market (APIs consumed for exported and domestically consumed formulations) is expected to grow at a CAGR of 11.1% between 2022 and 2026. The API consumption for domestic formulations is also expected to drive high demand in the next four to five years. This growth is in line with the overall growth of pharmaceutical drug consumption in the country. As disease patterns shift from acute to chronic and translate into high drug (and API) volume consumption, access to healthcare facilities and affordable medicine increases, and economic prosperity grows, the growth of the API industry is projected to follow suit. The export during the same period is also expected to grow at a rate of 7% to 9%, but the rate is forecasted to remain lower (than the domestic API market) as Indian formulation manufacturers expand capacity, reduce import dependence, and consume increasing amounts of domestically-produced APIs.

**Export of Bulk Drugs from India**

As India reduces its import dependency and expands its domestic manufacturing capacity, the exports are also expected to grow.

While India does import some bulk drugs, it is also one of the largest API exporters to regulated markets. High process efficiencies, the experience of working with regulatory bodies across the globe, and cost competitiveness have allowed India to emerge as one of the

world's largest API suppliers. In 2017, India exported USD 3 billion (INR 225 billion) worth of APIs, which increased to USD 5 billion (INR 356 billion) in 2022. The bulk drugs have mostly been exported to the United States, where bulk drugs and intermediates worth USD 816 million (INR 61,859) were exported in the calendar year 2022, followed by UAE (8% share), China (5% share), Hong Kong (4% share), Singapore (3% share), and Bangladesh (3% share).

There has been a multi-fold increase in API exports from India since the COVID-19 pandemic, due to reasons including the disruption of supply from China, leading to a shortage of several APIs and intermediates, high price volatility, and quality and pollution concerns (such as impurities) leading to factory shutdowns. It strengthened the adoption of the China Plus One strategy by several MNCs. As global pharmaceutical manufacturers started seeking new cost-effective partners, India owing to its existing strength in the segment and impetus from government policies (such as PLI and Bulk Drug Parks), was able to capture the opportunity.

**Competitive Advantages of India in the API Industry**

Cost competitiveness, coupled with robust infrastructure and strengthening patent laws, differentiates India as an API production destination.

*Strong Chemicals Industry Offering a Foundation for Intermediates and API Manufacturing*

India already has one of the world's largest specialty chemical industries and produces over 70,000 products. According to the IBEF, India is the sixth-largest producer of chemicals globally and the third-largest producer in Asia in terms of output. This provides the necessary foundation to manufacture intermediates and KSMs, including premium quality and advanced intermediates.

*Strong R&D Backbone Allowing for Process Optimization*

Intensive investment in R&D is required to produce APIs cost-effectively, mitigate the risk of poor quality, and reduce environmental degradation. India has a solid technical education infrastructure, including 3,500 engineering colleges, 3,400 polytechnics, and 200 schools of planning and architecture. In addition, India also has an emerging startup ecosystem and growing bilateral partnerships with several countries in the West for research. The strengthening R&D backbone allows for continuous improvement in large-scale manufacturing and product quality.

*Government Initiatives Expanding Manufacturing Capacity*

Fueled by an 'Atmanirbhar' drive and growing preference for India-made pharmaceutical raw materials, the government has introduced several initiatives to increase the capacity of production as well as make production more cost-effective. In addition to raising the FDI cap and implementing new intellectual property ("**IP**") rights framework to attract innovator companies, the Government of India is also driving clustering programs and production-linked schemes. The PLI Scheme will also incentivize API companies to expand capabilities into complex areas such as fermentation.

*Legacy of Serving Highly Regulated Markets for API and Finished Formulations*

India has been a leader both in terms of the number of U.S. DMF filings as well as operating U.S. FDA-approved API facilities. According to U.S. FDA data, in 2022, India accounted for 50% of DMF filings totaling 263 DMFs from a total of 524 filed globally in the year. Likewise, in 2022, India accounted for 28% (215 facilities) of the share of U.S. FDA-approved API plants, almost twice that of the United States (103 facilities) and China (135 facilities), and 28% (328 facilities) share in the overall formulations and APIs plants combined. This proficiency in API and formulations allows India to meet global API demand and offer end-to-end formulation solutions to customers.

*Cost Competitiveness Allows Global Pharmaceutical Manufacturers to Navigate Increasing Pricing Pressures*

Increasing pricing pressure on pharmaceutical drugs from the healthcare systems and insurers has put pressure on profit margins. As a result, formulation manufacturers seek APIs and other raw materials at a competitive price without compromising quality. India offers substantial cost advantages compared to western countries. Firstly, according to industry inputs, the cost of setting up a fully FDA-inspected plant in India is, on average, 50% less than the developed countries. Secondly, compared to the West, the cost of manufacturing and operations is almost 40% to 70% lower in India. Lastly, labor costs are also 60% to 70% lower than western peers.

**Global Pharmaceutical Market Overview**

There is unimpeded growth in the pharmaceutical industry with diverse dynamics across product technology, geographies, and disease areas. The global pharmaceutical industry is undergoing transformation across the entire value chain owing to a focus on product innovation, operational optimization, provider and patient engagement, and extrinsic pressure from governments and insurers to contain costs. Amidst this transformation and associated inherent challenges, the industry has delivered ground-breaking innovations at high speed, such as during the COVID-19 pandemic, driving resilient industry growth.

**Global Pharmaceutical Market Size**

The global pharmaceutical market was estimated to be USD 1.3 trillion (INR 110 trillion) in 2022 (Source: IQVIA MIDAS Dataset) and is expected to reach USD 1.6 trillion (INR 133 trillion) by 2026 growing at a CAGR of 4.8% from 2022 to 2026.

The increased growth in 2021 and 2022 is attributable to the utilization of vaccines and COVID-19 therapeutics. However, with COVID-19 cases declining, other therapeutic areas will again drive growth. Traditional and amplifying contributors of growth to the segment include aging populations with increasing incidence of chronic diseases and sedentary lifestyles leading to obesity, diabetes, and other costly health conditions. In addition, there is improving healthcare infrastructure and access in the emerging markets, which are driving high levels of demand. The pharmaceutical industry has responded to these versatile demands by launching new therapies with curative potential, improving existing therapies by making them more targeted and launching low-cost generic drugs to make medicine more accessible and affordable.

**TACROLIMUS**

Tacrolimus is a potent calcineurin inhibitor and an immunosuppressive agent indicated for preventing organ transplant rejection and treating moderate to severe atopic dermatitis. Initially approved by the FDA for use in liver transplantation, it is now prescribed to kidney, heart, lungs, pancreas, skin, cornea, and limb transplant patients. The originator owned by Astellas Pharma Inc. is sold under the brand names Prograf, Advagraf, Astagraf, and Graceptor. The product's patent expired in 2008, leading to the launch of several generic versions such as by Dr. Reddy Labs Ltd., Panacea Biotech Ltd., Sandoz, and Mylan N.V. Other formulation companies include Novartis, LEO Pharma A/S, Huadong Medicine and Asahi Kasei Pharma Corporation. There is an ongoing evolution in the formulation of tacrolimus. Companies have been introducing new versions of the tacrolimus product, such as extended-release, controlled release, or formulations with reduced dosing requirements. Moreover, as healthcare infrastructure in emerging markets, particularly in the Asia-Pacific, is improving and the number of transplants increasing, a large part of the growth is expected to be generated from these markets. In 2022, the Asian market contributed the highest sales, followed by the European market, accounting for 44% and 31%, respectively.

**CYCLOSPORINE**

Cyclosporine is a steroid-sparing calcineurin inhibitor used as an immunosuppressant for preventing organ rejection in kidney, liver, and heart allogeneic transplants. It is also prescribed for psoriasis, rheumatoid arthritis, and uveitis. In addition, to use as an immunosuppressant, cyclosporine is also used as a tear secretion enhancer. Initially marketed by Novartis, Cyclosporine is sold as Neoral, Sandimmune, and Restasis by AbbVie. Novartis generated USD 296 million (INR 24,495 million) in gross revenue in 2022, experiencing a decline of 15% over the previous year due to increased generic competition. AbbVie generated USD 2 to 3 billion gross revenue in 2022. The earliest patent loss for the product was in 1995, and since then, more than 10 different companies have launched generic formulations for Sandimmune. Restasis, though, has held ground and fended generic launch from 2014 until early 2022. In 2022, Novartis, AbbVie, Huadong Medicine, Sun Pharma, and Apotex collectively accounted for 85% of the market share. North America alone accounted for more than 82% of the total sales value, and Europe and Asia each accounted for an almost equal share of 7% to 10% in 2022.

**MYCOPHENOLIC ACID / MYCOPHENOLATE SODIUM**

Mycophenolate sodium is the sodium salt of mycophenolic acid sold under the brand Myfortic by Novartis. It is mainly used as an immunosuppressive prophylactic to prevent rejection during organ transplantation in combination with other drugs, i.e., cyclosporine and corticosteroids. It is specifically used to slow down the body's immune system response during kidney transplants. The drug was originally launched in 2002, and its patent expired in 2014. Currently, the drug is sold by its originator Novartis, and generic manufacturers, including Biocon Limited, Apotex, and Alkem Laboratories Limited ("**Alkem**"). In 2022, the top five formulation companies accounted for 92% of the market share, with Novartis alone accounting for 76% of sales value. In the same year, the greatest demand was generated from Asian markets accounting for 38% share, witnessing a jump from 23% in 2019. The North American and European markets accounted for 30% and 28% share, respectively, in the same year.

**MYCOPHENOLATE MOFETIL**

Mycophenolate Mofetil is an inosine monophosphate dehydrogenase ("**IMPDH**") inhibitor indicated for use in combination with other immunosuppressants for the prophylaxis of organ rejection in patients receiving renal, hepatic, or cardiac transplants. Besides transplant, it has been used successfully in primary and secondary glomerulopathies, uveitis, Crohn's disease, rheumatoid arthritis, and lupus. The drug has been in use since the 1990s and was initially launched by Roche under the brand name CellCept. Since the patent expiry in 2007, several companies such as Huadong Medicine, Teva, Alkem, and Intas have introduced generic versions. In 2022,

Mycophenolate Mofetil-based formulations generated sales value of USD 973 million (INR 80,517 million), with the largest contribution from Asian countries. In 2022, Asia accounted for nearly 47% of the market share by sales value, followed by EU5 and North America, accounting for approximately 20% of the share (each) in the market.

**PIMECROLIMUS**

Pimecrolimus is sold under the trade name Elidel and is prescribed as a second-line therapy to treat mild to moderate atopic dermatitis (eczema) in patients who have already been treated with other medicines that did not work well. Pimecrolimus belongs to a class of medicines known as topical calcineurin inhibitors that decrease inflammation. The drug was originally launched in 2001 to 2002 by Bausch Health Companies. The drug's patent expired in 2015 and opened U.S. markets for Teva and Glenmark in the United States. The launch of generic drugs in this segment is expected to cause price erosion that may lead to a decline in the total pimecrolimus formulation market in the future. In 2022, the largest market share (76%) was held by Bausch Health Companies Inc. and Viatris Inc., selling the innovator drug. Sales from North America accounted for 60% of the market in 2022. The highest gain has been witnessed in European sales, which contributed 17% of sales in 2019 and 22% in 2022.

**MUPIROCIN AND MUPIROCIN CALCIUM**

Mupirocin is an anti-bacterial ointment used to treat superficial skin infections such as impetigo caused due to bacteria and used to control MRSA outbreaks. Mupirocin was originally marketed under the brand name Bactroban and sold by GSK; however, it was discontinued in the United States market in June 2020. The key market suppliers were generic suppliers such as Glenmark, Sun Pharmaceutical, and Teva, and accounted for 43% (total generics) of the share by gross revenue. The total formulations sales were estimated to be USD 291 million (INR 24,116 million) in 2022, with North America accounting for 28% of the share and Asia accounting for 43% of the share. Within Asia, the higher demand was from the Southeast Asian region, accounting for a 32% share in 2022.

**TEICOPLANIN**

Teicoplanin is a glycopeptide antibiotic used to treat various infections caused by gram-positive bacteria. The antibiotic is especially used for the treatment of staphylococcal infections. It has been evaluated for various viruses such as Ebola, influenza, flavivirus, hepatitis C, human immunodeficiency ("**HIV**"), and coronaviruses such as MERS and SARS-CoV. With its patent's expiry in 2003, the formulations are now sold by several generic companies in addition to the innovator Sanofi, which commanded 42% of the market in 2022. Generic drugs accounted for 57% of the share in 2022, up from 40% in 2019. Teicoplanin (Targocid) was first approved in Europe in 1988 and is available in many other countries except the United States. Given the absence of drug approval in the United States, the largest sales value was generated in Europe and Asia, amounting to 39% and 56%, respectively, in 2022.

### Key Concerns

- Any delay, interruption or reduction in the supply of raw materials or the transportation of raw materials or products may adversely impact the pricing and supply of the products and have an adverse effect on the business
- Any manufacturing or quality control issues may damage reputation, subject CBL to regulatory action, and expose it to litigation or other liabilities, which could adversely affect the business, financial condition and results of operations.
- A slowdown or shutdown in manufacturing or research and development operations, all located in Gujarat, India, could adversely affect the business, financial condition and results of operations.
- Depends on a limited number of customers for a substantial portion of the revenues. Any significant reduction in demand for products from such customers may adversely affect the business and results of operations.
- If CBL is unable to obtain trademarks and patents for its products or protect such proprietary information, or inadvertently infringe on the patents of others, its business may be adversely affected.
- CBL is subject to extensive government regulations, and if it fails to obtain, maintain or renew its statutory and regulatory licenses, permits and approvals required for its business operations, its business, financial condition, results of operations and cash flows may be adversely affected.
- Inability to accurately forecast demand for its products, manage inventory and utilize manufacturing capacity optimally may have an adverse effect on the business, financial condition, results of operations and cash flows.
- CBL is subject to risks arising from exchange rate fluctuations.

- If CBL does not maintain and increase the number of its arrangements for the marketing and distribution of its products, its business, financial condition and results of operations could be adversely affected.
- Pricing pressure from customers may affect the ability to maintain or increase its product prices and, in turn, its revenue from product sales, gross margin and profitability, which may adversely affect the business, financial condition and results of operations.
- CBL has significant working capital requirements. If it experiences insufficient cash flows to fund its working capital requirements, there may be an adverse effect on the business, cash flows and results of operations
- CBL is currently entitled to certain incentive schemes. Any decrease in or discontinuation in such schemes may affect the results of operations
- Certain therapeutic areas (i.e. categories of medical treatments for diseases or conditions), contribute to a more significant portion of total revenue, and the business, prospects, results of operations and financial condition may be adversely affected if its products in these therapeutic areas do not perform according to the projections of its business plans or if competing products become available and gain wider market acceptance.
- Success depends on the ability to develop and commercialize new products in a timely manner. If CBL's research and development efforts do not succeed or the products it commercializes do not perform as expected, this may hinder the introduction of new products, and could adversely affect the business, financial condition and results of operations.
- Inability to successfully implement business plan, domestic and international expansion plans and growth strategies could have an adverse effect on the business, financial condition, results of operations and cash flows.
- International operations expose CBL to complex management, legal, tax and economic risks, which could adversely affect its business, financial condition and results of operations.
- The COVID-19 pandemic, or any future pandemic or widespread public health emergency, could adversely impact the business, financial condition, cash flows and results of operations.
- The pharmaceutical industry in which CBL operate is highly competitive.
- Non-compliance with and changes in environmental, health and safety, and labor laws and other applicable regulations may adversely affect the business, financial condition, results of operations and cash flows.
- CBL is exposed to counterparty credit risk and any delay in receiving payments or non-receipt of payments may adversely impact the business and results of operations.
- Inability to attract or retain companies who are looking to it for in-licensing in the future could adversely affect its market share.
- CBL enters into out-licensing arrangements for the distribution of its products in certain geographies.
- Delay or failure in the performance of contracts may adversely affect the business, financial condition and results of operations.
- Success depends on the ability to retain and attract qualified senior management and other key personnel, and if CBL is not able to retain them or recruit additional qualified personnel, it may be unable to successfully develop its business.
- The availability of counterfeit drugs, such as drugs passed off by others as its products, could adversely affect the goodwill and results of operations.
- Inability to meet obligations, including financial and other covenants under debt financing arrangements could adversely affect the business, financial condition, results of operations and cash flows.
- CBL currently relies extensively on its systems including information technology systems and products processing/quality assurance systems and their failure could adversely affect its manufacturing operations.
- Changes in technology may render current technologies obsolete or require CBL to make substantial capital investments
- CBL has in the past entered into related-party transactions and may continue to do so in the future.
- Ability to pay dividends in the future will depend on the earnings, financial condition, working capital requirements, capital expenditures and restrictive covenants of financing arrangements.

- CBL has contingent liabilities and capital commitments. Its financial condition could be adversely affected if any of these contingent liabilities or capital commitments materialize.
- Fluctuations in the market value of investments could adversely affect the results of operations and financial condition.
- Operations are labor intensive and CBL may be subject to strikes, work stoppages or increased wage demands by its employees or those of its suppliers.
- Compulsory licensing by the Indian Patent Office or by the patent offices in those jurisdictions where CBL distribute its products could have an adverse effect on the business, financial condition and results of operations.
- Exposed to government price controls that may change from time to time. Such changes, and the uncertainty thereof, may reduce the pricing of and demand for the products, affecting its business, financial condition and results of operations.
- Changing laws, rules and regulations and legal uncertainties, including adverse application of corporate and tax laws, may adversely affect the business, prospects and results of operations.
- CBL may be affected by competition law in India and any adverse application or interpretation of the Competition Act could in turn adversely affect the business.
- Current economic conditions may adversely affect the business, results of operations and financial condition.
- If the rate of Indian price inflation increases, CBL's business and results of operations may be adversely affected.
- Ability to raise foreign capital may be constrained by Indian law.
- Fluctuations in the exchange rate between the Indian Rupee and foreign currencies may have an adverse effect on the value of Equity Shares, independent of the operating results.

**Profit & Loss**

| Particulars (Rs in million) | FY23 | FY22 | FY21 |
|---|---|---|---|
| Revenue from operations | 8531.7 | 7129.3 | 6169.4 |
| Other Income | 353.1 | 234.2 | 138.1 |
| **Total Income** | **8884.8** | **7363.5** | **6307.5** |
| **Total Expenditure** | **5098.8** | **4396.6** | **2893.9** |
| Cost of Materials Consumed | 1670.7 | 1572.6 | 1311.7 |
| Purchases of stock-in-trade | 287.7 | 307.3 | 194.5 |
| Change In Inventories of Finished Goods & Work-In-Progress | -156.3 | -239.8 | -390.5 |
| Employee Benefits Expenses | 1102.8 | 956.9 | 694.7 |
| Other Expenses | 2193.9 | 1799.5 | 1083.6 |
| **PBIDT** | **3786.0** | **2966.9** | **3413.6** |
| Interest | 45.1 | 54.8 | 6.7 |
| **PBDT** | **3740.9** | **2912.1** | **3406.9** |
| Depreciation and amortization | 540.3 | 500.5 | 275.2 |
| **PBT** | **3200.5** | **2411.6** | **3131.7** |
| Share of Profit/ (loss) of Joint venture accounted using Equity method | 19.6 | -36.4 | -4.5 |
| **Tax (incl. DT & FBT)** | **795.5** | **588.8** | **778.3** |
| Current tax | 795.3 | 584.9 | 757.2 |
| Short / (excess) provision for tax of earlier years | 0.2 | 3.9 | -2.3 |
| Deferred tax (net) | 23.8 | 37.1 | 23.4 |
| **PAT** | **2400.8** | **1749.3** | **2348.9** |
| EPS (Rs.) | 23.0 | 16.7 | 22.5 |
| Face Value | 1 | 1 | 1 |
| OPM (%) | 40.2 | 38.3 | 53.1 |
| PATM (%) | 28.1 | 24.5 | 38.1 |

## Balance Sheet

| Particulars (Rs in million) As at | FY23 | FY22 | FY21 |
|---|---|---|---|
| **Non-current assets** | | | |
| Property, plant and equipment | 5,925.2 | 5,680.3 | 5,376.5 |
| Capital work-in-progress | 1,727.0 | 741.6 | 179.5 |
| Right of use assets | 2.6 | 13.7 | 21.5 |
| Intangible assets | 2.0 | 35.8 | 64.2 |
| Investment in joint venture | 0.0 | 0.0 | 3.7 |
| Financial assets | | | |
| *Investments* | 1.3 | 2.6 | 0.0 |
| *Others* | 101.94 | 24.96 | 27.72 |
| Non-Current Tax asset (Net) | 26.7 | 36.0 | 17.0 |
| Other non-current assets | 76.2 | 266.4 | 63.9 |
| **Total non-current assets** | **7,862.8** | **6,801.3** | **5,754.0** |
| **Current assets** | | | |
| Inventories | 2,123.2 | 1,951.2 | 1,536.1 |
| Financial assets | | | |
| *Investments* | 1,369.3 | 734.8 | 1,409.9 |
| *Trade receivables* | 2,737.6 | 2,321.7 | 1,775.2 |
| *Cash and cash equivalents* | 35.0 | 6.7 | 51.4 |
| *Other bank balances* | 399.5 | 882.7 | 556.8 |
| *Others* | 366.0 | 219.8 | 226.3 |
| Other current assets | 246.5 | 209.9 | 515.9 |
| **Total current assets** | **7,277.0** | **6,326.7** | **6,071.5** |
| **Total assets** | **15,139.8** | **13,128.0** | **11,825.5** |
| **EQUITY & LIABILITIES** | | | |
| **Equity** | | | |
| Equity share capital | 104.6 | 95.1 | 95.1 |
| Other equity | 12,795.4 | 10,937.1 | 9,898.6 |
| **Total equity** | **12,900.0** | **11,032.2** | **9,993.7** |
| **Liabilities** | | | |
| **Non-current Liabilities** | | | |
| Financial Liabilities | | | |
| *Borrowings* | 62.4 | 312.5 | 562.5 |
| *Lease liabilities* | 1.6 | 3.1 | 16.3 |
| Provisions | 23.0 | 18.7 | 21.0 |
| Deferred tax liabilities (net) | 234.4 | 209.7 | 174.5 |
| **Total non-current liabilities** | **321.4** | **544.0** | **774.3** |
| **Current liabilities** | | | |
| Financial liabilities | | | |
| *Borrowings* | 250.0 | 293.4 | 301.0 |
| *Lease liabilities* | 1.5 | 16.0 | 13.0 |
| *Trade payables* | | | |
| *Due to micro and small enterprise* | 170.2 | 89.7 | 83.3 |
| *Due to other than micro and small enterprise* | 767.8 | 741.4 | 380.7 |
| Others | 313.4 | 216.4 | 228.2 |
| Other current liabilities | 50.8 | 177.4 | 44.6 |
| Provisions | 274.8 | 17.5 | 6.6 |
| Current tax liabilities (net) | 90.0 | 0.0 | 0.0 |
| **Total current liabilities** | **1,918.5** | **1,551.7** | **1,057.4** |
| **Total liabilities** | **2,239.8** | **2,095.7** | **1,831.7** |
| **Total equity and liabilities** | **15,139.8** | **13,128.0** | **11,825.5** |

Source: RHP

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HDFC securities Limited, I Think Techno Campus, Building - B, "Alpha", Office Floor 8, Near Kanjurmarg Station, Opp. Crompton Greaves, Kanjurmarg (East), Mumbai 400 042 Phone: (022) 3075 3400 Fax: (022) 2496 5066

**Compliance Officer: Murli V Karkera Email: complianceofficer@hdfcsec.com Phone: (022) 3045 3600**

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