ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

3.A. ***[Reserved]***

3.B. ***Capitalization and indebtedness***

Not applicable.

3.C. ***Reasons for the offer and use of proceeds***

Not applicable.

3.D. ***Risk factors***

You should carefully consider all of the information set forth in this Form 20-F and in other documents we file with or furnish to the SEC, including the following risk factors that we face and that are faced by our industry. The risks below are not the only ones we face. Additional risks not currently known to us or that we presently deem immaterial may also affect our business operations. Our business, financial condition, results of operations and/or cash flows could be materially or adversely affected by any of these risks. This Form 20-F also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this report and our other SEC filings. For a summary of the risk factors included in this Item 3.D. and for further details on our forward-looking statements, see “Forward-Looking Statements and Risk Factors Summary” on page 2.

MATERIAL RISKS RELATING TO OUR COMPANY AND OUR BUSINESS

If we fail to comply with the regulatory standards of various regulatory agencies in manufacturing of quality products, it may have potential impact on our business, financials and operations.

Governmental authorities, including among others the U.S. Food and Drug Administration (“U.S. FDA”) and the U.K. Medicines and Healthcare Products Regulatory Agency (“MHRA”), heavily regulate the manufacturing of our products, including manufacturing quality standards. Periodic inspections are conducted on our manufacturing sites, and if the regulatory and quality standards and systems are not found adequate, it could result in an inspection observation (on Form 483, if from the U.S. FDA), or a subsequent investigative letter which may require further corrective actions. In recent years, a number of Indian generic pharmaceutical companies have been issued Official Action Indicated (“OAI”) status notices and warning letters by the U.S. FDA. A significant proportion of our manufacturing base of active pharmaceutical ingredients and formulations plants servicing the United States and other markets of our Global Generics business is based out of India. While our quality practices and quality management systems are designed and maintained in a manner to comply with the highest regulatory and quality standards, the inspections may often lead to non-conformity observations requiring corrective actions. Based on the criticality of the observations and the circumstances, the U.S. FDA may classify the inspection as Voluntary Action Indicated (“VAI”) status or OAI status, may issue warning letters and/or place our products on import alert detention lists. More generally, unless and until an issue, raised in a warning letter from the U.S. FDA is resolved to the agency’s satisfaction, they may withhold approvals of new products and new drug applications, issue import alert notices and/or take additional regulatory or legal action. The delay in approvals due to moving to an alternate site or alternate vendor, or the cost incurred in connection with remedial actions, can have significant adverse impacts on ongoing business, financial results and operations.

We deal with numerous third party manufacturers and, despite our oversight, any lapse in their quality practices and quality management systems could lead to similar adverse outcomes in the event of an inspection by the U.S. FDA.

In recent years China has introduced numerous reforms and proposals that attempt to address requirements for drug development and registration, including greater adoption of international technical guidelines and practices by the government. However, its unique regulatory requirements and procedures continue to pose challenges for multinational companies.

If we fail to meet all the quality and regulatory requirements of biologic drugs and fail to successfully challenge third party patents as allowed by national patent offices, it may impact production and revenues.

A portion of our portfolio are “biologic” products. Unlike traditional “small-molecule” drugs, biologic drugs cannot be manufactured synthetically, but typically must be produced from living animal cells or micro-organisms. As a result, the production of biologic drugs that meet all quality and regulatory requirements is especially complex and is more susceptible to batch failures.

Typically, biological therapeutics face third party intellectual property rights, otherwise known as freedom to operate (“FTO”) issues, more than small molecule therapeutics because of the types of patents allowed by national patent offices. Further, our ability to successfully challenge third party patent rights is dependent on the laws of the applicable countries.

The regulatory requirements are still evolving in many markets where we sell or manufacture products, including our biologic drugs, and regulatory requirements may be unclear due to lack of precedents, among other reasons, which may lead to delays in product approvals or other sanctions. In the United States, the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) created a statutory pathway and abbreviated approval processes for the approval of biosimilar versions of branded biological products. While the U.S. FDA has issued guidelines, the regulatory policies in this area are still evolving. Further, while a number of legal challenges concerning the requirements of the abbreviated biosimilar pathway, patent exchange and other provisions of BPCIA have been adjudicated in U.S. courts, legal challenges concerning FTO, patent exchange and trade matters, among others, continue.

For example, in April 2024 the U.S. FDA issued a complete response letter (“CRL”) in response to our biologics license application (“BLA”) for a biosimilar rituximab. The CRL was in reference to the ongoing resolution of observations arising from the October 2023 inspection of our Biologics facility in Hyderabad, India, as well as certain aspects pertaining to the BLA. Although we intend to address these concerns promptly and resubmit our BLA, there is no guarantee that the U.S. FDA will ultimately approve our resubmitted BLA, and we could experience further delays relating to the development of the biosimilar product.

Our success depends on our ability to successfully develop and commercialize new pharmaceutical products.

Our future results of operations depend, to a significant degree, upon our ability to successfully develop and commercialize additional products in our Global Generics and Pharmaceutical Services and Active Ingredients segments.

Our research and development efforts are also dependent on collaborating with third party partners and contract research organizations which have the capability to handle complex technologies and products. Lack of effective project management at our end, or any failure to manage collaboration arrangements among multiple partners, may pose significant risks to product development, to our ability to obtain requisite regulatory approvals in a timely manner, and to our ability to successfully and profitably produce and market such products.

Additionally, if we fail to adequately protect critical proprietary or confidential information or associated intellectual property rights or fail to manage third party partners and contract research organizations that our business depends on, it might have a material adverse impact on our product development execution.

From time to time we also acquire in-process research and development assets, which require significant resources and expenditures to continue to develop, both through our own efforts and through collaborations. Because of the inherent risk associated with research and development efforts in our industry, including the high cost and uncertainty of conducting clinical trials (where required), such efforts may not result in the successful introduction of new pharmaceutical products approved by the relevant regulatory bodies.

Our results of operations may suffer if these products are not timely developed, approved or successfully commercialized. Refer to Note 12 (“Property, plant and equipment”), Note 13 (“Goodwill”) and Note 14 (“Other Intangible Assets”) of our consolidated financial statements for details of impairment of non-current assets.

We must develop, test and manufacture generic products as well as prove that our generic products are bio-equivalent or biosimilar to their branded counterparts, either directly or in partnership with contract research organizations. The development and commercialization process, particularly with respect to complex molecules and biosimilars, is both time consuming and costly and involves a high degree of business risk.

In addition, the competitive landscape includes a high level of uncertainty as numerous companies are working on or may be evaluating similar targets, and a product considered as promising at the beginning of its development may become less attractive if a competitor addressing the same unmet need reaches the market earlier.

Our products currently under development, if and when fully developed and tested, may not perform as we expect or meet our standards of safety and efficacy. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to successfully and profitably produce and market such products. Our approved products may not achieve expected levels of market acceptance.

If we fail to comply fully with government regulations or to maintain continuing regulatory oversight applicable to our research and development activities or if a regulatory agency delays or denies approvals for new products, it may affect realization of product revenues.

Our research and development activities are heavily regulated. If we fail to comply fully with applicable regulations, then there could be a delay in the submission or approval of potential new products for marketing approval. In addition, the submission of an application to a regulatory authority does not guarantee that approvals required to market the product will be granted. Each authority may impose its own requirements and/or delay or refuse to grant approval, even when a product has already been approved in another country. This approval process increases the cost of developing new products to us and increases the risk that we will not be able to successfully sell such new products.

Delays in the receipt of, or failure to obtain approvals for, future products, or new indications and uses, could result in delayed realization of product revenues, reduction in revenues and substantial additional costs.

We are subject to the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws, which impose restrictions and may carry substantial penalties.

The U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to public officials or otherwise for the purpose of obtaining or retaining business. These laws may also require us to maintain accurate books and records, as well as to establish and monitor adequate controls, policies and processes to ensure business is conducted without the influence of bribery and corruption.

Ethics and compliance is core to our values and, in this pursuit, we have established a strong compliance framework program. Our policies mandate compliance with these anti-bribery laws, which if not complied, often carry substantial penalties including fines, criminal prosecution and potential debarment from public procurement contracts. Failure to comply may also result in reputational damages.

We operate in certain jurisdictions that experience governmental corruption to some degree or, are found to be low on the Transparency International Corruption Perceptions Index and, in some circumstances, anti-bribery and anti-corruption ("ABAC") laws may conflict with some local customs and practices. Business activities in many of these markets have historically been more susceptible to corruption. In many less-developed markets, we work with third party distributors and other agents for the marketing and distribution of our products. Our third party risk management ("TPRM") policy sets forth the ABAC policy standards required for all of our vendors and third party agents. In addition to requiring initial due diligence screenings and ABAC training and certification, our TPRM policy mandates that contracts with these third parties include ABAC compliance obligations. Nonetheless, any lapses in complying with ABAC laws by these third parties despite our TPRM policy may adversely impact us..

If our efforts to maintain a strong TPRM policy or adequate controls fail, we could be held responsible for the non-compliance of third party agents and distributors under applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act and other anti-bribery laws. In such an event, we may be subject to injunctions or limitations on future conduct, be required to modify our business practices and compliance programs and/or have a compliance monitor imposed on us, or suffer other criminal or civil penalties or adverse impacts, including lawsuits by private litigants or investigations and fines imposed by local authorities. Refer to Note 32 (under "Contingencies - Internal Investigation") of our consolidated financial statements for current internal investigation details.

We need to constantly review and update our compliance program to keep it current and active. If we fail to do so, our vulnerabilities may increase and our controls may be found to be inadequate.

Actions by our employees, or third-party intermediaries acting on our behalf, in violation of such laws, whether carried out in the United States or elsewhere, may expose us to liability for violations of such anti-bribery laws and accordingly may have a material adverse effect on our reputation and our business, financial condition, results of operations and/or cash flows.

Significant disruptions of information technology systems, breaches of data security or other cyber-attacks could adversely affect our business.

Our business is dependent upon increasingly complex and interdependent information technology ("IT") systems, including internet and cloud based systems, to support our business processes as well as internal and external communications. In addition, our businesses and operating models increasingly depend on outsourcing and collaboration, which requires exchanging data and information. The size and complexity and interconnectivity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion, computer viruses and other cyber-attacks.

Like many companies, we may experience certain of these events given that the external cyber-attack threat continues to grow. Although we and our third party service providers have invested in measures to reduce these risks, we cannot be assured that these measures will be successful in preventing the compromise and/or disruption of our information technology systems and related data.

Any such compromise or disruption may result in the loss, theft or unauthorized disclosure of key information and/or disruption of production and business processes, such as the conduct of scientific research and clinical trials, the submission of the results of such efforts to regulatory authorities in support of requests for product approvals, the functioning of our manufacturing and supply chain processes, our compliance with legal obligations and other key business activities, any of which could materially and adversely affect our business.

We maintain cybersecurity insurance to further mitigate these risks, but there can be no assurance that a policy exclusion will not apply, or that our insurance coverage limits will be sufficient to protect us against the financial, legal, business or reputational losses that may result from an interruption or breach of our systems, or that any such insurance proceeds will be paid to us in a timely manner.

In our pursuit of operational excellence, several change management initiatives across our organization are ongoing, including but not limited to information technology automation in the areas of manufacturing, research and development, supply chain and shared services. As part of our resiliency strategy, we have an IT disaster recovery plan in place for our key applications in order to minimize impacts from any unanticipated events and breakdowns.

We have outsourced our IT hardware and applications in order to improve IT capability and performance. Any failure by such outsourced service providers to deliver timely and quality services and to co-operate with one another could create disruption, which could materially adversely affect our business or results of operations. Further, any failure by us to effectively manage such change initiatives or implement adequate controls in automation, security or availability of information technology systems could have a material adverse effect on our business.

Increased outsourcing or use of cloud services for conducting our business requires highly secure controls to ensure adequate security of information, considering potential for sabotage as well as availability. Data integrity, confidentiality and data privacy requirements are increasingly concerning regulators, and are incorporated into legal contracts. While we have invested heavily in the protection of data and information technology to reduce these risks, there can be no assurance that our efforts or those of our third-party service providers would be sufficient to protect against data from being stolen or corrupted in the event of a security breach.

While our personnel work remotely, our dependence on secure access from remote work locations has increased and the risk of cyber incidents may be increased. If our information technology systems are unsuccessfully implemented, fail, suffer errors or interruptions, or become unavailable, that might have a materially adverse impact on our business operations and our financial position or results of operations and/or cash flows.

The Company’s growing use of artificial intelligence (“AI”) systems to automate processes, analyze data, and support decision-making poses inherent risks. Flaws, biases, or malfunctions in these systems could lead to operational disruptions, data loss, or erroneous decision-making, impacting the Company’s business operations, financial condition, and reputation. Ethical and legal challenges may arise, including biases or discrimination in AI outcomes, non-compliance with data protection regulations, and lack of transparency. Furthermore, the deployment of AI systems could expose the Company to increased cybersecurity threats, such as data breaches and unauthorized access leading to financial losses, legal liabilities, and reputational damage. The Company also faces competitive risks if it fails to adopt AI or other machine learning technologies in a timely fashion.

We are subject to data privacy and security laws and regulations in many different jurisdictions and countries where we do business, and our or our partners’ failure to comply could result in fines, administrative and criminal penalties, reputational damage, and could impact the way we operate our business.

We are subject to laws and regulations governing the collection, use, transfer and retention of personal data, including health information. As the legislative and regulatory landscape for data privacy and protection continues to evolve around the world, there has been an increasing focus on privacy and data protection issues that may affect our business. The European Union’s General Data Protection Regulation (“GDPR”), which became fully effective in May 2018, implemented stringent requirements on how a company may gather, retain, use and manage personal and sensitive personal data, as well as mandatory data breach notification requirements. The GDPR grants national authorities the power to apply fines of up to EUR 20 million or 4% of the previous financial year’s global turnover (whichever is greater) to the worst violations.

Additionally, the California Consumer Privacy Act (“CCPA”), as amended by California Privacy Rights Act (“CPRA”) of 2020, created new individual privacy rights for California consumers and increased the privacy and security obligations on entities handling personal data of consumers or households. These laws require covered companies to provide new disclosures to California consumers, provide such consumers with new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Similarly, several other U.S. states have recently enacted privacy laws which are either currently in effect or will come into effect during calendar years 2024 through 2026.

More recently, the Digital Personal Data Protection Act of India (the “DPDP Act”) was passed in 2023, with extra-territorial scope. The DPDP Act puts several obligations on ‘data fiduciaries’ which process digital personal data collected in India or processed in connection with offering goods and services to individuals in India. As per the DPDP Act, penalties levied for data breaches can be up to Rs.2.5 billion. The DPDP Act has not yet come into force, pending notification of its implementation rules by the Government of India.

Other countries in which we do business have, or are developing, laws governing the collection, use and transfer of personal information that may affect our business or require us to adapt our technologies and organizational measures. Some countries, are considering legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements.

Also, increasing data localization requirements and enforcement in countries such as Russia and China, along with the European Union’s stringent regulatory guidance related to cross-border transfer of personal data, further limits the ability to transfer personal data from such countries to the rest of the world.

In addition, a failure by us or our third-party vendors to comply with applicable data privacy and security laws could result in financial, legal, business, and reputational harm and may have a material adverse effect on the way we operate our business, our financial condition, results of operations and/or cash flows.

Evolving third-party relationships beyond the traditional vendor/supplier model and the increased use of digital solutions and applications, including emerging technologies such as artificial intelligence (“AI”), present new privacy and security challenges. These will require constant monitoring of new guidelines and regulations around the world, as well as a need for us to assess our capabilities in these areas.

The burdensome and often conflicting requirements under these various data protection laws require us to allocate increasingly greater resources towards ensuring compliance with them. Among other things, there is significant additional cost associated with the development, implementation and maintenance of upgrades to our information technology systems, as well as ongoing monitoring and governance efforts.

We have operations in certain countries susceptible to political and economic instability that could lead to disruption or other adverse impact on such operations.

We expect to derive an increasing portion of our sales from regions such as China, Latin America, Russia and other countries of the former Soviet Union, Central Europe, Eastern Europe and South Africa, all of which may be more susceptible to political and economic instability.

In February 2022, Russia initiated military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia. The broader economic consequences of the military conflict, geopolitical instability, the imposition of sanctions and other restrictive measures against Russia and any retaliatory actions taken by Russia in response to such measures could adversely affect the global geopolitical and economic environment. And that could in turn adversely impact our operations, cash flows and growth in Russia and other countries of the former Soviet Union. For details on the impacts of this conflict on our business, see the discussion in Section 4.B. of this report under “Our Principal Areas of Operations - Global Generics Segment - Russia and other Countries of the former Soviet Union and Romania - Impact on our Operations due to the military conflict between Russia and Ukraine.”

If the relationship between Russia and the United States significantly worsens, or if Russia, the United States, or other countries impose additional economic sanctions or supply chain restrictions, or if the military conflict between Russia and Ukraine results in significant further deterioration of the local economies of Russia, Ukraine and its neighboring countries, it could adversely impact our sales or cost of doing business in the region.

In addition, the war declared by Israel on Hamas in October 2023, and the military activity in the region, is ongoing and continues to evolve as of the date of this report. This military action could escalate and involve surrounding countries in the Middle East.

We continue to monitor the effects of these military conflicts, as well as to monitor significant political, legal, regulatory and other susceptible economic developments in these regions and attempt to mitigate our exposure where possible. However, mitigation is not always possible, and our international operations could be adversely affected by political, legal, regulatory and economic developments, such as changes in capital and exchange controls; expropriation and other restrictive government actions (e.g., Ukrainian Law restricting the circulation of medicines of a marketing authorization holder affiliated directly or indirectly with entities in Russia and Belarus, as adopted by the Ukrainian Parliament in May 2022); intellectual property protection and remedy laws; trade regulations; procedures and actions affecting approval, production, pricing, distribution and marketing of, reimbursement for and access to our products; and intergovernmental disputes, including embargoes and/or military hostilities.

Significant portions of our manufacturing operations for markets outside India in which our products are sold, and accordingly we often import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of closing of the borders of the countries in which we sell our products, or in which our operations are located.

This may result from economic, legislative, political or military conditions, including hostilities or acts of terror, in such countries. We currently face increased logistics costs as a result of requirements that we ship through longer marine routes or choose air shipments over sea routes.

A relatively small group of products may represent a significant portion of our net revenues, gross profit or net earnings from time to time.

In certain markets, sales of a limited number of products may represent a significant portion of our net revenues, gross profit and net earnings. If the volume or pricing of such products declines in the future, our business, financial position, results of operations and/or cashflows could be materially adversely affected.

If there is delay and/or failure in supplies of materials, services and finished goods from third parties or failure of finished goods from our key manufacturing sites, it may adversely affect our business and results of operations.

In some of our businesses, we rely on third parties for the timely supply of active pharmaceutical ingredients (“API”), specified raw materials, equipment, formulation or packaging services and maintenance services, and in some cases there could be a single source of supply.

Although, we actively manage these third party relationships to ensure continuity of supplies and services on time and to our required specifications, events beyond our control could result in the complete or partial failure of supplies and services or in supplies and services not being delivered on time.

We collaborate with several third-party contract research organizations and contract manufacturing organizations to facilitate the development and commercialization of certain drugs. However, any financial limitations or compliance challenges encountered by these external partners may lead to delays in product launches or cancellation of planned launches. In the event that we experience a shortage in our supply of raw materials, we might be unable to fulfill all of the API needs of our Global Generics segment, which could result in a loss of production capacity for this segment. Moreover, we may continue to be dependent on vendors, strategic partners and alliance partners for supplies of some of our existing products and new generic launches.

Any unanticipated capacity or supply related constraints affecting such vendors, strategic partners or alliance partners can adversely affect our business or results of operations. Our key generics manufacturing sites also may have capacity constraints and, at times, we may not be able to generate sufficient supplies of finished goods.

An escalation in the currently ongoing geopolitical and military conflicts in Ukraine and the middle east could also lead to challenges in supply fulfillment from our contract manufacturing organizations and other key suppliers of API and raw materials. That could impact our operations and delay our ability to manufacture finished dosages.

Our success depends on our ability to retain and attract qualified personnel and, if we are not able to retain them or recruit additional qualified personnel, we may be unable to successfully develop our business.

We are highly dependent on the principal members of our management and scientific staff, the loss of whose services might significantly delay or prevent the achievement of our business or scientific objectives. In India, it is not our practice to enter into employment agreements with our executive officers and key employees that are as extensive as are generally used in the United States, and each of those executive officers and key employees may terminate their employment upon notice and without cause or good reason. Currently, we are not aware of any executive officer’s or key employee’s departure that has had, or planned departure that is expected to have, any material impact on our operations.

Competition among pharmaceutical companies for qualified employees is intense, and the ability to retain and attract qualified individuals is critical to our success. Current or prospective employees may have changing expectations around workplace flexibility and the importance of a diverse and inclusive workplace culture, and a failure to meet these evolving expectations may result in reduced ability to attract and retain talent. There can be no assurance that we will be able to retain and attract such individuals currently or in the future on acceptable terms, or at all, and the failure to do so could have a material adverse effect on our business, financial condition, results of operations and/or cash flows. In addition, we do not maintain “key person” life insurance on any officer, employee or consultant.

Reforms in the health care industry and the uncertainty associated with pharmaceutical pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products.

Our businesses are operating in an ever more challenging environment, with significant pressures on the pricing of our products and on our ability to obtain and maintain satisfactory rates of reimbursement for our products by governments, insurers and other payors.

For example, in the United States, Congress passed the Inflation Reduction Act of 2022 (the “IRA”), which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of new rebates and financial penalties for drugs (including single-source generics) whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028. The long-term implications of the IRA remain uncertain and we are continuing to evaluate this law and its impact on our business.

The U.S. Congress also continues to consider other drug pricing legislation that, if passed and signed into law, could impact companies’ ability to increase prices for prescription drugs, even in case of increase in our input costs, to maintain our margins. For instance, the U.S. Department of Health and Human Services and U.S. FDA’s Safe Importation Action Plan was announced in July 2019. Following this framework, the U.S. FDA enacted a rule, which became effective in November 2020, allowing for the importation of certain lower-cost prescription drugs from Canada.

Under the rule, states or certain other non-federal governmental entities may submit importation program proposals to the U.S. FDA for review and authorization of two-year programs (with the opportunity to extend for two more years). In January 2024, the U.S. FDA approved Florida’s importation program proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted importation program proposals that are pending review by the U.S. FDA. Any such importation plans, when approved and implemented, may result in lower drug prices for products covered by those programs. Certain states have also proposed other measures that are designed to control the costs of pharmaceuticals for which they provide reimbursement.

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control healthcare spending even more tightly than in the past.

These pressures are particularly strong given the persistently weak economic and financial environment in many countries and the increasing demand for healthcare resulting from the aging of the global population and associated increases in non-communicable diseases. These pressures are further compounded by consolidation among distributors, retailers, private insurers, managed care organizations and other private payors, which can increase their negotiating power. In addition, these pressures are augmented by intense publicity regarding the pricing of pharmaceuticals by our competitors, as well as government investigations and legal proceedings regarding pharmaceutical pricing practices. Refer to Note 32 (“Contingencies”) of our consolidated financial statements for current investigations and legal proceedings. In many countries in which we currently operate, pharmaceutical prices are increasingly subject to regulation.

Our products continue to be subject to increasing price and reimbursement pressure that can limit the revenues we earn from our products in many countries due to, among other things:

- the existence of government-imposed price controls, tender systems, mandatory discounts and rebates, pricing transparency mandates and drug importation program;
- more governments using international reference pricing to set the price of drugs based on international comparisons (Refer to “Our Principal areas of Operations - Global Generic segment” in Item 4.B. below for details);
- increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
- increase in cost containment policies related to health expenses in the context of economic slowdown; and
- more demanding evaluation criteria applied by health technology assessment agencies when considering whether to cover new drugs at a certain price level.

We expect these efforts to continue as healthcare payors around the globe, in particular government-controlled health authorities, insurance companies and managed care organizations, step up initiatives to reduce the overall cost of healthcare.

We operate in a highly competitive and rapidly consolidating industry which may adversely affect our revenues and profits.

Our products face intense competition from products commercialized or under development by competitors in all of our business segments based in India, the United States and other markets. Many of our competitors have greater financial resources and marketing capabilities than we do.

Our competitors may succeed in developing technologies and products that are more effective, more popular or cheaper than any we may develop or license, thus rendering our technologies and products obsolete or uncompetitive, which would harm our business and financial results. It is also possible that alternate therapies or substitutable products that we developed for the same indication would lead to cannibalization of revenues from our products.

Further, in recent years the goals established under the Generic Drug User Fee Act, and increased funding of the U.S. FDA's Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition.

The U.S. FDA has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. While these improvements are expected to benefit our generic product pipeline, they will also benefit competitors that seek to launch products in established generic markets where we currently offer products. The U.S. FDA's efforts to increase the pace at which generics enter the market has also resulted in a trend of many first time generic manufacturers entering the market, which is further increasing competition in the market and increasing pressure on pricing.

In recent years, there has also been an increase in the number of generic manufacturers targeting significant new generic opportunities with exclusivity under the Hatch-Waxman Act, or which are complex to develop. Many of the smaller generic manufacturers have increased their capabilities, level of sophistication and development resources in recent years.

Our generics business is also facing increasing competition from brand-name manufacturers who do not face any significant regulatory approvals or barriers to enter into the generics market. These brand name manufacturers have devised numerous strategies to do so including, for example, by selling generic versions of their products directly, by forming strategic alliances with our competitor generic pharmaceutical companies or by granting them rights to sell "authorized generics". Moreover, brand companies continually seek new ways to delay the introduction of generic products and decrease the impact of generic competition, such as by: filing new patents on drugs whose original patent protection is about to expire, developing patented controlled-release products, changing the dosage form or dosing regimen of the brand product prior to generic introduction while the generic applicant seeks to amends its ANDA dossier to match the changes in the brand product; changing product claims and product labeling; developing and marketing as over-the-counter products those branded products that are about to face generic competition; or pricing the branded product at a discount equivalent to generic pricing.

Consolidation and integration of the drug wholesalers, retail drug chains, private insurers, managed care organizations and other purchasing organizations may continue to adversely affect pharmaceutical manufacturers. Such consolidations have resulted in these groups gaining additional purchasing leverage and, consequently, increasing the product pricing pressures facing our business. There are three large Group Purchasing Organizations ("GPOs") that account for a substantial majority of generics purchases in the United States in 2023, which provides each of them with significant bargaining power. We expect this trend of increased pricing pressures to continue. Such pressures have reduced, and could continue to reduce, our revenue, margins and profitability. The emergence of large buying groups representing independent retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, creates competition among pharmaceutical companies to have their products included in the formulary of those groups and enables those groups to extract price discounts on our products.

In our generics business, to the extent that we succeed in being the first to market a generic version of a significant product, and particularly if we obtain the 180-day period of market exclusivity in the United States provided under the Hatch-Waxman Act of 1984, as amended, our sales and profit can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of the equivalent product or the launch of an authorized generic.

Impairment charges or write downs in our books could have a significant adverse effect on our results of operations and financial results.

A substantial portion of the value of our assets pertains to various intangible assets and goodwill. The proportion of the intangible assets and goodwill to our total assets could increase significantly as we pursue various growth strategies. The value of these intangible assets and goodwill could be substantially impaired upon indications of impairment, with adverse effects on our financial condition and the value of our assets.

Our results of operations may suffer if our products are not timely developed, approved or successfully commercialized. Certain of our products were impaired during the years ended March 31, 2024, 2023 and 2022. Refer to Note 12 ("Property, plant and equipment"), Note 13 ("Goodwill") and Note 14 ("Other Intangible Assets") of our consolidated financial statements for further details.

If we fail to comply with environmental laws and regulations, or face environmental litigation, our costs may increase or our revenues may decrease.

We may incur substantial costs complying with requirements of environmental laws and regulations. In addition, we may discover currently unknown environmental problems or conditions. In all countries where we have production facilities, we are subject to significant environmental laws and regulations that govern the discharge, emission, storage, handling and disposal of a variety of substances that may be used in or result from our operations. In the normal course of our business, we are exposed to risks relating to possible releases of hazardous substances into the environment, which could cause environmental or property damage or personal injuries, and that could require remediation of contaminated soil and groundwater, which could cause us to incur substantial remediation costs that could adversely affect our consolidated financial position, results of operations or liquidity. Refer to Note 32 (“Contingencies - Environmental matters”) of our consolidated financial statements for further details on current environmental matters.

If any of our plants or the operations of such plants are shut down, it may severely hamper our ability to supply our customers and we may continue to incur costs in complying with regulations, appealing any decision to close our facilities, maintaining production at our existing facilities and continuing to pay labor and other costs, which may continue even if the facility is closed.

If we elect to sell a generic product prior to the final resolution of outstanding patent litigation, we could be subject to liabilities for damages.

At times we seek approval to market generic products before the expiration of patents for those products, based upon our belief that such patents are invalid, unenforceable, or would not be infringed by our products. As a result, we might be involved in patent litigation, the outcome of which could materially adversely affect our business. Based upon a complex analysis of a variety of legal and commercial factors, we may elect to market a generic product even though litigation is still pending. This could be before any court decision is rendered or while an appeal of a lower court decision is pending. To the extent we elect to proceed in this manner, if the final court decision is adverse to us, we could be required to cease the sale of the infringing products and face substantial liability for patent infringement. These damages may be significant as they may be measured by a royalty on our sales or by such damages as may be awarded by the court as a result of final litigation outcome. Refer to Note 32 (“Contingencies”) for further details on our current product and patent related litigations.

Because of the discount pricing typically involved with generic pharmaceutical products, patented brand products generally realize a significantly higher profit margin than generic pharmaceutical products. Furthermore, there may be risks involved in entering into in-licensing arrangements for products, which are often conditioned upon the licensee’s sharing in the patent-related risks.

For business reasons, we continue to examine such product opportunities (i.e., involving non-expired patents) going forward and this could result in patent litigation, the outcomes of which may have a material adverse effect on our results of operations, financial condition and/or cash flows.

We have concentrations of sales to certain customers, and consolidation among distributors and pharmaceutical companies could increase the concentration risk and also adversely impact our business prospects.

In the United States, similar to other pharmaceutical companies, we sell our products through wholesale distributors and large retail chains in addition to hospitals, pharmacies and other groups. During the year ended March 31, 2024, our ten largest customers accounted for approximately 77% of our North America Global Generics segment’s revenues, and two of these customers collectively represented approximately 15% of our total company revenues. Refer to Note 5 (under “Information about major customers”) of our consolidated financial statements for further details. As discussed above, industry consolidation trends have resulted in these groups gaining additional purchasing leverage and, consequently, increasing the product pricing pressures facing our business. Any further consolidation may lead to incremental pricing pressure.

Reduced or regulated ground water availability due to irregular weather patterns may cause droughts, thereby impacting business continuity.

Ground water availability may be adversely impacted by droughts due to irregular weather patterns. In case there is no alternate source of water during peak summers for reasons relating to adequate water quality or availability, it could adversely impact our operations. Further if tighter legal compliance for ground water usage and continuous monitoring of water levels are implemented, it could lead to restricted availability of water which could adversely impact our operations and create business interruptions.

Class action lawsuits could expose us to significant liabilities, result in negative publicity, harm our reputation and have a material adverse effect on the price of our ADSs.

Shareholders of a public company sometimes bring securities class action lawsuits against the company following periods of instability in the market price of that company's securities. Refer to Note 32 ("Contingencies") of our consolidated financial statements for details on our current securities class action lawsuits. As a public company grows in size, the risk of such litigations may increase. If we were to be sued in any such class action suit, irrespective of the merits of the underlying case, it could have adverse effects on us, including among other things: (a) a diversion of management's time and attention and other resources from our business and operations, which could harm our results of operations; (b) negative publicity, which could harm our reputation and restrict our ability to raise capital in the future; (c) require us to incur significant expenses to defend the suit; and (d) if a claim against us is successful, we may be required to pay significant damages and, in certain circumstances, to indemnify our directors and officers if they are named as defendants in the class action suit. Any of the foregoing could, individually or in the aggregate, have a material adverse effect on our financial condition, results of operations, cash flows and/or the price of our ADSs.

We may be susceptible to significant product liability claims that are not covered by insurance.

Our business inherently exposes us to potential product liability claims, and the severity and timing of such claims are unpredictable. Notwithstanding pre-clinical and clinical trials conducted during the development of potential products to determine the safety and efficacy of products for use by humans following approval by regulatory authorities, unanticipated side effects may become evident only when drugs are introduced into the marketplace. Due to this fact, our customers and participants in clinical trials may bring lawsuits against us for alleged product defects. In other instances, third parties may perform analyses of published clinical trial results which raise questions regarding the safety of pharmaceutical products, and which may be publicized by the media. Even if such reports are inaccurate or misleading, in whole or in part, they may nonetheless result in claims against us for alleged product defects.

Under the current regulatory scheme in the United States, branded drug manufacturers can independently update product labeling through the "changes being effected" ("CBE") supplement process, but a generic manufacturer is only permitted to use the CBE process to update its label if the branded drug manufacturer changes its label first. This can prevent generic manufacturers from complying with state law warning requirements and, as a result, state product liability suits based on failure-to-warn and design defect claims against generics manufacturers have generally been determined to be preempted by Federal law.

However, emerging developments in various countries laws relating to the liability of generic pharmaceutical manufacturers for certain product liability claims could increase our exposure to litigation costs and damages. This potential exposure to lawsuits would also have increased the risk that, in the future, we would not be able to obtain the type and amount of insurance coverage we desire at an acceptable price The risk of exposure to lawsuits is likely to increase as we develop limited competition/complex products, such as injectable vaccines or biosimilar products, in addition to making generic versions of drugs that have been in the market for some time. In addition, the existence or even threat of a major product liability claim could also damage our reputation and affect consumers' views of our other products, thereby negatively affecting our business, financial condition, results of operations and cash flows.

The off label use of our products may result in costly investigations, fines or sanctions by regulatory bodies if we or our distributors are deemed to have engaged in the promotion of these uses.

While physicians may prescribe products for uses that are not described in the product labeling and that differ from those approved by the U.S. FDA or other similar regulatory authorities (an "off label" use), we and our distributors are permitted to market our products only for the indications for which they have been approved. The U.S. FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses, and significant liability can be imposed on manufacturers found to be engaged in off-label marketing violations, including substantial civil penalties and fines, as well as criminal sanctions or exclusion from participation in government healthcare programs. If some of our products are prescribed off label, regulatory authorities such as the U.S. FDA could take enforcement actions if they conclude that we or our distributors have engaged in off label marketing.

With an increased focus from key stakeholders on climate-related and other environmental, social and governance ("ESG") disclosures, an inadequate performance and management of ESG topics could materially affect our growth and reputation.

In recent years, in addition to financial results, companies are increasingly being judged by their ESG practices. Several global and national organizations including ESG rating agencies, research analysts, and disclosure and standards organizations evaluate our work through in-depth analyses of our sustainability efforts. These include reviews of our publicly available documents, as well as independent quantitative and qualitative assessments, often involving discussions with our management and employees. The results of these ratings are publicly and widely available. Any negative score could adversely impact our reputation and brand value, and the trust placed in us by our stakeholders. As a result, this could negatively impact our ability to attract and retain employees, the implementation of our strategic objectives, our operations and financial results, our access to capital and our share price.

Due to our role in healthcare and society at large, we are expected to move to a primarily patient-centric business model and manage social factors such as market access, equitable pricing strategies, and responsible intellectual property management.

Our business model is supported by our ESG strategy. Implementing our ESG strategy requires a strong governance framework including responsible practices and commitment on business ethics, compliance, quality, transparency, and anti-corruption. Any failure in governance, performance management, or ESG strategy execution could lead to us being unable to meet our ESG goals, and could result in the adverse effects described above.

Technology disruptions have been identified as a risk for our business. In the near future, innovation in technology is expected to impact our drug development process and the supply chain, enhancing efficiency although also requiring new skill sets. If we do not upgrade technologies and increase the productivity of our operations, achievement of our ESG goals could be adversely impacted.

The achievement of our targets on carbon neutrality and renewable energy is dependent on multiple external factors including the pace of deployment of renewable energy, intermittency and variability, storage capacity and infrastructure challenges, technical challenges, the cost of carbon offsets etc. and may impact our ability to meet our goals, or stakeholder expectations and our reputation may be harmed.

We are expected to plan mitigation measures for ESG risks due to climate change and environment degradation, adapt to the realities of climate change, and disclose any material effect it may have on our business, financial condition, results of operations and cash flows. Our customers conduct audits on a continual basis on matters related to sustainability including climate change adaption and mitigation. Inadequate management of environmental resources could lead to loss of revenue, higher operational costs, and incidents that could harm our communities and the environment, leading to financial and reputational implications. Moving to new, more sustainable solutions for resource conservation may require increased capital expenditure.

We are subject to various laws and regulations concerning, among other things: employee safety; product safety; the handling, transportation, storage, use and disposal of chemicals; and the discharge of regulated materials and pollutants into the environment. Failure to adapt to or comply with existing or new regulatory requirements, or investor or stakeholder expectations and standards, on these ESG matters could negatively impact our reputation or harm our business.

In March, 2024, the SEC issued its long-awaited final rule, *The Enhancement and Standardization of Climate Related Disclosures for Investors*. This rule will require registrants, including foreign private issuers such as the Company, to disclose extensive climate-related information in their registration statements and periodic reports, including a registrant's greenhouse gas emissions. The Company is currently assessing the impact of this rule for disclosure to investors. Annual disclosure requirements would be effective for the Company as early as the fiscal year beginning April 1, 2026. The Company is evaluating the impact of these rules on its disclosures.

As ESG continues to gain significance with governments, corporates and investors, there have been multiple shifts in the ESG regulatory and reporting landscape globally and in India, along with changing stakeholder expectations. With growing pressure to improve and expand our ESG disclosures, we need to engage with our investors frequently and keep a close eye on their ESG-related concerns. Investor sentiment is also driven by global shifts, the political climate, and international policies. An inability to manage investor sentiment or address flags may negatively impact our positioning and valuation.

If we are unable to defend ourselves in patent challenges, we could be subject to injunctions preventing us from selling our products, or we could be subject to substantial liabilities that could adversely affect our profits and cash flows. Further, our patent settlement agreements with the innovators may face government scrutiny, exposing us to significant damages.

There has been substantial patent related litigation in the pharmaceutical industry concerning the manufacture, use and sale of various products. In the normal course of business, we are regularly subject to lawsuits and the ultimate outcome of litigation could adversely affect our results of operations, financial condition and cash flow. Regardless of regulatory approval, lawsuits are periodically commenced against us with respect to alleged patent infringements by us, such suits often being triggered by our filing of an application for governmental approval, such as an ANDA or NDA.

The expense of any such litigation and the resulting disruption to our business, whether or not we are successful, could harm our business. The uncertainties inherent in patent litigation make it difficult for us to predict the outcome of any such litigation.

California passed the Preserving Access to Affordable Drugs (AB-824), legislation that could adversely impact our ability to settle patent litigations. The law, which took effect on January 1, 2020, creates a presumption that a patent settlement has anti-competitive effects, and thus violates California's state antitrust law, if it provides for the generic pharmaceutical company to receive “anything of value” from the branded pharmaceutical company and if the generic pharmaceutical company agrees to delay the launch of a generic product for any period of time. The law specifically identifies exclusive licenses and agreements by the branded pharmaceutical company “not to launch an authorized generic version” of its branded product as things of value that would trigger the presumption. Such presumption may make it more difficult to negotiate settlement agreements which are subject to this new law.

If we are unsuccessful in defending ourselves against these suits, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or to damages, which may be substantial. An injunction or substantial damages resulting from these suits could adversely affect our consolidated financial position, results of operations or liquidity.

Further, we have been involved in various litigations involving challenges to the validity or enforceability of registered patents and therefore settling such patent litigations has been and is likely to continue to be an important part of our business.

Parties to patent litigation settlement agreements in the United States, including us, are required by law to file them with the Federal Trade Commission (“FTC”) and the Antitrust Division of the Department of Justice for review. The FTC has publicly stated that, in its view, some of the brand-generic settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies that have entered into such agreements. Accordingly, such settlement agreements may expose us to antitrust violation claims.

EMERGING RISKS

We analyze reports and insights issued by the World Economic Forum, audit and consulting firms, banks and insurance companies, and investigations on the internet from selected reliable sources, regarding trends for the coming years and main threats and opportunities to be anticipated by pharmaceutical industry.

Increasing use of social media and mobile communication tools could give rise to liability or breaches of data security.

We and our business associates are increasingly relying on social media and mobile communication tools as a means of communications. To the extent that we seek as a company to use these tools as a means to communicate about our products or about the diseases our products are intended to treat, there are significant uncertainties as to either the rules that apply to such communications, or as to the interpretations that health authorities will apply to the rules that exist. As a result, despite our efforts to comply with applicable rules, there is a significant risk that our use of social media and mobile communication tools for such purposes may cause us to nonetheless be found in violation of them. In addition, because of the universal availability of social media and mobile communication tools, our associates or third parties may make use of them in ways that may not be sanctioned by us, and that may give rise to liability, or that could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others. Social engineering attacks, reputation threats, and the proliferation of misinformation and disinformation indeed pose significant risks to companies globally. Growing sophistication of these threats is a potential operating risk.

Social media posts could also contain information purported to be disclosed by us that is false or otherwise damaging, which could have a material adverse effect on our reputation and the price of our equity shares and ADSs.

Maintaining transparency and promptly addressing any instances of misinformation or disinformation is crucial for preserving our reputation. We monitor online channels for potential threats to aid early detection and mitigation of reputational risks. Ultimately, staying vigilant, proactive and adaptable in addressing emerging threats is essential for us to navigate the evolving landscape of cybersecurity and to safeguard our operations, reputation and financial assets.

Counterfeit versions of our products could harm our patients and reputation.

Our industry has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening.

Counterfeit medicines may contain harmful substances, the wrong dose of the API or no API at all. Counterfeiters may use the same brand name and packaging as the genuine pharmaceutical company, so as to make it visually indistinguishable from the authentic version and thereby deceive distributors and consumers. Counterfeit medicines are manufactured in unsafe conditions and are not approved by regulatory authorities. They are inherently unsafe and pose a serious risk to public health.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product.

Various governments have enacted laws intended to combat counterfeiting, including the U.S. Drug Quality and Security Act and the EU's Falsified Medicines Directive, as further discussed in Section 4.B. (Business Overview). In addition to complying with these laws, we have put in place internal mechanisms to monitor incidents that come to our notice and we proactively carry out regional surveys.

GENERAL RISKS THAT ARE NOT SPECIFIC TO OUR COMPANY

Current economic conditions may adversely affect our industry, financial position, results of operations and cash flows.

In recent years, the global economy has experienced volatility and an unfavorable economic environment, and these trends may continue in the future. Reduced consumer spending, reduced funding for national social security systems or shifting concentrations of payors and their preferences, may force our competitors and us to reduce prices. The growth of our business may be negatively affected by high unemployment levels and increases in co-pays, which may lead some patients to delay treatments, skip doses or use less effective treatments to reduce their costs.

We have exposure to many different industries and counterparties, including our partners under our alliance, research and promotional services agreements, suppliers of raw materials, drug wholesalers and other customers, who may be unstable or may become unstable in the current economic environment. We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies.

Significant changes and volatility in the consumer environment and in the competitive landscape may make it increasingly difficult for us to predict our future revenues and earnings.

In addition, there has recently been an accelerated rate of inflation (a trend which is expected to continue in the near future) that has resulted, and may continue to result, in increased costs of labor, raw materials, other supplies and commodity prices and freight and distribution costs, among others. For the pharmaceutical industry, the pricing dynamics of our products generally does not provide the opportunity to pass on such costs to customers. Inflation may also result in higher interest rates and increased costs of capital.

Risks from disruption to production, supply chain or operations as a result of events emanating from climate change, and the related impacts of laws intended to mitigate climate change, could adversely affect our business and operations and cause our revenues to decline.

Climate change has the potential to increase the frequency and severity of natural disasters and extreme weather events. We are an integrated pharmaceutical company operating in multiple geographies such as India, Mexico, the United States and the United Kingdom. Several of our operations can be exposed to different climate-related regulations. In addition, current or emerging laws or regulations intended to limit greenhouse gas emissions or water usage, such as carbon pricing, taxes on emissions, fuel and energy, or to mitigate the impacts of climate change may become more prevalent, which could increase our operating costs and the costs charged by suppliers. These events could have a material adverse effect on our business.

We must consider the emergence and management of different types of climate-related risks affecting our business in different time horizons, both from an operational and strategic perspective. Besides addressing the physical aspects of climate change we also face external stakeholder pressure to assess and reduce the climate impact of our medicines, the construction of new projects, sites, and buildings, and any large capital expenditures.

Stringent labor laws may adversely affect our ability to have flexible human resource policies; labor union problems could negatively affect our production capacity and overall profitability.

Labor laws may restrict our ability to have human resource policies that would allow us to react swiftly to the needs of our business. As of March 31, 2024, approximately 1.7% of our employees belonged to a number of different labor unions. If we experience problems with our labor unions, that may adversely affect our production capacity and our overall results and operations.

India's Code on Social Security, 2020, which aims to consolidate, codify and revise certain existing social security laws, received Presidential assent in September 2020 and has been published in the Gazette of India. However, the related final rules have not yet been issued and the date on which this Code will come into effect has not been announced. We will assess the impact of this Code and the rules thereunder when they come into effect.

If we have difficulty in identifying candidates for or consummating acquisitions and strategic alliances, our competitiveness and our growth prospects may be harmed.

In order to enhance our business, we frequently seek to acquire or make strategic investments in complementary businesses or products, or to enter into strategic partnerships or alliances with third parties. It is possible that we may not identify suitable acquisition, strategic investment or strategic partnership candidates, or if we do identify suitable candidates, we may not complete those transactions on terms commercially acceptable to us. We compete with others to acquire companies, and we believe that this competition has intensified and may result in decreased availability or increased prices for suitable acquisition candidates. Even after we identify acquisition candidates and/or announce that we plan to acquire a company, we may ultimately fail to consummate the acquisition. For example, we may be unable to obtain necessary regulatory approvals, including the approval of antitrust regulatory bodies.

All acquisitions involve known and unknown risks that could adversely affect our future revenues and operating results. For example:

- We may fail to successfully integrate our acquisitions in accordance with our business strategy.
- The initial rationale for the acquisition may not remain viable due to a variety of factors, including unforeseen regulatory changes and market dynamics after the acquisition, and this may result in a significant delay and/or reduction in the profitability of the acquisition.
- We may not be able to retain the skilled employees and experienced management that may be necessary to operate the businesses we acquire. If we cannot retain such personnel, we may not be able to locate or hire new skilled employees and experienced management to replace them.
- We may purchase a company that has contingent liabilities that include, among others, known or unknown patent or product liability claims or environmental liability claims.
- We may purchase companies located in jurisdictions where we do not have operations and as a result we may not be able to anticipate local regulations and the impact such regulations have on our business.

If we improperly handle any of the dangerous materials used in our business and accidents result, we could face significant liabilities that would lower our profits.

We handle dangerous materials, including explosive, toxic and combustible materials. If improperly handled or subjected to the wrong conditions, these materials could cause accidents resulting in injury, property and environment damage, and business disruptions. Changes in business and operations in our plants from the introduction of new products, or increased demand for existing products, can also pose increased safety hazards. Such hazards can be addressed and mitigated through project risk assessment, employee and contractor training, proper governance systems and other safety measures, and the failure to carry these out can lead to industrial accidents.

Any of the foregoing could subject us to significant litigation or adversely impact our other litigation matters then outstanding, which could lower our profits in the event we were found liable, and could also adversely impact our reputation.

In a worst case scenario, this could also result in a government forced shutdown of our manufacturing plants, which in turn could lead to product shortages that delay or prevent us from fulfilling our obligations to customers and would adversely affect our business and results of operations.

Fluctuations in exchange rates and interest rate movements may adversely affect our business and results of operations.

A significant portion of our revenues are in currencies other than the Indian rupee, especially in the U.S. dollar, the Euro, the Russian rouble, and the U.K. pound sterling, while a significant portion of our costs are in Indian rupees. As a result, if the value of the Indian rupee appreciates relative to these other currencies, our revenues measured in Indian rupees may decrease and our financial performance may be adversely impacted.

Further, we may also be exposed to credit risks in some of the emerging markets from our customers on account of adverse economic conditions.

We use derivative financial instruments to manage interest rate fluctuations and some of our net exposure to currency exchange rate fluctuations in certain key foreign currencies.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, and the resulting restrictive measures and economic impacts may materially and adversely impact our business and results of our operations.

The pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, and responses to curtail them may have a number of risks and challenges for our business, including among others its impacts on the global supply chain, on governmental processing time for product and patent approvals, on health and safety of employees and on the economy in general. In the years ended March 31, 2024 and 2023, we did not experience significant impacts or delays from any pandemic or epidemic on our business operations. However, we had experienced certain disruptions relating to the COVID-19 pandemic during the year ended March 31, 2021, and we cannot be certain whether COVID-19 or other pandemics will adversely impact our business operations and results in future periods.

The use of tender systems and other forms of price control could reduce prices for our products or reduce our market opportunities.

A number of markets in which we operate have implemented or may implement tender systems in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender.

For example, this has resulted in more than 90% of generic products currently sold in German retail “pharmacies” being supplied through contracts procured in competitive bidding tenders, thereby causing significant pressure on product margins.

If we fail to maintain a supply of compliant, quality product, it may adversely affect our reputation and our business.

We may experience difficulties, delays and interruptions in the manufacturing and supply of our products for various reasons, including among other reasons:

- demand significantly in excess of forecast demand, which may lead to supply shortages (this is particularly challenging before the launch of a new product);
- supply chain disruptions, including those due to natural or man-made disasters at one of our facilities or at a critical supplier or vendor;
- delays in construction of new facilities or the expansion of existing facilities, including those intended to support future demand for our products (the complexities associated with biologics facilities, especially for drug substance, increases the probability of delay);
- the inability to supply products due to a product quality failure or regulatory agency compliance action such as license withdrawal, product recall or product seizure;
- other manufacturing or distribution problems, including changes in manufacturing production sites, limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, or physical limitations or other business interruptions that could impact continuous supply; and
- the difficulties inherent in the manufacture and sale of sterile products, including oncology products, which are technically complex to manufacture, and require sophisticated environmental controls. Because the production process for such products is so complex and sensitive, any production failures may lead to lengthy supply interruptions.

Any failure to comply with the complex reporting and payment obligations under the Medicare and Medicaid programs or other laws regulating marketing practices may result in litigation or sanctions and adversely impact our business.

The U.S. laws and regulations regarding Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Some of the applicable laws may impose liability even in the absence of a specific intent to defraud. The subjective decisions and complex methodologies used in making calculations under these programs are subject to review and challenge, and it is possible that such reviews could result in material changes in the calculation outcomes.

In addition, government authorities have significant leverage to persuade pharmaceutical companies to enter into corporate integrity agreements, which can be expensive and disruptive to operations.

If any of the above queries and/or investigations were to result in a lawsuit that was determined adversely to us or in a large cash settlement, it could require us to pay significant amounts.

Changes in tax regulations of the countries we operate in may increase our tax liabilities and thus adversely affect our financial results.

Currently we are entitled to concessional tax rate under Indian tax laws for one of our subsidiaries in India. Concessional tax rates are reduced rates applicable to companies engaged in manufacturing activities which have been set-up and registered in India on or after October 1, 2019 and which commenced manufacturing or production on or before March 31, 2024. Any changes in these laws may increase our tax liability and thus affect our financial results accordingly.

India's Finance Act, 2016 amended the test of residence for foreign companies. While a non-resident company is generally taxed only on its Indian sourced income, a resident company is taxed on its global income. Under the amended rule, a company not formed under the laws of India would be considered a resident in India if its place of effective management in the previous year was in India.

The term "place of effective management" (or "PoEM") has been defined to mean a place where key management operates and commercial decisions that are necessary for the conduct of the business of an entity as a whole are in substance made.

We operate in various countries, and changes in tax rate or tax laws of countries in which we have significant operations could result in a material impact on our cash tax liabilities and tax charges, resulting in either an increase or a reduction in financial results depending upon the nature of the change. There may be changes in tax rates in a few countries due to initiatives such as the Pillar Two Inclusive Framework on the Base Erosion and Profit Shifting ("BEPS") project undertaken by the Organization for Economic Cooperation and Development ("OECD"), which seeks to establish a global minimum tax rate of 15%. Currently, numerous countries are drafting or have enacted legislation to implement Pillar Two rules with some effective dates as early as January 1, 2024. Tax and compliance costs are expected to be increased by the adoption of Pillar Two regulations in these countries. We continue to monitor pending OECD guidance and legislation enactment and implementation by individual countries.

We operate in jurisdictions that impose transfer pricing and other tax-related regulations on our intercompany arrangements, and any failure to comply could materially and adversely affect our profitability.

We are required to comply with various transfer pricing regulations in India and other countries. Failure to comply with such regulations may impact our effective tax rates and consequently affect our net margins. Additionally, we operate in numerous countries and our failure to comply with the local and municipal tax regimes may result in additional taxes, penalties and enforcement actions from such authorities.

Although our intercompany arrangements are based on accepted tax standards, tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in such jurisdictions, which may increase our tax liabilities and could have a material adverse effect on the results of our operations and cash flows. Further, the BEPS project undertaken by the OECD contemplates changes to numerous international tax principles. Various countries have incorporated such tax principles into their domestic legislations by way of enactment. These enactments are significant in nature and require compliance on a regular basis. Although we will continue to adhere to such compliance, significant uncertainties remain as to the outcome of these efforts.

Opposition to free trade agreements and changes in trade policies of countries in which we operate could adversely affect the pricing and demand for our products.

Opposition to free trade agreements was an important component of the campaign platform of the new U.S. administration, and there are ongoing efforts to achieve that goal. For example, the United States withdrew from the Trans-Pacific Partnership ("TPP") free trade agreement and recently announced that it will end preferential trade treatment for India, currently being extended under its Generalized System of Preferences ("GSP"). In the current scheme, there might not be any direct impact on U.S. imports of pharmaceutical products due to this withdrawal. However, any such changes in free trade agreements could, among other things, interfere with free trade in goods, impose additional customs duties or tariffs, increase the costs and difficulties of international transactions and potentially disturb the international flow of goods and, in particular, trade between the United States and other countries, and thus may have an adverse effect on our financial performance.

Any new tariffs or other changes in U.S. trade policy could trigger retaliatory actions by affected countries, potentially escalating and resulting in "trade wars". For example, in March and April 2018, the U.S. government announced new tariffs on steel and aluminum from China, as well as more than 1,300 other Chinese exports. In response, the Chinese government announced that it would enact retaliatory tariffs on more than 100 American products. Trade policy changes or internal policy changes such as these can result in increased costs for goods, which may reduce customer demand for these products if the parties having to pay those tariffs increase their prices, or in increased costs to trading partners. If these consequences are realized, they may materially and adversely affect our sales and our business.

If the world economy is affected due to acts of terrorism, wars or regional hostilities, it may adversely affect our business and results of operations.

Several areas of the world, including India, have experienced terrorist acts and retaliatory operations in recent years. Local disturbances, terrorist attacks, riots, social disruption, wars, or regional hostilities in the countries in which we or our partners and suppliers operate (including but not limited to Russia and Ukraine) could affect the economy, our operations and employees by disrupting operations and communications, making travel and the conduct of our business more difficult, and/or causing our customers to be concerned about our ability to meet their needs. If the economy of any of our key markets (including but not limited to the United States, the United Kingdom, Germany, India, China, Russia, and Ukraine) is affected by such acts, our business, results of operations and cash flows may be adversely affected as a consequence.

From time to time we enter new markets, and face risks arising out of our limited knowledge of the market and the customs, laws and regulatory systems that may apply.

From time to time, we enter new markets in which we have limited knowledge of the market and the customs, laws, regulatory, political and social systems that may apply. Our success in these new markets is dependent upon the acceptability of our product and brand, the ease of doing business in such market and various other social and economic factors that may be specific to such market. Further, limitations by the local authorities of repatriation of generated funds may pose a risk to our success in these new markets. Our sales and profit margins may be adversely affected if we fail to provide competitive options in the market or our brands fail to gain acceptability in the market.

Risks from disruption to production, supply chain or operations from natural disasters could adversely affect our business and operations.

If flooding, droughts, hurricanes, tornados, wildfires, earthquakes, volcanic eruptions or other natural disasters or extreme weather events were to directly damage, destroy or disrupt our manufacturing facilities or facilities of our suppliers, it could disrupt our operations, delay new production and shipments of existing inventory or result in costly repairs, replacements or other costs, all of which would negatively impact our business. We are an integrated pharmaceutical company with manufacturing operations in multiple geographies such as India, Mexico, the United States and the United Kingdom. Few of the regions have experienced earthquakes, floods or droughts in the past. Even if we take precautions to provide back-up support in the event of such a natural disaster, the disaster may nonetheless affect our facilities, harming production and ultimately our business. And, even if our manufacturing facilities are not directly damaged, a large natural disaster may result in disruptions in distribution channels or supply chains. The impact of such occurrences depends on the specific geographic circumstances but could be significant. Current or future insurance arrangements may not provide adequate protection for losses that may arise from such events, particularly if such events are catastrophic in nature or occur in combination.

RISKS RELATING TO INVESTMENTS IN INDIAN COMPANIES

We are an Indian company. Our headquarters are located in India, a substantial part of our operations are conducted in India, and a significant part of our infrastructure and other assets are located in India. In addition, a portion of our total revenues for the year ended March 31, 2024 continued to be derived from sales in India. As a result, the following additional risk factors apply that are not specific to our company or industry.

We may be subjected to additional compliance and litigation risks as a result of periodic amendments in certain key Indian regulations, including The Indian Companies Act, 2013, SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, the Foreign Exchange Management Act, 1999 and other laws, regulations, as applicable to our company.

As a company that is incorporated in India, we are governed by certain key Indian rules and regulations, including the Indian Companies Act, 1956, as amended, and The Companies Act, 2013. Some of the significant changes from The Companies Act, 2013 were in the areas of board and governance processes, boardroom responsibilities, disclosures, corporate social responsibility, audit matters, initiation of class action suits by shareholders or depositors, fraud reporting and whistle-blower mechanisms.

In addition, the Securities and Exchange Board of India ("SEBI") issued the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 (the "Listing Regulations") which replaced the former Listing Agreement, that must be followed by all listed Indian public companies. The Listing Regulations were intended to consolidate and streamline the provisions of the then existing listing agreements for different segments of the capital markets (e.g., equity securities, debt securities, Indian depository receipts, etc.). The Listing Regulations have thus been structured to provide ease of reference by consolidating into one single document across various types of securities listed on the stock exchanges.

Key features of the Listing Regulations include:

A framework has been prescribed for disclosure of material events and information by listed entities to the Indian stock exchanges. Certain events mentioned in the regulations are deemed material and disclosure is mandatory. Subject companies are also required to make adequate disclosure of events or information which may have material effect. Certain events are to be disclosed based on application of the guidelines for materiality as prescribed. The Board of Directors is required to frame a policy for determination of materiality and disclose the same on the website of the company.

Entities are required to frame policies on preservation of documents, determination of material subsidiaries, risk management, code of conduct, remuneration of directors, key managerial personnel and other employees, board diversity, materiality of related party transactions and dealing with related party transactions, criteria for evaluation of directors, and certain other matters.

However, certain provisions of the Companies Act, 2013 and the SEBI Listing Regulations provisions are subject to varying interpretations and their application in practice may evolve over time as additional guidance is provided by regulatory and governing bodies. Further, the Companies Act, 2013, the rules made thereunder and the SEBI Listing Regulations have been and are being amended from time to time.

These amendments relate to, among other things, governance, related party transactions, financial reporting, audits and auditors, disclosures and other board and shareholders related matters. All of the foregoing may collectively result in continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions.

RISKS RELATING TO OUR ADSS THAT ARE NOT SPECIFIC TO OUR COMPANY OR INDUSTRY

Our principal shareholders have significant influence over us and, if they take actions that are not in the best interests of our minority shareholders, the value of their investment in our ADSs may be harmed.

Our full time executive directors and members of their immediate families, in the aggregate, beneficially owned 26.65% of our issued shares as of March 31, 2024. As a result, these people, acting in concert, are likely to have the ability to exercise significant influence over most matters requiring approval by our shareholders, including the election and removal of directors and significant corporate transactions. This significant influence by these directors and their family members could delay, defer or prevent a change in control, impede a merger, consolidation, takeover or other business combination involving us, or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. As a result, the value of the equity shares and/or ADSs of our minority shareholders may be adversely affected or our minority shareholders might be deprived of a potential opportunity to sell their equity shares and/or ADSs at a premium.

Fluctuations in our quarterly revenues, operating results and cash flows may adversely affect the trading price of our shares and ADSs.

Our quarterly revenues, operating results and cash flows have fluctuated significantly in the past and may fluctuate substantially from quarter to quarter in the future. Such fluctuations result from a variety of factors, including but not limited to changes in demand for our products, timing of regulatory approvals and of launches of new products by us and our competitors (particularly where we obtain the 180-day period of market exclusivity in the United States provided under the Hatch-Waxman Act of 1984), timing of our retailers' promotional programs and successful development and commercialization of limited competition and complex products. Such fluctuations may result in volatility in the price of our equity shares and our ADSs. In such an event, the trading price of our shares and ADSs may be adversely affected.

Negative media coverage and public scrutiny may adversely affect the prices of our equity shares and ADSs.

Media coverage, including social media coverage such as blogs, of us has increased dramatically over the past several years. Any negative media coverage, regardless of the accuracy of such reporting, may have an adverse impact on our reputation and investor confidence, resulting in a decline in the share price of our equity shares and our ADSs.

Indian law imposes certain restrictions that limit a holder's ability to transfer the equity shares obtained upon conversion of ADSs and repatriate the proceeds of such transfer, which may cause our ADSs to trade at a premium or discount to the market price of our equity shares.

Under certain circumstances, the Reserve Bank of India must approve the sale of equity shares underlying ADSs by a non-resident of India to a resident of India. The Reserve Bank of India has given general permission to effect sales of existing shares or convertible debentures of an Indian company by a resident to a non-resident, subject to certain conditions, including the price at which the shares must be sold. Additionally, except under certain limited circumstances, if an investor seeks to convert the Indian rupee proceeds from sale of equity shares in India into foreign currency and then repatriate that foreign currency from India, he or she will have to obtain an additional approval from the Reserve Bank of India for each such transaction. Required approval from the Reserve Bank of India or any other government agency may not be obtained on terms favorable to a non-resident investor or at all.

Investors who exchange our ADSs for our underlying equity shares may be subject to the provisions of the Companies Act, 2013 and to the disclosure obligations that may be necessary pursuant to the deposit agreement with our applicable depositary. The Companies Act, 2013 requires that, where the registered owner of shares does not hold the beneficial interest in such shares, both the registered owner and the beneficial owner of such equity shares are required to disclose to the company the nature of their interest, particulars of the registered owner and certain other details.

There are limits and conditions to the deposit of shares into the ADS facility.

Indian legal restrictions may limit the supply of our ADSs. The only way to add to the supply of our ADSs will be through a primary issuance because the depositary is not permitted to accept deposits of our outstanding shares and issue ADSs representing those shares. However, an investor in our ADSs who surrenders an ADS and withdraws our shares will be permitted to redeposit those shares in the depositary facility in exchange for our ADSs. In addition, an investor who has purchased our shares in the Indian market will be able to deposit them in the ADS program, but only in a number that does not exceed the number of underlying shares that have been withdrawn from and not re-deposited into the depositary facility. Moreover, there are restrictions on foreign institutional ownership of our equity shares as opposed to our ADSs.

The global pandemic, geo-political conflicts, persistently weak global economic and financial environment in many other countries, particularly emerging market countries, and increasing political and social instability could have a material adverse effect on our business and the price and liquidity of our shares and our ADSs.

It is uncertain how long the effects of global pandemic, geo-political conflicts, persistently weak global economic and financial environment, and increasing political and social instability in many other countries, particularly emerging market countries will last, or whether economic and financial trends will worsen or improve. These effects could have a material adverse effect on our business and the price and liquidity of our shares and our ADSs.

If U.S. investors in our ADSs are unable to exercise preemptive rights available to our non-U.S. shareholders due to the registration requirements of U.S. securities laws, the investment of such U.S. investors in our ADSs may be diluted.

A company incorporated in India must offer its holders of shares preemptive rights to subscribe and pay for a proportionate number of shares to maintain their existing ownership percentages prior to the issuance of any shares, unless these rights have been waived by at least 75% of its shareholders present and voting at a shareholders' general meeting.

U.S. investors in our ADSs may be unable to exercise preemptive rights for the shares underlying our ADSs unless a registration statement under the Securities Act of 1933 is effective with respect to the rights or an exemption from the registration requirements of the Securities Act is available. Our decision to file a registration statement will depend on the costs and potential liabilities associated with a registration statement as well as the perceived benefits of enabling U.S. investors in our ADSs to exercise their preemptive rights and any other factors we consider appropriate at the time. We might choose not to file a registration statement under these circumstances. If we issue any of these securities in the future, such securities may be issued to the depositary, which may sell them in the securities markets in India for the benefit of the investors in our ADSs.

There can be no assurances as to the value, if any, the depositary would receive upon the sale of these securities. To the extent that U.S. investors in our ADSs are unable to exercise preemptive rights, their proportional interests in us would be reduced.

Our equity shares and our ADSs may be subject to market price volatility, and the market price of our equity shares and ADSs may decline disproportionately in response to adverse developments that are unrelated to our operating performance.

Market prices for the securities of Indian pharmaceutical companies, including our own, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

Factors such as the following can have an adverse effect on the market price of our ADSs and equity shares:

general market conditions,

speculative trading in our shares and ADSs, and

developments relating to our peer companies in the pharmaceutical industry.

Investors who hold our ADSs may not be able to sell their ADSs at or above the price at which they purchased such ADSs. The price of our ADSs fluctuate from time to time, and we cannot predict the price of our ADSs at any given time. The risk factors described herein could also cause the price of our ADSs to fluctuate materially.

These broad market and industry factors may materially harm the market price of our ADSs, regardless of our operating performance. In addition, the price of our ADSs may be affected by the valuations and recommendations of the analysts who cover us, and if our results do not meet the analysts' forecasts and expectations, the price of our ADSs could decline as a result of analysts lowering their valuations and recommendations or otherwise.

There may be less company information available in Indian securities markets than securities markets in developed countries.

We are incorporated in India, and there are certain differences in the rights and protections of shareholders under the laws of India as compared to the laws of the United States and other developed economies.

For example, there is a difference between the level of regulation and monitoring of the Indian securities markets over the activities of investors, brokers and other participants, as compared to the level of regulation and monitoring of markets in such other countries. The Securities and Exchange Board of India is responsible for improving disclosure and other regulatory standards for the Indian securities markets. The Securities and Exchange Board of India has issued regulations and guidelines on disclosure requirements, insider trading and other matters. There may, however, be less publicly available information about Indian companies than is regularly made available by public companies in developed countries, which could affect the market for our equity shares and ADSs.

Indian stock exchange closures, broker defaults, settlement delays, and Indian Government regulations on stock market operations could affect the market price and liquidity of our equity shares.

The Indian securities markets are smaller than the securities markets in the United States and Europe and have experienced volatility from time to time. The regulation and monitoring of the Indian securities market and the activities of investors, brokers and other participants differ, in some cases significantly, from those in the United States and some European countries. Indian stock exchanges have at times experienced problems, including temporary exchange closures, broker defaults and settlement delays and if similar problems were to recur, they could affect the market price and liquidity of the securities of Indian companies, including our shares. Furthermore, any change in Indian Government regulations of stock markets could affect the market price and liquidity of our equity shares and ADSs.

Sale of our equity shares may adversely affect the prices of our equity shares and ADSs.

The Government of India's Depository Receipts Scheme, 2014, permits liberalized rules for sponsored and unsponsored secondary market issue of depository receipts, subject to the existing sectorial cap on foreign investment. Under the regulations implemented, an Indian company's equity shares can be freely issued to a depository for the purpose of issuing depository receipts through any mode permissible for the issue of such securities to other investors. This enables us to more readily issue shares to the depositary for our ADSs and conduct U.S. securities issuances of our ADSs, which may impact the share price and available float in Indian stock exchanges as well as the price and availability of our ADSs on the NYSE. Refer to Item 10.D. "Exchange controls – ADS guidelines" for further details.

Further, the SEBI introduced a detailed framework for issuance of Depository Receipts ("DRs") by a company incorporated and listed on a recognized stock exchange in India pursuant to its circular dated October 10, 2019. The framework inter alia sets out eligibility requirements, permissible jurisdictions, international exchanges, and permissible holder of DRs, as well as certain other obligations to be complied with by issuers of DRs, the Indian depository, the foreign depository and the domestic custodian. Further, pursuant to its circular dated November 28, 2019 and December 18, 2020, the SEBI gave notice of the permissible jurisdictions for listing of DRs and amended the scope and process for permissible holders of DRs, respectively.

The price of our ADSs and the U.S. dollar value of any dividends we declare may be negatively affected by fluctuations in the U.S. dollar to Indian rupee exchange rate.

Our ADSs trade on the NYSE in U.S. Dollars. Since the equity shares underlying the ADSs are listed in India on the BSE and the NSE and trade in Indian Rupees, the value of our ADSs may be affected by exchange rate fluctuations between the U.S. dollar and the Indian Rupee. In addition, dividends declared, if any, are denominated in Indian Rupees, and therefore the value of the dividends received by the holders of ADSs in U.S. Dollars will be affected by exchange rate fluctuations.

ITEM 4. INFORMATION ON THE COMPANY

4.A. *History and development of the Company*

Dr. Reddy's Laboratories Limited was incorporated in India under the Companies Act, 1956, by its promoter and our former Chairman, the late Dr. K. Anji Reddy, as a Private Limited Company on February 24, 1984. We were converted to a Public Limited Company on December 6, 1985 and listed on the BSE Limited (formerly known as the Bombay Stock Exchange Limited), the National Stock Exchange of India Limited and certain other Indian stock exchanges in August 1986, and on the New York Stock Exchange on April 11, 2001. We also listed on the NSE IFSC Limited, a stock exchange in the International Financial Services Centre in Gujarat, India, on December 9, 2020. We are registered with the Registrar of Companies, Hyderabad, Telangana, India as Company Identification No. L85195TG1984PLC004507. Our registered office is situated at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India and the telephone number of our registered office is +91-40-49002900. The name and address of our registered agent in the United States is Dr. Reddy's Laboratories, Inc., 107 College Road East, Princeton, New Jersey 08540. Our main corporate website address is https://www.drreddys.com.

The SEC maintains an Internet website (at www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. This annual report on Form 20-F and other information filed by us with or furnished by us to the SEC can be accessed via such website. Certain (but not all) of such materials are also available on our website, at www.drreddys.com, as soon as reasonably practicable after having been electronically filed with or furnished to the SEC. Information contained in our website, www.drreddys.com, is not part of this annual report on Form 20-F and no portion of such information is incorporated herein or any other materials filed with or furnished to the SEC.

Key business developments:

Agreement with Coya Therapeutics, Inc. ("Coya")

In December 2023, we entered into an agreement with Coya for the development and commercialization of COYA 302, an investigational combination therapy for the treatment of Amyotrophic Lateral Sclerosis ("ALS") under which Coya has granted us an exclusive license to commercialize COYA 302, a proprietary co-pack kit containing combination of low dose IL-2 and CTLA-4 Ig (abatacept) in the United States, Canada, the European Union and the United Kingdom. Coya will have responsibility for the clinical development and for seeking regulatory approval.

We paid an upfront consideration of Rs.622 million (U.S.$7.5 million) to Coya. Further milestones are payable upon achievement of certain development and regulatory milestones aggregating to Rs.2,118 million (U.S.$ 25.4 million).

Investment in O2 Renewable Energy IX Private Ltd

In July 2023, we entered into a Security Subscription and Shareholders' Agreement with TEQ Green Power XI Private Limited. Pursuant to this agreement, we have invested in O2 Renewable Energy IX Private Ltd, with ownership held 26% by us and 74% by TEQ Green Power XI Private Limited and its affiliates, which will supply renewable energy to us for our consumption. This investment will enable us to access to renewable power through solar and wind power plants through inter-state transmission systems under a captive structure.

Acquisition of MenoLabs® product portfolio from Amyris, Inc. ("Amyris")

In January 2024, we acquired from Amyris the MenoLabs® products portfolio from, a leading women's health and dietary supplement branded portfolio, for aggregate consideration of Rs.228 million (U.S.$3 million). This includes seven branded products designed to provide health support and to address symptoms of perimenopause and menopause. The acquisition also includes the MenoLife® health tracker app, which supports the product line and provides community, education, and information to consumers regarding menopause.

Distribution agreement with Sanofi Healthcare India Private Limited ("SHIPL")

In March 2024, we entered into exclusive distribution agreement with SHIPL to promote and distribute SHIPL's vaccine brands, including well-established pediatric and adult vaccines, in India. The partnership gives us a strong portfolio and major presence in the vaccine segment, taking us to the second position among vaccine sellers in India. SHIPL will continue to own and manufacture these brands and shall supply them to us.