3.D. *Risk factors*

You should carefully consider all of the information set forth in this Form 20-F and 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 or results of operations 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. See “Forward-Looking Statements.”

RISKS RELATING TO OUR COMPANY AND OUR BUSINESS

If we fail to comply fully with government regulations or to maintain continuing regulatory oversight applicable to our research and development activities or regarding the manufacture of our products, or if a regulatory agency amends or withdraws existing approvals to market our products, it may delay or prevent us from developing or manufacturing our products.

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. In many of the international markets into which we sell our products, including the United States, the approval process for a new product is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to several years from the date of application. This approval process increases the cost to us of developing new products and increases the risk that we will not be able to successfully sell such new products.

Regulatory agencies may at any time reassess the safety and efficacy of our products based on new scientific knowledge or other factors. Such reassessments could result in the amendment or withdrawal of existing approvals to market our products, which in turn could result in a loss of revenue, and could serve as an inducement to bring lawsuits against us. In our biosimilar business, due to the intrinsic nature of biologics, our bio-similarity claims can always be contested by our competitors, the innovator company and/or the applicable regulators.

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. For example, in the years ended March 31, 2017, 2018 and 2019, we experienced delays in obtaining approvals from the U.S. Food and Drug Administration (“U.S. FDA”) for various generic and specialty products as anticipated, principally as a result of the warning letter referenced below.

Additionally, governmental authorities, including among others the 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 audits are conducted on our manufacturing sites, and if the regulatory and quality standards and systems are not found adequate, it could result in an audit 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 were issued import alerts 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. There has been an increasing trend by the U.S. FDA and governmental regulators in other developed countries towards Indian manufacturing site audits. While our quality practices and quality management systems are conducted in a manner designed to satisfy these types of audits, we cannot guarantee that our efforts will prevent adverse outcomes such as audit observations, corrective action requests, warning letters or import bans.

For example, in November 2015, we received a warning letter from the U.S. FDA relating to cGMP deviations at three of our manufacturing facilities - two API manufacturing facilities and one injectable oncology formulations manufacturing facility in India. Refer to Note 33 of our consolidated financial statements under “Receipt of warning letter from the U.S.FDA” for further details.

More generally, unless and until an issue raised in a warning letter from the U.S. FDA is resolved to the U.S. FDA’s satisfaction, the U.S. FDA may withhold approvals of our new products and new drug applications, refuse admission of products manufactured at the facilities noted in the warning letter into the United States, and/or take additional regulatory or legal action against us. 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 our ongoing business, financial results and routine operations.

In recent years, there has been increasing regulatory scrutiny of pharmaceutical manufacturers, resulting in product recalls, plant shutdowns and other required remedial actions. We have been subject to increasing scrutiny of our manufacturing operations, and in previous years several of our facilities have been the subject of significant regulatory actions requiring substantial expenditures of resources to ensure compliance with more stringently applied production and quality control regulations. These regulatory actions also adversely affected our ability to supply various products worldwide and to obtain new product approvals at such facilities. If any regulatory body were to require one or more of our significant manufacturing facilities to cease or limit production, our business could be adversely affected. In addition, because regulatory approval to manufacture a drug is site-specific, the delay and cost of remedial actions, or of obtaining approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations.

Furthermore, 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 audit.

If we or our third party suppliers fail to comply fully with applicable regulations or to take corrective actions that are mandated, then there could be a government-enforced shutdown of our production facilities or an import ban, which in turn could lead to product shortages that delay or prevent us from fulfilling our obligations to customers, or we could be subjected to government fines.

Further, 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 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 fines in the tens or hundreds of millions of dollars, as well as criminal sanctions. 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.

An increasing 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 biosimilar products, 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.

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.

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.

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 companies sell generic versions of their products to the market directly or by acquiring or forming strategic alliances with our competitor generic pharmaceutical companies or by granting them rights to sell “authorized generics.” Moreover, brand-name companies continually seek new ways to delay the introduction of generic products and decrease the impact of generic competition, such as filing new patents on drugs whose original patent protection is about to expire, developing patented controlled-release products, changing product claims and product labeling, or 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.

Our competitors, which include major multinational corporations, are consolidating, and the strength of the combined companies could affect our competitive position in all of our business areas. Furthermore, if one of our competitors or their customers acquires any of our customers or suppliers, we may lose business from the customer or lose a supplier of a critical raw material. In addition, our increased focus on innovative and specialty pharmaceuticals requires much greater use of a direct sales force than does our core generic business.

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. Prices of generic drugs typically decline, often dramatically, especially as additional generic pharmaceutical companies receive approvals and enter the market for a given product. Consequently, our ability to sustain our sales and profitability of any product over time is dependent on both the number of new competitors for such product and the timing of their approvals.

In our proprietary products business, many of our competitors have greater experience than we do in clinical testing, human clinical trials, obtaining regulatory approvals and commercialization. They may be able to respond more quickly to new or emerging market preferences or to devote greater resources to the development of new products and/or technologies than we can. As a result, any products and/or innovations that we develop may become obsolete or non-competitive before we can recover the expenses incurred in connection with their development. Since these products are designed to address unmet or inadequately met medical needs, there is an increased need for our sales organization to emphasize to physicians, patients and third-party payors the benefits of our products relative to competing products which are often more familiar or otherwise better established. If competitors introduce new products or new variations on their existing products, our proprietary products, even those protected by patents, may experience substantial reductions in market shares and may require substantial price reductions in order to remain competitive.

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, 2019, our ten largest customers accounted for approximately 77% of our North America Global Generics segment's revenues. 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 has resulted in these groups gaining additional purchasing leverage and, consequently, increasing the product pricing pressures facing our business. We expect this trend of increased pricing pressures to continue. Such pressures have reduced, and could continue to reduce, our revenue, margins and profitability.

Additionally, 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.

If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and other efforts, sales of our generic products may be adversely impacted.

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay or eliminate generic competition. These efforts have included:

- pursuing new patents for existing products that may be granted just before the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;
- selling the brand product as an authorized generic, either by the brand company directly or through a marketing partner;
- introducing "next-generation" products prior to the expiration of market exclusivity for the generic product, which often materially reduces the demand for the generic product for which we seek regulatory approval;
- obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations;
- using the Citizen Petition process to request amendments to U.S. FDA standards on testing bio-equivalence;

- seeking changes to U.S. Pharmacopeia, an organization that publishes industry recognized compendia of drug standards;
- attaching patent extension amendments to non-related federal legislation;
- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing;
- seeking patents on methods of manufacturing certain active pharmaceutical ingredients;
- attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled; and
- entering into agreements with pharmacy benefit management companies that have the effect of blocking the dispensing of generic products.

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. 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.

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.

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. 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. 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, and pricing transparency mandates;
- more governments using international reference pricing to set the price of drugs based on international comparisons.

- 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;
- more demanding evaluation criteria applied by Health Technology Assessment (“HTA”) agencies when considering whether to cover new drugs at a certain price level; and

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.

In addition, there has been legislation and legislative proposals concerning drug prices and related issues, including the perceived need to bring more transparency to drug pricing, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

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 outlets being supplied through contracts procured in competitive bidding tenders, thereby causing significant pressure on product margins.

Certain other countries may consider the implementation of a tender system or other forms of price controls. Even if a tender system is ultimately not implemented, the anticipation of such a system could result in price reductions. Failing to win tenders, or the implementation of similar systems or other forms of price controls in other markets leading to further price declines, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

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. 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 and results of operations and/or the price of our ADSs.

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 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 and 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 addition, our systems are potentially vulnerable to data security breaches, whether by employees or others that may expose sensitive data to unauthorized persons. Such data security breaches 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. Such breaches of security could result in reputational damage and could otherwise have a material adverse effect on our business, financial condition and results of operations. Further, increasing use of information technology (“IT”) systems in manufacturing processes would require us to manage issues arising out of human error and/or sabotage.

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. 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 effects 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 deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a security breach.

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, penalties, reputational damage, and could impact the way we operate our business.

We are subject to laws and regulations governing the collection, use and transmission of health information, including personal data. 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. For example, the European Union’s General Data Protection Regulation (“GDPR”) that became fully effective in May 2018, requires Companies to satisfy new requirements regarding the handling of personal and sensitive data and includes significant new penalties for non-compliance, with fines up to the higher of EUR 20 million or 4% of total annual worldwide revenue.

Additionally, California recently enacted the California Consumer Privacy Act (“CCPA”), which creates new individual privacy rights for consumers and places increased privacy and security obligations on entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches.

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

These and similar initiatives could increase the cost of developing, implementing or maintaining our IT systems and require us to allocate more resources to compliance initiatives thereby increasing our costs. 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 to us and could have a material adverse effect on the way we operate our business, our financial condition and results of operations.

Increasing use of social media could give rise to liability or breaches of data security.

We and our business associates are increasingly relying on social media and mobile 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 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 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. Such uses of social media could have a material adverse effect on our business, financial condition and results of operations. 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.

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, Pharmaceutical Services and Active Ingredients, and Proprietary Products segments. 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 proprietary products and biosimilars, is both time consuming and costly and involves a high degree of business risk. 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.

Our research and development efforts are increasingly 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 expenses 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.

For example, during the year ended March 31, 2017, we acquired eight Abbreviated New Drug Applications in the United States from Teva Pharmaceutical Industries Limited (“Teva”) and an affiliate of Allergan plc. The consideration for such purchase was U.S.$350 million in cash at closing, which was funded through borrowings from certain institutional lenders. Our results of operations may suffer if these products are not timely developed, approved or successfully commercialized.

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 a 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.

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.

Following the United States Supreme Court's June 2013 ruling in Mutual Pharmaceutical Co. v. Bartlett upholding such preemption and immunity of generic manufacturers, the U.S. FDA had proposed a new rule in November 2013 that would have allowed generic manufacturers to independently update product labeling through the CBE supplement process. If the U.S. FDA's proposed new rule was adopted, it may have eliminated this preemption and increased our potential exposure to lawsuits relating to product safety, side effects and warnings on labels. This new 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 and self-insurance may become the sole commercially reasonable means available for managing the product liability risks of our business. After twice delaying publication of a final rule, the U.S. FDA withdrew its proposed rule during 2017.

The risk of exposure to lawsuits is likely to increase as we develop our own new patented products, or limited competition/complex products, such as injectable 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 and results of operations.

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.

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.

Increasing scrutiny and changing expectations from customers, regulators, investors, and other stakeholders with respect to our environmental, social and governance practices may impose additional costs on us or expose us to new or additional risks.

Companies are facing increasing scrutiny from customers, regulators, investors, and other stakeholders related to their environmental, social and governance practices. Investor advocacy groups, investment funds and influential investors are also increasingly focused on these practices, especially as they relate to the environment, health and safety, supply chain management, diversity and human rights. Failure to adapt to or comply with regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation or harm our business and financial results.

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 hurt our employees, cause damage to our properties and harm the environment. Also, increases in business and operations in our plants, and the consequent hiring of new employees, can pose increased safety hazards. Such hazards need to be addressed through training, industrial hygiene assessments and other safety measures and, if not carried 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.

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 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. For example, as a result of severe political instability and conflict in Ukraine, the United States and the European Union have imposed sanctions on certain individuals and companies in Ukraine and Russia, including sanctions targeted at the Crimea region of Ukraine which was annexed by Russia. Political instability in the region, combined with low worldwide oil prices, resulted in significant devaluation of the Russian rouble

We monitor significant political, legal, regulatory and 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; intellectual property protection and remedy laws; trade regulations; procedures and actions affecting approval, production, pricing 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 are conducted outside the markets 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, due to economic, legislative, political and military conditions, including hostilities and acts of terror, in such countries.

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.

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 for the purpose of obtaining or retaining business. These laws may require not only accurate books and records, but also sufficient controls, policies and processes to ensure business is conducted without the influence of bribery and corruption. Our policies mandate compliance with these anti-bribery laws, which 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 laws may conflict with some local customs and practices. In many less-developed markets, we work with third-party distributors and other agents for the marketing and distribution of our products. Although our policies prohibit these third parties from making improper payments or otherwise violating these anti-bribery laws, any lapses in complying with such anti-bribery laws by these third parties may adversely impact us. Business activities in many of these markets have historically been more susceptible to corruption.

If our efforts to screen third-party agents and detect cases of potential misconduct fail, we could be held responsible for the non-compliance of these third parties under applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act. Compliance with the U.S. Foreign Corrupt Practices Act and other anti-bribery laws has been subject to increasing focus and activity by regulatory authorities in recent years. 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.

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 or results of operations.

If the world economy is affected due to acts of terrorism, wars or epidemics, 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 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 and Russia) is affected by such acts, our business and results of operations may be adversely affected as a consequence.

Uncertainty and volatility in relation to the UK’s planned exit from the EU

On June 23, 2016, the United Kingdom (“U.K.”) held a remain-or-leave referendum on its membership within the European Union (“EU”), the outcome of which was a decision for the U.K. to exit from the EU (the “Brexit”).This was meant to be effective as of March 29, 2019 after the U.K. invoked Article 50 of the Treaty on European Union. A process of negotiation will likely determine the future terms of the U.K.’s relationship with the EU, as well as whether the U.K. will be able to continue to benefit from the EU’s free trade and similar arrangements. As pharmaceutical legislation in the U.K. is largely derived from the EU law and relies on mutual recognition of decision making, implementation of a number of practical steps is required before the U.K. exits the EU.

In November 2018, the U.K. and E.U. agreed upon a draft agreement that set out the terms of the U.K.'s withdrawal. In January 2019, the draft withdrawal agreement was rejected by the U.K. parliament, creating significant uncertainty about the terms (and timing) under which the U.K. will exit the EU. The departure date has now been extended to October 31, 2019, although it could be earlier if the U.K. Parliament approves the draft withdrawal agreement. If the U.K. leaves the EU with no withdrawal agreement, it will likely have an adverse impact on trade, in addition to creating further short-term uncertainty and currency volatility. Brexit could also lead to legal uncertainty and potentially divergent national laws and regulations in the U.K. and E.U.

Given the uncertainty surrounding the terms of the U.K.'s withdrawal and its consequences, until the Brexit negotiation process is completed, it is difficult to anticipate the potential impact on our market share, sales, profitability and operations. For example, in the immediate aftermath of the Brexit, it is possible that the capacity at major ports both in the U.K. and the EU is materially reduced for an indeterminate period of time. This could adversely affect our ability to transport medicines, raw materials and intermediates to the U.K and/or the EU with a consequential adverse impact. The Brexit could also result in restrictions on the movement of persons, deterioration in market access or trading terms, delay or restrictions to the movement of goods, potential changes to intellectual property rights, regulatory approval requirements and pharmaceutical regulations, or increased cost and burdens arising from other new or diverging rules and regulations, any of which may have a significant adverse impact on our operations, profitability and business model.

In addition, following the Brexit vote in the U.K., the EU has decided to move the headquarters of the EU's health authority, the EMA, from the U.K. to the Netherlands by March 2019. It is expected that a significant percentage of the current employees of the EMA will decide not to make the move to the Netherlands. This raises the possibility that new drug approvals in the EU could be delayed as a result.

The longer-term effects of the Brexit are difficult to predict but could include further financial instability and slower economic growth or an economic downturn in the U.K., the EU and/or the global economy. Furthermore, uncertainty around the form and timing of any withdrawal agreement and the form and timing of any post-withdrawal trading arrangements (whether with the EU or third parties) could increase instability and volatility and lead to adverse effects on the economy of the U.K., the EU and the rest of the world. Any of the foregoing could, in turn have an adverse economic impact on our operations. As the process of Brexit evolves, we will continue to assess its impact on us.

Our Proprietary Products segment, particularly our Specialty businesses in the United States, faces intense competition from companies that are more entrenched than we are or have greater resources than ours.

Our risk profile for our Proprietary Products segment is lower than the comparable risk profile of companies working with completely novel entities. Nevertheless, the risk that the businesses in this segment face is higher than that of the Generics business due to several factors outlined below.

Market penetration requires successful commercial positioning in relation not only to past therapies but also new competitors. All of the therapeutic areas in which we compete have many active competitors, each vying for market share in similar indications with products that may have some similar attributes. As such, success in our Proprietary Products segment requires the ability to strategically differentiate our offerings from those of our competitors. .

Even if we are able to successfully develop a differentiated version, favorable unrestricted reimbursement from payors for our products is necessary in order to realize the desired potential. Typically, a managed care plan relies on a committee comprised of physicians and other decision makers and influencers to decide which drugs will appear on its formulary. The randomized clinical trial data generated to obtain U.S. FDA approval will no longer be sufficient to gain a favorable access decision. Typically, all managed care plans attempt to aggressively direct their patients towards generic medicines due to their lack of belief in differentiation or overall cost improvement. Thus it is imperative to satisfy the committee that there is sufficient evidence that the impact of the differentiation and/or incremental innovation of our products is significantly higher, in order to persuade them to list it on their respective formularies. Without our products having a reasonable position on the formulary of managed care plans, patients will not be able to obtain access to our products and physicians become less likely to prescribe our products.

Additionally, because the Specialty business of our Proprietary Products segment works primarily with known active molecules, there remains a risk that these products are easier to engineer around than products possessing composition of matter patents. Although we strive to create a robust intellectual property “ring fence” to protect these assets, the products in our U.S. Specialty business portfolio may nonetheless enjoy fewer years of exclusivity than traditional innovative products.

Research and development efforts invested in our differentiated formulations and biologics products may not achieve expected results.

In our Proprietary Products segment, our business model focuses on building a pipeline in the therapeutic areas of neurology and dermatology. In our biologic segment, our business model focuses on building a pipeline in various therapies targeted at both emerging markets and highly regulated markets. We must invest increasingly significant resources to develop differentiated products and biosimilars, both through our own efforts and through collaborations, in-licensing and acquisition of products from or with third parties. The development of differentiated products and biosimilars involves processes and expertise significantly more complex than those used in the development of generic drugs, which increases the risks of failure. During each stage, we may encounter obstacles that delay the development process and increase expenses, leading to significant risks that we will not achieve our goals and may be forced to abandon a potential product in which we have invested substantial amounts of time and money. These obstacles may include: preclinical failures; difficulty enrolling patients in clinical trials; delays in completing formulation and other work needed to support an application for registration; adverse reactions or other safety concerns arising during clinical testing; insufficient clinical trial data to support the safety or efficacy of the product candidate; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured.

Because of the amount of capital required to be invested in augmenting our differentiated products and biosimilar pipeline, in some cases we are reliant on partnerships and joint ventures with third parties, and consequently face the risk that some of these third parties may fail to perform their obligations, or fail to reach the levels of success that we are relying on to meet our revenue and profit goals.

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 are 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 the profits lost by the patent owner and not by the profits we earned.

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. In the case of a willful infringer, the definition of which is unclear, these damages may even be trebled.

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 cash flows.

Failure to maintain supply of compliant, quality product.

- 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; and
- 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.
- We also manufacture and sell a number 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.

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.

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.

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.

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.

There has been a trend of increased regulatory review of over-the-counter products for safety and efficacy questions, which could potentially affect our over-the-counter products business.

In recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain over-the-counter medicine products. Litigation, particularly in the United States, sometimes gives rise to these questions. As a result, health authorities around the world have begun to re-evaluate some important over-the-counter products, leading to restrictions on the sale of some of them and even the banning of certain products. If the U.S. FDA or another regulator were to review one or more of our over-the-counter products for such purposes, and if such review resulted in the U.S. FDA or another regulator charging us with violations applicable to such product, it could have a significant adverse effect on our sales of such over-the-counter products and, thus, our overall profitability.

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.

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 and results of operations could be materially adversely affected.

If we are unable to patent new products and processes or to protect our intellectual property rights or proprietary information, or if we infringe on the patents of others, our business may be materially and adversely impacted.

Our overall profitability depends, among other things, on our ability to continuously and timely introduce new generic as well as proprietary products. Our success depends, in part, on our ability in the future to obtain patents, protect trade secrets, intellectual property rights and other proprietary information and operate without infringing on the proprietary rights of others. Our competitors may have filed patent applications, or hold issued patents, relating to products or processes that compete with those we are developing, or their patents may impair our ability to successfully develop and commercialize new products.

Our success with our proprietary products depends, in part, on our ability to protect our current and future innovative products and to defend our intellectual property rights. If we fail to adequately protect our intellectual property, competitors may manufacture and market products similar to ours. We have been issued patents covering our innovative products and processes and have filed, and expect to continue to file, patent applications seeking to protect our newly developed technologies and products in various countries, including the United States. Any existing or future patents issued to or licensed by us may not provide us with any competitive advantages for our products or may even be challenged, invalidated or circumvented by competitors. In addition, such patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation that we seek to protect, in part by confidentiality agreements with licensees, suppliers, employees and consultants. It is possible that these agreements may be breached and we may not have adequate remedies for any such breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors. Therefore, despite all of our information security systems and practices, we may still not be able to ensure the confidentiality of information relating to such products.

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. However, to distributors and patients, counterfeit products may be visually indistinguishable from the authentic version.

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. In addition, there could be thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels.

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. We do not use derivative financial instruments or other hedging techniques to cover all of our potential exposure.

A significant portion of our borrowing costs are linked to U.S. dollar London Interbank Offered Rate (“LIBOR”), and hence any increase in U.S. dollar LIBOR adversely impacts our financial performance.

In July 2017, the United Kingdom’s Financial Conduct Authority, which regulates LIBOR, announced that it intends to phase out LIBOR by the end of 2021. It is unclear if LIBOR will cease to exist or if new methods of calculating LIBOR will be established such that it continues to exist. As such, depending on the future of LIBOR, a comparable or successor reference rate as determined under our credit agreements may apply, or we may need to renegotiate certain terms of our credit agreements to replace U.S. dollar LIBOR with a new standard. In either case, our interest rates and interest expense could increase, which could adversely affect our financial condition, operating results and cash flows.

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. 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 would have a material adverse effect on our business, financial condition and results of operations. In addition, we do not maintain “key person” life insurance on any officer, employee or consultant.

Since a large part of our business centers around the United States, changes to the U.S. immigration laws could make it more difficult to obtain nonimmigrant work authorizations in the United States. There have been and will continue to be calls for extensive changes to U.S. immigration laws regarding the admission of highly-skilled temporary and permanent workers.

There are some legislative proposals which, if passed and signed into law, could add further costs and/or restrictions to some of the high-skilled temporary worker categories and, in turn, our cost of doing business in the United States may increase. This could have a material and adverse effect on our business, revenues and operating results.

Compliance with new and changing corporate governance and public disclosure requirements adds uncertainty to our compliance policies and increases our costs of compliance.

Changing laws, regulations and standards relating to accounting, corporate governance and public disclosure, including the Sarbanes Oxley Act of 2002, new SEC regulations, New York Stock Exchange rules, provisions of India’s Companies Act 2013, Securities and Exchange Board of India rules and Indian stock market listing regulations, create uncertainty for our company. These new or changed laws, regulations and standards may lack specificity and are subject to varying interpretations. Their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions to such governance standards.

We are committed to maintaining high standards of corporate governance and public disclosure, and our efforts to comply with evolving laws, regulations and standards in this regard have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, the new laws, regulations and standards regarding corporate governance may make it more difficult for us to obtain director and officer liability insurance. Further, our board members, chief executive officer, chief operating officer and chief financial officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may face difficulties attracting and retaining qualified board members and executive officers, which could harm our business. If we fail to comply with new or changed laws or regulations and standards differ, our business and reputation may be harmed.

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.

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 various tax benefits and exemptions under Indian tax laws, such as tax benefits on research and development spending and exemptions applicable to income derived from manufacturing facilities located in certain tax exempted zones. Any changes in these laws or their application may increase our tax liability and thus adversely affect our financial results.

For instance, presently under Indian tax laws, weighted deduction on research and development activities is available at 150% which will be reduced to 100% commencing April 1, 2020. Further, Special Economic Zone (“SEZ”) units commencing manufacture or production of article and things after April 1, 2020 will not be eligible for SEZ tax deductions currently available.

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 and commercial decisions that are necessary for the conduct of the business of an entity as a whole are in substance made.

Effective July 1, 2017, a Goods and Services Tax (“GST”) was introduced in India, replacing various taxes such as central excise duty, service tax, octroi, value added tax, sales tax and entry tax, thus avoiding the multiple layers of taxation that had previously existed in India. The GST rate applicable to finished dosages is generally 12%, whereas API are subject to a GST rate of 18%. Taxing finished dosages at lower rates than API reduces the competitiveness of domestically manufactured finished dosages as compared to imported finished dosages - sometimes referred to as an “inverted duty structure”. Relevant procedures have been prescribed in the GST legislation relating to tax credits allowing for refunds to offset the adverse impact of such inverted duty structure. Accumulation of tax credits is likely to persist at any point of time owing to the lag between the time the tax credit arises and the time that the refund is received.

Further, the effective rate of corporate dividend distribution tax ("DDT") has been increased several times since 2013. Effective April 1, 2018, the effective rate of DDT increased from 20.3576% to 20.5553%.

In December 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "TCJA"). The TCJA made broad and complex changes to the U.S. Internal Revenue Code, including, but not limited to, reducing the U.S. federal corporate income tax rate from 35% to 21% effective for tax years beginning after December 31, 2017. The TCJA also put in place new tax laws that may impact our taxable income for tax years beginning after December 31, 2017, which include, but are not limited to (i) expanded limitations on the deductibility of interest, (ii) immediate expensing of capital expenditures, (iii) the migration from a "worldwide" system of taxation to a territorial system, (iv) the creation of an anti-base erosion minimum tax system; and (v) the modification or repeal of many business deductions and credits.

Changes in tax regimes in countries other than India, such as the TCJA, 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.

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. Further, the base erosion and profit shifting ("BEPS") project undertaken by the Organization for Economic Cooperation and Development ("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.

We enter into various agreements in the normal course of business which periodically incorporate provisions whereby we indemnify the other party to the agreement.

In the normal course of business, we periodically enter into agreements with vendors, customers, alliance partners, innovators and others that incorporate terms for indemnification provisions. Our indemnification obligations under such agreements may be unlimited in duration and amount. We maintain insurance coverage that we believe will effectively mitigate our obligations under certain of these indemnification provisions (for example, in the case of outsourced clinical trials). However, should our obligations under an indemnification provision exceed our coverage or should coverage be denied, it could have a material adverse impact on our business, financial position and results of operations.

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

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.

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

If flooding, droughts, earthquakes, volcanic eruptions or other natural disasters were to directly damage, destroy or disrupt our manufacturing facilities, 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. A significant portion of our manufacturing facilities are situated around Hyderabad, India, a region that has experienced earthquakes, floods and 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.

In addition, there is increasing concern that climate change is occurring and may have dramatic effects on human activity without aggressive remediation steps. A modest change in temperature may cause a rising number of natural disasters. We cannot predict the economic impact, if any, of natural disasters or climate change.

Our principal shareholders have significant control 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 directors and members of their immediate families, in the aggregate, beneficially owned 26.77% of our issued shares as at March 31, 2019. As a result, these people, acting in concert, are likely to have the ability to exercise significant control over most matters requiring approval by our shareholders, including the election and removal of directors and significant corporate transactions. This significant control 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.

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 substantial portion of our total revenues for the year ended March 31, 2019 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 introduction of the Companies Act, 2013 in India and the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

As a company that is incorporated in India, we are governed by the rules and regulations covered under the Indian Companies Act, 1956. Significant amendments to the Companies Act were adopted in 2013 and 2014 and a majority of the provisions of the new Act (called the "Companies Act, 2013") were implemented beginning in April, 2014. Some of the significant changes were in the areas of board and governance processes, boardroom responsibilities, disclosures, compulsory corporate social responsibility, audit matters, initiation of class action suits by shareholders or depositors, fraud reporting and whistle-blower mechanisms.

In addition, on September 2, 2015, the Securities and Exchange Board of India ("SEBI") issued the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 (the "Listing Regulations") that must be followed by all listed Indian public companies effective December 1, 2015. These Listing Regulations were intended to consolidate and streamline the provisions of the 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. 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 and criteria for evaluation of directors.

However, certain provisions of the Companies Act, 2013 and the new 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 new Listing Regulations are subject to various ongoing changes. In 2017, certain amendments to the Companies Act, 2013 were implemented through the Companies (Amendment) Act, 2017 in the areas of related party transactions, financial reporting, audit and auditors, board matters and others. Certain of such amendments are yet to be effective.

In 2018, certain amendments to SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 were amended through the SEBI (Listing Obligations and Disclosure Requirements) (Amendment) Regulations, 2018. These amendments relate to, among other things, governance, related party transactions, financial reporting, audits and auditors, board matters. Such amendments are primarily effective from April 1, 2019.

All of the foregoing may collectively result in continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions.

A slowdown in economic growth in India may adversely affect our business and results of operations.

Our performance and the quality and growth of our business are necessarily dependent on the health of the overall Indian economy. The Indian economy has grown significantly over the past few years. Any future slowdown in the Indian economy could harm us, our customers and other contractual counterparties. In addition, the Indian economy is in a state of transition. The share of the services sector of the Indian economy is rising while that of the industrial, manufacturing and agricultural sector is declining. It is difficult to gauge the impact of these fundamental economic changes on our business.

If wage costs or inflation rise in India, it may adversely affect our competitive advantages over higher cost countries and our profits may decline.

Wage costs in India have historically been significantly lower than wage costs in developed countries and have been one of our competitive strengths. However, wage increases in India may increase our costs, reduce our profit margins and adversely affect our business and results of operations.

Due to various macro-economic factors, the rate of inflation has recently been volatile in India. If the inflation rises, we may not be able to pass these inflationary costs on to our customers by increasing the price we charge for our products.

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. Approximately 3.54% of our employees belong 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.

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

The market price of our ADSs may be volatile, and the value of your investment could materially decline.

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 cause the price of our ADSs to fluctuate materially. In addition, the stock market in general, including the market for generic and specialty pharmaceutical companies, has experienced price and volume fluctuations. 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.

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 a 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.

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 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.

Many of the world's largest economies and financial institutions continue to be impacted by a weak ongoing global economic and financial environment, with some continuing to face financial difficulty, liquidity problems and limited availability of credit. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. In addition, these issues may be further impacted by the difficult conditions existing in parts of the Middle East, anti-immigrant activities, social unrest and fears of terrorism that have followed in many countries.

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.

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

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 the United States and other developed economies. 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 enacted the Depository Receipts Scheme, 2014, effective as of December 15, 2014. This law permits liberalized rules for sponsored and unsponsored secondary market issue of depository receipts, subject to the existing sectorial cap on foreign investment. Once the regulations are 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 would enable us to more readily issue shares to the depositary for our ADSs and conduct U.S. securities issuances of our ADSs, which would 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.

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 are registered with the Registrar of Companies, Hyderabad, Telangana, India as Company No. 4507 (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:

Re-Audit of the Warning letter impacted sites

Refer to Note 33 of our consolidated financial statements under “Receipt of warning letter from the U.S. FDA” for details.

In response to the warning letter and subsequent reinspections, we implemented various global corrective actions, as well as some specific corrective actions. Additionally, a detailed response was submitted to the U.S. FDA which included root cause assessments, corrective actions and preventive actions and impact assessment. We remain fully committed to following high standards of quality and strive towards further strengthening of our quality management systems and processes for sustainability. Our plans to enhance our quality management systems and operations include improvements in rigor of investigations and document control systems, standardization of instrument calibrations, strengthening controls with respect to information technology, strengthening shop floor training programs, and simplifying and standardizing standard operating procedures and batch records at the shop floor.

Further, we have initiated additional operational improvements with respect to areas such as shop floor supervision and Gemba walks (also known as process walks) into the shop floor, engineering, implementation of electronic batch records to eliminate manual errors, and focus on robustness of processes.

Throughout the process of remediating issues raised in the Warning Letter, we have been continually engaged with the U.S. FDA in conveying the progress we have made. We are fully committed to produce safe and efficacious products for our patients.

Asset purchase agreement with Teva Pharmaceutical Industries Ltd

During the year ended March 31, 2017, we acquired from Teva Pharmaceutical Industries Limited and an affiliate of Allergan plc a portfolio of eight ANDAs for our North American Generics business. Refer to Note 32 of our consolidated financial statements for further details.

Principal capital expenditures:

During the years ended March 31, 2019, 2018 and 2017, we invested Rs.8,376 million, Rs.8,894 million and Rs.12,234 million (net of sales of capital assets), respectively, in capital expenditures for manufacturing, research and development facilities and other assets. We believe that these investments will create the capacity to support our strategic growth agenda. As of March 31, 2019, we also had contractual commitments of Rs.2,495 million for capital expenditures. We currently intend to finance our additional capital expansion plans entirely through our operating cash flows and through cash and other investments.