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IPO Note – Gland Pharma Ltd

07-November-2020

RETAIL RESEARCH

Gland Pharma Ltd

Issue Snapshot:
Issue Open: Nov 09 – Nov 11, 2020

Price Band: Rs. 1490 – 1500

*Issue Size: 43,196,968 eq shares
(Fresh Issue of 8,333,333 eq sh + Offer for sale of 34,863,635 eq sh)

Issue Size: Rs. 6436.3 – 6479.5 cr

Reservation for:

QIB	Upto 50% eq sh
Non Institutional	atleast 15% eq sh
Retail	atleast 35% eq sh

Face Value: Rs 1

Book value: Rs 255.79 (June 30, 2020)

Bid size: - 10 equity shares and in multiples thereof

100% Book built Issue

Capital Structure:

Pre Issue Equity:	Rs. 15.49 cr
Post issue Equity:	Rs. 16.33 cr

Listing: BSE & NSE

Book Running Lead Manager: Kotak Mahindra Capital Company Ltd, Citigroup Global Markets India Private Ltd, Haitong Securities India Private Ltd, Nomura Financial Advisory and Securities (India) Private Ltd

Registrar to issue: Link Intime India Private Limited

Shareholding Pattern

Shareholding Pattern	Pre issue %	Post issue %
Promoter and Promoter Group	74.0	58.4
Public & Employee	26.0	41.6
Total	100.0	100.0

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

Background & Operations:

Gland Pharma Ltd (GPL) is one of the fastest growing generic injectables-focused companies by revenue in the United States from 2014 to 2019. It sells its products primarily under a business to business ("B2B") model in over 60 countries as of June 30, 2020 including the United States, Europe, Canada, Australia, India and the Rest of the world. It has a consistent compliance track record with a range of regulatory regimes across these markets and has an extensive track record in complex injectables development, manufacturing and marketing and a close understanding of the related sophisticated scientific, technical and regulatory processes.

GPL is focused on meeting diverse injectables needs with a stable supply of affordable and high quality products. It has established a portfolio of injectable products across various therapeutic areas and delivery systems. At present GPL is in sterile injectables, oncology and ophthalmics, and focus on complex injectables, NCE-1s, First-to-File products and 505(b)(2) filings. Its delivery systems include liquid vials, lyophilized vials, pre-filled syringes, ampoules, bags and drops. It is expanding its development and manufacturing capabilities in complex injectables such as peptides, long-acting injectables, suspensions and hormonal products as well as new delivery systems such as pens and cartridges.

Over the years, GPL has made substantial investments in its manufacturing infrastructure to support its product portfolio needs and reach. It has seven manufacturing facilities in India, comprising four finished formulations facilities with a total of 22 production lines and three API facilities. As of June 30, 2020, it had manufacturing capacity for finished formulations of approximately 755 million units per annum. Its API facilities provides with in-house manufacturing capabilities for critical APIs, enabling to control costs and quality and mitigate supply chain related risks around its key products.

As of June 30, 2020, GPL along with its partners had 267 ANDA filings in the United States, of which 215 were approved and 52 were pending approval. The 267 ANDA filings comprise 191 ANDA filings for sterile injectables, 50 for oncology and 26 for ophthalmics related products. Out of these 267 ANDA filings, 101 represent ANDAs owned by GPL, of which 71 ANDA filings are approved and 30 are pending approval. The company along with its partners had a total of 1,427 product registrations, comprising 371 product registrations in the United States, Europe, Canada and Australia, 54 in India and 1,002 in the Rest of the world. It has a consistent regulatory compliance track record and all its facilities are approved by the USFDA from whom it has had no warning letters since the inception of each facility.

Objects of Issue:

The Offer comprises of the Fresh Issue and Offer for Sale. The proceeds of the Offer for Sale shall be received by the Selling Shareholders. GPL will not receive any proceeds from the Offer for Sale.

The Fresh Issue

GPL proposes to utilise the Net Proceeds towards funding of the following objects:

- Funding incremental working capital requirements of GPL
- Funding capital expenditure requirements of GPL; and
- General corporate purposes

Competitive Strengths

Extensive and vertically integrated injectables manufacturing capabilities with a consistent regulatory compliance track record: GPL's seven manufacturing facilities are situated in southern India including two sterile injectables facilities, one dedicated Penems facility, one oncology facility and three API facilities. Its manufacturing process is designed to facilitate production flexibility and deliver high and consistent product quality. Its four finished formulation manufacturing facilities with a total of 22 production lines possess the flexibility to accommodate different product requirements without the need to install new production lines. This allows the company to adapt quickly

to changes in product specifications, market demand and production requirements. In addition, GPL consider that diversification of product approvals across its multiple manufacturing units for its key products mitigates its exposure to regulatory risk with respect to any particular unit and provides increased certainty of supply.

GPL's manufacturing facilities has established a consistent record of regulatory compliance with the USFDA highlighting its focus on quality assurance and quality control. It has also received WHO GMP certifications for its facilities from the Drugs Control Administration (Governments of Telangana and Andhra Pradesh, India) (DCA) and it had three ISO certifications as of June 30, 2020 for its quality management, environment management and occupational health and safety management systems. GPL has a total of three API facilities that provide it with in-house manufacturing capabilities for critical APIs. 24 of its ANDAs covering GPL's key products are supported by in-house APIs. It consider that its ability to integrate backwards to manufacture its own critical APIs allows GPL to develop products that other companies may not focus on due to their uncertainty of API supply. Its vertical integration allows to achieve greater control over manufacturing processes to meet required standards, increase operating efficiencies, accelerate product development, strengthen product quality control and improve supply chain efficiencies.

Diversified B2B-led model across markets, complemented by a targeted B2C model in India*:* GPL's primary business model is B2B, covering IP-led, technology transfer and contract manufacturing models, complemented by a B2C model in its home market of India. It consider that its various B2B business models enables to (i) grow market share in key markets such as the United States, Europe, Canada and Australia, particularly the United States, while reducing the marketing investments it need to make, (ii) leverage the reputation of marketing partners in home markets to build own presence in these markets, (iii) build own reputation as a complex injectables manufacturer with a consistent compliance record attracting confidence from other potential marketing partners, and (iv) balance profitability and capacity utilisation while continuing to deliver high manufacturing and quality standards to a broad range of customers. Under the B2B CMO model which is primarily for the India market, GPL provides fill and finish services for aseptically or terminally sterilised injectables to other pharmaceutical companies for already approved products. It enter into loan and license agreements with these pharmaceutical companies and receive manufacturing and packaging payments per unit manufactured. Under the B2B CMO model, its customer retains ownership of the relevant dossier as well as development, intellectual property and marketing rights of a product, while it retain the manufacturing right during the term of the agreement.

Under the B2C model, GPL engage in direct marketing solely in India which leverages its brands in this market to drive its focus on injectables. As a majority of products pipeline is fully owned by GPL, it provides the ability to expand its own direct sales platform in the Indian market. As of June 30, 2020, it had a sales force of over 200 employees and an extensive countrywide distribution network to ensure coverage in approximately 2,000 corporate hospitals, nursing homes and government facilities. In Fiscals 2018, 2019 and 2020, its revenue generated from the B2C model constituted 3.73%, 4.43% and 4.01%, respectively, of its total revenue from operations for the relevant year. In the three months ended June 30, 2020, its revenue generated from the B2C model constituted 3.06% of its total revenue from operations for the relevant period.

Extensive portfolio of complex products supported by internal R&D and regulatory capabilities*:* GPL is a vertically integrated company with demonstrated ability to advance a product from the R&D stage through commercialisation. Its capabilities include internal research and development expertise, robust manufacturing capabilities (including the ability to synthesise and manufacture critical APIs in-house), a strict quality assurance system, extensive regulatory experience and established marketing and distribution relationships. As of June 30, 2020, it had a total workforce of 3,766 excluding contract labourers across these business divisions, including an in-house R&D team for product development, regulatory affairs for obtaining product registrations, manufacturing, supply chain management, and sales and marketing. GPL is present in sterile injectables, oncology and ophthalmics, and focus on complex injectables, NCE-1s, First-to-File products and 505(b)(2) filings. It has established a portfolio of injectable products across various therapeutic areas and delivery systems. Its delivery systems cover liquid vials, lyophilized vials, pre-filled syringes, ampoules, bags and drops. It is expanding its development and manufacturing capabilities in complex injectables such as peptides, long-acting injectables, suspensions and hormonal products as well as new delivery systems such as pens and cartridges. Its product development is underpinned by its internal R&D expertise. In addition its R&D laboratories are engaged in the development of key processes such as formulation development, analytical method development, API process development and stability studies.

GPL's product capabilities are further reinforced by its drug regulatory capabilities to facilitate registration of complex injectables across the lifecycles and markets for these products. Its regulatory team has extensive experience in the regulatory requirements of its key markets to facilitate new product registrations. Its regulatory team is constantly engaged with regulators including the USFDA, and plays an active role in achieving operational efficiencies by undertaking CBE-30 filings for site and line changes as well as filing for change of APIs when cheaper sources are available.

Track record of growth and profitability from a diversified revenue base with healthy cash flows*:* GPL's total revenue from operations has grown at a CAGR of 27.38% from Fiscals 2018 to 2020. Its EBITDA has grown at a CAGR of 36.90% from Fiscals 2018 to 2020. Restated profit for the year has grown at a CAGR of 55.15% from Fiscals 2018 to 2020.Its products are developed and manufactured in India which has previously conferred R&D and manufacturing cost advantages on Indian pharmaceuticals manufacturers compared to their

competitors in higher cost markets. GPL strive to be a capital efficient business. In Fiscals 2018, 2019 and 2020 and the three months ended June 30, 2020, its debt equity ratio was 0.002, 0.002, 0.001, and 0.001, respectively. It does not have any significant borrowings. Its revenue base is diversified by business model as well as by key customers (with whom it generally has long term contracts) and markets. GPL's top five customers in Fiscals 2018, 2019 and 2020 and the three months ended June 30, 2020 accounted for 49.92%, 47.86%, 48.86%, and 44.45%% respectively, of its total revenue from operations for the relevant period. Some of these customers have contracted with it for products sold across multiple markets.

Experienced management and qualified team and are promoted by Shanghai Fosun Pharma: GPL has a professional and experienced management team with significant expertise in the pharmaceutical industry. It considers this facilitates effective operational coordination and continuity of business strategies. Its management team includes experienced senior executives, many of whom have been with the Company for a significant period of time. One of its Promoters, Shanghai Fosun Pharma, is a global pharmaceutical major with extensive pharmaceutical manufacturing, distribution and R&D expertise internationally, and in China. Its relationship with Shanghai Fosun Pharma provides with widened market access opportunities arising from its own continuing internationalisation. In particular, it had benefitted from Shanghai Fosun Pharma's established presence in China and Africa, both of which it consider to be key growth markets for injectables.

Business Strategy:

Expand product portfolio and delivery systems to drive revenue growth: GPL has maintained a focus on achieving a diverse product mix offering products at various stages of their lifecycle as well as a robust product pipeline. As of June 30, 2020, GPL along with its partners had 267 ANDA filings in the United States, of which 215 were approved and 52 pending approval. The company is present in sterile injectables, oncology and ophthalmics, and focus on complex injectables, NCE-1s, First-to-File products and 505(b)(2) filings. It has established a portfolio of injectable products across various therapeutic areas and delivery systems. Its delivery systems cover liquid vials, lyophilized vials, pre-filled syringes, ampoules, bags and drops. GPL is expanding its development and manufacturing capabilities in complex injectables such as peptides, long-acting injectables, suspensions and hormonal products as well as new delivery systems such as pens and cartridges. It intends to continue enhancing its product portfolio to offer a diverse suite of products to cater to the growing demand for injectables.

GPL will continue to focus on developing products primarily for the U.S. market and leverage this product portfolio to extend across other markets. This is enabled by its continued adherence to high quality control and regulatory compliance across its facilities and development processes in order to meet evolving regulatory standards particularly around new products for the U.S. market. To cater to the needs of other key markets, it also has started to develop products aligned with the requirements of those markets. It also intends to increase its product offerings by continuing to invest in new technologies to maintain its competitive strengths in both product development and product manufacturing capabilities for complex injectables.

Continue to invest in manufacturing and related technological capabilities to meet future demand: GPL aims to continue investing in manufacturing technologies to build new capabilities to support the production of its future portfolio of complex injectables, primarily for the U.S. market. To maintain its competitive position, it intends to expand its current manufacturing capacity for key products and continue to invest in new technologies and manufacturing capabilities in complex injectables such as peptides, long-acting injectables, suspensions and hormonal products as well as new delivery systems such as pens and cartridges. It has increased its manufacturing capacities from 670 million units per annum in Fiscal 2018 to 755 million units as of June 30, 2020.

Since obtaining the first USFDA approval at Pashamylaram, Hyderabad, GPL has expanded the manufacturing capacity of its manufacturing facilities at that location. It is in the process of commissioning additional capacity to support its future portfolio of complex injectables including suspensions, cartridges and hormonal products. It aims to continue investing in manufacturing technologies to build new capabilities to support the production of its future portfolio of complex injectables. GPL plans to purchase additional equipment, such as (i) production and packing equipment; (ii) electrical panel and fitting equipment; (iii) Heating, Ventilation and Air Conditioning ("HVAC") equipment; (iv) lab equipment; (v) R&D equipment; (vi) utilities equipment; and (vii) warehouse equipment.

GPL's technological capabilities has also ensured ANDA filings and approvals track record which it will seek to maintain. It will continue to invest in innovative technologies to enhance complex injectables manufacturing capabilities. Key focus areas include peptides, long acting injectables, suspensions and hormones. This will allow GPL to enrich its product pipeline and improve the competitiveness of its product portfolio. GPL will seek to ensure continued high quality standards across its products, processes and facilities to maintain consistent track record of regulatory compliance

Increase current market presence and enter new markets: GPL intends to maintain its strategic emphasis on the United States, Europe, Canada and Australia, while continuing to pursue growth opportunities in China, India, Brazil and the Rest of the world. It plans to grow its business in the United States, Europe, Canada and Australia by maintaining an appropriate product mix in its portfolio with products which it consider will improve its profitability as well as utilise its capacities more efficiently. It will also focus efforts on establishing effective relationships with existing and new marketing partners to commercialise its portfolio of products. In Brazil it seeks to increase

demand for its products in line with changes in healthcare standards, insurance penetration and government spending on healthcare. GPL plans to expand its presence in these markets by increasing its portfolio of product registrations and by increasing its customer and distributor base through marketing arrangements with local distributors and pharmaceutical companies.

In India GPL has been focusing on growing its presence through own sales and distribution network by using its own brands and personnel, and also by co-marketing with leading pharmaceutical companies with a strong brand and wide sales reach. While it has a strong presence in the cardiac and pain management therapeutic areas, as part of its growth strategy it has recently launched the infertility therapeutic area to further diversify its portfolio. It will continue to evaluate other opportunities for growth in the India market. For the Rest of the world markets (excluding India), it intend to continue working with business partners and distributors having a well-established local presence.

Align with Shanghai Fosun Pharma to increase market share: GPL intends to continue its strategic alignment with Shanghai Fosun Pharma to increase its market share in the global generic injectables industry. It intends to leverage Shanghai Fosun Pharma's existing infrastructure and global presence to access new markets, including the Chinese and African markets. Its relationship with Shanghai Fosun Pharma has enabled it to initiate product filings in China, with its first filing completed for the Chinese market in 2019.

Pursue strategic acquisitions and partnerships: To complement GPL's organic growth and internal expertise, it may also pursue strategic acquisitions of companies, products and technologies to add to its capabilities and technical expertise or enter into partnerships to strengthen GPL's product and technology infrastructure in areas including steroidal hormonal products, suspensions, anti-neoplastics and nasal and inhalation products. It will seeks to identify API suppliers that complement its business with niche capabilities including fermentation technology, corticosteroid APIs and hormonal APIs as well as partners with USFDA approved facilities to reduce market entry time. In certain markets where there is a preference for local manufacturers, it may partner with or acquire suitable local manufacturers with manufacturing, R&D and marketing capabilities to complement its product development capabilities.

Continued focus on cost management: GPL aims to continue to maintain its cost management focus, including in-house integrated manufacturing capabilities, across its business to deliver growth as well as to achieve economies of scale. In addition, it aims to continue to achieve supply chain efficiencies through lifecycle management of products, including in the R&D and manufacture processes. It considers that its products for the U.S. market benefit from its ability to integrate backwards to manufacture its own critical APIs, providing it with security and cost advantages in its supply chain. The backward integration for its critical APIs also allows GPL to gain greater market competitiveness. The Company will continue to seek to manage its supply chain costs through optimal inventory levels, economic orders and other measures. It will also continue to ensure timely filings of applications for alternative cost-effective APIs and components sourced externally, change in batch sizes and additional equipment qualifications for better yields.

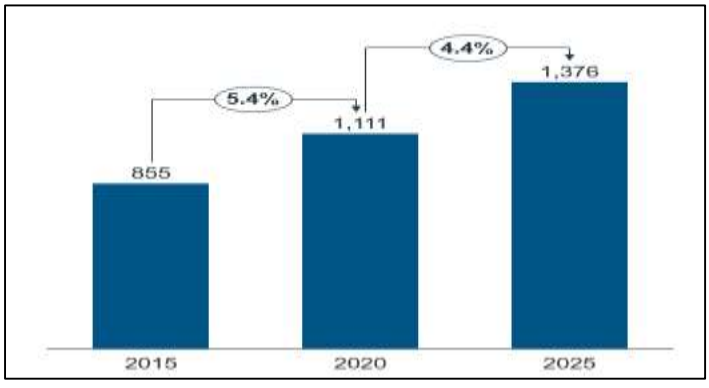
Industry

Global Pharmaceutical Market

Size and Growth of Global Formulation Market

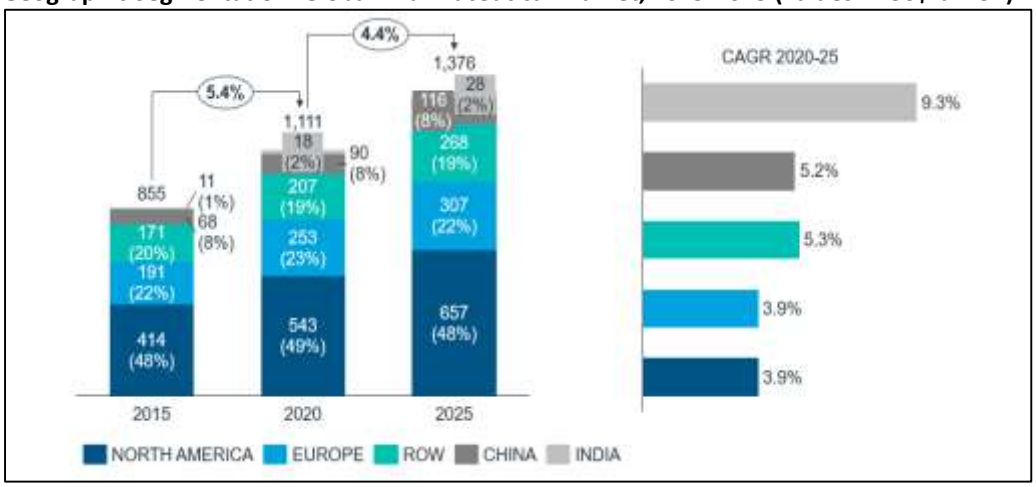
According to the IQVIA Report, the global formulation market grew at a CAGR of approximately 5.4% from 2014 to reach approximately US$1,111 billion in 2020. The market is estimated to grow at a CAGR of approximately 4.4% to reach approximately US$1,376 billion by 2025.

Global Pharmaceutical Market, 2015-2025 (values in US$ billion)



According to the IQVIA Report, North America is expected to constitute approximately 49% of the overall market by value and grow at a CAGR of approximately 3.9%. India and China are expected to contribute approximately 2% and 8%, respectively, of the market by value, with India expected to grow at a faster rate of approximately 9.3% and China at a CAGR of approximately 5.2% during 2020 to 2025.

Geographic Segmentation: Global Pharmaceutical Market, 2015-2025 (values in US$ billion)



Segmentation of Global Pharmaceutical Market

According to the IQVIA Report, oral solids, the largest delivery form in the market by value, was estimated to be US$494 billion in 2020, growing at a CAGR of approximately 3% from 2015 to 2020. However, the market share by value of oral solids declined from approximately 50% in 2015 to 44% in 2020. Injectables are the second largest delivery form in global pharmaceutical market. IQVIA estimated that the global injectables market grew at a CAGR of approximately 9.8% from 2015 to 2020 to reach approximately US$445 billion in 2020. Market share by value of injectables increased from approximately 33% in 2015 to approximately 40% in 2020.

Product Type Segmentation

Market share by value remained approximately the same for generics and innovator molecules from 2015 to 2020. Generics grew at a CAGR of approximately 4.4% and innovators grew at a CAGR of approximately 5.9% from 2015 to 2020.

Geographic Segmentation

North America continued to form the major share of the global pharmaceutical market by value at approximately US$543 billion in 2020, growing at approximately 5.5% from 2015 to 2020. India had the least market share by value but has grown at the fastest rate of approximately 11.4% between 2015 and 2020.

Size and Growth of Global Generics Formulation Market

According to the IQVIA Report, the global generics market was estimated to be US$392 billion in 20201, constituting approximately 35% of the global pharmaceutical market. The market grew at a CAGR of approximately 4.4% from 2015 to 2020 and is estimated to grow at a CAGR of approximately 5.3% to reach approximately US$509 billion by 2025, constituting approximately 37% of the global pharmaceutical market by 2025. North America, the largest generic market in 2020, was estimated to be US$126 billion in 20202 and expected to grow at a CAGR of approximately 2.9% from 2020 to 2025, slower than other regions due to price erosion resulting from increased competition. The European generic market was estimated to be US$94 billion and expected to grow at a CAGR of approximately 5.3% from 2020 to 2025 to reach US$121 billion in 2025. India and RoW were expected to grow at a faster rate of more than 8% from 2020 to 2025, primarily driven by volumes.

According to the IQVIA Report, Indian manufacturers accounted for approximately 33% market share by volume in the generics market in the United States (largest market within North America) in 2019. Indian manufacturers have increased their share significantly by approximately 10% from 2017 to 2019. This was primarily driven by quality manufacturing capacity and competitive pricing. India also has the highest number of USFDA-approved manufacturing facilities outside the United States, accounting for approximately 20% of manufacturing facilities of finished dosage forms. According to the IQVIA Report, the pricing of generic molecules from Indian manufacturers is lower compared to non-Indian manufacturers in the United States market. For example, average price of key molecules such as Amlodipine, Glimepiride and Metformin from Indian manufacturers were 40-50% lower than non-Indian generics in 2019. The lower pricing is primarily driven by the lower cost of production in India, which is nearly 30-40% lower than that of the United States, attributable to a range of factors including competitive land rates, skilled labour and low utility (water and electricity) cost.

Geographic Segment Overview

United States

According to the IQVIA Report, the United States pharmaceutical industry was estimated to be US$499 billion in 20193, growing at CAGR of 6.3% from US$368 billion in 20144, characterised by multinational companies forming the core of the business which operate across the world in both developed and emerging markets. One of the key regions of growth will continue to be the United States with an approximately 4% to 7% CAGR from 2019 to 2023. Despite its own research and development capabilities and innovations, the market has

also been widely open to generics. The United States currently has the highest generic sales in the world at US$111 billion, contributing to approximately 28% of overall generic market by value.
The ageing population of 65 years and above in the United States is expected to increase to approximately 18% of the total population in 2024 from 16% in 2019, resulting in more consumers for pharmaceutical products. Growing demand for pharmaceutical products will generate a need for more generics in the market.

India
According to the IQVIA Report, the Indian pharmaceutical market was estimated to be US$18 billion in 2019, growing approximately 11.6% CAGR from US$11 billion in 2014. The industry has been able to offer a wide variety of high quality and affordable generics across the world. Increasing incidence of chronic diseases due to changing lifestyle, improving affordability, growing penetration of medical insurance, government policies such as Ayushman Bharat are expected to improve the diagnosis and treatment rates in India, driving the growth of the pharmaceutical industry despite population growth slowdown in 2020 to 2024. Real GDP growth was forecasted to reach 5.8% in 2020 from an estimated growth rate of 4.2% in 2019. According to the IMF projections in April 2020, India is however expected to witness a GDP growth rate of 1.9% in 2020, given the COVID-19 pandemic and consumer price inflation of 3.3%, which is 1.2% points lower than the 2019 average.

China
According to the IQVIA Report, the Chinese pharmaceutical market was estimated to be approximately US$92 billion in 2019, growing at a CAGR of 7.1% from US$65 billion in 2014. According to the IMF projections in April 2020, real GDP growth was forecasted to decline to 6% from 6.1% in 2019 but will now be 1.2% in 2020, given the COVID-19 pandemic, while consumer price growth will rise to an average of 3% annually in 2020.

Global Injectables Market

According to the IQVIA Report, injectables are the second largest form of drug delivery systems, accounting for approximately 40% of the global pharmaceutical market by value in 2020. Injectables have numerous advantages over other traditional dosage forms: Injectables have close-to-immediate onset of action. Injectables allow patients who are unable to take other dosage forms due to difficulties in consuming oral medication to adhere to their medication regimen. Injectables are particularly useful for unconscious or comatose patients who are otherwise not capable of consuming medication. Injectables offer a unique capability of giving the administrator control over drug delivery to a specific location in a measured manner. The development of self-injection devices like pen injectors and auto injectors has made administering drugs more convenient and easy for patients. Patients can now use these novel devices and self-administer their medication in the comfort of their homes without medical supervision. There is an increase in the number of new drug formulations which are less water soluble and/or have very low permeability to allow for adequate absorption from the gastrointestinal tract following oral administration. The only way to make such drugs available in the body is through an intravenous administration. According to the IQVIA Report, the global injectables market was estimated to be US$445 billion in 2020, growing at a CAGR of approximately 9.8% from 2015 to 2020. The market share by value of injectables grew from approximately 33% in 2015 to approximately 40% in 2020.

Growth Drivers for Injectables
The growth of injectables has been among the fastest across all drug delivery formats primarily due to the following factors:

Rising prevalence of chronic diseases
- There is a strong increase in the prevalence of diabetes and other chronic diseases which treatment is primarily administered through injectables.
- According to a WHO Global Report on Diabetes, the global prevalence of diabetes has nearly doubled since 1980 and is expected to continue rising. Consequently, there is an increase in the demand for injectables.
- Most chemotherapy drugs are delivered through injectables, which is one of the key growth drivers of injectables globally. According to the WHO – International Agency for Research on Cancer Fact Sheet, the number of new cancer cases was approximately 18 million in 2018 and is expected to increase to over 23 million by 2030.

Convenience and benefits of New Drug Delivery Systems ("NDDS")
- There is a rising demand for self-administered medications which has now become a major trend. The development of new injectable delivery devices such as auto injectors, pen injectors, pre-filled syringes ("**PFS**") and needle-free injectors has led to the increased access to self-administered medications. These NDDS offer greater convenience and safety while self-administering, as well as allow patients to reduce the frequency of their hospital visits.
- Advancements in NDDS technology has resulted in development of self-injectors that are increasingly being used in areas other than diabetes, such as the treatment of orphan diseases in oncology or hormone therapy, where multiple doses are needed over time.

New market opportunities

The market for injectable drugs is increasing as new ailments such as rheumatoid arthritis, multiple sclerosis, cancers and autoimmune disorders are now being treated through injectables solutions. Pharmaceutical companies are developing and investing heavily in the development of new complex molecules to target these diseases.

Growth of biologics

Biologics are gaining popularity in the pharmaceutical industry, and injectables, especially prefilled syringes, are witnessing increased adoption as the preferred drug delivery systems due to their ease of handling, less overfills and more safety to patients. In the coming few years, many biologic drugs will witness loss of patent exclusivity. This is expected to result in a surge in their biosimilar products thereby increasing demand for the injectable drug delivery devices for these formulations.

Market Entry Barriers

Injectables form appears to have high entry barriers due to its inherent complex nature. Injectables manufacturers face high entry barriers such as high capital investments, operational costs, manufacturing complexities, stricter compliance requirement due to the sterile nature of products and high-quality standards, resulting in limited competition in the market. These factors have resulted in lesser competitors in the injectables segment relative to other segments. For the United States generic injectables market, 70% of the market by value has less than half the number of manufacturers compared to the oral solids segment, corroborating high level of entry barriers for injectables. Due to highly complex and stringent development and manufacturing process involved, injectables continue to remain a specialised area within the pharmaceutical industry. The inherent complicated nature of injectables leads to fewer companies having the capability to operate in this segment.

Geographic Segmentations Of Global Injectables Market

According to the IQVIA Report, North America accounted for the largest share by value of approximately 56% in 2020 and is estimated to be worth approximately US$249 billion, followed by Europe with a market share of approximately 21% with an estimated value of US$94 billion. China accounted for approximately 11% of market share with an estimated market of US$47 billion, while India has approximately 1% market share with an estimated US$3 billion market. The remaining 12% was contributed by the RoW, with an estimated US$52 billion market.

According to the IQVIA Report, Japan, Russia, Korea, Australia and Saudi Arabia are the key markets contributing to approximately 68% of overall RoW injectables market. Japan's injectable market size is estimated at US$23.7 billion in 2020 and has grown at a CAGR of approximately 4.0% in the last five years from 2015 to 2020, followed by Russia and Korea with an estimated market size of approximately US$4 billion each with a CAGR of approximately 11.3% and 9.0%, respectively. India's injectables market witnessed growth primarily on account of rising prevalence of chronic diseases such as diabetes and growth in demand of insulin and certain therapeutic areas (i.e. nervous system, musculoskeletal system, gastro intestinal system, respiratory system and systemic anti-infective), which constitutes approximately 73% of the generic injectables market in India in 2020.

Global Generic Injectables Market

According to the IQVIA Report, China and North America have the highest and lowest generic penetration by volume in the injectables form in 2020. Generic penetration has mostly increased across the geographies during the last few years, except for North America and China where the value of the market has however, increased and grown by 12.1% and 1.2% respectively. The key generic injectable molecule volumes that have decreased in North America are Hydromorphone, Ondansetron, Morphine, Vancomycin & Midazolam. The generic injectable molecules that have decreased in volumes in China are Ascorbic Acid, Pyridoxine & Levofloxacin. North America has the lowest generic penetration of approximately 73% across the geographies. China has the highest generic injectables market share estimated at 89%, followed by India, and Europe, both having a generic injectables market share of approximately 76% respectively.

Overview of Delivery Systems in Global Injectables Market

Injectables globally are administered through multiple delivery systems which include infusion systems, pre-filled syringes ("**PFS**"), vials, cartridges, ampoules and a few other delivery forms. Infusions, PFS and vials are the most preferred delivery systems contributing to approximately 85% of the global injectables market in 2020. Infusion therapy is an alternative to oral treatment in which the medication is administered into a vein and secured. This treatment traditionally predominant in hospitals is now being increasingly used in outpatient treatment with focused infusion therapy centres and at home by trained nurses.

Fill and finish, or aseptic technology is gaining prominence among manufacturing partners

Fill and finish is an advanced aseptic processing technology, which uses a continuous process to form, fill with drug or biologic and seal the container in a sterile environment. Most of the manufacturing partners specialising in injectables outsourcing are developing fill-finish capabilities to meet the growing needs of the market PFS grew in preference for healthcare professionals at a CAGR of approximately 14.5% from 2015 to 2020. PFS is a single dose packet of vaccine to which the needle has been fixed by the manufacturer. PFS has multiple advantages on counts of convenience, affordability, accuracy and safety for both patients and healthcare professionals. PFS also benefits the pharmaceutical companies by saving on the cost of vials as PFS works well with both safety devices and auto-injection systems.

Overview Of The United States Injectables Market

According to the IQVIA Report, innovator molecules contributed approximately 81% and generics contributed approximately 19% of the market by value in 2020. The market is estimated to grow at a CAGR of approximately 15.3% to reach approximately US$489 billion by 2025. Innovator molecules are expected to cover approximately 80% of the market along with expected new drug introductions, and generics are estimated to form approximately 20% of the market by value in 2025.According to the IQVIA Report, injectables in the United States constituted the largest form of drug delivery systems, accounting for approximately 47% by value of the United States pharmaceutical market in 2020. The United States injectables market was estimated to be approximately US$240 billion in 2020, growing at a CAGR of approximately 12.8% from 2015 to 2020, faster than the other segments. Injectables have grown from having an approximate 34% market share by value in 2015 to approximately 47% in 2020.

Overview Of Key Business Models In Injectables Manufacturing

There are primarily two models which global injectables manufacturing companies operate: *B2C (Business to Consumer)* – this is the traditional model where the finished dose formulations are marketed by major pharmaceutical companies to the final customers. These companies can manufacture the formulation or outsource the manufacturing, incur development expenses, and own intellectual property rights. Major players who follow this B2C model include Hikma, Fresenius Kabi, Amphastar, Sagent, American Reagent, Mylan, Teva and Sandoz.

B2B (Business to Business) – this predominantly includes value-added manufacturing partners which specialise in manufacturing various injectables formulations and provides other value-added services to injectables marketing companies. Drug marketer companies partner with CMOs who offer them outsourced manufacturing solutions. Major players who follow this B2B model in injectables include Gland, Recipharm, Lonza and Piramal Pharma Solutions. Some of the large B2C pharmaceutical companies are also active in the B2B market, such as Pfizer Centreone, Merck Bioreliance, Abbvie, Baxter, Ratio Pharma, Sanofi and GSK.

The Impact Of The Covid-19 Pandemic On Global Pharmaceutical Growth

The COVID-19 pandemic has been fast-moving and has had very serious and unprecedented effects in many countries, which are still unfolding. Regions in North America, Europe, China and India have seen a lower pharmaceutical market growth rate in 2020 due to the COVID-19 pandemic. Any potential impacts on pharmaceutical consumption are also complex, multifaceted and very difficult to predict. Although there is currently no treatment or vaccine for COVID-19, the pandemic is still expected to impact pharmaceutical markets, with seven key themes identified:

1. ***Economic impact on growth:*** The COVID-19 pandemic is already causing a slowdown in economic growth around the world and this may have knock-on effects for pharmaceutical markets which are sensitive to the country's economic growth. In contrast, in many developed markets it is thought that pharmaceutical sales are generally protected from economic downturns.

2. ***Impact on APIs/Generics:*** The industry faces interruptions to the supply chain, given that China is a key global source of APIs. For example, India's dependence on China for around 70% of API imports meant that disruptions in China's API production caused upward pressure on drug prices in India in early 2020. Where disruption to the supply from China and India persists, especially if COVID-19 spreads significantly in India, this could trigger price increases globally for affected products, particularly generics.

3. ***Upsurge in demand for medicines to alleviate COVID-19 symptoms:*** Shortly following the COVID-19 outbreak significant consumer panic purchasing of OTC medication was witnessed in several countries. This has included increases in the sale of immunity enhancing treatments, vitamins, analgesics (especially paracetamol), anti-infectives, and cough and cold medications. This is expected to lead to a short term boost in retail volume growth in those countries most affected.

4. ***Delays in treatment of non-COVID-19 patients:*** Hospitals under increasing pressure to accommodate COVID-19 inpatients have deprioritised elective surgeries and other treatments. The drug sales for certain treatments could reduce due to the reduced focus on non-COVID-19 patients.

5. ***Face-to-Face interactions minimised:*** Due to concerns regarding COVID-19 transmission, face-to-face interactions between healthcare professionals and pharmaceutical industry representatives has already fallen in many countries. This trend is expected to continue and may lead to a small negative impact on pharmaceutical sales.

6. ***Impact on innovation:*** Manufacturers may consider postponing their approach to new product launches to beyond the peak of the pandemic. Lack of personnel could also result in delays to regulatory approvals and formulary listings. This may have a short-term impact on pharmaceutical sales growth in the countries affected, most notably in the hospital sector.

7. ***Travel Restrictions & Medical Tourism*:** Reductions in medical tourism is expected to cause a decrease in sales and retail sector pharmaceutical consumption. Widespread travel restrictions and border closures globally, will constrain pharmaceutical consumption through hospital and private sector outlets.

Key Concerns:

- GPL's industry is heavily regulated and its business activities require various approvals, licenses, registrations and permissions.
- Success is dependent on GPL's business arrangements with marketing partners and customers for the sale of its products.
- If GPL's API production is interrupted or it fails to produce or procure high-quality APIs in the quantities it require in a cost-effective manner, sales of its products could be delayed or interrupted.
- Any manufacturing or quality control problems may disrupt business operations, damage reputation for high quality production and expose GPL to potential litigation or other liabilities, which would negatively impact the business, prospects, cash flows, results of operations and financial condition.
- Business of GPL is dependent on the sale of products to its key customers and in key markets, particularly the United States, Europe, Canada and Australia.
- A significant portion of GPL's income is dependent on sales of its key injectable formulations. If the sales volume or pricing of such products declines in the future, or if it can no longer sell any of the key compounds for any reason, its business, financial condition, cash flows and results of operations could be materially adversely affected.
- Susceptible to product liability claims and associated risks of litigation that could expose GPL to material liabilities, loss in revenues and increased expenses and thus may have a material adverse effect on the business and financial condition.
- Regional conflicts, civil disturbances and terrorist attacks in South Asia may have an adverse effect on GPL's business.
- The COVID-19 pandemic, or any future pandemic or widespread public health emergency, could materially and adversely impact GPL's business, financial condition, cash flows and results of operations.
- Business subjects GPL to risks in multiple countries that could materially adversely affect the business, cash flows, results of operations and prospects.
- Profitability, cash flows and results of operations may be adversely affected in the event of increases in the price of raw materials, fuel costs, labour or other inputs, shortfall in the supply of raw materials as well as interruption in the supply of machinery and equipment required for GPL's manufacturing facilities.
- If GPL do not successfully develop new products or continue its product portfolio expansion in a timely and cost effective manner, its business, financial condition, cash flows and results of operations may be adversely affected.
- Manufacturing facilities are located in the southern Indian states of Andhra Pradesh and Telangana. Any delay in production at, or shutdown of, any of these facilities may adversely affect GPL's business, cash flows, results of operations and financial condition
- Require certain approvals and licenses in the ordinary course of business, and the failure to obtain or retain them in a timely manner may adversely affect GPL's business, financial condition, cash flows and results of operations
- GPL's markets are highly competitive, both globally and domestically, and if it is unable to compete successfully against existing or new competitors, its revenues could decline and its future profitability could be affected.
- GPL may be required to conduct clinical trials for some of its products in the future. Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and it may be unable to achieve successful results in its clinical trials.
- The availability of spurious pharmaceutical products could lead to losses in revenues and harm the reputation of GPL's products, which may in turn result in a material adverse effect on its business, financial condition, cash flows and results of operations.
- Reforms in the healthcare industry and the uncertainty associated with pharmaceutical pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for GPL's products.

- Dependent upon the experience and skill of GL's management team and key employees.
- GPL may not be able to correctly assess the demand for its products, which may adversely affect the business, financial condition, cash flows and results of operations.
- If GPL fails to keep pace with evolving technological standards in the pharmaceutical industry, create new products or intellectual property, or respond to changes in market demand or customer requirements, its business and financial results could be adversely affected.
- Business success depends on the strength of GPL's brand, product image and reputation.
- GPL has significant working capital requirements. If it experience insufficient cash flows to fund its working capital requirements or if it is not able to provide collateral to obtain letters of credit, bank guarantees, and performance bonds in sufficient quantities, there may be an adverse effect on its business, cash flows and results of operations.
- GPL is exposed to risks associated with foreign exchange rate fluctuations.
- GPL is currently entitled to certain tax incentives and export promotion schemes. Any decrease in or discontinuation of such tax incentives or export promotion schemes may adversely affect its results of operations, cash flows and financial condition.
- GPL has power and water requirements and any disruption to power or water sources could increase its production costs.
- Certain of GPL's business transactions are entered into with government or government-funded entities in India and any change in the government policies, practices or focus may adversely affect its business, cash flows and results of operations.
- A slowdown in economic growth in India may adversely affect GPL's business, financial condition, cash flows, results of operations and prospects.
- Recent global economic conditions have been challenging and continue to affect the Indian market, which may adversely affect the business, financial condition, cash flows, results of operations and prospects.
- Any downgrading of India's debt rating by an international rating agency could have a negative impact on GPL's business.
- The United Kingdom's vote to leave the European Union will have uncertain effects and could adversely affect GPL.

Balance Sheet

Particulars (Rs in Million)	Q1FY21	FY20	FY19	FY18
Non-current assets				
Property, plant and equipment	9502.4	9671.5	9287.4	8426.4
Capital work-in-progress	2,544.1	1884.7	1231.6	1988.8
Right-of-use assets	9.0	9.5	9.7	11.3
Financial Assets				
Other financial assets	574.3	69.2	64.3	60.9
Tax assets (net)	16.0	14.5	189.6	198.4
Other non-current assets	567.6	748.2	878.4	1287.3
Total Non Current Assets	**13213.5**	**12397.5**	**11660.9**	**11973.1**
Current assets				
Inventories	10089.4	7,562.79	9,118.76	5,128.30
Financial Asset				
Trade receivables	6740.2	6017.9	5061.0	4752.1
Cash and cash equivalents	3817.8	1695.0	2364.0	3728.4
Bank Balances other than Cash and Cash Equivalents	11471.1	11557.0	5169.5	2980.0
Loans	10.3	5.0	2.8	3.1
Other financial assets	156.0	151.0	71.0	33.9
Tax assets (net)	0.0	95.4	0.0	0.0
Other current assets	1414.3	1379.0	1787.6	695.8
Total current Assets	**33699.2**	**28462.9**	**23574.6**	**17321.6**

Total Assets	**46912.7**	**40860.4**	**35235.5**	**29294.7**
EQUITY AND LIABILITIES				
Equity				
Equity share capital	155.0	155.0	155.0	155.0
Other Equity	39479.7	36307.4	28465.0	23948.6
Total Equity	**39634.7**	**36462.4**	**28620.0**	**24103.6**
Non-current liabilities				
Financial liabilities				
Borrowings	40.7	40.7	49.6	54.9
Other financial liabilities	26.6	26.6	162.5	387.2
Deferred tax liabilities (net)	732.6	740.5	1075.7	957.1
Total Non current liabilities	**799.8**	**807.8**	**1287.8**	**1399.2**
Current liabilities				
Trade payables				
Total outstanding dues of micro, small and medium enterprises	47.4	33.2	14.3	23.4
Total outstanding dues of creditors other than micro, small and medium enterprises	4727.6	2457.8	4447.7	2894.7
Other financial liabilities	282.1	303.8	219.8	149.2
Provisions	209.9	174.8	28.8	21.1
Current tax liabilities (net)	758.5	107.2	110.0	129.0
Other current liabilities	452.8	513.5	507.0	574.5
Total Current Liabilities	**6478.2**	**3590.2**	**5327.7**	**3791.9**
Total Liabilities	**7278.0**	**4398.0**	**6615.5**	**5191.1**
Total Equity and Liabilities	**46912.7**	**40860.4**	**35235.5**	**29294.7**

(Source:RHP)

Profit & Loss

Particulars (Rs in Million)	Q1FY21	FY20	FY19	FY18
Revenue from Operations	8842.1	26332.4	20442.0	16228.9
Other Income	320.8	1391.7	855.6	487.9
Total Income	**9162.9**	**27724.1**	**21297.7**	**16716.8**
Total Expenditure	**4715.9**	**16777.7**	**13377.0**	**10876.1**
Cost of materials consumed	3056.0	10902.5	9548.9	7183.0
Purchase of traded goods	46.0	186.7	162.8	91.2
(Increase)/ decrease in inventories of finished goods, stock-in-trade and work-inprogress	97.5	-69.0	-1141.5	-666.7
Excise duty on sale of goods	0.0	0.0	0.0	29.5
Employee benefits expense	723.4	2776.6	2229.5	1790.8
Power and fuel	167.7	785.0	740.3	603.5
Other expenses	625.3	2195.9	1837.0	1844.7
PBIDT	**4447.0**	**10946.4**	**7920.7**	**5840.8**
Interest	4.7	71.8	36.7	42.4
PBDT	**4442.3**	**10874.5**	**7884.0**	**5798.3**
Depreciation	242.3	945.9	821.2	783.7
PBT	**4200.0**	**9928.7**	**7062.8**	**5014.7**
Exceptional items	0.0	0.0	200.0	0.0
Tax (incl. DT & FBT)	**1064.1**	**2200.1**	**2344.2**	**1804.1**
Current tax	1068.6	2514.0	2212.3	1694.6
Deferred tax (credit)/ charge	-4.5	-318.2	119.7	106.0
Taxes for earlier year	0.0	4.3	12.3	3.5
PAT	**3135.9**	**7728.6**	**4518.6**	**3210.5**
EPS (Rs.)	20.2	49.9	29.2	20.7
Equity	155.0	155.0	155.0	155.0
Face Value	1.0	1.0	1.0	1.0
OPM (%)	46.7	36.3	34.6	33.0
PATM (%)	35.5	29.4	22.1	19.8

(Source:RHP)

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