AXIS CAPITAL

IPO NOTE

GLAND PHARMA LIMITED

Issue highlights

- Incorporated on March 20, 1978 and promoted by Fosun Singapore and Shanghai Fosun Pharma, Gland Pharma Limited ("**Gland Pharma**") is one of the fastest growing generic injectables-focused companies by revenue in the United States from 2014 to 2019.
- Gland Pharma 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.
- The company 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.
- Gland Pharma has focused on meeting diverse injectables needs with a stable supply of affordable and high quality products. They are present in sterile injectables, oncology and ophthalmics, and focusing 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. They are 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.
- As of June 30, 2020, Gland Pharma along with its partners had 267 ANDA filings in the United States, of which 215 were approved and 52 were pending approval.
- Gland Pharma has 7 manufacturing facilities in India, comprising 4 finished formulations facilities with a total of 22 production lines and 3 API facilities. As of June 30, 2020, they had manufacturing capacity for finished formulations of approximately 75.5 crore units p.a.
- Gland Pharma has a successful track record of operating a B2B model with leading pharmaceutical companies such as Sagent Pharmaceuticals Inc. and Apotex Inc. as well as Fresenius Kabi USA LLC and Athenex Pharmaceutical Division LLC in the United States and the Rest of the world.
- The shares will be listed on BSE and NSE.

Brief Financial Details*

(₹ In Cr)

Particulars	As at June 30,		As at March 31,		
	2020	2019	2020	2019	2018#
Equity Share Capital	15.50	15.50	15.50	15.50	15.50
Reserves as stated	3,947.97	3,028.32	3,630.74	2,846.50	2,394.86
Net worth as stated	3,963.47	3,043.82	3,646.24	2,862.00	2,410.36
Revenue from Operations	884.21	674.46	2,633.24	2,044.20	1,622.89
Revenue Growth (%)	31.10%	-	28.82%	25.96%	-
EBITDA as stated	444.70	296.98	1,094.64	792.07	584.08
EBITDA (%) as stated	50.29%	44.03%	41.57%	38.75%	35.99%
Profit Before Tax	420.00	274.33	992.87	686.28	501.47
Net Profit for the period	313.59	183.77	772.86	451.86	321.05
Net Profit as % to Revenue	35.47%	27.25%	29.35%	22.10%	19.78%
EPS (₹)	20.24	11.86	49.88	29.16	20.72
RONW (%)	7.91%	6.04%	21.20%	15.79%	13.32%
NAV (₹)	255.79	196.44	235.32	184.71	155.56
ROCE	7.76%	5.79%	20.74%	15.11%	12.59%
Debt Equity Ratio	0.001	0.002	0.001	0.002	0.002

*Source: RHP, * Restated summary, Ratios calculated for 30th June 2020 & 30th June 2019 are not annualised.*

Issue Details

Fresh Issue of Equity shares aggregating up to ₹1,250 Cr and Offer for sale of up to 34,863,635Equity Shares.

Issue highlights

Issue size: ₹ 6,445 Cr – 6,480 Cr
No. of shares: 43,252,897 – 43,196,968 Shares
Face value: ₹ 1

Issue summary

Price band: ₹ 1,490 – 1,500
Bid Lot: 10 Shares and in multiple thereof

Post Issue Implied Market Cap: ₹ 24,337 Cr – 24,492 Cr

BRLMs: Kotak Mahindra Capital, Citigroup Global, Haitong Securities, Nomura Financial
Registrar: Link Intime India Pvt. Ltd.

Issue opens on: Monday, 9th **Nov'2020**
Issue closes on:Wednesday,11th **Nov'2020**

Indicative Timetable

Activity	On or about
Finalisation of Basis of Allotment	17-11-2020
Refunds/Unblocking ASBA Fund	18-11-2020
Credit of equity shares to DP A/c	19-11-2020
Trading commences	20-11-2020

Listing: BSE and NSE

Issue break-up

Cat	No. of Shares ('000)	₹ In Cr	% of Issue
QIB*	21,626 - 21,598	3,222 – 3,240	**50%**
NIB	6,488 - 6,480	967 – 972	**15%**
Retail	15,139 - 15,119	2,256 – 2,268	**35%**
Total	**43,253 - 43,197**	**6,445 – 6,480**	**100%**

**Company may allocate up to 60% Shares of the QIB Portion to Anchor Investors.*

Shareholding (No. of Shares)

Pre issue	Post issue~	Post issue^
154,949,490	163,338,752	163,282,823

#@ Lower Price Band ^@ Upper price Band

Shareholding (%)

	Pre-Issue	Post-Issue
Promoters & Promoters Gr	74.00%	58.36%
Public	26.00%	41.64%
Total	**100.00%**	**100.00%**

BACKGROUND

The company was incorporated as 'Gland Pharma Private Limited' on March 20, 1978 as a private limited company. Fosun Singapore and Shanghai Fosun Pharma are the Promoters of the company.

As on the date Fosun Singapore holds 114,662,620 Equity Shares which aggregates to 74% of the pre-Offer, issued, subscribed and paid-up Equity Share capital of the company.

Shanghai Fosun Pharma holds 100% of the share capital of Fosun Industrial Co., Limited, which holds 100% of the share capital of Fosun Singapore. Shanghai Fosun Pharma does not directly hold any of the pre-Offer, issued, subscribed and paid-up Equity Share capital of the Gland Pharma Ltd.

Details of the Promoters

Fosun Singapore: Fosun Singapore was incorporated on July 13, 2016 under the laws of Singapore. Fosun Singapore is engaged in the business of general wholesale trade, including general import and export, and investment in the pharmaceutical sector.

Fosun Industrial Co., Limited holds 100% of the share capital of Fosun Singapore. Shanghai Fosun Pharma indirectly, through Fosun Industrial Co., Limited, holds 100% of the share capital of Fosun Singapore.

Shanghai Fosun Pharma: Shanghai Fosun Pharma was incorporated on May 31, 1995 under the laws of China. Shanghai Fosun Pharma is presently engaged in the business of biological and chemical products, reagent, services of biological technological development, biological technological transfer, biological technical consultation and biological technological service, production and sales of self-developed products, instruments and meters, electronic products, computer, chemical raw materials (excluding dangerous goods), consultation service; operation of export business of products produced by the enterprise and relevant technology, operation of import business of raw and auxiliary materials, mechanical equipments, instruments and meters, spare parts and relevant technology needed by production and scientific research of the enterprise.

As on September 30, 2020, Shanghai Fosun High Technology (Group) Co., Ltd. ("**Fosun High Tech**") held 38.54% of the share capital of Shanghai Fosun Pharma and the remaining 61.46% of the share capital of Shanghai Fosun Pharma is held by public shareholders.

The holding company of Shanghai Fosun Pharma is Fosun High Tech. The ultimate holding company of Shanghai Fosun Pharma is Fosun International Holdings Limited, and the ultimate controlling shareholder of Shanghai Fosun Pharma is Guo Guangchang.

Yiu Kwan Stanley Lau is the Chairman and Independent Director of the company. He is a director on the board of directors of Solasia Pharma K. K. and TaiLai Bioscience Ltd. He was previously the chief executive officer of Amsino Medical Group, the chief operating officer of Eddingpharm Investment Co. Ltd, and the president of China Biologic Products, Inc. He has also worked with Merck Sharp & Dohme (Asia) Ltd and Baxter (China) Investment Co., Ltd.

Srinivas Sadu is the MD and CEO of the company. He has previously worked at Natco Pharma Limited and is presently a director on the board of Sadu Advisory Services Pvt. Ltd. He has over 21 years of experience in business operations and management.

Qiyu Chen is the Non-Executive Nominee Director of the company. He is the global partner of the Fosun group. He is also the executive director and chairman on the board of Shanghai Fosun Pharmaceutical (Group) Co. Ltd., chairman of Shanghai Fosun High Technology (Group) Co., Ltd, and an executive director and co-chief executive officer on the board of Fosun International Limited, a company listed on the Hong Kong Stock Exchange, and chairman of Fosun Healthcare Holdings, and Fosun Health Insurance and Health Management Group. He is also on the boards of Sinopharm Group Co. Ltd., a company listed on the Hong Kong Stock Exchange, and Beijing Sanyuan Foods Co. Ltd., a company listed on the Shanghai Stock Exchange. He joined the Fosun group in April 1994.

Dongming Li is the Non-Executive Nominee Director of the company. He has served as a senior vice president of Shanghai Fosun Pharmaceutical Industry Co., Ltd since April 2017. He is also the vice president of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. He previously worked at Shanghai Pharmaceuticals (Group) Co. Ltd, and at Shanghai Roche Pharmaceutical Co., Ltd. from May 2008 to November 2013.

Xiaohui Guan is the Non-Executive Nominee Director of the company. She joined the Fosun group in May 2000. She is the senior vice president and chief financial officer of Shanghai Fosun Pharmaceutical (Group) Co. Ltd. and non-executive director of Sinopharm Group Co. Ltd.

Yifang Wu is a Non-Executive Nominee Director of the company. He was the chairman and chief executive officer of Wanbang Biopharma from April 2011 to July 2020. He has been associated with Shanghai Fosun Pharmaceutical (Group) Co. Ltd since 2004, and is presently an executive director and chairman on its board of directors and its chief executive officer.

Udo Johannes Vetter is a Non-Executive Nominee Director of the company. He has been associated with the Vetter/ Vetter Pharma group of companies since 1987, and is currently the chairman on the board of directors of Vetter Pharma (Corporation).

Essaji Goolam Vahanvati and **Satyanarayana Murthy Chavali** are the Independent Director of the company.

Ravi Shekhar Mitra is the CFO of the company. He has over 20 years of experience in finance. Prior to joining the company, he has worked at Indian Oil Corporation Ltd, Vedanta-Sterlite Industries (India) Ltd, Ranbaxy Laboratories Ltd (now merged with Sun Pharmaceutical Industries Ltd) and Wockhardt Ltd. He joined the company as the CFO on September 30, 2019.

P. Sampath Kumar is the Company Secretary and Compliance Officer of the company. He has over 16 years of experience in the field of corporate secretarial and finance.

The company has won several Certificates of Recognition/ Certificates of Appreciation awards:

Year	Award
2019	• The "Best Exporter" by the Hyderabad Customs • The "Express Pharma Excellence Awards 2019" under the turnover base ₹ 500 – 2000 crore category organized by the Express Pharma and Optel Group • The Company was awarded the "Telangana Best Employer Brand Award" at the 14th Employer Branding Awards organised by the Employer Branding Institute, India
2018	• The "Top Exporter" by the Hyderabad Customs, Customs and Central Excise, GoI • The "Outstanding Export Performance Award" under Formulations Silver Star category by Pharmaceuticals Export Promotion Council of India

OFFER DETAILS

The Offer	
Fresh Issue (₹ 1,250 *Cr)*	**Upto 8,389,262^ - 8,333,333~ Equity Shares**
	(~ at lower price band and ^ upper price band)
**** Offer for sale by:***	**Upto 34,863,635 Equity Shares**
Fosun Pharma Ltd - The Promoter Selling Shareholder	*Up to 19,368,686 Equity Shares*
Gland Celsus Bio Chemicals Pvt. Ltd - The Selling Shareholder	*Up to 10,047,435 Equity Shares*
Empower Discretionary Trust - The Other Selling Shareholder	*Up to 3,573,014 Equity Shares*
Nilay Discretionary Trust - The Other Selling Shareholder	*Up to 1,874,500 Equity Shares*

OBJECTS OF THE ISSUE

(₹ In Cr)

Objects	Amount
Funding incremental working capital requirements of the company;	769.50
Funding capital expenditure requirements of the company; and	168.00
General Corporate Purposes	[•]
Total	[•]

BUSINESS OVERVIEW

Gland Pharma Limited ("Gland Pharma") is one of the fastest growing generic injectables-focused companies by revenue in the United States from 2014 to 2019 (Source: IQVIA Report). Gland Pharma 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. They have a consistent compliance track record with a range of regulatory regimes across these markets. Gland Pharma also 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. They were established in Hyderabad, India in 1978 and have expanded from liquid parenterals to cover other elements of the injectables value chain, including contract development, own development, dossier preparation and filing, technology transfer and manufacturing across a range of delivery systems. They have a professional management team and one of its Promoters, Shanghai Fosun Pharma, is a global pharmaceutical major.

Gland Pharma has focused on meeting diverse injectables needs with a stable supply of affordable and high quality products. They have established a portfolio of injectable products across various therapeutic areas and delivery systems. They are present in sterile injectables, oncology and ophthalmics, and focusing 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. They are 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, Gland Pharma has made substantial investments in its manufacturing infrastructure to support its product portfolio needs and reach. They have 7 manufacturing facilities in India, comprising 4 finished formulations facilities with a total of 22 production lines and 3 API facilities. As of June 30, 2020, they had manufacturing capacity for finished formulations of approximately 75.5 crore units p.a. Its API facilities provide them with in-house manufacturing capabilities for critical APIs, enabling them to control costs and quality and mitigate supply chain related risks around its key products. Its capabilities as a vertically integrated company include internal research and development ("**R&D**") expertise, robust manufacturing capabilities, a strict quality assurance system, extensive regulatory experience and established marketing and distribution relationships.

Gland Pharma has a successful track record of operating a B2B model with leading pharmaceutical companies such as Sagent Pharmaceuticals, Inc. and Apotex Inc. as well as Fresenius Kabi USA, LLC and Athenex Pharmaceutical Division, LLC in the United States and the Rest of the world using long-term development, licensing and manufacturing and supply agreements. Its primary B2B model covers IP-led, technology transfer and contract manufacturing models, complemented by a B2C model in its home market of India leveraging the brand strength and sales network.

Gland Pharma has a track record of revenue delivery and profitability across the United States, Europe, Canada, Australia, India and the Rest of the world.

The revenue from operations based on the customer location as a percentage of the total revenue from operations.

	3 Months ended June 30,		Fiscal 2020	Fiscal 2019	Fiscal 2018
	2020	2019			
United States	62.61%	65.49%	66.74%	62.50%	71.25%
Europe	3.40%	4.85%	4.44%	5.38%	3.39%
Canada	2.34%	0.78%	1.78%	1.12%	1.08%
Australia	0.43%	0.16%	0.50%	0.44%	0.69%
Total for US, Europe, Canada & Australia	**68.78%**	**71.28%**	**73.46%**	**69.44%**	**76.41**
India	14.52%	17.13%	17.74%	18.97%	18.49%
Rest of the world	16.70%	11.59%	8.80%	11.59%	5.10%

- The Total Revenue from operations has grown at a CAGR of 27.38% from Fiscals 2018 to 2020.
- The EBITDA has grown at a CAGR of 36.90% from Fiscals 2018 to 2020.
- The Restated Profit for the year has grown at a CAGR of 55.15% from Fiscals 2018 to 2020.
- In Fiscals 2018, 2019 and 2020, the Debt Equity ratio was 0.002, 0.002 and 0.001, respectively. The company do not have any significant borrowings.

As of June 30, 2020, Gland Pharma had 3,766 full-time employees and over 3,496 contract labourers. As of June 30, 2020, they 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.

BUSINESS UPDATE – COVID 19

THE IMPACT OF THE COVID-19 PANDEMIC ON GLOBAL PHARMACEUTICAL GROWTH

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

The Company is closely monitoring the impact of the pandemic on all aspects of their business, including how it will impact its customers, employees, vendors and business partners. The Company based on the information available to date, both internal and external, considered the uncertainty relating to the COVID-19 pandemic in assessing the impact. Based on the current estimates, the Company expects to fully recover the carrying amount of assets and do not foresee any impact on its operations. As the outbreak continues to evolve, the Company will continue to closely monitor any material changes to future economic conditions.

RESEARCH & DEVELOPMENT

Gland Pharma is increasingly engaged in R&D programs to develop innovative product delivery systems and manufacturing methods. Its centralised R&D laboratory is located at its manufacturing facility at Dundigal, Hyderabad with supporting personnel based at each of its manufacturing facilities. The centralised R&D laboratory has an in-house team of nearly 250 scientists. The company possess internal R&D expertise in developing complex injectables such as lyophilized products, high-potent drugs and long-acting suspensions. In addition, its R&D laboratory is engaged in the development of key processes such as formulation development, analytical method development, API process development and stability studies.

Its R&D expertise further includes synthesis of complex drug molecules such as Low Molecular Weight Herapins, Steroids and Cytotoxics. Its R&D team also developed complex generic molecules such as Cytotoxic and lyophilized ready to use formulations. These R&D activities are scientifically driven and backed by thorough literature review, using sophisticated analytical techniques that include LC-MS, GC-MS and ICP-MS, enabling identification and characterisation of organic and inorganic impurities through synthesis or isolation. In addition to its process development expertise, they also possess knowledge in defining the thresholds for the impurities and arriving at shelf-life definition. Its design and validation of analytical methods are in compliance with global regulatory requirements.

Their R&D efforts have also enabled them to possess technology required to characterise complex molecules in its products and product candidates such as the synthesis and characterisation of glycosaminoglycans, including heparin, low molecular weight heparins, chondroitin sulphate, hyaluronic acid, and drug conjugates of glycosaminoglycans. The company also possess the technology to develop complex steroids such as vecuronium, rocuronium, fulvestrant and vitamin D analogues.

The company also has experience in 505(b)(2) filings for new drug applications and paragraph IV filings for ANDAs required by the USFDA. In Fiscals 2018, 2019 and 2020 and the 3 months ended June 30, 2020, total research and development expenditure was ₹61.49 crore, ₹96.58 crore and ₹92.19 crore and ₹25.20 crore, respectively.

INTELLECTUAL PROPERTY AS OF JUNE 30, 2020

	Registered	Application Pending/renewal
Patent	12	9
Trademarks	66	2

ABBREVIATED NEW DRUG APPLICATION ("ANDA") FILING

As of June 30, 2020, Gland Pharma 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 them, of which 71 ANDA filings are approved and 30 are pending approval.

As of the same date, they 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.

They have a consistent regulatory compliance track record and all its facilities are approved by the USFDA from whom they have had no warning letters since the inception of each facility. Other key regulatory agencies for which certain of its facilities have approvals include MHRA (UK), TGA (Australia), ANVISA (Brazil), AGES (Austria) and BGV Hamburg (Germany).

The revenue from new product launches, which amounted to ₹349.26 crore, ₹271.73 crore and ₹229.23 crore and ₹73.38 crore in Fiscals 2018, 2019 and 2020 and the 3 months ended June 30, 2020, respectively, indicates company's ability to consistently receive regulatory approvals and commercialise its pipeline to achieve market penetration.

KEY PRODUCT PORTFOLIO

Gland Pharma is focused on meeting diverse injectables needs with a stable supply of affordable and high quality products. They are present in sterile injectables, oncology and ophthalmics, and focus on complex injectables, NCE-1s, First-to-File products and 505(b)(2) filings. They have 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.

The key therapeutic areas to which the key products belong as well as the markets in which such products are sold and product applications are filed:

Molecules	Markets			
	United States	Europe, Canada and Australia	India	Rest of the World
Anti-diabetic				
• Huminsulin	No	No	Yes	Yes
Anti-infectives				
• Azithromycin	Yes	Yes	Yes	Yes
• Daptomycin	Yes	Yes	Yes	Yes
• Vancomycin HCl	Yes	No	Yes	Yes
• Caspofungin	Yes	Yes	Yes	Yes
• Micafungin Sodium	Yes	No	Yes	Yes
• Voriconazole	Yes	Yes	Yes	Yes
Anti-malarials				
• Quinine Dihydrochloride	No	No	No	Yes
Anti-neoplastics				
• Melphalan HCl	Yes	Yes	Yes	Yes
• Oxaliplatin	Yes	Yes	Yes	Yes
• Paclitaxel	Yes	No	Yes	Yes
• Temsirolimus	Yes	No	Yes	Yes
Blood-related				
• Heparin Sodium	Yes	No	Yes	Yes
• Doxercalciferol	Yes	No	Yes	Yes
• Tranexamic Acid	Yes	Yes	Yes	Yes
Cardiac				
• Bivalirudin	Yes	Yes	No	Yes
• Enoxaparin Sodium	Yes	Yes	Yes	Yes
• Nadroparin Calcium	No	No	No	Yes
• Esmolol Hydrochloride	Yes	No	Yes	Yes
• Milrinone Lactate	Yes	No	Yes	Yes
• Dexrazoxane	Yes	No	Yes	Yes
• Chlorothiazide	Yes	No	Yes	Yes
Gastro-intestinal				
• Ondansetron	Yes	Yes	Yes	Yes
• Palonosetron HCl	Yes	Yes	Yes	Yes
• Fosaprepitant Dimeglumine	Yes	Yes	Yes	Yes
Hormones				
• Methylprednisolone Sodium Succinate	Yes	No	No	No
• Dexamethasone Sodium Phosphate	Yes	No	No	Yes
Neurological and central nervous system				
• Levetiracetam	Yes	Yes	Yes	Yes
• Haloperidol	Yes	No	Yes	Yes
• Ziprasidone Mesylate	Yes	No	Yes	Yes
• Midazolam	Yes	No	Yes	Yes
• Levoluecovorin	Yes	No	Yes	Yes
• Dexmedetomidine	Yes	Yes	Yes	Yes
• Olanzapine	Yes	Yes	No	No
Ophthalmics and otologicals				
• Olopatadine Hydrochloride	Yes	No	Yes	Yes
• Bimatoprost	Yes	No	Yes	Yes
Pain, neuro-muscular blocking agents and analgesics				
• Etomidate	Yes	Yes	Yes	Yes
• Ketorolac Tromethamine	Yes	Yes	Yes	Yes
• Zoledronic Acid	Yes	Yes	Yes	Yes
• Atracurium Besylate	Yes	No	Yes	Yes
• Cisatracurium Besylate	Yes	No	Yes	Yes
• Rocuronium Bromide	Yes	Yes	Yes	Yes
• Vecuronium Bromide	Yes	No	Yes	Yes
Respiratory				
• Chlorpheniramine	No	No	No	Yes
• Acetylcysteine	Yes	No	No	No

Molecules	Markets			
	United States	Europe, Canada and Australia	India	Rest of the World
Vitamins, minerals and nutrients				
Cyanocobalamin	Yes	No	No	Yes
Others				
• Mesna	Yes	No	Yes	Yes
• Levothyroxine Sodium	Yes	Yes	Yes	Yes

BUSINESS MODELS AND CUSTOMERS

In markets such as the United States, Europe, Canada and Australia as well as the Rest of the world such as Brazil, Africa, Asia Pacific, Middle East, North Africa, Commonwealth of Independent States and South Africa, company's primary business model is B2B, covering IP-led, technology transfer and contract manufacturing models. In such markets, they partner with leading pharmaceutical companies. As of June 30, 2020, they along with their 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.

Company's primary business model in the India market is B2C, where its products are primarily marketed and sold to institutions such as hospitals, long-term care facilities and clinics through stockists and distributors. They also have B2B presence in India where they supply products to pharmaceutical companies.

A summary of the typical features of these business models for regulated markets is set out as follows:

		Rights/Ownership				
		ANDA/Product Registration ownership	Development by Gland Pharma	IP ownership	Marketing rights	Royalty/Profit Sharing
B2B IP-Led	Own filing	Yes	Yes	Yes	Yes	Yes
	Partner filing	No	Yes	Co-owned	No	Yes
B2B Technology Transfer		No	Yes	No	No	Yes
B2B CMO		No	No	No	No	No
B2C		Yes	Yes	Yes	Yes	N.A.

B2B IP-Led

The company adopt the B2B IP-led model primarily for marketing its portfolio of products. Under the B2B IP-led model, its R&D team develops the product which they license out to their marketing partners for commercialisation. The company has the right to license the product to its marketing partners on an exclusive or non-exclusive basis. The company enters into long-term development, licensing, manufacturing and supply agreements with its marketing partners, which are generally for a term of 5 to 10 years. This model is adopted for the sale of its products across key markets including the United States, Europe, Canada, Australia, India, Asia, Middle East and Africa. The key partners for B2B IP-led own filings include Athenex Pharmaceutical Division, LLC and its key partners for B2B IP-led partner filings include Sagent Pharmaceuticals, Inc. and Apotex Inc.

B2B Technology Transfer

Under the B2B technology transfer model, the product is partially developed by its partner and the technology required for the manufacture, testing and packaging of such product is subsequently transferred to the company. They engage in certain product studies such as method transfer and validation, execution of scale-up and exhibit batches, stability studies as well as supporting its customer with dossier compilation.

Where the B2B technology transfer model is adopted, its partner retains ownership of the relevant dossier as well as intellectual property and marketing rights of the product, while the company retain the manufacturing right during the term of the technology transfer agreement, which is generally for a term of 5 to 10 years. This model is adopted for the sale of their products across key markets, namely the United States, Europe, Canada, Australia and India.

B2B CMO

This model is adopted primarily for the sale of its products in India. Under the B2B CMO model, the company provides fill and finish services for aseptically or terminally sterilised injectables to other pharmaceutical companies for already approved products. They enter into loan and license agreements with these pharmaceutical companies and receive fixed 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 the company retain the manufacturing right during the term of the agreement. The pharmaceutical companies generally procure raw materials themselves. This model allows the company to utilise its capacity efficiently.

In Fiscals 2018, 2019, 2020 and in the 3 months ended June 30, 2020, its revenue generated from the B2B model constituted 96.27%, 95.57%, 95.99% and 96.94%, respectively, of its total revenue from operations for the relevant year.

B2C

Under the B2C model, the company engage in direct marketing of its brands in India to drive its focus on injectables. As a majority of its product pipeline is fully owned by them, it provides them the ability to expand its own direct sales platform in the Indian market. With a sales force of over 200 employees as of June 30, 2020 and an extensive countrywide distribution network, they have effective coverage in approximately 2,000 corporate hospitals, nursing homes and government facilities. Some of the market leading brands that they market under the B2C model include Hep 5, Hep 25, Cutenox and Synject.

Under the B2C model, the company retain ownership of the relevant dossier as well as development, intellectual property and marketing rights of a product. In Fiscals 2018, 2019, 2020 and in the 3 months ended June 30, 2020, their revenue generated from the B2C model constituted 3.73%, 4.43%, 4.01% and 3.06%, respectively, of the total revenue from operations for the relevant year.

MANUFACTURING UNITS AND FACILITIES

Company's 7 manufacturing facilities are situated in southern India including 2 sterile injectables facilities, 1 dedicated Penems facility, 1 oncology facility and 3 API facilities.

Their flagship sterile injectables facility in Dundigal, Hyderabad, which possesses capabilities across various delivery formats, obtained USFDA approval in 2003. Its other sterile injectables facility in Pashamylaram, Hyderabad, which substantially increased their manufacturing capacity, commenced domestic sales in September 2015 and sales in the United States in September 2016 following receipt of USFDA approval in March 2016. They also have a dedicated Penems facility which filed its first ANDA in February 2014 and obtained USFDA approval in March 2016.

Its manufacturing facilities have established a consistent record of regulatory compliance with the USFDA highlighting its focus on quality assurance and quality control. They are certified as GMP compliant at all of its manufacturing facilities by the USFDA and certain facilities by the MHRA (UK), ANVISA (Brazil), AGES (Austria), TGA (Australia) and BGV Hamburg (Germany). **They have had no warning letters from the USFDA (whether as a result of facility inspections or otherwise) since the inception of each facility**. They have also received WHO GMP certifications for its facilities from the Drugs Control Administration (Governments of Telangana and Andhra Pradesh, India) (DCA) and they had 3 ISO certifications as of June 30, 2020 for its quality management, environment management and occupational health and safety management systems. Their focus on quality standards is supported by a quality assurance and quality control team which numbered 1,161 full-time employees as of June 30, 2020.They have a total of 3API facilities that provide them with in-house manufacturing capabilities for critical APIs. 24 of its ANDAs covering its key products are supported by in-house APIs.

Details of the manufacturing facilities:

Location	Facility	Presentation	Capacity		Capacity Utilisation (%) in Fiscal				Key product	Key regulatory approval
			(Lines)	(Units p.a.)	3 months ended June 30, 2020	2020	2019	2018		
Dundigal, Hyderabad,	Sterile injectables	Liquid Vials	6	24.0 Cr	88%	91%	90%	87%	Enoxaparin Sodium, Caspofungin, Levetiracetam, Daptomycin	USFDA (US), MHRA (UK), ANVISA (Brazil), TGA (Australia), BGV Hamburg (Germany)
		Lyophilizers (7 Nos)	N/A	4.8 Cr	76%	75%	74%	81%		
		Ampoules	1	6 Cr	11%	26%	35%	69%		
		Pre-filled Syringes	2	6 Cr	59%	50%	75%	30%		
		Bags	2	0.5 Cr	10%	51%	75%	22%		
		Ophthalmics	1	4.5 Cr	49%	17%	17%	-		

Location	Facility	Presentation	Capacity		Capacity Utilisation (%) in Fiscal				Key product	Key regulatory approval
			(Lines)	(Units p.a.)	3 months ended June 30, 2020	2020	2019	2018		
Pashamylaram, Hyderabad,	Sterile injectables	Liquid Vials	3	13.2 Cr	67%	73	59	47	Heparin Sodium, Vancomycin	USFDA (US), GUB Munich (Germany)
		Lyophilizers (3 Nos)	N/A	1.8 Cr	69%	76	73	34		
		Ampoules	2	12.0 Cr	24%	29	21	22		
Pashamylaram, Hyderabad,	Penems	Vials (2 Lyophilizers)	1	0.8 Cr	-	-	-	-		USFDA (US)
		Dry Powder	1	0.4 Cr	-	-	-	-		
Visakhapatnam	Oncology	Liquid Vials	3	1.1 Cr	35%	48	28	36	Paclitaxel, Bortezomib	USFDA (US), AGES (Austria), TGA (Australia)
		Lyophilizers (4 +1)	N/A	0.5 Cr	41%	24	28	16		
Dundigal, Hyderabad,	API	-	-	N/A	-	-	-		-	USFDA (US), MHRA (UK), ANVISA (Brazil), TGA (Australia), BGV Hamburg (Germany)
Visakhapatnam	API	-	-	3,000 kg/year	-	-	-		-	USFDA (US), ANVISA (Brazil)
Visakhapatnam	API	-	-	8,000 kg/year	-	-	-		-	USFDA (US), DMA (Denmark)

COMPETITIVE STRENGTHS

- ***Extensive and vertically integrated injectables manufacturing capabilities with a consistent regulatory compliance track record***

Company's manufacturing process is designed to facilitate production flexibility and deliver high and consistent product quality. Its 4 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 them to adapt quickly to changes in product specifications, market demand and production requirements.

- ***Diversified B2B-led model across markets, complemented by a targeted B2C model in India***

The company consider that its various B2B business models enable them to:

- Grow market share in key markets such as the United States, Europe, Canada and Australia, particularly the United States, while reducing the marketing investments they need to make,
- Leverage the reputation of its marketing partners in their home markets to build its own presence in these markets,
- Build its own reputation as a complex injectables manufacturer with a consistent compliance record attracting confidence from other potential marketing partners, and
- Balance profitability and capacity utilisation while continuing to deliver high manufacturing and quality standards to a broad range of customers.

- ***Extensive portfolio of complex products supported by internal R&D and regulatory capabilities***

Gland Pharma 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.

They have 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. They are expanding their 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.

- ***Track record of growth and profitability from a diversified revenue base with healthy cash flows***

Company's revenue base is diversified by business model as well as by key customers (with whom they generally have long term contracts) and markets. Its top 5 customers in Fiscals 2018, 2019 and 2020 and the 3 months ended June 30, 2020 accounted for 49.92%, 47.86%, 48.86% and 44.45%, respectively, of the total revenue from operations for the relevant period. Some of these customers have contracted with the company for products sold across multiple markets.

- ***An experienced management and qualified team and promoted by Shanghai Fosun Pharma – a global pharma major***

The company has a professional and experienced management team with significant expertise in the pharmaceutical industry. They consider this facilitates effective operational coordination and continuity of business strategies. The management team includes experienced senior executives, many of whom have been with them for a significant period of time. Their mentor, Dr. Ravindranath Penmetsa has been associated with the company since 1992 and its Chief Technology Officer, KVGK Raju, has been with the company since 1992. The MD and CEO, Srinivas Sadu, has been with them in various capacities since 2000 and the CFO, Ravi Shekhar Mitra, has joined the company with nearly 2 decades of relevant experience. Its employees possess a range of qualifications including scientific, pharmacy post graduate and graduates.

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. Their relationship with Shanghai Fosun Pharma provides the company with widened market access opportunities arising from its own continuing internationalisation. In particular, they have benefitted from Shanghai Fosun Pharma's established presence in China and Africa, both of which they consider to be key growth markets for injectables.

KEY BUSINESS STRATEGIES

- ***Expand product portfolio and delivery systems to drive revenue growth***

Gland Pharma 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. They have established a portfolio of injectable products across various therapeutic areas and delivery systems. They are expanding their 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. They will continue to focus on developing products primarily for the U.S. market and leverage the product portfolio to extend across other markets. To cater to the needs of other key markets, they also have started to develop products aligned with the requirements of those markets.

- ***Continue to invest in manufacturing and related technological capabilities to meet future demand***

Gland Pharma aim 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, they intend to expand their current manufacturing capacity for key products and continue to invest in new technologies and manufacturing capabilities in complex injectables. In order to support its manufacturing needs for the product pipeline, in addition to its flagship sterile injectables facility in Dundigal, Hyderabad, they built another sterile injectables facility in Pashamylaram, Hyderabad.

The company aim to continue investing in manufacturing technologies to build new capabilities to support the production of its future portfolio of complex injectables. They plan 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. They will continue to invest in innovative technologies to enhance its complex injectables manufacturing capabilities. Key focus areas include peptides, long acting injectables, suspensions and hormones.

- ***Increase current market presence and enter new markets***

The company 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. In China they will continue their relationship with Shanghai Fosun Pharma to grow its business in the Chinese generics drug market and develop China-specific products.

According to the IQVIA Report, the Chinese pharmaceutical market was estimated to be US$90 billion in 2020, accounting for approximately 11% of the global injectables market at an estimated US$47 billion. The Chinese pharmaceutical market is expected to grow to US$116 billion in 2025. To tap this market potential, Gland Pharma has **filed 6 products in Fiscal 2020 and plan to accelerate its rate of filings**. The company is currently developing products specifically for the Chinese market so as to expand its product offerings there.

In India, while they have a strong presence in the cardiac and pain management therapeutic areas, as part of its growth strategy they have **recently launched the infertility therapeutic area to further diversify its portfolio**. For the Rest of the world markets (excluding India), they intend to continue working with business partners and distributors having a well-established local presence.

- ***Align with Shanghai Fosun Pharma to increase market share***

Gland Pharma intends to leverage Shanghai Fosun Pharma's existing infrastructure and global presence to access new markets, including the Chinese and African markets. Their relationship with Shanghai Fosun Pharma has enabled them to initiate product filings in China, with its first filing completed for the Chinese market in 2019. **As of June 30, 2020, its product filings for 6 products in China were under approval.**

The company expect to benefit from Shanghai Fosun Pharma's (i) market experience and know-how in navigating through the rapidly evolving Chinese healthcare landscape, (ii) ability to access key markets to provide coverage for a portfolio of products, (i ii) scale and bargaining power to procure raw materials and equipment from China, and (iv) extensive sales, logistics and distribution network to enable market penetration across China.

- ***Pursue strategic acquisitions and partnerships***

To complement its organic growth and internal expertise, Gland Pharma may also pursue strategic acquisitions of companies, products and technologies that will add to its capabilities and technical expertise or enter into partnerships to strengthen its product and technology infrastructure in areas including steroidal hormonal products, suspensions, anti-neoplastics and nasal and inhalation products.

They will seek 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.

- ***Continued focus on cost management***

The company aim 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, they aim to continue to achieve supply chain efficiencies through lifecycle management of products, including in the R&D and manufacture processes.

The quality assurance and quality control team will continue to support the lifecycle management of its products to improve manufacturing efficiencies. The company consider that its products for the U.S. market benefit from their ability to integrate backwards to manufacture its own critical APIs, providing them with security and cost advantages in its supply chain.

COMPETITION

According to the IQVIA Report, injectable manufacturers face high entry barriers such as high capital investments, operational costs, manufacturing complexities, stricter compliance requirement (because of the sterile nature of products) and high-quality standards resulting in limited competition in the market. Many pharmaceutical companies generally outsource the manufacturing of injectables due to significant costs involved in setting up injectables facilities, the length of time required for the development and manufacturing of injectables as well as stringent requirements relating to the quality and safety of injectable products, among other things.

Accordingly, **Gland Pharma face and will face significant competition from pharmaceutical companies that adopt the B2B model and focus on the generic injectables markets such as Recipharm AB, Catalent, Inc., Lonza Group AG and Piramal Pharma Solutions**. In the B2C market, they also compete in India with other injectables manufacturers and distributors.

The primary competitive factors consist of compliance record, price, and size of product portfolio. To stay ahead of its competitors, Gland Pharma regularly updates existing technology and develops new technology for its manufacturing activities.

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