

May 17, 2021

PICK OF THE MONTH

VOL-7, NO-06

Industry: Pharmaceuticals

Gland Pharma Limited

BUY

CMP: Rs.2882

TARGET PRICE: Rs.3305

TIME : 12 months

OVERVIEW: Pharma Industry:

Dosage Forms: Dosage Forms (DF) is defined as the physical form of a dose of a chemical compound used as a drug or medication intended for administration or consumption. The route of administration (ROA) for drug delivery is dependent on the dosage form of the substance.

Exhibit 01: Types of Dosage Forms

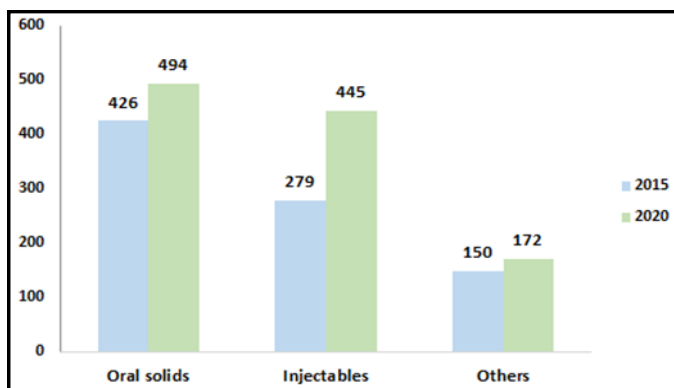
Route of Administration	<ul style="list-style-type: none"> Oral, Topical, Rectal, Parenteral, Vaginal, Inhaled, Ophtalmic, OtcI
Physical Form	<ul style="list-style-type: none"> Solid, Semi-solid, Liquid, Gaseous

Source: webstor.srmist.edu.in/web_assets/srm_mainsite/files/downloads/Dosage_forms.pdf, Progressive Research

Oral Solid Dosage: It is the most common pharmaceutical dosage form which includes both tablets and capsules which is the most prominent and convenient form for administration. **Oral Solids** (the largest delivery form in the market by value), was estimated to be USD494bn in 2020, which clocked a CAGR of ~3% from 2015-2020; whereas, the market share by value of oral solids reported a drop from an ~50% in 2015 to 44% in 2020 (As per IQVIA Report).

Injectables (parenteral): is regarded as the **second largest delivery form** in global pharmaceutical market. (Injectables refer to a drug delivery system that acts as an alternative to the oral administration of drugs). According to the IQVIA Report, injectables account for ~40% of the global pharmaceutical market by value in 2020. This market grew at a CAGR of ~9.8% from 2015 to 2020 to reach an approximate figure of USD445bn in 2020; whereas the market by value saw an increase to 40% in 2020 from the earlier 33% in 2015.

Exhibit 02: Global Pharma Market- Delivery Forms (USDbn)



Source: Company RHP, Progressive Research

Global Injectables Drug Delivery Market: Injectables enable the transmission of the formulated drugs in the liquid form while the ROA path could either be intravenous, subcutaneous, intramuscular, intradermal and others in order to treat medical conditions. According to IQVIA, in the global pharmaceutical market, injectables accounted for 39% of the Pharma market in 2019 (from 32% in 2014), making it the second-largest segment in formulations after oral solids. Injectables recorded a CAGR of 10.1% over 2014-19, significantly ahead of 5.8% recorded by the overall Pharma market.

SNAPSHOT				
52 week H / L	Mcap (INR mn)			
2982/1701	4,71,491			
Face value: 1				
BSE Code	NSE CODE			
543245	GLAND			
Annual Performance				
(Rs mn)	FY19	FY20	FY21E	FY22E
Total Revenue	20,442	26,332	33,840	39,312
EBITDA	7,063	9,555	12,690	15,332
EBITDA (%)	34.6	36.3	37.5	39.0
Other Income	856	1,392	1,101	1,101
Interest	36	72	41	41
Depreciation	820	946	1,056	1,174
PBT	7,064	9,929	12,694	15,218
PAT	4,519	7,729	9,648	11,413
Equity (Rs mn)	155	155	164	164
EPS (INR)	29	50	59	70
Quarterly Performance				
Parameters (Rs mn)	Mar-20	Jun-20	Sept-20	Dec-20
Sales (Net)	-	8,842	8,315	8,594
EBITDA	-	4,126	2,977	2,642
EBITDA (%)	-	46.7	35.8	30.7
Other Income	-	321	204	351
Interest	-	5	8	12
Depreciation	-	242	247	250
PAT	-	3136	2179	2,049
Equity (Rs mn)	-	155	155	155
Ratio Analysis				
Parameters (Rs mn)	FY19	FY20	FY21E	FY22E
EV/EBITDA (x)	66.4	49.2	36.9	30.5
EV/Net Sales (x)	23.0	17.8	13.9	11.9
M Cap/Sales (x)	23.1	17.9	13.9	12.0
M Cap/EBITDA (x)	66.8	49.3	37.2	30.8
Debt/Equity (x)	0.05	0.03	0.03	0.03
ROCE (%)	26	30	30	29
Price/Book Value (x)	15.6	12.2	10.2	8.2
P/E (x)	94.6	57.8	46.4	37.8
Shareholding Pattern as on 31st March, 2021				
Parameters	No of Shares	%		
Promoters	95,293,934	58.25		
Institutions	37,814,880	23.12		
Public	30,484,109	18.63		
TOTAL	163,592,923	100		

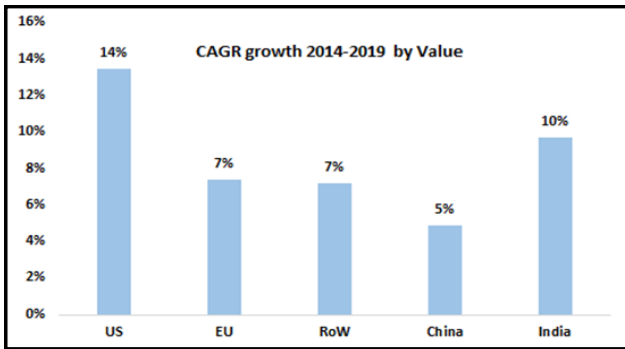
Source: Annual Report

Note: All the data is calculated as per Market Price on 14 May, 2021

OVERVIEW: Industry (contd.)

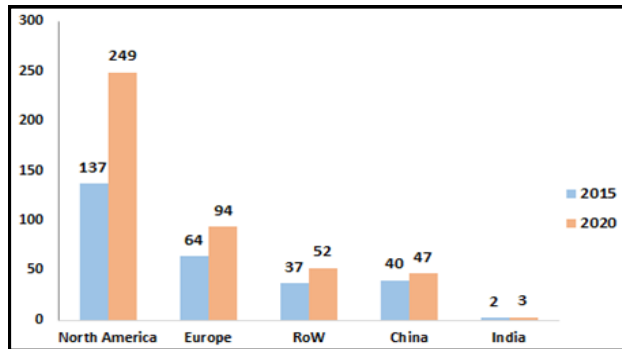
Geographic Segmentation: According to the IQVIA Report, North America accounted for the largest share by value in the global injectables space of ~56% in 2020 and is estimated to be worth ~USD249bn, followed by Europe with a market share of ~21% with an estimated value of USD94bn. On the other hand, China accounted for an approximate market share of 11% with an estimated market of USD47bn, while India came in at a market share of 1% with an estimated USD3bn market. The remaining 12% was contributed by the RoW, with an estimated USD52bn market.

Exhibit 03: Injectables Growth across Geographies



Source: IQVIA Data, Progressive Research

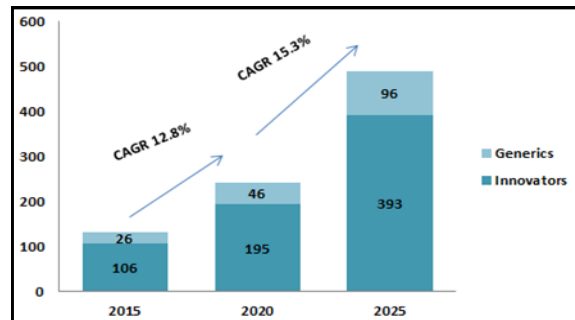
Exhibit 04: Global Injectables Market (in USDbn)



Source: Company RHP, Progressive Research

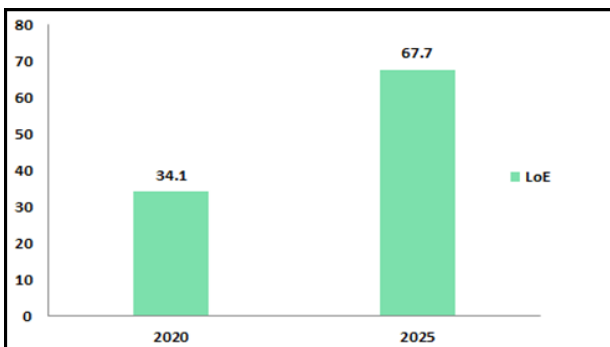
Opportunities in the US Injectable Market: The US injectable market is estimated to reach USD489bn valuation by 2025 and grow at ~15.3% CAGR from 2020 to 2025, faster than other segments. The value of injectables molecules which may lose patent protection during 2020-2025 stands ~USD67.7bn, double the value of the last 5 years. (as per the RHP). In the US, the injectables market is fairly concentrated with a few therapies (including small molecules) forming approximately 80% of the market by value. The injectables space is less competitive compared to that for oral solids. It has relatively high entry barriers and as a result, in the US generic injectables space the average number of competitors per product is almost half of that in oral solids. High entry barriers are due to high capital investments, manufacturing complexity & higher operational costs, high quality requirements and consolidation trend to favour established players.

Exhibit 05: US Injectables Market (in USDbn)



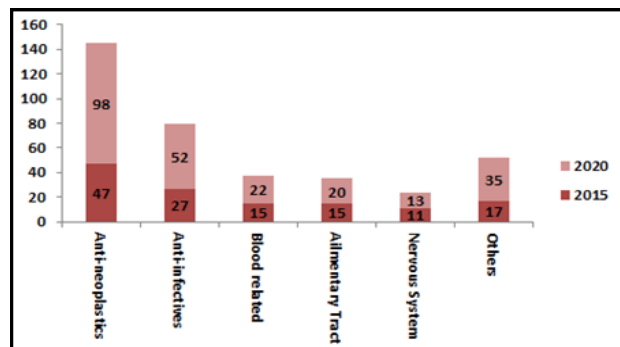
Source: Company RHP, Progressive Research

Exhibit 06: Loss of Exclusivity (LoE, in USDbn)



Source: IQVIA, Progressive Research

Exhibit 07: US Therapy Growth (in USDbn)



Source: Company RHP, Progressive Research

Traditional v/s Injectables Dosage Form: Dating back to traditional forms of dosages which involved tablets, pills, capsules as the only form of medication; it has paved way to more technologically advanced, effective, convenient and smarter drug delivery systems over a period of time. Injectables possess numerous advantages over conventional dosage forms which includes but not limited to (a) injectables have close-to-immediate onset of action (b) ease of access in drug administration to patients who face difficulties in consuming oral medication (c) self-injection devices such as pen and auto injectors led to easy self-medication in a convenient and comfortable manner, right from ones home and lastly (d) with an increase in number of new drug formulations which are less water soluble and/or have very low permeability can be directed through the injectables route.

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OVERVIEW: Industry (contd.)

Factors influencing the growth of injectables are listed below:

- **Rising Prevalence of Chronic Diseases:** A strong increase in diabetes and other chronic diseases; treatment of which is primarily administered via injectables
- **Benefits of New Drug Delivery Systems (NDDS):** Demand in self-care medications thereby reducing the patient visits to hospitals would drive the growth of new injectable devices such as pen and auto injectors, pre-filled syringes etc.
- **New Market Opportunities:** New ailments such as rheumatoid arthritis, multiple sclerosis, cancer and autoimmune disorders are now being treated through injectables solutions
- **Growth of Biologics:** With biologics gaining immense popularity, injectables, especially PFS has witnessed increased adoption as the preferred drug delivery systems due to its ease of handling, less overfills and more safety to patients
- **Entry Barriers:** Being complex drug delivery system, injectables tend to have high entry barriers that includes extensive capital investments, operational costs, stricter regulatory requirements, high quality standards leading to a limited competitive market

Injectable Shortages in the Past: Biologics are typically administered via an injection that are mainly intended to treat cancer, rheumatoid arthritis, multiple sclerosis, etc. Despite the growth in the biologics' medication; as per ICRA, back in 2015-2019, many injectables worth ~USD16bn were expected to go off-patent especially in the US. As a matter of fact, injectable products being sterile in nature, are expected to meet the strictest quality standards imposed by the regulatory authorities (especially regarding contamination). Apart from the regulatory check, injectables require high supervision during manufacturing, packaging, storage and distribution. Failure to comply to any of these led to shortages of many significant injectable products in the US markets. According to the USFDA, another prominent reason for the shortage of drugs was attributed to the rise in cost of production of old molecules that led to a transitional shift to low-cost countries such as India and China; thus paving way for Indian generic players to capitalize on this opportunity and bridge the shortage gap by small deals/acquisitions.

Exhibit 08: M&A Deals in Injectables Space

Acquisition (Year)	Location	Consideration (USD mn)	Investment Rationale
Baxter Claris (2017)	India	635	To become a global leader in the injectable pharmaceuticals space
Fosun Gland Pharma (2017)	India	1,477	To bolster capability in technology used for injectable formulations
Pfizer acquired Hospira (2015)	Global	17,000	To expand its presence and become the largest player in generic injectables and biosimilars
Pfizer acquired Inno Pharma (2014)	USA	360	To strengthen its capabilities in complex injectable manufacturing like injection pens, depot injections along with other delivery technologies
Hikma Pharma Plc. acquired Bedford Laboratories (Assets) (2014)	USA	375	Strengthen its R&D pipeline and prepare it for US generic market
Hikma Pharma. Plc. acquired Ben Venue Labs. (Assets) (2014)	USA	NA	To boost manufacturing and R&D in injectables
Par Pharmaceuticals Inc. acquired JHP Group Holdings (2014)	USA	490	To expand its portfolio with 14 specialty injectable products
Mylan Inc. acquired Agila Specialities (2013)	Global	1,850	To expand its product portfolio with 1,200 approved injectable products globally

Source: ICRA Report, Progressive Research

Upcoming Patent Expiries:

Patent expiry or loss of exclusivities of injectable products has increased significantly over the last few years. Injectable drugs that lost exclusivity between 2014-2019 amounted to USD32.8bn in revenue in 2013. In comparison, injectable drugs that will lose exclusivity between 2020-2024 had revenue of USD61.3bn in 2019. In terms of industry revenue, a large amount of drug exclusivity is set to expire during 2022-2023. This presents an opportunity for the generic injectables in US. Within small-molecule injectables, drugs worth USD7.9bn (2019) will lose patent exclusivity over the next five years.

Exhibit 09: Injectables Going Off-Patent for US

Brand Name	Innovator	Therapeutic Area	Earliest US Patent Expiry	CY15 Revenues (USDmn)
Zyvox	Pfizer	Antibiotic	2015	564
Tygacil	Pfizer	Antibiotic	2016	110
Norditropin	Novo-Nordisk	Hormonal	2017	550
Levemir	Novo-Nordisk	Diabetes	2019	2,016
Alpidra	Sanofi	Diabetes	2018	163
Zaltrap	Sanofi	Oncology	2020	24
Alimta	Eli Lilly	Oncology	2016	1,162
Forteo	Eli Lilly	Osteoporosis	2018	612

Source: ICRA Report, Progressive Research

About the Company:

Established in 1978, Gland Pharma Ltd (Gland Pharma) has grown from being a contract manufacturer of small liquid parenteral products to become one of the largest and fastest growing injectable focused company with production capacity of ~755mn units (name plate capacity) per annum of various formulations as of 30th June, 2020. The company sells products primarily under a Business to Business (B2B) model in over 60 countries including the US, Europe, Canada, Australia, India and RoW. Its expertise lies in development and manufacturing of injectable products by meeting the required regulatory standards. The business existence ranges from sterile injectables, including oncology and ophthalmic, focus on high value generics such as complex molecules, first-to-file products. Gland has expanded its portfolio base from liquid parenterals to cover other elements of injectable value chain, including contract development, own development, dossier preparation and filing, technology transfer and manufacturing across a range of delivery systems. Gland was the first Indian company to get USFDA approval for an injectables site in India in 2003. In terms of products, Gland Pharma was the pioneer in producing Heparin and Enoxaprin in India and is still the only supplier to the US market from India. (These two products accounted for approx 25% of the company's revenues in FY20). The company has 7 manufacturing facilities in India comprising 4 finished formulations facilities (sterile injectables, penems facility at Pashamylaram, Hyderabad) with a total of 23 production lines and 3 API (oncology facility at Vishakhapatnam) facilities. The company is promoted by Shanghai Fosun Pharma, a global pharmaceutical major. Gland Pharma has Mr. Srinivas Sadu as the Managing Director and the CEO.

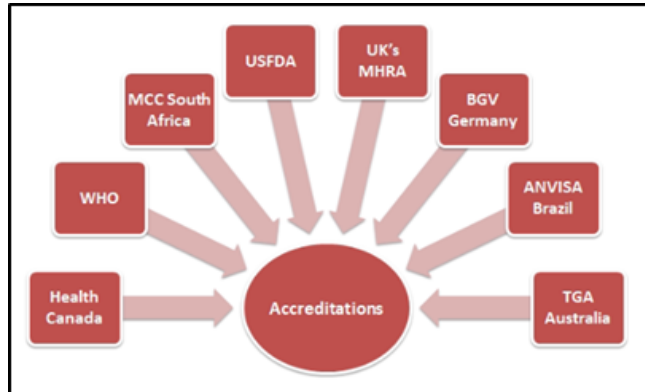
With a well-equipped, in-house manufacturing capabilities, the company's 3 API facilities (at Dundigal Hyderabad, SEZ, Vishakhapatnam and JNPC, Vishakhapatnam) assist in managing and controlling costs (the backward integration move) and thus enable to mitigate on the supply chain related issues. Gland Pharma has at its disposal, 4 best-in-class cGMP-compliant **formulation** manufacturing facilities that manufacture a wide range of injectables using aseptic filling or terminal sterilization. Bearing production flexibility at these facilities, the company can easily switch the product lines thus discarding the need to install additional product lines to meet the market demand. Gland Pharma has a strong regulatory compliance track record with the USFDA. All of the manufacturing facilities are certified as GMP-compliant by the USFDA. No manufacturing facility for Gland Pharma has ever received warning letter/OAI from the USFDA. *Over the last 5 years, USFDA has raised its compliance standards considerably, leading to an increased number of plant inspections being classified as OAI/ given warning letters globally. Further, plants for other injectable manufacturers have received warning letters/OAI multiple times over the past few years.*

INVESTMENT RATIONALE:

The Promoters- Fosun Pharma:

Shanghai Fosun Pharma is the biggest shareholder in Gland Pharma, with 58.4% stake in the company after the IPO in Nov 2020. It invested in Gland Pharma in 2017 when it bought stake from private equity firm KKR and the original promoter. The company is managed independently by the professional management team at Gland Pharma. Fosun Pharma, was established in 1994 and is present across all key segments of the healthcare industry including Pharmaceutical R&D and manufacturing, Medical devices and diagnostics, healthcare services, Pharmaceutical distribution and retail. Fosun Pharma is owned by Fosun International which besides Healthcare has interests in Tourism (Happiness) and Financial services (Wealth). The revenue contribution is 47% from Happiness, 23% from Health and 30% from the Wealth segment. With the help of a strong and established parent company, Gland Pharma would benefit (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 (iii) 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.

Exhibit 10: Accreditation Basket



Source: Company Website, Progressive Research

Exhibit 11: Facilities Portfolio

Sterile Injectable Facility in Dundigal	Sterile Injectable Facility in Pashamylaram	Penems Facility	Oncology Facility, SEZ
<ul style="list-style-type: none"> • 6 vials lines with 7 lyophilizers: 240mn units/year & 48mn lyo units/year • 1 ampoules line: 60mn units/year • 2 PFS lines: 60mn units/year • 2 bag filling line: 5mn units/year • 1 Ophthalmic line: 45mn units/year 	<ul style="list-style-type: none"> • 2 vial lines for liquid filling: 132mn units/year • 1 vial line with 3 lyophilizers: 18mn units/year • 2 ampoule lines: 120mn units/year 	<ul style="list-style-type: none"> • Dry powder line: 4mn units/year • Liquid vial line with two lyophilizers: 8mn lyo units/year 	<ul style="list-style-type: none"> • 3 vial lines with 4 lyophilizers: 11mn units/year & 5mn lyo units/year

Source: Company Website, Progressive Research

INVESTMENT RATIONALE (contd.)

The Promoters- Fosun Pharma: contd.

Except for Gland, none of the other entities under Fosun have a USFDA approved injectable plant. Fosun intends to drive its sterile product initiatives in developed market through Gland Pharma. For the other companies, distribution and retail business is primarily through Sinopharm. Sinopharm is China's largest pharmaceutical and health care products distributor and leading supply-chain service provider. The company was jointly established in 2003 by Fosun Pharma and China National Pharmaceutical Group Corporation. Fosun Pharma currently has 49% stake in Sinopharm.

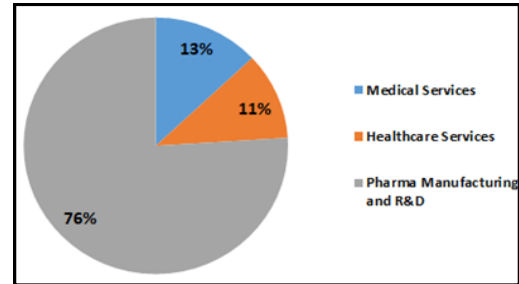
Business of the Company:

Exhibit 13: Geographic Mix

Geographies	2018	2019	2020	9MFY21
United States	71.30%	62.50%	66.70%	61.00%
India	18.50%	19.00%	17.70%	16.80%
Europe	3.40%	5.40%	4.40%	4.30%
Canada	1.10%	1.10%	1.80%	2.10%
Australia	0.70%	0.40%	0.50%	0.35%
RoW	5.10%	11.60%	8.80%	15.60%

Source: Q3FY21 PPT, Company RHP, Progressive Research

Exhibit 12: Fosun Pharma Revenue Breakup

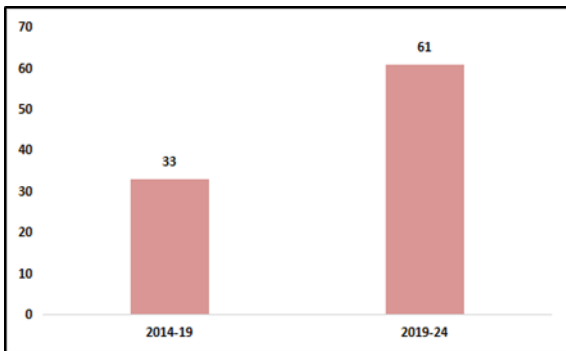


Source: Fosun Pharma, Progressive Research

Injectables Industry: An Opportunistic Route

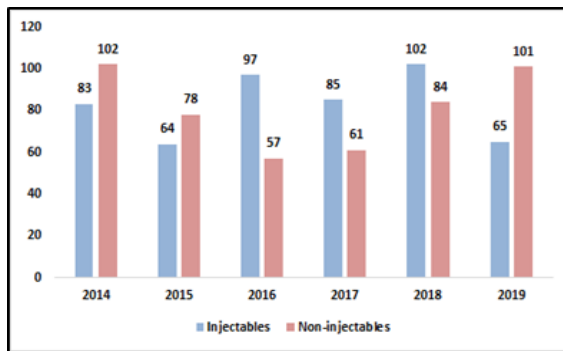
According to IQVIA, given the nature of drug administration and sterile nature of products, injectable manufacturers face high entry barriers viz; huge capital investments (1.3-1.5x more capex v/s oral solids), operational costs, manufacturing complexities, stricter compliance, high quality standards, all of which create a limited competitive market. Drug shortages in the US, branded injectables to lose patent protection between 2020-2024, rising prevalence of chronic disease, new market opportunities all of these would drive growth for the injectables space.

Exhibit 14: Loss of Exclusivity-Injectables (USDbn)



Source: Q3FY21 PPT, Progressive Research

Exhibit 15: Demand Driven by Drug Shortage



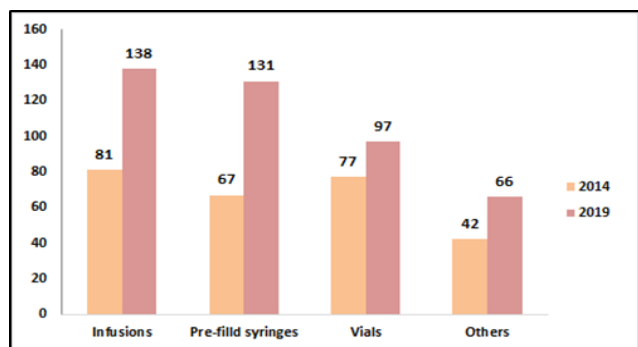
Source: Q3FY21 PPT, Progressive Research

(A) Unique Business Model Adoption: The revenue breakup between B2B and B2C businesses is 96% and 4% respectively. B2B IP-led business contributes ~69% of the revenue of B2B business. The B2B technology business model involves the transfer of technology by clients which accounted for ~27% of the revenues. In this business, the client develops the products, and the technology required to manufacture, testing and packaging of such product is subsequently transferred to Gland Pharma.

Reasons for B2B Model Adoption:

- Lower working capital requirements
- Lower R&D litigation risks
- With the help of strong partnerships, long term contracts with its marketing partners (3-5 years), all of this enables a steady cash flow generation for the company
- An efficient cost profile structure enables Gland Pharma to generate better operating margins **{(Gland Margins: 58.1% for 2019), B2C Players: 40.1% for 2019)}**
- Sub-diversification under the B2B model enables Gland Pharma to achieve economies of scale at the product as well as at the formulation level.

Exhibit 16: Global Injectables Market (USDbn)

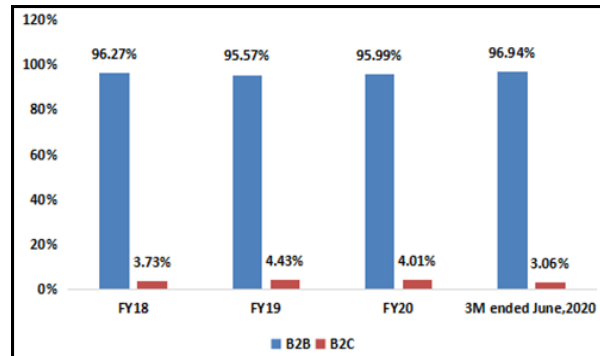


Source: Q3FY21 PPT, Progressive Research

INVESTMENT RATIONALE (contd.):

B2B Model: This has been Gland Pharma's primary business model in the US, Europe, Canada and Australia as well as RoW (Brazil, Africa, Asia Pacific, Middle East, North Africa, Commonwealth of Independent States and South Africa). This model contributed ~96% of the revenues in FY20. **B2B model can be further bifurcated into B2B IP-led, B2B tech transfer and B2B Contract Manufacturing Models (CMO).** In the B2B business model, Gland primarily focuses on cost-effective product development and large-scale manufacturing without any cost towards marketing, but does leverage on the marketing infrastructure of the partner companies. This leads to operating with relatively high-capacity utilization and offers a well-diversified basket of products. In the B2B model, Gland earns more from manufacturing and less from the profits of the front-end operation, which is actually market price dependent. This helps deal with volatility in the financials compared to the front-end players, particularly in the US generic market.

Exhibit 17: Business Wise Revenue Split



Source: Company RHP, Progressive Research

Exhibit 18: Salient Features of Business Model

	B2B Model			B2C Model	
	B2B IP Led		B2B Tech Transfer	B2B CMO	
	Own Filing	Partner Filing			
Overview	(i) Out-license to marketing partners (ii) Long term product supply contracts		(i) Co-development with Partner (ii) Manufacturing by Gland	(i) Fill and finish service (ii) Loan and license agreements	(i) Direct marketing of products
Revenue Model	(i) License & milestone payments (ii) Selling price per unit dose+ Profit share		(i) Tech transfer fee (ii) Selling price per unit dose+ Royalties	(i) Fixed per unit dose	(i) Direct sale of products
ANDA Ownership	Yes	No	No	No	Yes
Development	Yes	Yes	Yes	No	Yes
IP Ownership	Yes	Co-owned	No	No	Yes
Marketing Rights	Yes	No	No	No	Yes
Royalty/ Profit Sharing	Yes	Yes	Yes	No	Not Applicable
Key Markets	USA, Canada, Australia, India, Asia, Middle-East & Africa		USA, Europe, Canada, Australia & India	India	India
Select Clients/ Partners	Global Pharma Companies			Indian Pharma Companies	~2000 corporate hospitals, nursing homes and govt. facilities

Source: Company RHP, Q3FY21 PPT, Progressive Research

B2B IP-led Model: Gland Pharma enters into long-term, manufacturing, development and supply agreements with pharmaceutical companies and retains the IP related to product development and manufacturing. The key markets where it operates under this model include the US, Europe, Canada, Australia, India, Asia, Middle East and Africa with the key partners in B2B IP led own filings being Athenex, Fosun Pharma, Alvogen. Some of the company's key partners are Fresenius Kabi, Sagent Pharma, Apotex, Mylan and Sandoz. The licensing fees and milestone payments are linked to completing certain defined stages related to product development. Once the commercialization of the product is done, Gland receives the predetermined price/unit dose of the product for product manufacturing and earns profit share based on the actual net profit or net sales of the product. If the partner files the dossier, then Gland co-owns (with the partner) the development and intellectual property rights, whereas the partner retains ownership of the relevant dossier and marketing rights.

B2B Technology Transfer Model: Gland Pharma is involved in the process of technology transfer required for manufacturing, testing and packaging of the product. The product is partially developed by the partner and then transferred to Gland's manufacturing facilities for commercialization. Upon commercialization of the product, Gland receives a technology transfer fee and royalties as percentage of revenue. The ownership of the dossier is retained by the partner, and the partner owns the intellectual property and the marketing rights. Gland Pharma retains the manufacturing right during the term of the technology transfer agreement, which is generally for a period of 5-10 years.

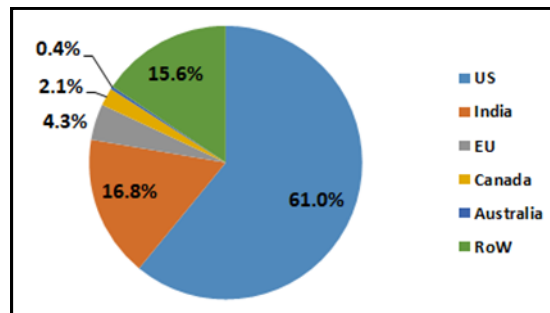
INVESTMENT RATIONALE (contd.):

B2B CMO Model: This is the contract manufacturing model, where Gland Pharma provides just the fill and finish services for injectable products. Such agreements are largely for the Indian market. Gland Pharma enters into agreements with pharma companies and charges a fixed per-unit price for manufacturing. The customer retains ownership of the dossier, intellectual property and marketing rights of a product while Gland retains the manufacturing right during the term of the agreement.

B2C Model: Gland Pharma directly markets the product, and the model is solely for the Indian market. As of Mar, 2020, the company had a sales force of over 200 employees and an extensive countrywide distribution network to ensure coverage in ~2,000 corporate hospitals, nursing homes and government facilities. Under this model, Gland retains ownership of the relevant dossier as well as development, intellectual property and marketing rights of a product. Key brands marketed under this model include Hep 5, Hep 25, Cutenox and Synject.

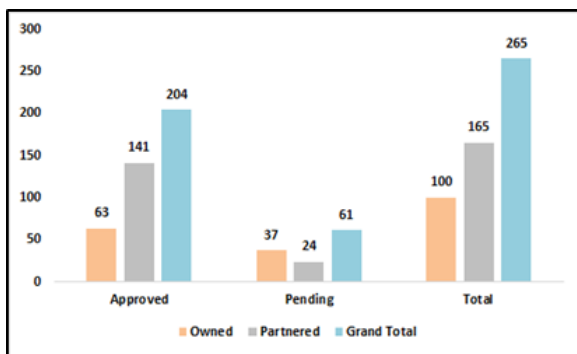
US Business: US is the largest market for Gland Pharma, with ~60% of revenue contribution. Gland Pharma is one of the fastest-growing companies in the small-molecule injectable space, according to IQVIA. The company along with its partner has filed 282 ANDAs and has received approval for 226 ANDAs (including 24 tentatively approved ANDAs) as of Dec 2020. The remaining 56 ANDAs are under approval. The filed ANDAs comprise 204 ANDAs for sterile injectables, 51 for oncology and 27 for ophthalmics. These ANDA numbers take into account multiple partnerships for a single product. Out of these, 113 are the company's own ANDA filing, of which 79 are approved. Gland Pharma markets ~93 molecules in the US, with an estimated current pipeline of ~30 molecules. Incrementally, the company has been filing more ANDAs on its own. While Gland Pharma owns ~35% of the approved ANDAs, it owns ~61% of the ANDAs that are pending approval. Every year, the company expects to file ~22-25 ANDAs of which ~75-80% are likely to be company's own ANDA filing. As per the company, it has exported ~94mn units to the US in FY20. Moreover, the company launched 6 products (4 molecules) in Q3FY21 and 31 product (19 molecules) in 9MFY21 (in its core markets).

Exhibit 19: Geographic Reach 9MFY21



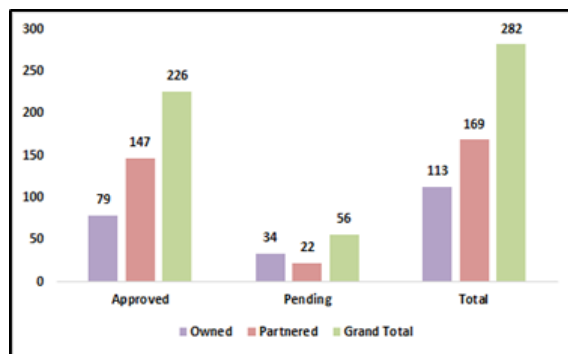
Source: Q3FY21 PPT, Progressive Research

Exhibit 20: ANDA Pipeline-March'20



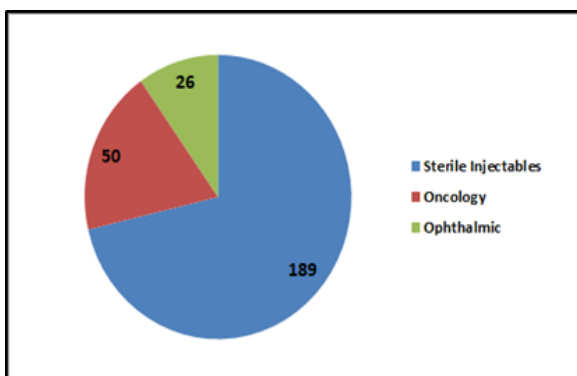
Source: AR2020, Progressive Research

Exhibit 21: ANDA Pipeline-Dec'20



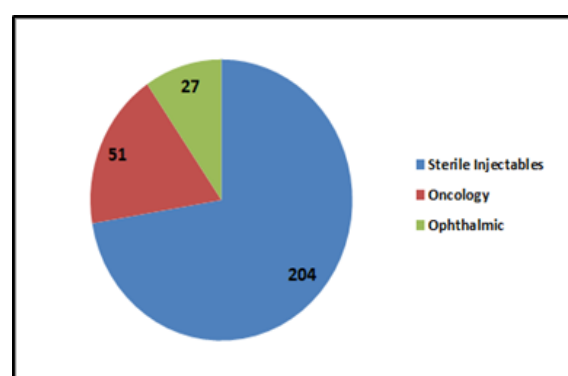
Source: Q3FY21 PPT, Progressive Research

Exhibit 22: Portfolio Bifurcation-Mar'20



Source: AR2020, Progressive Research

Exhibit 23: Portfolio Bifurcation-Dec'20

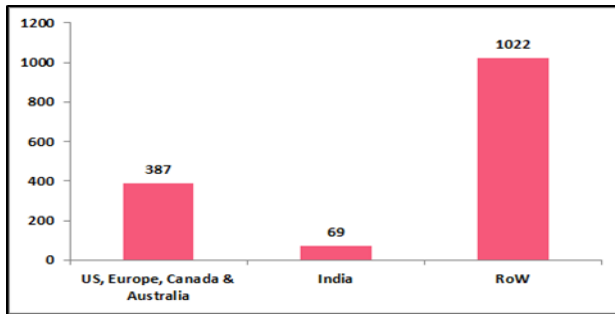


Source: Q3FY21 PPT, Progressive Research

INVESTMENT RATIONALE (contd.):

With regard to the key products to bet on for US launches, major growth in the past was driven by few products like Enoxaparin, Daptomycin and Micafungin. Going forward, **Ertapenem** is an attractive opportunity for Gland Pharma in the near term (~USD15mn potential revenues) which is expected to be launched in FY22E. The remaining growth in the US would be driven by market share gains in older products like Enoxaparin and other smaller new launches. The company expects 15-20 new launches in the US each year, in tandem to the rate of product filings in the recent past.

Exhibit 24: Global Registration-Dec'20



Source: Q3FY21 PPT, Progressive Research

Exhibit 25: US Filings Update

US Filings	Q3FY21	9MFY21
ANDA Filed	12	19
ANDA Approved	6	*24
DMF's Filed	1	5
*includes 5 Tentative Approvals		

Source: Q3FY21 PPT, Progressive Research

China: emerges as an important market for Gland Pharma for future growth. After the US, China would be the largest opportunity and presence of Fosun should further be an advantage with regard to regulatory approvals and distribution. As per the IQVIA, of the total China injectable market of USD49bn, around USD34bn is the generic injectable. On comparing with US, which has generic injectable market of USD46bn and higher discounting; China looks more attractive for the company. Gland has filed 6 dossiers and expects another 10-12 by FY22E. The registration time for drugs in China has reduced over the years with approvals expected in 12-24 months. The first approval is expected to come through in FY22E with some revenue contribution to commence from end FY22E or early FY23E. The company expects revenues to ramp up significantly beyond FY23E and the company expects to achieve revenues of ~Rs5bn by FY25E.

RoW markets: Sales outside of US, India and China as categorized as the RoW markets, which include emerging markets in LatAM, Africa, Asia Pacific, Europe, Australia and Japan. The company has been gradually focusing on these markets to leverage its product portfolio. Due to the pandemic, there has been an increase in the demand for injectables, and with supply disruptions alternate suppliers are being sort which has opened up avenues for Gland Pharma to participate and develop relationship with key institutions, evident through the step-up sales reported by the company, growth of 80% y-o-y expected for FY21.

Europe Injectable Market is estimated at USD87bn of which USD29bn is the value of the generic injectable market which has grown at a healthy CAGR of 9.8% over 2014-2019 as per IQVIA. Across Europe, growth is supported by patent expiries and increasing penetration of generic injectables. Gland Pharma has a small presence in Europe with ~15 registrations and an equal number under approval (EU is a highly fragmented market). One of the drawbacks for EU market is that supply chain is better managed with local manufacturing presence. This has led to the company considering inorganic opportunities to establish a manufacturing base in EU. The second important and larger geography in the RoW is **Latin America**, where Gland Pharma has more than 300 registrations (both approved and under approval) in the region. It also has a tie up with Mylan for this region. The company is exploring avenues in **Africa** under the experience of Fosun with more than 300 registrations. Overall, RoW should emerge as a key market for the company with the new base of FY21 sales and expects to sustain double-digit growth going forward.

India: is the second-largest market for Gland Pharma in terms of revenue contribution. It contributed ~17% to the company's revenues in 9MFY21. In India, the company operates through both B2B as well as B2C model. The B2C model accounts for ~4% of the company's overall revenues. Apart from the B2C business, the segment includes revenues from B2B CMO business (contract manufacturing of Insulin for Sanofi) and technology transfer revenues from Dr Reddy's. With regards to the Covid portfolio, Gland has also initiated manufacturing of Remdesivir for its domestic market from Pashamylaram facility. Gland launched 4 product SKUs (2 molecules) in Q3FY21 and 10 product SKUs (4 molecules) in 9MFY21.

(B) Extensive Product Basket: Being an exclusive manufacturer of parenterals, Gland has always laid focus on fulfilling the diverse injectable demand assisted by a stable supply of affordable and high-quality products. As stated earlier, the company is present in sterile injectables, oncology and ophthalmics, emphasis being laid upon complex injectables, NCE-1s, FTF products and 505(b)(2) filings. The established portfolio spans across various therapeutic areas and delivery systems (which cover liquid vials, lyophilized vials, pre-filled syringes, ampoules, bags and drops). **The key molecules include Heparin Sodium Injection, Enoxaparin Sodium Injection, Rocuronium Bromide Injection, Daptomycin Injection, amongst others.** The company's products are mainly put to use in the critical care segment. Gland Pharma has plans in place to cater to new areas of complex injectables such as peptides, long-acting injectables, suspensions and hormonal products as well as new delivery system

Exhibit 26: Therapeutic Range

Anti-infectives	Hormones
Anti-diabetic	Neurological and CNS
Anti-malarials	Ophthalmics and Otologicals
Anti-neoplastics	Pain, neuro-muscular blocking agents and analgesics
Blood related	Respiratory
Cardiac	Vitamins, minerals and nutrients
Gastro-intestinal	Others

Source: Company RHP, Progressive Research

INVESTMENT RATIONALE (contd.):

Key Products:

Enoxaparin: This is the largest product for Gland Pharma in the US. As per IQVIA, there are total 8 players (including private label) in the market. Gland has partnered with 2 players Apotex and Fresenius that had 12% and 9% market share by value and volume respectively. As of Q3FY21, Apotex accounts for ~90% of volumes and remaining ~10% is accounted by Fresenius Kabi. Fresenius Kabi sells Enoxaparin manufactured by Sanofi (AG) and by Gland (generic). The AG has market share of ~20% and going forward, Gland should gain this market share over time. With the shift in volumes from Heparin, Enoxaparin is expected to benefit going forward, adjusting for the additional competition from Chinese and Indian players.

Daptomycin: Gland Pharma was one of the early entrants in this product and the product contributed significantly in FY19/20. As per IQVIA, there are 16 players and Gland Pharma partners with 6 of them with Sagent, Xellia and Dr. Reddy's being some of the key partners. With the daptomycin market having declined sharply owing to price erosion and intensified competition, we expect stable market share with stable pricing for Gland going forward.

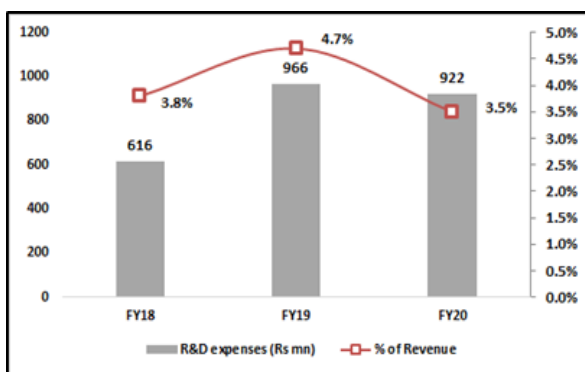
Heparin: As per IQVIA, there are 15 players in the market and Gland has partnered with 2 players namely Sagent and Fresenius Kabi that have 8% and 5% market share by value and volume respectively. Gland's market share is down from peak market share of 12% and 11% by value and volume respectively (in FY18). Going forward, some pricing pressure along with shift in volumes towards Enoxaparin is expected.

Micafungin: This is a limited competition drug with Fresenius (partner for Gland) having 180 days exclusivity, key contributor for Gland in FY21E. Currently there are only two players in market, Astellas which is the innovator and Fresenius Kabi (gained 30% market share by value and volume). Apotex which also has a final approval now is partnered with Gland.

Opportunities: Analysing the key products, shows there is no specific large opportunity in the immediate term. In gAggrastat, Gland Pharma has sole exclusivity, but it is very small product. Among the larger products, gLexiscan could be an interesting opportunity, as we believe there is a reasonable probability of the litigated patents being invalidated in the district court, where hearing is scheduled in Jun'21. For Glatiramer Acetate or gCopaxone, the opportunity is likely to be in the form fill-finish (tied up with Dr Reddy's) and hence the revenue impact may be limited.

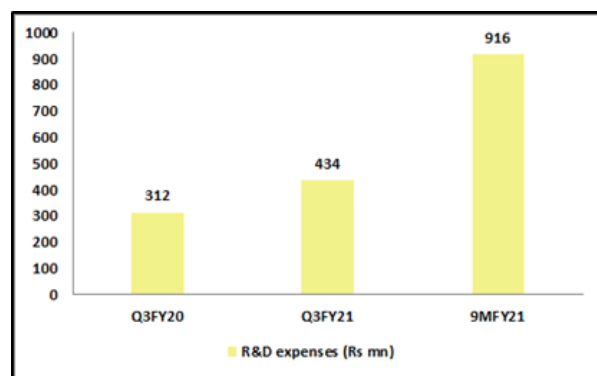
(C) Innovation is the Key: The R&D team at Gland Pharma directly supports in necessitating the regulatory filings worldwide. The company has a centralized R&D laboratory located at Dundigal, Hyderabad facility, with supporting personnel at each manufacturing facility. This facility has an in-house team of ~265 personnel including PhDs, pharmacy post graduates and chemists. Expertise covers a wide spectrum not only at the process development stage of a drug but also assists in defining the thresholds for presence of impurities (if any) and thereby arriving at the shelf-life definition. All the design and validation methods undertaken by Gland are in compliance with the global regulatory standards. The company has rich experience that is needed to characterize complex drugs, 505(b)(2) filings for new drug applications and Para IV filings for ANDAs required by the USFDA. Plans are in place to set up a new R&D building at Pashamylaram, Hyderabad.

Exhibit 27: R&D Spend Trend (FY's)



Source:Q3FY21 PPT, Progressive Research

Exhibit 28: R&D Spend Trend (Quarterly)



Source:Q3FY21 PPT, Progressive Research

Notable Developments-The Vaccine Trigger: 2020 was the year of disruption in terms of logistics, supply chain, economic downturn, lower business momentum, all in all affecting almost all the sectors of the economy. With cases reaching almost its peak somewhere in mid Feb and when the nation as a whole was already accustomed to the new normal, the country was yet again hit by a second wave in 2021. In order to fight against the fire, several companies joined hands and laid more emphasis on the development of a Vaccine at the earliest; which otherwise takes years for the manufacture of a mass production for a country like India.

Some of the leading players already in the limelight include Serum Institute of India (SII): *Covishield*, Bharat Biotech: *Covaxin*, Biological E: *Biological E*, Zydus Cadila: *ZyCoV-D*, Hetero Biopharma: *Sputnik V*, Dr. Reddy's Laboratories: *Sputnik V*, Panacea Biotech: *Covaxin*, Genovax: *HGCO19*, Mynvax: *Mynvax* etc.

Some companies are ready to launch their product while others are awaiting approvals. Currently, Covishield and Covaxin are ruling the Indian market to curb the spread of the virus.

May 17, 2021

PICK OF THE MONTH

VOL-7, NO-06

Industry: Pharmaceuticals

Gland Pharma Limited

BUY

CMP: Rs.2882

TARGET PRICE: Rs.3305

TIME : 12 months

INVESTMENT RATIONALE (contd.):

How big is the Opportunity for Gland Pharma?

Being a niche injectable player, Gland Pharma was in active discussions with companies in order to manufacture Covid-19 vaccine for both the Indian and the global markets with an initial plan to manufacture nearly 40 million vials of finished product annually and allowing a headroom of adding more capacities as and when needed. As per media articles, the company has begun the production of Remdesivir (used to treat adults and children hospitalized with severe presentations of the virus) for the Indian market, currently producing for Mylan (Mylan produces the generic version of Remdesivir drug under the brand name 'Desrem' in India). The production capacity is around 6-7 lakhs vials per month, with an intent to increase the production capacity as and when the need arises.

The Russian Direct Investment Fund (RDIF) Deal: In March, 2021, Gland Pharma signed an agreement with the RDIF for manufacture of nearly 252 million doses of Sputnik V Covid-19 vaccine. According to the deal, the company will initially undertake the technology transfer of the drug substance to its facilities and will then manufacture the filled vials under aseptic conditions. As per the article, the Sputnik V vaccine production was scheduled for Q3FY21 at the company's drug substance and drug product facilities in Hyderabad, India, with estimated delivery in Q4FY21.

Fosun Pharma-BioNTech SE Joint Venture (JV): Fosun Pharma, the Chinese pharmaceutical company (promoter of Gland Pharma) in its filing on 9th May, 2021 announced setting up of a JV with BioNTech SE in China with a capacity to manufacture upto 1 billion doses of their candidate against Covid-19. As per Bloomberg Report, Fosun Pharma would invest nearly USD100mn including cash, while BioNTech would invest USD100mn through assets including production technology and a proprietary license. Although the vaccine is yet to be approved in Mainland China (which requires an in-country clinical trial). The JV aims to supply shots for the Chinese population by the month of July. In the short term, Gland Pharma may participate in the vaccine requirements but this would be limited as the company will not be manufacturing the drug substance. However, in the long run it is possible for Gland to consider vaccine manufacturing as a dedicated business segment. There is limited visibility on long-term demand for Covid-19 vaccine. It will depend on the duration of protection that the current vaccines provides and there is not much information on this matter. Overall, Gland continues to leverage its strength in the injectable manufacturing space and would keep an eye on the vaccine development to grab more opportunities in the near future.

Next Leap of Growth: The company has a defined roadmap for achieving a diverse product mix at various stages of lifecycle coupled with a robust product pipeline.

- Intent to expand the development and manufacturing capabilities in complex injectables such as peptides, long-acting injectables, suspensions and hormonal products
- Pursue strategic acquisitions and partnerships
- Expanding development and manufacturing capabilities in new delivery systems such as pens and cartridges
- Geographic expansion into emerging markets to diversify revenue base while maintaining healthy profitability

Financials:

Raw Material Sourcing: Gland procures the raw materials that include some APIs that are not produced by them in-house, intermediates, primary packaging materials that includes ampoules, vials, glass bottles, rubber stoppers, etc. The company sources the same from vendors and ensures timely availability and continuity of supply from them. On the other hand, the material sourcing is not dependent on a single supplier, the company is open to options from alternate sources. The company's RM cost has been closer to 41-42% over FY18-20.

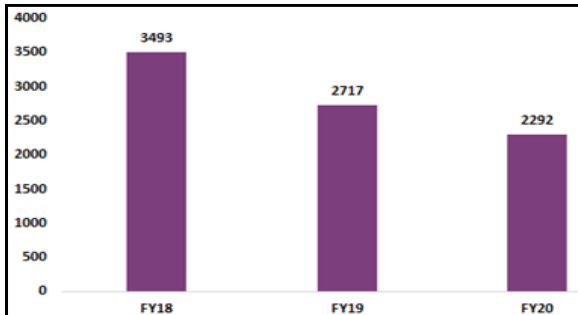
Integrated Supply Chain: The company's ability to manufacture its own API, enhances its vertical integration route, especially for critical APIs that are difficult to be sourced. This strategy allows the company to develop products that quite often other companies may give it a miss on account of the uncertainties involved in API supply. Gland has a constant check in place on the inventory levels, APIs and other components that are sourced, change in batch sizes (if any); all of which would enable the company to develop a sufficient supply chain management.

Revenue Trend: The company's performance has increased at a CAGR of 27.5% over the period FY18-20. The revenue grew from Rs16,199mn in FY18 to Rs26,332 in FY20; driven by increased exports. The company has generated revenues worth Rs2292mn in FY20 with 51 product launches (9% of revenues) as against Rs2717mn in FY19 with 45 product launches (13% of revenues).

Capex Spend: The management has been of the view to continue its investments in order to keep building new capabilities to support its next leap of growth that hails from complex injectables, peptides, long-acting injectables, suspensions, hormonal products as well as pen and cartridges as the new delivery systems. In order to give the move a necessary push, the company has increased its manufacturing capacities from 670 million units per annum in FY18 to 755 million units as on 30th June, 2020. Gland is a net cash company and uses internal accruals for maintenance and expansionary capex. The company spends ~Rs500-600mn annually on maintenance and remaining on expansionary capex. It spent Rs1,826mn on capex during 9MFY21. The capex spend includes increasing capacity by adding new lines at Pashamylaram facility, increasing Vizag API plant's capacity by adding new block, and adding capacity in the oncology facility at Vizag.

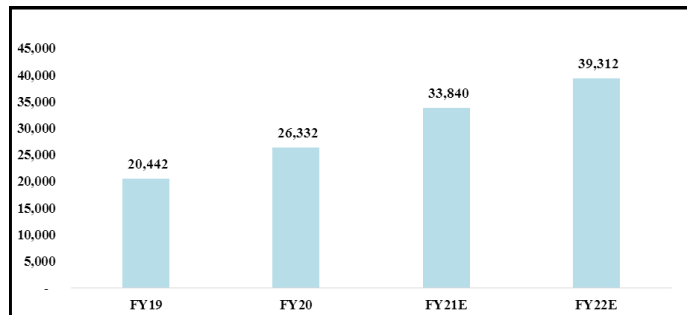
Financials:

Exhibit 29: Product Launch (Rsmn)



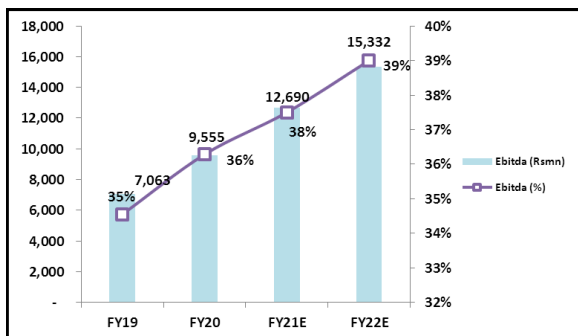
Source: Q3FY21 PPT, Progressive Research

Exhibit 30: Revenue Trend (Rsmn)



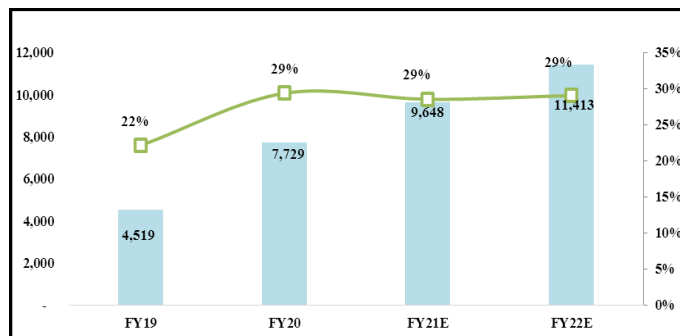
Source: Annual Report, Progressive Research

Exhibit 31: Ebitda vs. Ebitda Margins



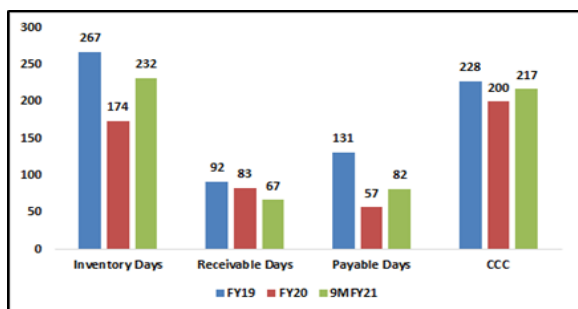
Source: Annual Report, Progressive Research

Exhibit 32: PAT vs. PAT Margins



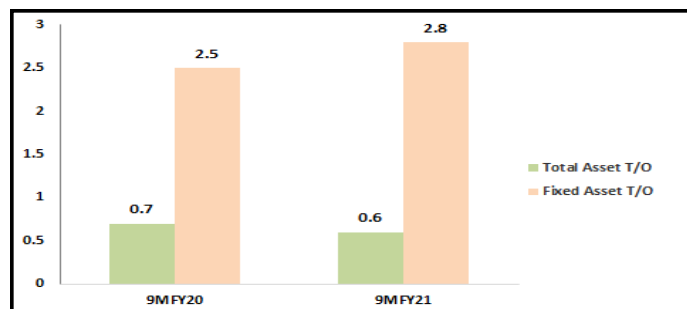
Source: Annual Report, Progressive Research

Exhibit 33: Cash Conversion Cycle (CCC)



Source: Q3FY21 PPT, Progressive Research

Exhibit 34: Turnover Ratios



Source: Q3FY21 PPT, Progressive Research

Risks and Concerns:

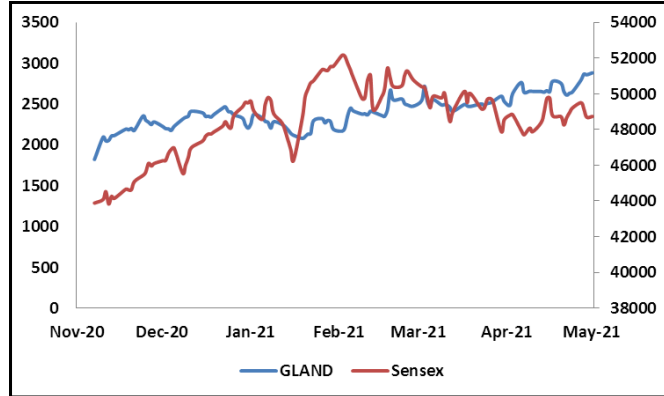
- Pricing pressures, fluctuations in demand-supply of injectable products can lead to a decline in revenue and margins
- Changes in regulatory requirements or delay in receiving permits/approvals for drugs may affect the business
- Dependence on B2B marketing partners to market some of the company's products may subject it to a number of risks
- Supply chain disruptions in sourcing of raw materials may lead to an interruption in injectables production
- Regulatory checks/scrutinies by the USFDA and other regulatory bodies may result in enforcement action if not promptly and adequately cured leading to litigation and product liability claim risks
- More than 80% of the revenues are generated from outside India. In part, it is naturally hedged against the company's import of raw material and equipment. In most of the markets including emerging markets the billing is in USD
- Disruption in API supplies may lead to delay/interruption in the production of injectables. Gland is dependent on import of key raw material like Heparin for its key products. Any disruption of supplies presents risk.
- Disruption in business operations due to manufacturing or quality problems.
- Increased competition in current product portfolio could lead to both loss of market share as well as pricing pressure.
- Top-5 products account for 40-45% of Gland's US sales, where competition is still limited in Enoxaparin and Caspofungin

Outlook and Recommendations:

Gland has been a niche injectable player and has shown consistent improvement in the revenues, profitability and the margins in FY18-20. Even though the US market have been of prime importance for the company, the management envisions to increase its market presence and be able to enter new markets assisted by better product mix and utilisation of existing and lined up capacities in an efficient manner. With certain drugs expected to go off patent in the near future, the demand for injectables would drive the business further for the company. The company has forayed into the vaccine space against Covid-19 and is eyeing further opportunities that fit their domain. The unique business model adoption enables the company enter into tie-ups directly with major players in the industry. On the ANDA portfolio front, the company has had a good track record whenever the inspections took place in the past and has a decent approval basket in place.

The company continues its investments in technological capabilities and pursue organic/inorganic investments as it deems fit in the near future. Strong product basket, growth in the injectables industry, efficient supply chain management, good return ratios, all of it adds optimism to the company prospects. **Considering the current valuations we feel that the company is an apt SIPPING candidate for a long term target of Rs3305.**

Exhibit 35: Price v/s Sensex



Source: Ace Equity, Progressive Research

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