



Private Circulation Group

Report on Gland Pharma Ltd.

By JRK Research Desk

25 May' 2022

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ABOUT THE COMPANY



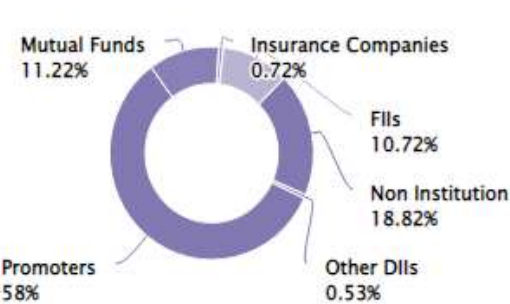
Established in 1978, **Gland Pharma Ltd (GPL)** is one of the largest and fastest growing, generic injectable-focused company. GPL offers services that cover the entire injectables value-chain, including contract development, own development, dossier preparation and filing, technology transfer and manufacturing across a range of delivery systems. **Over the last four decades, GPL has proven its excellence in evolving into a renowned complex injectables development & manufacturing Company.**

Market Cap	47,250 Cr
CMP (25 May'22)	2,875
52 week Range	4350/2801
NSE Symbol	GLAND
EPS	73.8
PE (x)	39x
Book Value	436
P/Bv (x)	6.6x
No of Facilities:	
API	4
Formulations	4
Quality culture: Gland has never got a warning letter from the US FDA	

GPL's portfolio of injectables products spans across multiple therapeutic areas and delivery systems. The company is present in sterile injectables, oncology and ophthalmics, and focus on complex injectables, NCE-1s, First-to-File products and 505(b) (2) filings. The delivery systems include liquid vials, lyophilized vials, pre-filled syringes, ampoules, bags and drops. **With a strong R&D team and growing manufacturing capacities, GPL is widening its offerings into complex injectables.**

Over the years, GPL has made substantial investments in its manufacturing infrastructure, with eight manufacturing facilities in Southern India, comprising of four finished formulations facilities with a total of 28 production lines and four API facilities. The manufacturing facilities consists of two sterile injectables facilities, one dedicated Penems facility and one oncology facility with finished formulations facility with a capacity of 1000 million units per annum. The Company sells its products primarily under a business to business ("B2B") model in over 60 countries with its core markets being United States, Europe, Canada, Australia and India.

Shareholding Snapshot



INDUSTRY OVERVIEW

Global pharmaceutical industry is undergoing a major revamp. **Cross-country and cross-enterprise collaboration in areas such as research and development, flexible production, focus on precision medicine, attention on supply-chain management, and technology innovation with emphasis on digitisation** were some of the major trends seen since 2020.

At present the developed markets of North America and Europe dominate the pharmaceutical market with over 70% market share. With growth picking up at a faster pace in the 'pharmerging' markets like China and India the market share of these countries are expected to increase steadily. The market is currently mostly innovator based, but the share of generic (medicine that has gone off-patent) is expected to rise from 35% as of 2020 to 37% by 2025, growing at a CAGR of ~5.3% to reach ~ US\$ 509 billion.

GLOBAL INJECTABLES MARKET: Injectables are the second largest form of drug delivery systems and account for over 41% of the global market share, on back of increasing volume and marginal increase in prices. North America the biggest market has been capturing more market share as the usage increases in the region. While, Japan, Russia, Korea, Australia and Saudi Arabia are some of the other key markets contributing to more than two-third of overall RoW injectables market.

While within the injectable market, generics-injectable valued at US\$ 133 billion is in 2021. It represents 28% of overall injectables by value. Generic Injectable penetration has mostly increased across the geographies during the last few years both in terms of volume and value.

Injectables have numerous advantages over other traditional dosage forms:

- Long acting Injectables delivery systems enhance product quality by decreasing dosing frequency, simplifying the drug regimen. Parenteral depots reduce the relapse rate of disease and the maintenance phase of therapy, hence improving efficacy and treatment adherence.
- Injectables have almost 100% bioavailability as they avoid the 1st pass metabolism. They have an immediate onset of action which is better than other dosage forms.
- Injectables allow patients who cannot intake other dosage forms due to difficulties in orally consuming the medication to adhere to their medication regimen.
- The development of self-injection devices like pen-injectors and auto-injectors has made administering drugs much more convenient and relatively easy for patients.
- There is an increase in the number of new drug formulations that are not very water soluble and/or have very low permeability to allow for their adequate absorption from the gastrointestinal tract following oral administration. Hence the only way to make such drugs bioavailable in the body is through an intravenous administration.



INDUSTRY OVERVIEW

USA - Biggest Pharmaceutical Market- United States pharmaceutical market is expected to grow with the rise in ageing population. Multinational companies form the core of the business and operate across the world in both developed and emerging markets. Despite of a strong research and development capabilities and innovations, the USA market has been widely open to generics. USA has the highest generic sales in the world, with ~28% share in 2020.

Injectables constitute the largest form of drug delivery with a 48% market share in 2021, while the US injectable market was estimated to be at ~US\$ 259 billion (in 2021) and has grown at ~11% CAGR during 2016-21.

Key Drivers:

Ease of Administration: Innovation in the field of New Drug Delivery Systems (NDDS) has led to a rising demand for self-administered medications. The invention of new injectable delivery devices like auto injectors, pen injectors, pre-filled syringes (PFS) and needle-free injectors has made self-administration of drugs more convenient and easier for patients.

Treatment of Chronic Diseases: Chronic diseases like cancer (chemotherapy drugs) and diabetes (insulin) which are treated primarily through injectables is witnessing an increased demand. Diabetes prevalence has doubled since 1980 and is expected to continue rising, with increase in obesity, sedentary lifestyle, poor eating habits, and ageing population. The number of cancer patients is expected to increase from 18 million in 2018 to 23 million plus by 2030.

Novel markets: Pharmaceutical companies are developing and investing heavily in the development of new complex molecules to find new cure for diseases such as rheumatoid arthritis, multiple sclerosis, cancers and auto-immune disorders. These treatments are now being administered through injectables, especially prefilled syringes, is becoming the preferred drug delivery systems due to their ease of handling, less chance of overfills and increased safety to patients. There is also an increase in the number of new drug formulations which can only be administered intravenously.

Growth of Biologics: Biologics are gaining popularity in the pharmaceutical industry. In the coming few years, many biologic drugs will witness loss of patent exclusivity thereby resulting in a surge in their biosimilars products. This will lead to increased demand for the injectable drug delivery devices for these formulations.

Market Entry Barriers: High capital investments, operational cost, manufacturing complexities, stricter compliance requirement due to the sterile nature of products and high-quality standards lead to natural entry barrier in the industry. The inherent complex nature of injectables leads to a concentrated market as compared to other segments.



Core Strengths of Gland Pharma



Diversified Business Model with Focus on Growth & Stability: Gland Pharma work with multiple pharmaceutical companies on an expense and profit sharing basis. Its value added end-to-end solutions include API development, formulation development, analytical method development, and dossier compilation and submission.

The products offered are in various stages of development, ranging from lab-scale formulations to ready-to-scale up formulations. Gland also offers ready-to-register portfolio to partners for launch in their respective markets.

Diversified B2B-led Model Across Markets, Complemented by a Targeted B2C Model in India

	B2B (Global)				B2C (India)
	B2B – IP Led		B2B Tech Transfer	B2B CMO	B2C
	Own Filing	Partner Filing			
Overview	<ul style="list-style-type: none">• Out-license to Marketing partners• Long term product supply contracts		<ul style="list-style-type: none">• Co-development with Partner• Manufacturing by Gland	<ul style="list-style-type: none">• Fill and finish service• Loan and license agreements	<ul style="list-style-type: none">• Direct marketing of products
Revenue Model	<ul style="list-style-type: none">• License and milestone payments• Selling price per unit dose + Profit Share		<ul style="list-style-type: none">• Tech transfer fee• Selling price per unit dose + Royalty	<ul style="list-style-type: none">• Fixed per unit price	<ul style="list-style-type: none">• Direct sale of products
ANDA Ownership ⁽¹⁾	✓	✗	✗	✗	✓
IP Ownership ⁽¹⁾	✓	Co-owned	✗	✗	✓

Advantages of B2B models:

- ✓Stable Cash Flows, Better Profitability Profile, and Margin Stability.
- ✓Reduce risk by partnering with a marketing partner to cover R&D litigation expenses.
- ✓Products licensed to marketing partners strong in particular therapeutic areas resulting in higher market share.
- ✓IP-led model helps generate revenue from transfer pricing and profit sharing. Revenues and profits through transfer pricing are immune to raw material price fluctuations. Transfer pricing also helps regulate any adverse impact from price erosion in end-formulations, as it gets restricted to the profit share component.

Glands’ B2C operations are executed by a vast network of field operatives, corporate and government hospitals and health facilities, giving the company a coast-to-coast reach across India.



Core Strengths of Gland Pharma



Extensive & Vertically Integrated Manufacturing Capabilities: Gland Pharma is vertically integrated and has four API & Finished Formulation facilities each with a production capacity of 11,000 kg per year in API and 1,000 million units in Formulations. **The facilities provide in-house manufacturing capabilities for critical APIs supporting the Company's key products.** As on March 31, 2022, the Company along with its Partners have filed total 311 ANDAs, out of which 252 were approved and 59 are pending approval.

The world class GMP-compliant facilities produces a wide range of injectables and APIs. Glands' greater efficiency in manufacturing, operations, and quality control is a result of highly integrated processes that also ensure seamless manufacturing capabilities.

Glands' API facilities have in-house manufacturing capabilities that help the company to integrate backward and develop products that many others may overlook because of API supply uncertainty. This gives Gland a better control of the supply chain and enhances cost efficiencies.

Overview



- ✓ 28 production lines with flexibility to accommodate different product requirements
- ✓ In process of commissioning additional capacity
- ✓ New R&D building at Pashamylaram, Hyderabad
- ✓ Greater control over costs and quality and mitigate supply chain related risks

Manufacturing Footprint

<p>Dundigal, Hyderabad</p>	<p>Dundigal, Hyderabad</p> <p>Sterile Injectables Facility (Flagship)</p> <ul style="list-style-type: none"> Liquid Vials, Lyophilizers, Ampoules, Pre-filled syringes, Bags and Ophthalmics <p>API Facility</p> <ul style="list-style-type: none"> R&D pilot plant 	<p>USFDA (US), MHRA (UK), ANVISA (Brazil), TGA (Aus), BGV (Germany)</p>
<p>Pashamylaram, Hyderabad</p>	<p>Pashamylaram, Hyderabad</p> <p>Sterile Injectables Facility</p> <ul style="list-style-type: none"> Liquid Vials, Lyophilizers, Ampoules and Pre-filled syringes <p>Penems Facility</p> <ul style="list-style-type: none"> Vials (2 Lyophilizers), Dry Powder 	<p>USFDA (US), GUB Munich (Germany)</p>
<p>Vishakhapatnam</p>	<p>Vishakhapatnam</p> <p>Oncology Facility</p> <ul style="list-style-type: none"> Liquid Vials, Lyophilizers <p>2 API Facilities</p> <ul style="list-style-type: none"> Cumulative capacity of 11,000 kg / year 	<p>USFDA (US), AGES (Austria), TGA (Australia), ANVISA (Brazil), DMA (Denmark)</p>

Note: (1). Includes recent acquired Biotech Drug Substance Facility at Genome Valley, Hyderabad





Core Strengths of Gland Pharma



Consistent Regulatory Compliance Track Record: Gland Pharma is driven by decades of experience and expertise in injectable manufacturing. Its facilities are regularly audited by global authorities, who have given recognition to Glands' consistent compliance track record on multiple occasions, making it as one of the most reputable injectable manufacturer in the global market.

"No Warning Letters from USFDA Since Inception of Each Facility"



Focus on Quality Control:

- ✓ 1,449 full time employees in Quality Control and Quality Assurance.
- ✓ 31% of the workforce in Quality Control and Quality Assurance.
- ✓ Corporate reporting structure for identifying and developing standard operating procedures.
- ✓ Laboratory Information Management System software for quality control at all manufacturing locations.
- ✓ 40+ audits on average per year, including customer audit and regulatory agency audit.
- ✓ Conduct internal audits across all facilities on a quarterly basis.



Core Strengths of Gland Pharma



Extensive Portfolio of Complex Products Supported by Internal R&D and Regulatory Capabilities: Gland Pharma’s complex product portfolio is supported by its right capability matrix in products and delivery systems. In addition to long-standing delivery capabilities, Gland is expanding its development and manufacturing capabilities in complex injectables such as Peptides, suspensions, and hormonal products as well as new delivery systems such as pens and cartridges.

Glands’ R&D team comprises of more than 315 personnel including PhDs, pharmacy postgraduates, and chemists with expertise in the synthesis of low molecular weight injectables drugs, steroids, and oncology drugs and in developing complex injectables such as lyophilized products, high-potent drugs, and long-acting suspensions.

Extensive Portfolio of Complex Products	Internal R&D & Regulatory Capabilities
<p>Present in sterile injectables, oncology and ophthalmics, and focus on complex injectables, NCE-1s, First-to-File products and 505(b)(2) filings</p> <p>Delivery Systems:</p> <ul style="list-style-type: none"> • Liquid vials • Lyophilized vials • Pre-filled syringes • Ampoules • Bags • Drops <p>Therapeutic Areas:</p> <ul style="list-style-type: none"> • Anti-diabetic • Anti-infectives • Anti-malarials • Anti-neoplastics (Oncology) • Blood-related • Cardiac • Gastro-intestinal • Hormones • Neurological and Central Nervous System • Ophthalmics and Otologicals • Pain, neuro-muscular blocking agents & analgesics • Respiratory • Vitamins, minerals & nutrients 	<p>Centralized R&D Laboratory located at Dundigal, Hyderabad facility, with supporting personnel at each manufacturing facility</p> <ul style="list-style-type: none"> – ~315 personnel team including PhDs, pharmacy post graduates and chemists – New R&D building at Pashamylaram, Hyderabad – R&D expertise supports regulatory filings globally <p>Regulatory Track Record</p> <ul style="list-style-type: none"> • 311 ANDA Filings in US – 252 approved; 59 pending ⁽¹⁾ <ul style="list-style-type: none"> – Of 311, 139 owned by Gland Pharma out of which 100 are approved and 39 are pending for approval – 227 for sterile injectables, 54 for oncology and 30 for ophthalmics related products • 1,557 product registrations globally, of which 418 in United States, Europe, Canada and Australia, 69 in India and 1070 in Rest of the world ⁽¹⁾






Glands’ key molecule (injectables) products like Heparin Sodium, Micafungin, Caspofungin, Daptomycin, Enoxaparin Sodium, and Rocuronium Bromide etc are highly quality driven and hence are mainly used in critical care segment in a vast range of therapeutic categories.



Core Strengths of Gland Pharma



Professional and Experienced Management Team: Gland Pharma is managed by a professional and experienced team with significant expertise in the pharmaceutical industry.

Name		Qualification
Management Team		
	Srinivas Sadu <i>Managing Director and Chief Executive Officer</i>	<ul style="list-style-type: none"> Master's degree in science (industrial pharmacy) from Long Island University, New York Master's degree in business administration from University of Baltimore; Post graduate certificate in finance & management from London School of Business & Finance
	Ravi Shekhar Mitra <i>Chief Financial Officer</i>	<ul style="list-style-type: none"> Bachelor's degree in commerce from University of Calcutta Associate member of the Institute of Chartered Accountants of India Associate member of the Institute of Company Secretaries of India
	K V G K Raju <i>Chief Technology Officer</i>	<ul style="list-style-type: none"> Bachelor's degree in science from Andhra University
	C S Venkatesan <i>Senior Vice President – R&D</i>	<ul style="list-style-type: none"> Master's degree in science in organic chemistry from Annamalai University Doctor of philosophy degree from the Indian Institute of Science, Bangalore
	Surapanini Sridevi <i>Senior Vice President – R&D</i>	<ul style="list-style-type: none"> Master's degree in pharmacy from Banaras Hindu University Doctor of philosophy degree in pharmaceutical science from Osmania University
	Prakash Baliga <i>Vice President – Strategic Sourcing, Procurement & Commercial</i>	<ul style="list-style-type: none"> Master's degree in pharmacy from Bangalore University
	Shilpi Sahay <i>General Manager – Human Resources</i>	<ul style="list-style-type: none"> Bachelor's degree in science from the Fergusson College, University of Pune Executive diploma in human resource management from XLRI, Jamshedpur
	Susheel Ogra <i>Assistant Vice President – Sales and Marketing</i>	<ul style="list-style-type: none"> Bachelor's degree in science from Maulana Azad Memorial College, University of Jammu
	Sampath Kumar Palleriamudi <i>Company Secretary and Compliance Officer</i>	<ul style="list-style-type: none"> Bachelor's degree in law from Andhra University Faculty of Law Post graduate diploma in business management from Institute of Public Enterprise Associate member of the Institute of Company Secretaries of India

Promoted by Shanghai Fosun Pharma: Shanghai Fosun Pharma is Global Pharmaceutical Major with Extensive Pharmaceutical Manufacturing, Distribution and R&D Expertise globally. Relationship with Fosun Pharma provides Gland widened market access opportunities arising from its own continuing internationalization. Gland has benefited from Shanghai Fosun Pharma's established presence in China and Africa, both of which are key growth markets for injectables.

Continue Strategic Alignment with Shanghai Fosun Pharma to Increase Market Reach

Leverage existing infrastructure and global presence to access new markets, including China and Africa	Benefit from regulatory know-how to navigate the rapidly evolving healthcare landscape in China	Benefit from bargaining power and scale to procure raw materials & equipment from China	Access extensive sales, logistics and distribution network to enable market penetration in China	Leverage ability to access key markets to provide coverage for a portfolio of products
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Future Plans

Gland is aggressively looking to expand its product portfolio and capacity both organically and inorganically. The Company's primary focus will continue to be on maintaining high-quality standards across products, processes and facilities and deliver value to all its stakeholders.

New Product Development: Gland has always maintained a focus on achieving a diverse product mix offering with a robust product pipeline. The Company will continue to focus on high value generic injectables including complex molecules, and First to File products.

Learning's and infrastructure support from vaccine business will accelerate Glands' long term strategy of entering into biosimilar CMO/CDMO space. At the same time the Company is expanding in high technology products such as peptides, long acting injectables, hormones, suspensions. Gland is also exploring building niche capabilities for manufacturing pens, cartridges and inhalation products.

Innovation-driven: To cater to the growing demand, Gland aims to continue investing in R&D and manufacturing capabilities. The Company will continue to invest in new technologies to maintain competitive strengths in both product development and manufacturing capabilities for complex injectables. In its endeavor to integrate its operations, the Company will further strengthen its API manufacturing capabilities for injectables.

Acquisitions and partnerships: In addition to organic capacity expansion and product development, Gland continues to explore M&A opportunities that meet the internal return on capital benchmarks. The Company continues to explore possible acquisitions across local manufacturers as well as API suppliers, that complements the Company's overall long-term strategy.

This includes acquisition in the field of fermentation technology, corticosteroid APIs and hormonal APIs. Moreover, Gland continue to evaluate investments in assets that help strengthen backward integration, in areas like fermentation technology, corticosteroid APIs and hormonal APIs.



Future Plans

With proven track record in complex injectables across development, manufacturing and marketing, Gland Pharma is sufficiently enabled to meet diverse injectable needs across a vast range of specific requirements. **Its 28 production lines for finished formulations across four facilities are complimented by four facilities for Active Pharmaceutical Ingredients (API).** Plans are underway to augment the present manufacturing capacity of approximately 1000 million units in the medium term to support future growth.

Focus on expanding capabilities in Complex Injectables: GPL's near-term focus remains on establishing a strong portfolio of complex injectables. At present the GPL is working on development of 17 Complex Injectables in first phase. It has completed four complex injectable filings in Q3 FY22 which includes three hormonal products and one complex peptide. These products have an addressable market size of USD 983 Mn in the US market. Meanwhile, GPL has completed submission batches for next set of three products and the filings are expected by Q2 FY23. These planned filings include one complex peptide and two hormonal products.

Building capability for Biotech and Vaccine Manufacturing: GPL is making investments towards creating robust infrastructure for the vaccine and bio-similar space. The company is working towards building biosimilars / biologics CDMO capabilities and exploring partnerships to accelerate entry into the Biologics CDMO market which is estimated at nearly USD 13 Bn, growing at a CAGR of 15% over last 5 years. It's capacity expansion for Drug Substance manufacturing (~ 8KL) at its biotech facility has been completed in the previous quarter. **However, GPL will not be involved in product development, it will only provide development work for other companies. While GPL has created R&D team and a manufacturing team to address all the technologies, it will not be developing on any of its own product portfolio.** So, it will be only doing a service for other biosimilars company, unlike the generic injectables where GPL are also developing products.

In the Vaccine space, Tech Transfer has been completed for Sputnik Light in Q3 FY22. After successful clearance of samples from Kasauli and joint inspection of Drug Substance and Drug Product facilities by CDSCO and DCA during the Q3, GPL has received the Export NOC for 50 million doses from CDSCO. The company expect to receive the manufacturing license soon to initiate manufacturing of Sputnik Light vaccine.

Expanding capabilities in:

- Peptides
- Long-acting injectables
- Suspensions
- Hormonal products

Expanding in new delivery systems:

- Pens
- Cartridges



Profit and Loss statement

in ₹ (Crores)

Year to March	FY21	FY22	FY23E	FY24E
1. Revenue from operations	3462.90	4400.7	5148.0	6180.0
4. Operating Expenses	2160.65	2890.5	3505	4140
5. Operating Profit	1302.25	1510.2	1643	2040
6. Depreciation	98.8	110.3	125.2	145
7. Finance Cost	3.41	5.24	8.8	12
8. Other Income	134.8	223.9	280	335
9. PBT	1334.8	1618.6	1789	2218
10. Taxes	337.8	406.9	447	555
11. PAT	997	1211.7	1342	1663
12. EPS	63.07	73.81	81.74	102

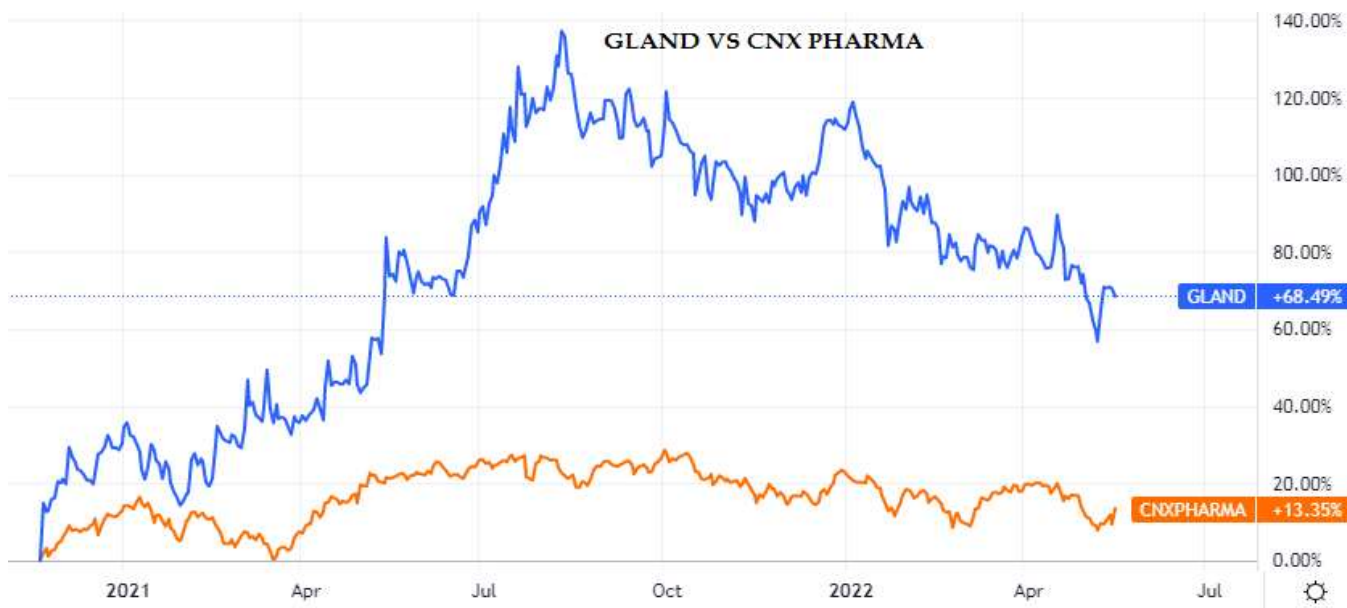
Balance Sheet

in ₹ (Crores)

Year to March	FY21	FY22	FY23E	FY24E
Share Capital +	16	16	16	16
Reserves	5,887	7,142	8,505	10,142
Borrowings	4	5	19	10
Other Liabilities +	589	671	808	891
Total Liabilities	6,496	7,834	9,348	11,059
Fixed Assets +	954	1,512	1838	2,060
CWIP	338	181	218	151
Investments	1	163	175	213
Other Assets +	5,203	5,978	7,117	8,635
Total Assets	6,496	7,834	9,348	11,059



Valuations & Concerns



Since listing, Gland Pharma has out-performed the CNX Pharma index. However, lately, in last one year GPL is under-performing the benchmark index. We expect this trend to reverse soon as market starts discounting GPL's foray into Bio-similar space and its capabilities in Complex injectables. Gland Pharma has traded at a price to earnings multiple above 45x (Median PE) since listing. **We arrived at a target price for the stock ₹ 4,080 over a period of two years. (discounting the stock to trade at 40x of FY24E EPS of ₹ 102)**

Investment Risks & Concerns:

- 1) Dependence on the success of B2B Marketing partners:** In relation to Glands' B2B business model, its success in many markets depends on their B2B marketing partners, in particular their sales expertise and relationships with their end customers. The performance of Glands' marketing partners and their ability to reach out to treatment providers and promote products are crucial to the future growth of Glands' business.
- 2) The injectables pharmaceutical market is highly competitive:** Competition from established market participants, new entrants to the generic injectables pharmaceutical market could substantially reduce Glands' market share and have a material adverse effect on its revenues and profit margins.



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