

India Healthcare

Gland Pharma Ltd

Rating

Outperform

Target Price

 **GLAND.IN**
3,824.00 INR
Nithya Balasubramanian

+91-2268421433

nithya.balasubramanian@bernstern.com

Praveen Shreenivas

+91-226-842-1445

praveen.shreenivas@bernstern.com

Gland Pharma: Biosimilars CMO and China entry to push growth into a higher orbit; Initiating at Outperform

We are initiating on Gland with an Outperform rating at a target price of INR3824. Gland is currently a niche sterile injectables CDMO with a resilient base business. Over the next two years, we expect vaccine production will spike revenues. Beyond that, we view biosimilars contract manufacturing and injectables in China as long-term opportunities that can fundamentally shift the growth trajectory.

Sustained growth in the US: Gland's B2B business model will enable growth in the base business in addition to growth from a strong pipeline of new launches. We expect US CAGR of 19% in the next 3 years. Gland's wide portfolio, ability to manufacture products at scale and capture a larger market share through multiple partners and protection from pricing risk will set them apart from generic peers.

Accelerated entry into China injectables: We expect Fosun's (not covered) regulatory and commercial expertise in the China market to accelerate Gland's market entry and enable penetration in VBP and branded market. We estimate 7% revenue contribution by FY24.

Vaccine manufacturing to be a long-term profitable business: The agreement with RDIF opens up another high growth, high profitability avenue of biosimilars contract manufacturing. We estimate EBITDA of \$0.5-0.6 USD/dose from the Sputnik V deal and believe this segment can contribute 20% to revenues in the long term.

EBITDA and EPS to double by FY24: We expect margins to expand from increasing backward integration and higher operating leverage on R&D and employee expenses. We model core-EBITDA of 38.2% in FY24 which is a ~100 bps improvement over FY21 and growth of 27%.

Investment Implications

We value Gland using a combination of forward PE for the base portfolio and DCF for the vaccine/biosimilars business. TP = ₹3,824, upside = 19%, implied PE of 29.8x FY23 EPS.

EPS Reported	F21A	F22E	F23E
GLAND.IN (INR)	62.99	90.95	128.48
MXAPJ	30.46	40.01	45.79

Financials	F21A	F22E	F23E	CAGR
Revenues (M)	35,977	52,158	73,410	42.9%
Gross Profit (M)	21,058	29,137	39,240	36.5%
EBITDA (M)	14,370	20,551	28,758	41.5%
Net Earnings (M)	9,970	14,497	20,479	43.3%
EBITDA Margin (%)	39.94	39.40	39.17	
Net Income Margin (%)	27.71	27.79	27.90	

Close Date	31-May-2021
GLAND.IN Close Price (INR)	3,153.85
Target Price (INR)	3,824.00
Upside/(Downside)	21%
52-Week Low	1,700.00
52-Week High	3,514.85
MXAPJ	698.55
FYE	Mar
Indicated Div Yield	NA
Market Cap (INR) (M)	516,931
EV (INR) (M)	503,739

Performance	YTD	1M	6M	12M
Absolute (%)	34.8	13.4	43.9	NA
MXAPJ (%)	5.5	0.3	12.3	46.7
Relative (%)	29.3	13.1	31.6	NA



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Valuation Metrics	F21A	F22E	F23E
P/E Reported (x)	50.07	34.68	24.55

DETAILS

In this report, we provide a Portfolio Manager's Summary of our investment thesis followed by a detailed introduction to the company. We then elaborate on our investment thesis detailing the key growth drivers in turn a) base business resilience and growth in the large US market, b) accelerated entry into China, and c) vaccine/biosimilars contract manufacturing as sustainable long-term growth opportunity.

We have written about Gland extensively since before their IPO. I have had the opportunity to work with the company as a client in my previous role, so we draw from my personal experience where relevant to assess their capabilities. Links to our pre-IPO report and others since are here.

[Gland Pharma pre-IPO: An injectables CMO player with world class capabilities](#)

[Gland Pharma: SEBI approval for IPO, questions from investors galore](#)

[Gland Pharma: Strong debut, management confidence high in the near term](#)

[India Healthcare: B2B play in US Gx injectables better than B2C; Webinar with CEO of Gland Pharma](#)

PORTFOLIO MANAGER'S SUMMARY

Sustained growth in the US market: We estimate 19% CAGR in the US in the next 3 years. Gland's unique B2B business model allows them to grow the base portfolio by expanding their customer base. They are also less exposed to pricing risk since all of their contracts include transfer pricing (<50% include royalty) and contracts are long term in nature. This sets them apart from generic peers where consistent base erosion from pricing headwinds and competition is a norm. In addition, Gland has a healthy pipeline of PIV products that will continue to support growth. We expect ~3-4% growth in the base portfolio and an incremental 15% growth from new launches. Key launches in the near term will include gErtapenem (partnered with DRL, FY21), gRegadenoson (FY23), gPlerixafor (FY23), gPemetrexed (FY23), gEpinephrine (FY23), gCopaxone (fill-finish for DRL, FY23). Their ability to operate at scale, low cost manufacturing base and blemish-less track record will allow them to sustain and win contracts.

Accelerated entry into China injectables: We expect China to become material and contribute 6-7% in FY24 and continue to grow in the long term. Gland is better positioned to capture the injectables market opportunity in China compared to other Indian generic peers due to the backing of Fosun's commercial and regulatory muscle. While the expansion of the Volume Based Procurement model (VBP) levels the playing field for Indian competitors, VBP penetration is still low at 15-20% and players will need to operate in the central tender market as well in the branded generic market. Fosun has won 17 bids in the various VBP Waves (out of 29 with QCE approval) and also boasts of a 6000 member sales and marketing team on the ground. We expect 2 launches in FY23 and 3 more in FY24 and believe the company will file 2-3 products every year to sustain growth. In our view, this opportunity is under-appreciated.

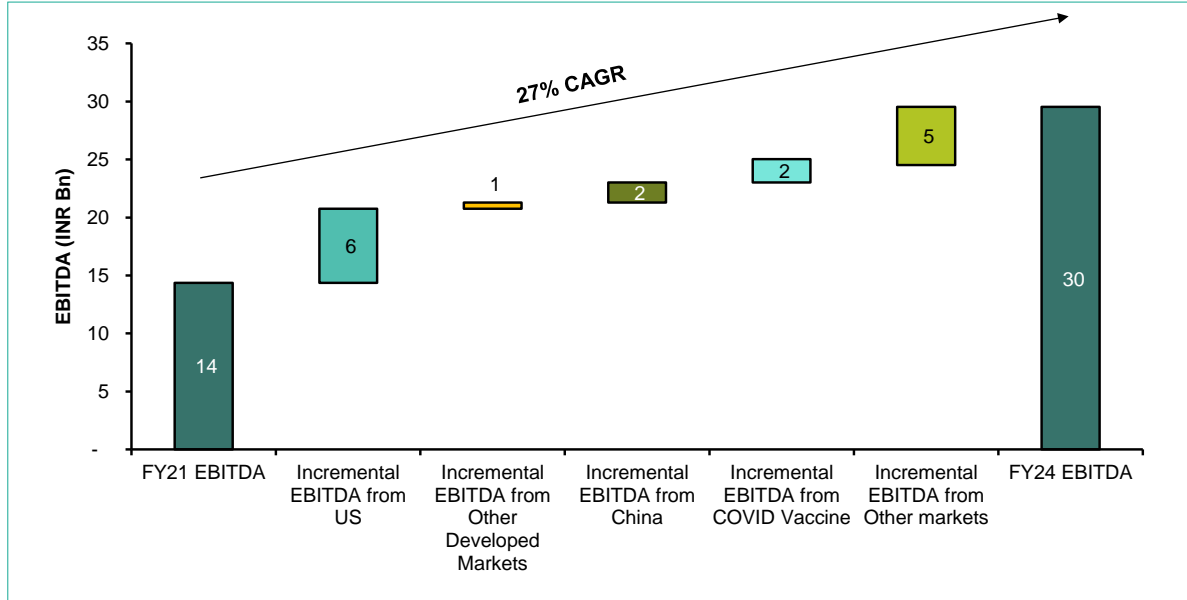
Vaccine/biosimilars manufacturing to be a long-term profitable business: We believe biosimilars manufacturing can contribute 20% to revenues in the long term and the capabilities built for manufacturing Sputnik V can be repurposed to address the attractive contract manufacturing opportunity. We believe Sputnik V is an incremental \$375 Mn opportunity spread across FY22 and FY23. We estimate pricing of \$1.5/dose and EBITDA of \$0.5-0.6/dose. With the "take-or-pay" agreement with RDIF these revenues are fully protected for Gland irrespective of vaccine demand. These capacities when repurposed can help Gland address the large \$62Bn (biologic brands losing exclusivity from 2021-25) opportunity in biosimilars. Fosun's capabilities in biosimilars and their pipeline of 19 products under development can provide Gland the initial leg-up required to establish themselves in the market. While the market appreciates the opportunity in Sputnik V, we do not believe the growth potential from this becoming a long-term business is in the price.

EBITDA and EPS to double by FY24: We estimate core EBITDA at 38.2% in FY24, a 100bps increase from FY21 (interim years are not strictly comparable due to Sputnik V impact). We also estimate EBITDA and EPS to grow at 27% and double by FY24. While gross margins will trend down as the biosimilars contract manufacturing revenues pick up it will be compensated by higher levels of backward integration. R&D will remain at 3-4% sales and other expenses will trend down as a percentage of sales from operating leverage.

Valuation: We value Gland using 1-year forward PE for the base business and DCF for the vaccine/biosimilars contract manufacturing business. We believe the resilience in the base business, attractive margin profile and growth prospects should allow Gland to command a substantial premium to Indian generic peers. Compared to other CDMO players like Catalent, Lonza,

Divis Labs, we believe they should trade at a slight discount since they boast of innovators as customers. DCF of the vaccine/biosimilars business contributes ₹708/share and we value the entire company at ₹3,824/share. The implied multiple is 29.8x FY23 EPS and upside is 19%.

EXHIBIT 1: **Gland - EBITDA growth drivers**



+ ~70% of incremental EBITDA between FY21 and FY24 from 3 business segments – 1) US generic injectables, 2) China injectables and 3) vaccines/biosimilars contract manufacturing

Source: Bernstein estimates and analysis

EXHIBIT 2: **Gland – trading comparables**

Company	Market Cap (\$ Bn)	Trading currency	Share price	P/E			EPS growth		PEG	EV/EBITDA		
				FY21	FY22	FY23	FY22	FY23		FY21	FY22	FY23
Indian generic peers												
Cipla	10.4	INR	934	25	27	23	6%	21%	1.3	14	15	13
Sun	22.19	INR	670	24	26	22	5%	15%	1.4	16	16	14
Lupin	7.57	INR	1,209	43	32	25	59%	27%	0.8	18	17	14
DRL	11.93	INR	5,195	30	26	22	29%	20%	1.9	17	16	13
Aurobindo	8.27	INR	1,022	9	15	17	46%	-10%	NA	6	11	10
CDMO peers												
Divis	15.1	INR	4,125	49	46	38	23%	21%	1.7	34	32	27
Catalent	17.86	USD	104.83	37	37	31	44%	19%	1.9	20	20	18
Lonza	48.22	USD	64.29	44	43	38	-2%	14%	2.4	27	27	23
Indian peers average				26	25	22	29.0%	14.8%	1.4	14	15	13
CDMO peers average				43	42	35	21.5%	18.2%	2.0	27	27	23
Gland (Cons)	7.30	INR	3,205	41	42	34	27.8%	23.7%	1.9	30	31	25
Gland (BERN)		INR	3,824			30	44.0%	41.0%	1.9			

Source: Bloomberg, Bernstein estimates and analysis

Note: Divis, Catalent and Lonza are not covered by Bernstein

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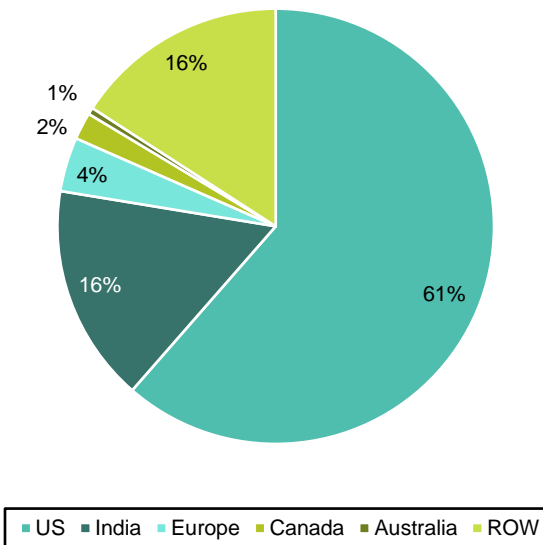
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INTRODUCTION

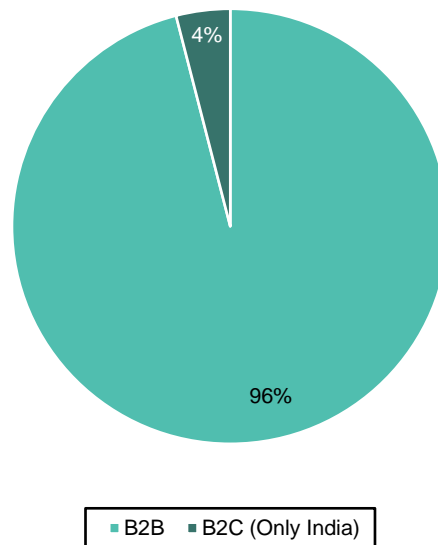
Gland Pharma established in 1978, is a fast growing contract development and manufacturing (CDMO) organization primarily focusing on sterile injectables and some other sterile preparations like ophthalmics. They have emerged as one of the largest manufacturers of generic injectables across the globe boasting of capacities >750 Mn units per annum. They have presence in more than 60 countries with US, EU, Canada, Australia and India being the largest markets. They operate predominantly through a B2B model with B2C presence only in India (Exhibit 3 & Exhibit 4).

EXHIBIT 3: **Revenues by Sales 2021**



Source: Company Reports, Bernstein analysis

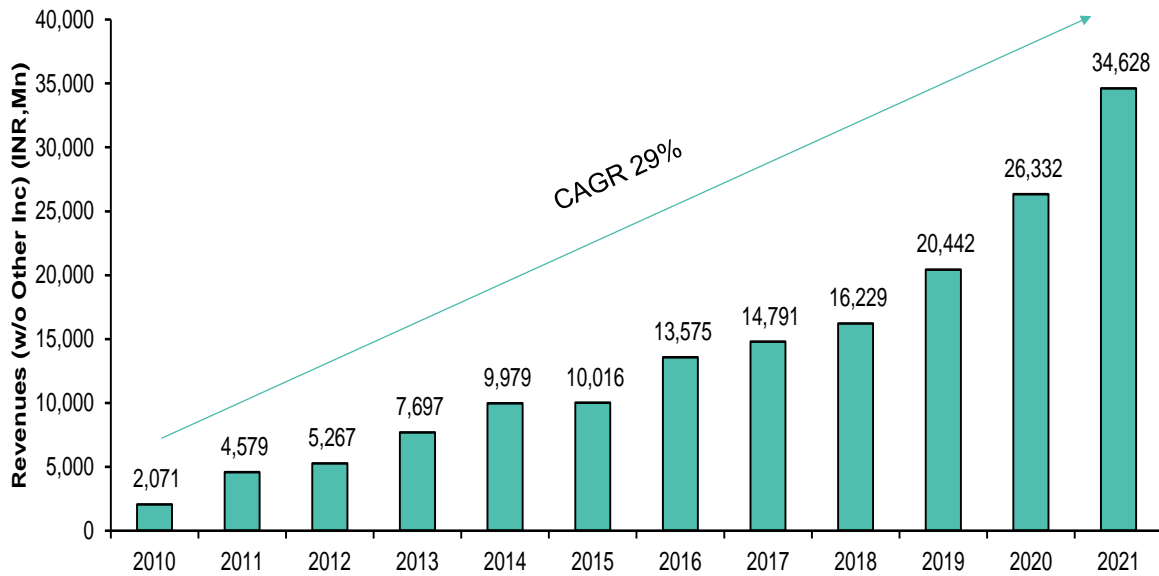
EXHIBIT 4: **Revenues by Business Model 2021**



Source: Company Reports, Bernstein analysis

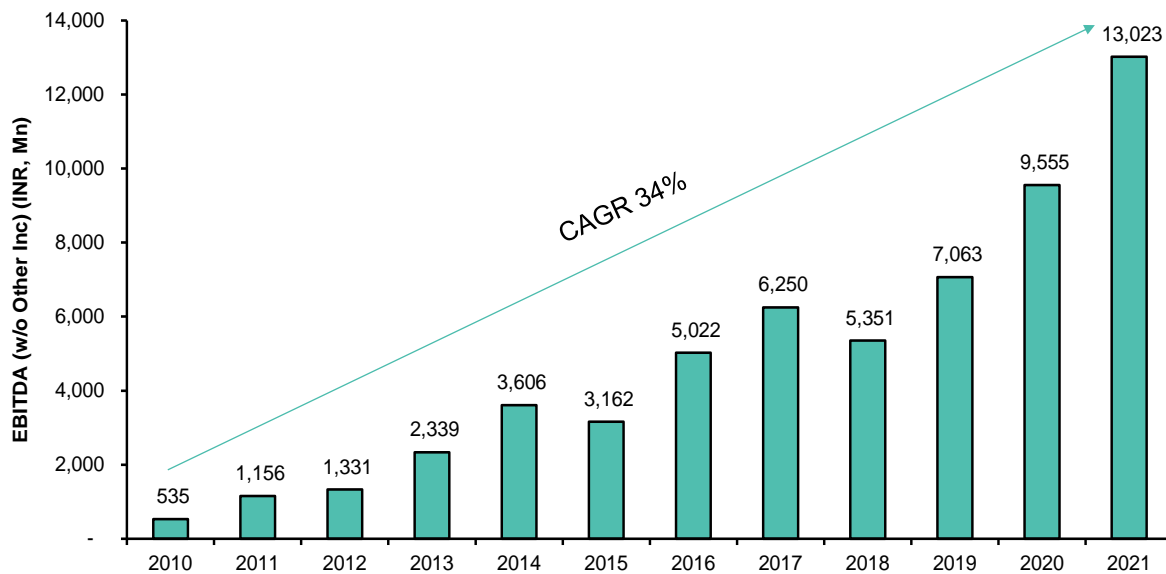
Over the past 10 years, the company has seen an impressive revenue CAGR of 29% and EBITDA CAGR of 34% (Exhibit 5 & Exhibit 6).

EXHIBIT 5: **Gland revenues 2010-2021**



Source: Company Reports, Bernstein analysis

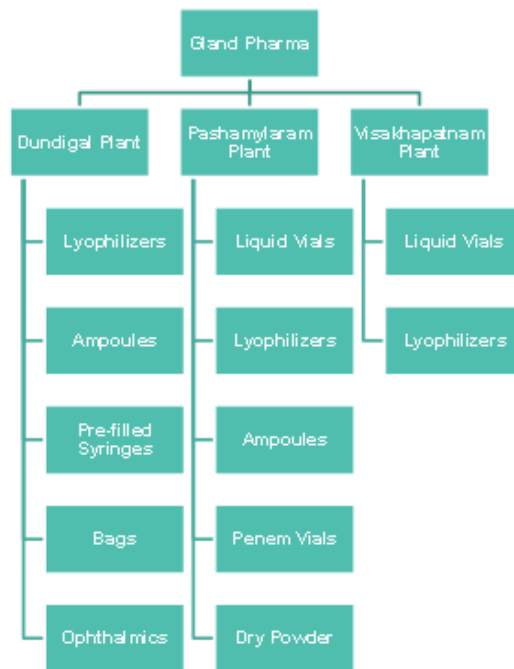
EXHIBIT 6: **Gland EBITDA 2010-2021**



Source: Company Reports, Bernstein analysis

Gland have largely maintained a debt-free balance sheet funding expansion through cash generation. Gland is credited as the pioneer in producing Heparin and Enoxaparin in India and now boasts of an extensive portfolio of products as well as technologies – vials, ampoules, bags, lyophilized injections, penems and hormones to name a few (Exhibit 7).

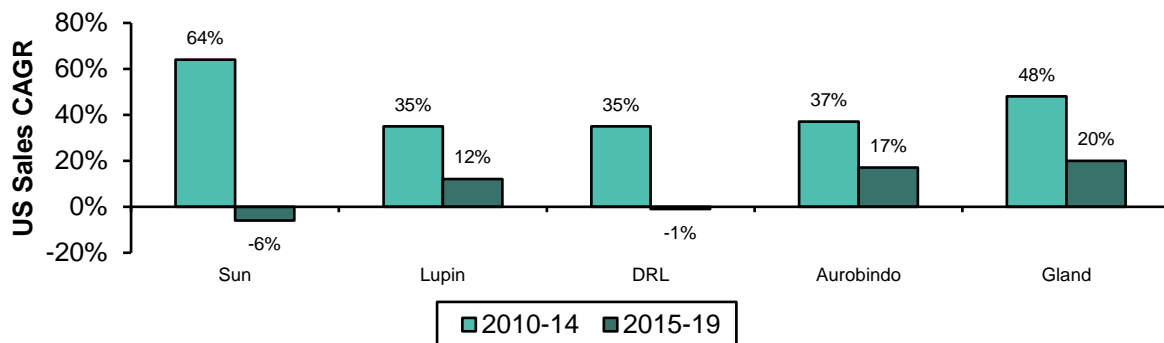
EXHIBIT 7: Gland Manufacturing Capabilities



Source: Gland Pharma DRHP, Bernstein analysis

Gland stands out among other Indian peers both in terms of their business model as well as the growth trajectory in the last 10 years. When all large Indian players saw significant price winds in US generics and subsequent contraction of revenues and EPS in the 2015-19 time period, Gland has managed to grow both topline as well as bottom-line (Exhibit 8).

EXHIBIT 8: Growth of Indian Pharma in US Generics Market in Last Decade



Source: Company Reports, Bernstein analysis

The difference lies in the more favorable competitive dynamics in their target injectables market, their business model which allows them to drive operating leverage, investments in manufacturing and quality and strong execution. Gland continue to focus on their core competency of sterile manufacturing but are expanding investments in more complex manufacturing technologies like suspensions, peptides and microsphere injections as well as vaccines and biosimilars. In addition, penetration into more markets will provide additional growth opportunities.

Fosun is now the largest shareholder in Gland Pharma with a 58.4% stake post the IPO in Nov 2020. Fosun bought Gland from KKR and the original promoters in 2017. The promoters have exited the business and the firm is run entirely by a professional

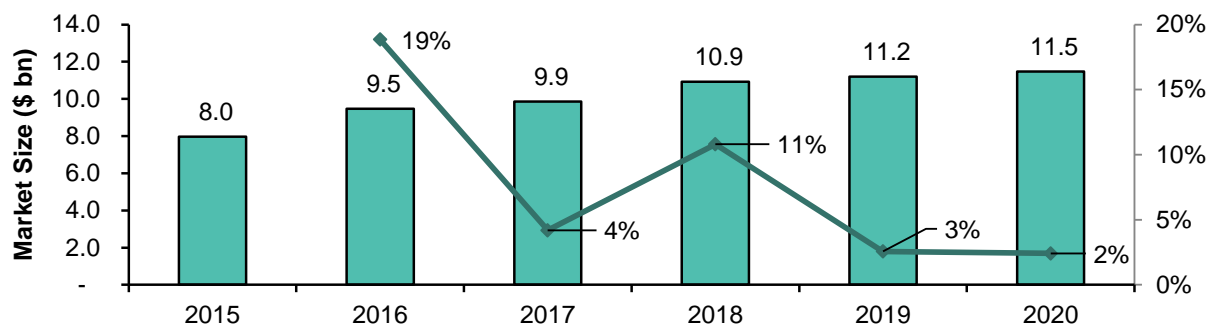
management team, many of whom have served in the company for more than 20 years. Management commitments to investments in manufacturing operations and quality and a sharp eye on driving efficiencies has been responsible for their reputation as a reliable supplier as well the high return metrics they enjoy.

STRONG GROWTH DRIVERS IN THE US

INJECTABLES IS A LARGE AND GROWING MARKET

Injectable generics is a large \$11.5 Bn market in the US, which has grown at 8% CAGR in the last 5 years (Exhibit 9). We wrote a deep dive on the attractiveness of this market here ([US generic injectables market primer - high margins, limited competition; a hidden gem](#)).

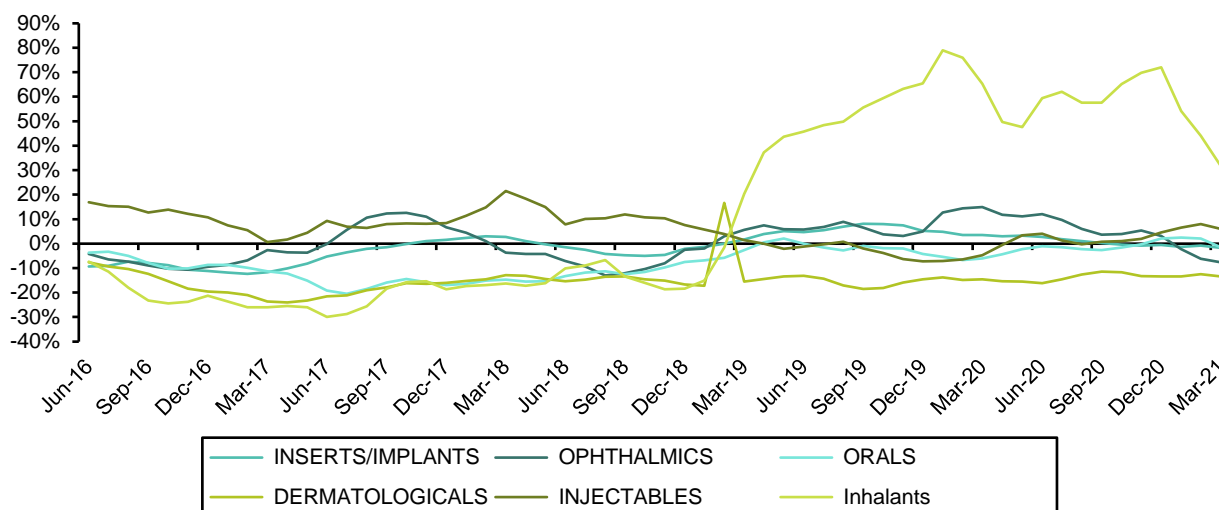
EXHIBIT 9: **Injectables Generic market in US**



Source: IQVIA, Bernstein analysis

While the larger generics market and oral solids in particular was characterized by pricing headwinds driven by hyper-competition and distributor consolidation, injectables have continued to enjoy pricing power and have grown by an incremental ~400 bps compared to oral solids. Exhibit 10 shows the relative pricing growth in different dosage forms in the US.

EXHIBIT 10: **Price Erosion by Dosage Forms**



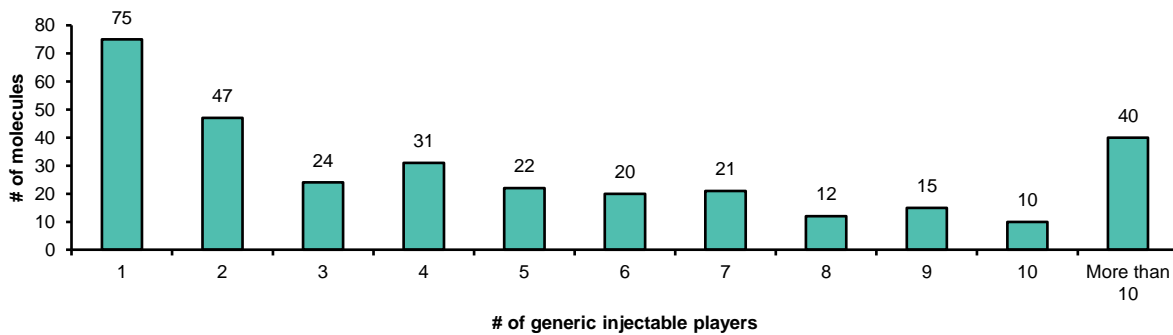
Source: IQVIA, Bernstein analysis

MULTIPLE FUTURE GROWTH DRIVERS

We expect the generic injectables market to continue to expand at double digits driven by 3 growth drivers - a) increased penetration opportunity in genericized products, b) substantial opportunity in new brands losing exclusivity, and c) limited competition complex generics opportunity.

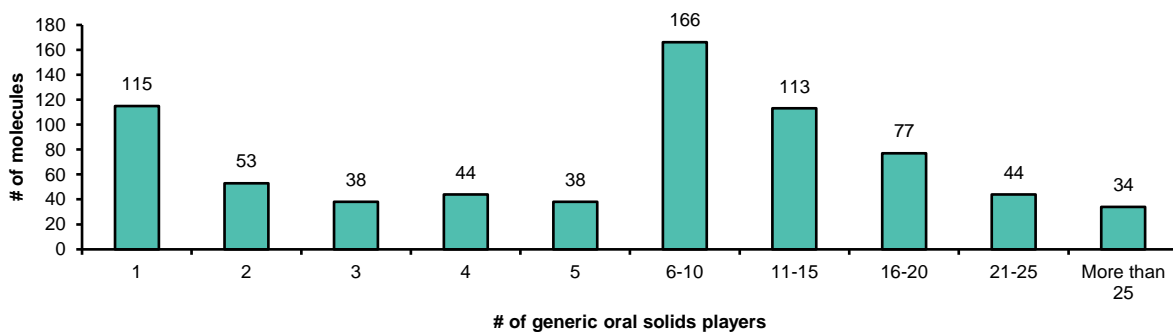
Generic injectables see relatively lower competition compared to oral solid dose forms. The average number of competitors in injectables is 5 per molecule compared to 9 per molecule in oral solids. More importantly, there are a large number of generic injectables which see competition from <3 players (Exhibit 11 & Exhibit 12). Exhibit 13 lists molecules with substantial market sizes but with limited competition. We believe manufacturers will continue to target this opportunity in the genericized molecules and drive substantial growth.

EXHIBIT 11: **Competition in Injectable Generics Players**



Source: IQVIA, Bernstein analysis

EXHIBIT 12: **Competition in Oral Solids Players**



Source: IQVIA, Bernstein analysis

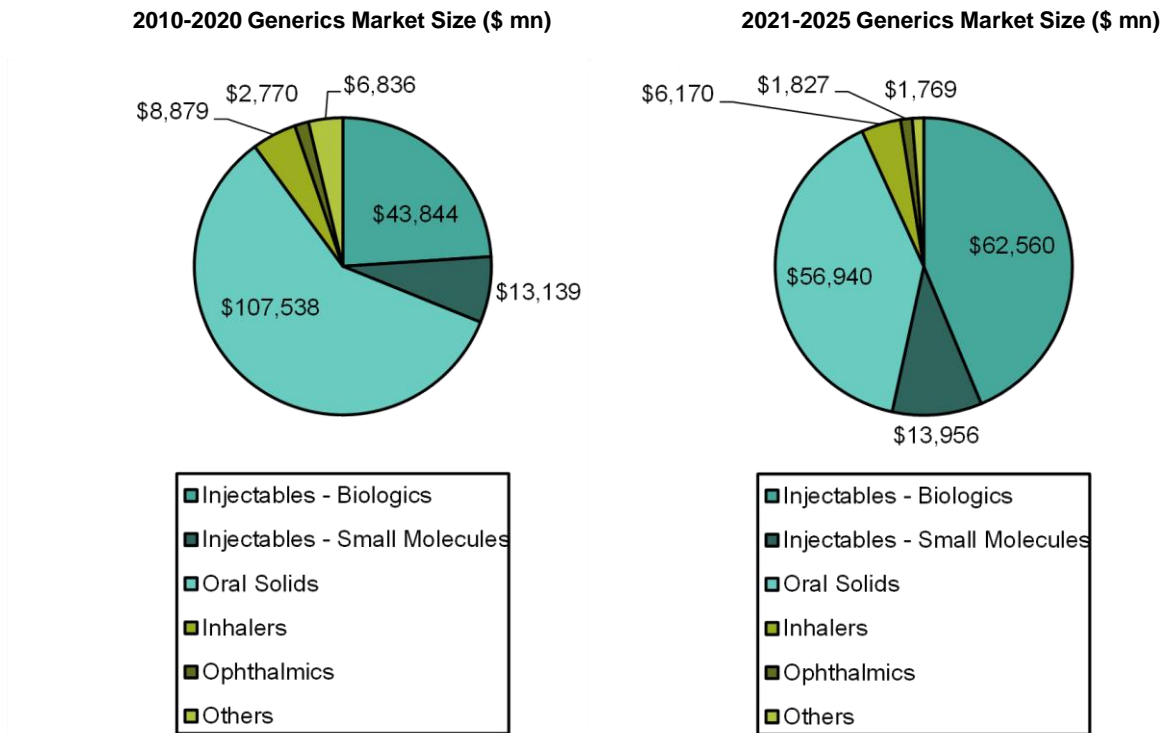
EXHIBIT 13: **Molecules with large market sizes and limited competition**

Molecule	IQVIA Sales 2020 (\$ Mn)	Volume Growth 2015-2020 (CAGR)	Value Growth 2015-2020 (CAGR)	# Generics	Generic Penetration
Glatiramer	2,032	-6%	-10%	2	19%
Vasopressin	751	19%	44%	1	0%
Iron Ferric	524	12%	29%	2	7%
Hyaluronic Acid	509	3%	10%	1	76%
Albumin	369	13%	11%	1	9%
Amphotericin B	131	4%	10%	1	2%
Buprenorphine	94	-3%	54%	3	14%
Dihydroergotamine	80	-4%	-10%	3	98%
Methylene Blue	67	9%	25%	2	0%
Aztreonam	63	-36%	-3%	1	84%

Source: IQVIA, Bernstein analysis

The opportunity in injectables brands losing exclusivity in the future is also a substantial \$14 Bn in the 2021-25 timeframe (Exhibit 14). This is an increase compared to 2010-2020 when injectables accounted for only 7% of the total opportunity. Note that this opportunity includes brands that have lost exclusivity but see no generic competition yet.

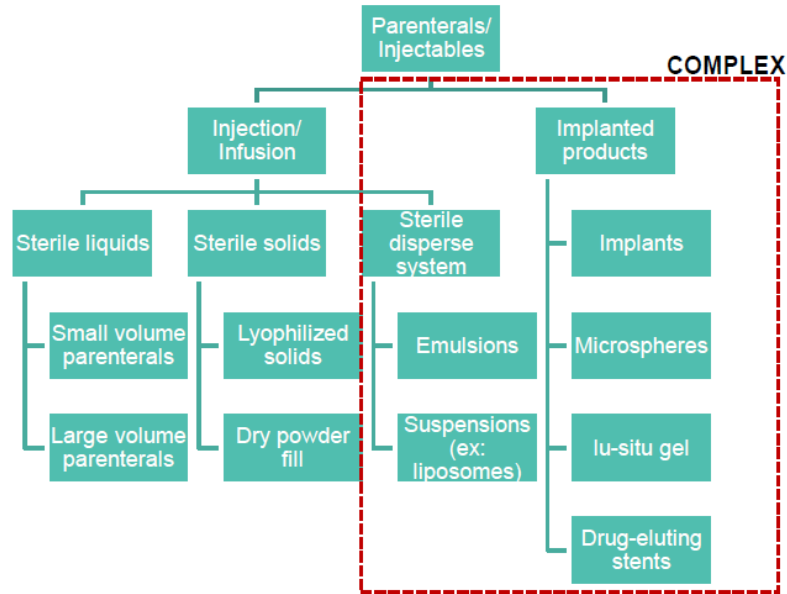
EXHIBIT 14: **Opportunity in Injectables is increasing in 2021-25**



Source: Evaluate Pharma. Bernstein analysis

While the opportunity in complex generics is included in the \$14 Bn mentioned earlier, we call that out here because of the limited competition nature of the opportunity. The US FDA includes the following in complex injectables – injectable emulsions, suspensions, and long acting depot injectables - implants, microspheres, in-situ gel and drug-eluting stents (Exhibit 15). In addition, the FDA considers all peptide injectables as complex.

EXHIBIT 15: **Complex Injectable Generics**



Source: FDA, Bernstein analysis

Exhibit 16 identifies the large complex injectables that are losing exclusivity from 2021 – 25. Amongst the material opportunities, there are two categories that are prominent – a) long acting depot microsphere injectables, and b) peptide injectables.

EXHIBIT 16: **Large Complex Injectables Losing Exclusivity from 2021 – 25**

Brand	Pre-LOE Sales (\$Mn)	Patent Expiry	Category
Invega Sustenna	1,710	Ungenericized	Depot
H P Acthar Gel	944	Ungenericized	Peptide
Mirena	883	Ungenericized	Hormone
Sandostatin LAR	861	Ungenericized	Peptide/Depot
Premarin	717	Ungenericized	Hormone
Forteo	636	Ungenericized	Peptide
Nexplanon	558	Ungenericized	Hormone
Invega Trinza	402	Ungenericized	Depot
Risperdal Consta	314	Ungenericized	Depot
GlucaGen	274	Ungenericized	Peptide
Abraxane	980	2022	Chemotherapy
Exparel	544	2023	Depot
Abilify Maintena	876	2024	Depot
Somatuline	517	2024	Peptide/Depot

Source: Evaluate Pharma, Bernstein analysis

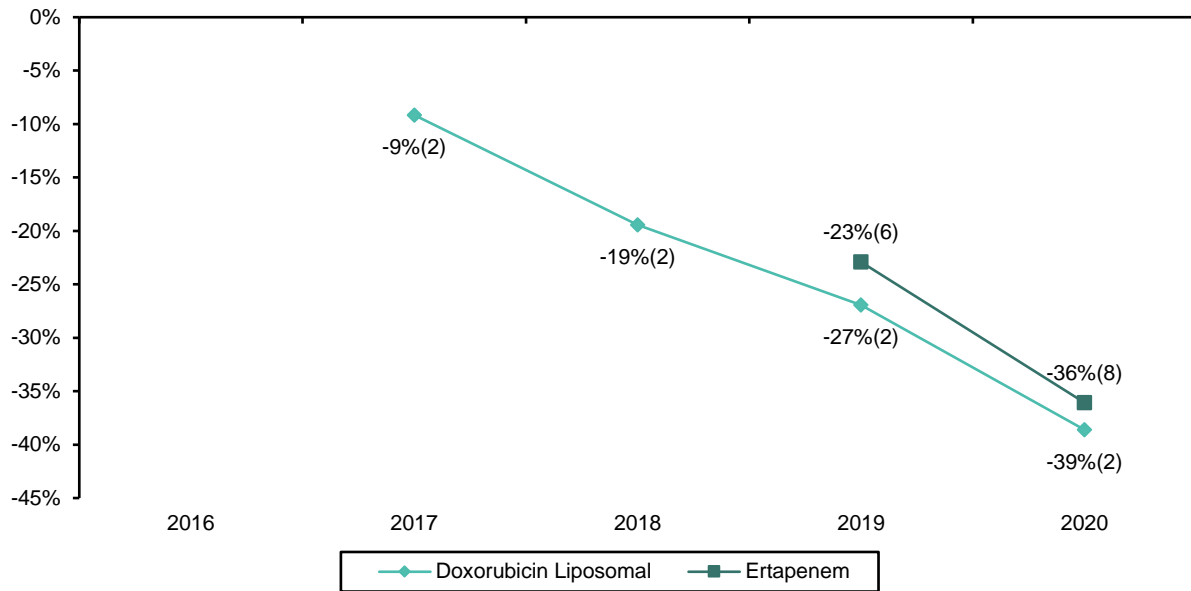
Long acting depot injections are complex formulations of drugs that when injected slowly release the drug over a predefined period of time. Different formulation technologies are employed to achieve the desired drug release profile – microspheres, implants, in-situ gel technologies, but we will focus on microspheres which is more widely employed. Examples include Lupron 1 month, 3 month and 6 month depot injections that are extended release formulations of Leuprolide for treating endometriosis, Risperdal Consta, which is a once-in-two weeks injection of Risperidone for schizophrenia. The complexity in the product stems from the microsphere technology used to formulate the drug. The first complexity lies in the formulator's ability to control a) the initial burst of the drug on administration, b) the lag phase where very little of the drug is released, and c) the continuous drug release phase and match this closely to the reference drug profile. The second complexity is in scale up from lab scale to manufacturing scale while controlling the properties of the microsphere. The bioequivalence studies mandated by the FDA also take a long time. Indian generic companies have been investing since 2013/14 with no filings to show so far.

For peptide injectables with a specifically designed amino acids sequence, the complexity stems from the presence of impurities that could have been inadvertently introduced during the production process. These impurities are difficult to detect, analyze and control since they may have sequences similar to the amino acids. The US FDA recommends advance analytical techniques like nuclear magnetic resonance (NMR), asymmetric field flow fractionation (AFFF) coupled with multi-angle light scattering (MALS) and liquid chromatography coupled with mass spectrometry (LC-MS) to assess equivalence to the reference drug. Suffice it to say that companies need high quality R&D teams and upfront investments in complex machinery to be able to develop peptide generics. We have seen some filings from India so far in Copaxone (Natco, DRL, Biocon) and Cipla recently announced 2 filings.

While these are complex and require significant upfront investments in R&D and manufacturing, the attraction for generic companies is obvious. Competition is likely to be limited and price erosion will be restrained. Exhibit 13 shows price erosion in 2 complex injectable products – gDoxil and gInvanz. Price erosion is 36% of original brand price after entry of 7 players in gInvanz

and it is ~40% of original brand price in gDoxil with only 2 generics. At these prices, these products likely enjoy gross margins more than 80% and their potential to expand EBITDA margins and return ratios is apparent.

EXHIBIT 17: Price Erosion in Complex Injectables is Limited



Source: IQVIA, Bernstein analysis
 Note: Number in parenthesis refers to number of generics

STRUCTURAL DIFFERENCES SUPPORT LARGE INCUMBENTS

Manufacturing is complex and requires significant investments

Drug products that are delivered through injectables present an increased risk of infection or harm to the patient since they bypass many of the body's defense mechanisms. To ensure patient's safety, the US FDA requires that these products be sterile products. It is this requirement of sterility that places onerous requirements on the manufacturer. Sterility can be achieved through terminal sterilization or aseptic manufacturing and sterile fill-finish. Terminal sterilization is where the products are filled and sealed under high quality environmental conditions and then subject to sterilization using heat or radiation. Aseptic manufacturing and sterile fill-finish is more complex, in which the drug product, container and closure are first subject to sterilization methods separately and then brought together in a highly controlled sterile environment.

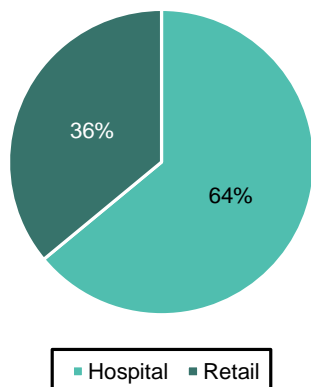
The higher capital intensity is linked to investments in drug product component and container systems sterilization equipment, cleanroom design and facilities, specialized equipment for manipulation and filling like isolators, in-line weight checking and personnel highly trained in cleanroom behavior and other operational procedures. Injectables facilities require 1.3-1.4x the investment in oral solid facilities. Approximately 70% of the costs in injectables manufacturing is fixed and high utilization becomes imperative for managing margins and return metrics. Injectables manufacturing and supply is specialized, capital intensive and doing this sustainably at scale is not everybody's cup of tea.

Scale matters - more than in other dose forms

In injectables manufacturing scale matters, a lot! Both market dynamics, high share of large volume products and buyer dynamics, GPO preference for players with large portfolios and supply reliability, reward players with scale and incumbents.

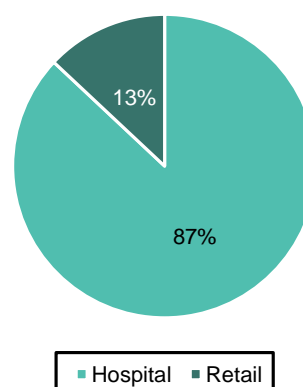
~64% of the generic injectables market by value and 87% by volume is sold through the hospital channel today (Exhibit 18 & Exhibit 19).

EXHIBIT 18: Share of Generic Injectables Sales by Channel



Source: IQVIA, Bernstein analysis

EXHIBIT 19: Share of Generic Injectables Volumes by Channel



Source: IQVIA, Bernstein analysis

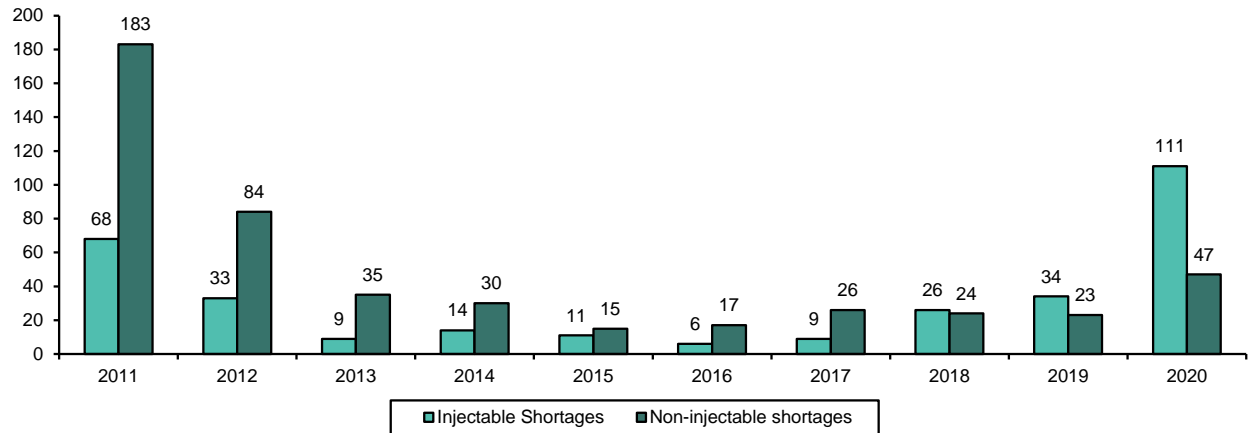
The hospital supply chain is different from the retail supply chain due to the presence of large Group Purchasing Organizations (GPOs). These GPOs negotiate contracts and prices on behalf of the hospitals without taking control of the goods or assuming any credit risks. The physical movement of the goods is still handled by traditional wholesalers or their specialty pharmacy subsidiaries. While the GPOs are concentrated (Top 4 players account for 90% of the market), they do not behave like the buying consortiums in the retail space. The following buying factors are important in hospital product:

- + Most injectables consumed in the hospital channel are deemed "medically necessary" products. Antibiotics, anesthetics, pain medications are consumed in high volume and their availability is critical to patient outcomes. Shortages here can have catastrophic impact. GPOs therefore care more for supply reliability than for pricing.
- + GPOs would typically like to award single source contracts to reduce their administrative expenses and drive prices down, but they cannot guarantee volumes to manufacturers since hospitals are not bound to purchase only from them. For a manufacturer this translates into upfront investments in large scale manufacturing which is necessary to make the supply commitment and win the GPO contract without the necessary demand-side guarantee from the GPO. This makes it particularly difficult for manufacturers with small capacities to build a sustainable business playing into the hands of the large incumbents.
- + GPOs also prioritize contracting with manufacturers that can provide a broad portfolio of molecules. They also appreciate a diversified portfolio beyond drugs since hospitals buy other supplies like surgical consumables, medical devices and software as well through GPOs. To be considered a significant player, manufacturers need not just scale but also breadth in their portfolio which makes it doubly difficult for small and new players to enter the market.

Shortages will further fuel growth

Injectable shortages have decreased in recent years compared to the peaks observed in 2010/11 but they seem to be climbing back up (Exhibit 20).

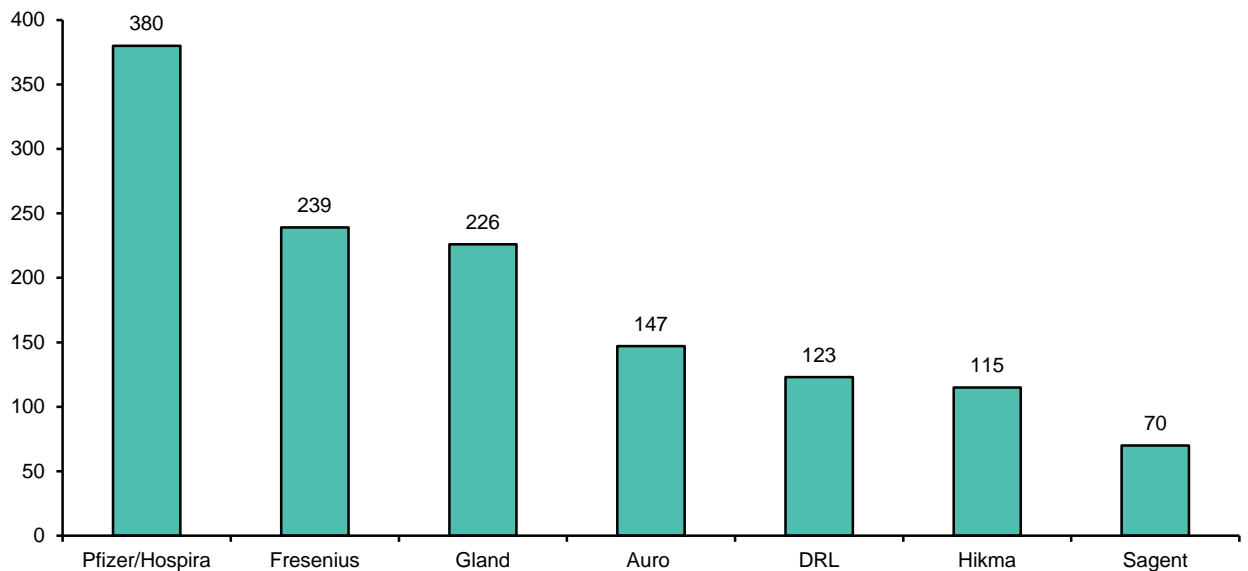
EXHIBIT 20: Drug Shortages in US Market



Source: FDA, Bernstein analysis

Injectables remain the largest contributor to overall shortages in the market; and given the complexity in manufacturing, we can expect current levels to sustain. Manufacturers who produce at scale and have a wide portfolio will benefit from ongoing shortages. Large players including Fresenius, Hospira, Hikma and Gland have wide portfolios who can benefit from this (Exhibit 21).

EXHIBIT 21: ANDA Portfolio in US



Source: FDA Orange Book, Bernstein analysis

In summary, players need the following to be successful in the generic injectables market.

- + Ability to service large volumes through scale in manufacturing
- + A wide portfolio to win GPO contracts which will include ongoing investments in the pipeline to keep the portfolio relevant
- + Supply reliability and strong compliance track record

GLAND'S BASE PORTFOLIO IS RESILIENT WITH MULTIPLE GROWTH OPPORTUNITIES

Gland has a unique B2B business model serving partners across markets. 96% of the revenues come from B2B and only 4% from India come from B2C. In the IP-led B2B model, Gland is responsible for developing the ANDA and manufacturing the product. IP ownership is shared and ANDA ownership depends on the deal structure. In the B2B technology transfer model, the ANDA is partially developed by Gland with support from the partner and the ANDA is owned by the partner. In both these models, Gland enjoys royalties or profit sharing in addition to transfer pricing. The third model is where they are a pure contract manufacturer. The product is developed entirely by the partner and Gland only support in manufacturing scale-up. The ANDA is also owned by the partner. Financial arrangements are typically a standard margin over the cost of production. Please see Exhibit 22 for a summary.

EXHIBIT 22: Diversified B2B Model of Gland

	B2B (c.96% of FY21 Revenue)			
	B2B – IP Led		B2B Tech Transfer	B2B CMO
	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
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 + Royalties 	<ul style="list-style-type: none"> Fixed per unit price
ANDA Ownership ⁽¹⁾	✓	✗	✗	✗
Development ⁽¹⁾	✓	✓	✓ ⁽²⁾	✗
IP Ownership ⁽¹⁾	✓	Co-owned	✗	✗
Marketing Rights ⁽¹⁾	✓	✗	✗	✗
Royalty / Profit Sharing ⁽¹⁾	✓	✓	✓	✗
Key Markets				
Select Clients / Partners	<ul style="list-style-type: none"> Global Pharma Companies 			<ul style="list-style-type: none"> Indian Pharma Companies

Source: Company Report, Bernstein analysis

Gland is less exposed to end market price fluctuations by virtue of their B2B model. When prices inch down, royalties come down, but margins are protected to an extent from the transfer pricing. Similarly, the CMO business is also protected since markups over COGS are not negotiated often. Gland's contracts carry a ~5-year term and prices are renegotiated only under extraordinary circumstances like raw material pricing surge or supply issue. GPOs in the market also prefer long term contracts of 3-5 years and Gland therefore enjoys a stable revenue stream for a sustained period. Based on discussion with the management, we understand 67% of the business is B2B IP-led or B2B technology transfer where they tend to earn higher gross margins of 75% in the year of launch which tends towards 60% in steady state and the remaining 29% of the business is CMO where they earn 45% gross margins. The CMO business though at a lower gross margin serves the important purpose of keeping capacity utilization high.

Gland's business model also allows them to grow the base portfolio by selling the same molecule to multiple players. They have the flexibility to do so since only IP is exclusive to their partners and manufacturing is not. B2C players tend to outsource their older products to companies like Gland to free up their capacities for new products and improve margins. B2C players lack this option of expanding their base and hence are exposed to yearly erosion both from loss of market share to competition and lower pricing. In various management calls, Gland have mentioned that their base portfolio has expanded at ~6-7%. Gland's business model makes growth and margins less volatile compared to B2C players.

Gland mentions ~40 molecules as their top revenue contributors in their DRHP. We have analyzed these molecules and identified their partners in the US market. Exhibit 23 shows end market sales of their own ANDAs as well as partner owned ANDAs in the US (we show top 20 where market is >\$30 Mn). The top 10 products contribute more than 40% of sales. Typically, concentrated portfolios are not good news in the US generic market. However, in the case of Gland we note that they sell through a minimum of two players in all molecules and an average of 3 players in their top 10 molecules. Their market shares range between 10-46% and the spread of partners reduces concentration risk. We will now look at each of the Top 10 molecules in turn to understand growth opportunities and risk if any.

EXHIBIT 23: Top 20 Molecules by market size that Gland operates in

Molecule	2020Sales (\$Mn)	Value Growth	Volume Growth	Gland's Partners	Gland's Market Share By Volume
Enoxaparin Sodium	531	-3%	8%	Apotex, Kabi	31%
Dexmedetomidine	337	17%	29%	DRL	0%
Heparin	286	6%	10%	Sagent	1%
Daptomycin	282	-21%	11%	Blue Point, DRL, Kabi, Northstar, Pfizer, Sagent, xellia	46%
Vecuronium	211	12%	19%	Kabi	14%
Cisatracurium	141	30%	32%	Sandoz	11%
Micafungin	126	8%	12%	Apotex, Kabi	16%
Fosaprepitant	104	-13%	8%	Apotex, Blue Point, Lupin	6%
Levothyroxine	70	1%	17%	Athenex	8%
Esmolol	67	6%	12%	Sagent	5%
Doxercalciferol	65	-10%	7%	DRL	0%
Ketorolac	59	5%	8%	Alvogen, Fosun	11%
Rocuronium	55	12%	15%	Alvogen, Athenex, Viatris	13%
Bivalirudin	52	-26%	6%	Apotex, Athenex, DRL	21%
Palonosetron	51	-33%	5%	Blue Point, DRL, Northstar, Sagent	36%
Levetiracetam	50	2%	19%	Athenex, Pfizer	12%
Melphalan	49	-13%	9%	Athenex, Fosun	10%
Midazolam	49	9%	7%	Athenex, Almaject, Avet, Alvogen	17%
Haloperidol	41	-5%	7%	Sagent	3%
Zoledronic acid	31	-16%	12%	Apotex, Athenex, Kabi, BPI Labs, DRL	29%
Ondansetron	30	0%	6%	Athenex, Avet, Viatris, Fosun	25%

Source: IOVIA, Bernstein analysis

Profiling Gland's Top 10 molecules

Enoxaparin (Lovenox):

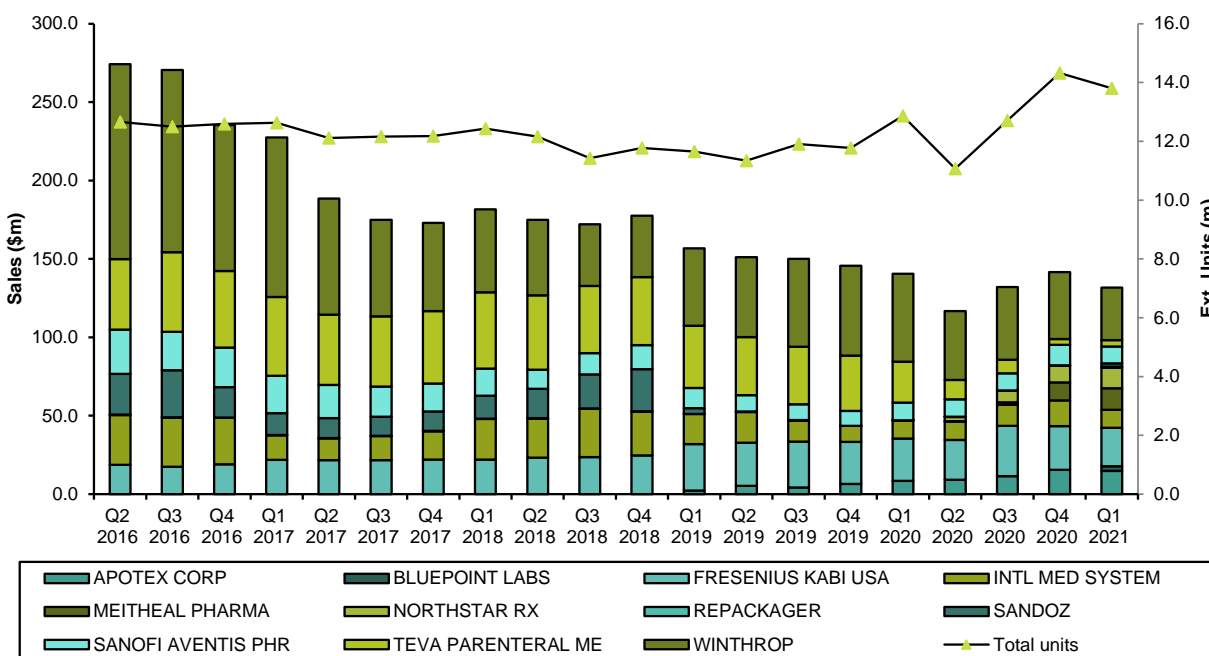
- + FY21 end market sales of Gland's partners (IQVIA): \$160.5 Mn
- + Market share: 31%
- + Currently in shortage by the FDA: No

Enoxaparin is an anticoagulant that helps prevent the formation of blood clots. It is used to treat and prevent deep vein thrombosis and pulmonary embolism including during pregnancy and following certain types of surgery. It is also used in those with acute coronary syndrome and heart attacks.

Enoxaparin volumes have trended down slightly in the last 5 years with newer anticoagulants now available in the market, but the consumption remains at an elevated level of >45 Mn units/year. The uptick seen in 2020 is likely a result of use in severe COVID-19 patients, which we expect to normalize in 2021 as cases and hospitalizations are trending down in the US. Fresenius Kabi and Apotex are their partners in the US who command 21% and 10% market share today.

The market is crowded with 6 players already in the market and 3 in the waiting including Gland's own ANDA, Sagent and Mylan. Gland's current partners are Kabi and Apotex who command 10% and 21% share respectively. Gland expects to gain share with Kabi as they transition from selling the AG starting from 4QFY21. Some of the gains could be tempered by pricing competition especially from the likes of Nanjing-King Friend which is likely fully backward integrated in this product. Gland sources the KSM (key starting material) from China but is now exploring Fosun's strong vendor network to further strengthen their cost position. We expect revenues to expand in FY23 as they gain share with Kabi.

EXHIBIT 24: Enoxaparin Sodium



Source: IQVIA, Bernstein analysis

Daptomycin (Cubicin):

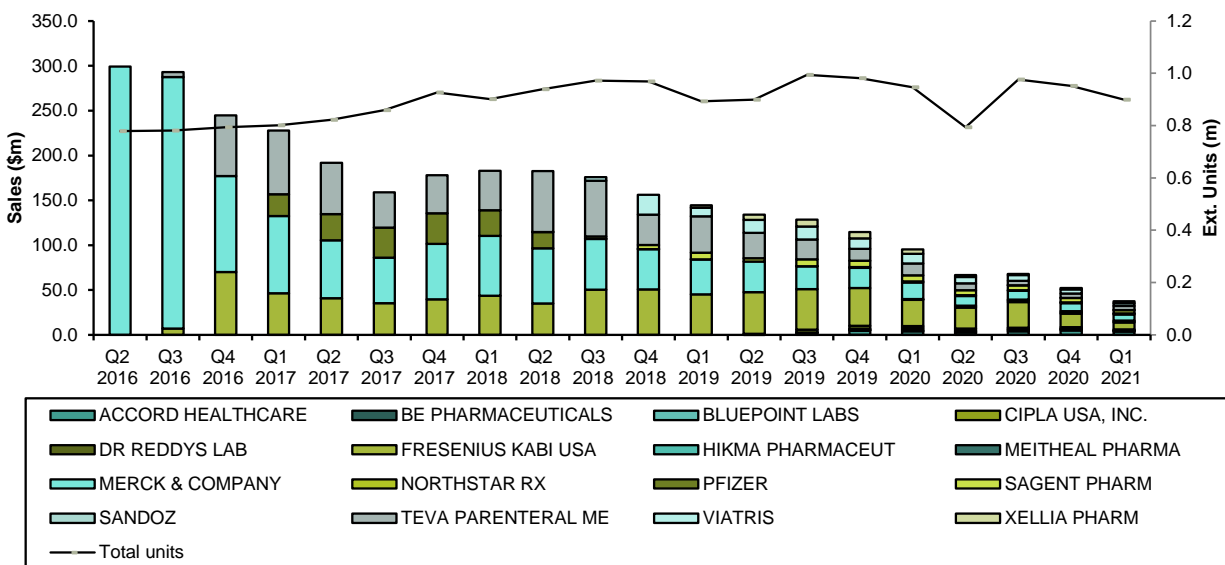
- + FY21 end market sales of Gland's partners (IQVIA): \$112.6 Mn
- + Market share: 50%
- + Currently in shortage list by the FDA: No

Daptomycin is a lipopeptide antibiotic used in the treatment of systemic and life-threatening infections caused by Gram-positive organisms. It is indicated to use in complicated Skin and Skin Structure Infections, Staphylococcus aureus Bloodstream Infections (Bacteremia), including those with Right-Sided Infective Endocarditis, caused by Methicillin-Susceptible and Methicillin-Resistant Isolates.

Daptomycin volumes have remained largely flat in the last 5 years even as newer antibiotics have hit the market. Pfizer (Hospira), DRL, Bluepoint, Xellia and Northstar are their partners in the US, major partners being Fresenius Kabi and Sagent who command 33% and 9% market share today respectively.

The market is crowded with 7 players already in the market other than Gland & there is significant price competition. Hospira and Hisun also have approvals and should enter the market soon. The innovator launched Cubicin RF, a new formulation that is stable at room temperatures. However, the patent protection on that product will likely last till 2026-27. With a 42% market share, Gland is the largest player and we expect their sales to be stable.

EXHIBIT 25: **Daptomycin**



Source: IQVIA, Bernstein analysis

Heparin:

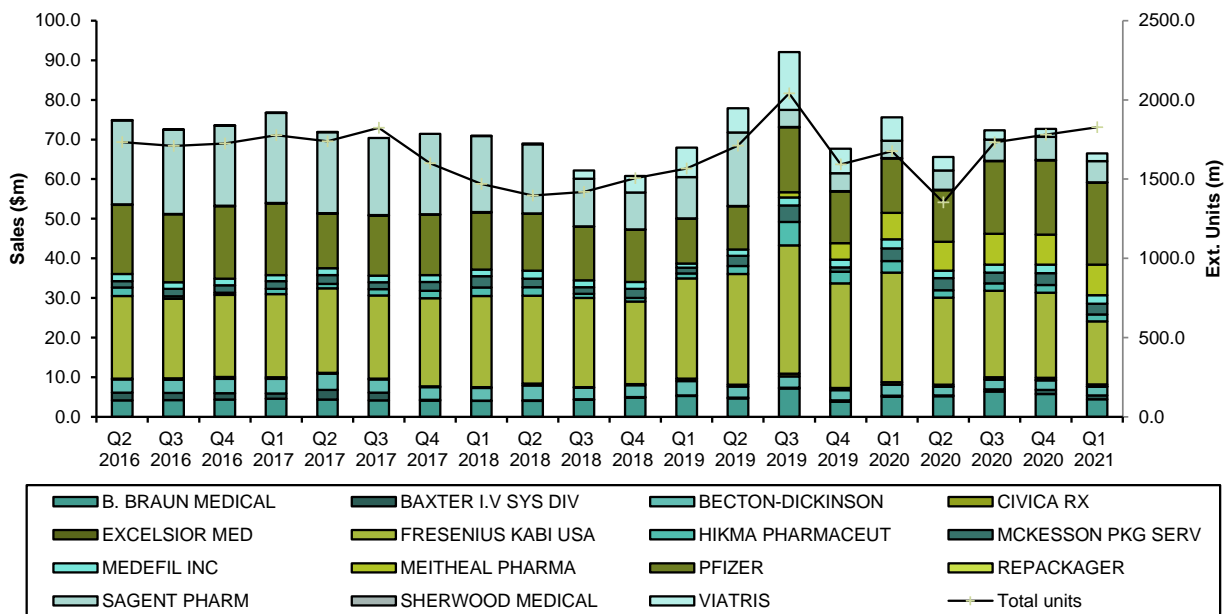
- + FY21 end market sales of Gland's partners (IQVIA): \$21.4 Mn
- + Market share: 8%
- + Currently in shortage list by the FDA: No

Heparin is an anticoagulant. It is used to decrease the clotting ability of the blood and help prevent harmful clots from forming in blood vessels. Heparin is used to prevent or treat certain blood vessel, heart, and lung conditions. Heparin is also used to prevent blood clotting during certain surgeries and blood transfusions. It is used in low doses to prevent the formation of blood clots in certain patients who must remain in bed for a long time. Heparin may also be used to diagnose and treat a serious blood condition called disseminated intravascular coagulation (DIC).

Heparin volumes have trended down in the last 5 years with alternative anticoagulants now available in the market. Enoxaparin continues to take share away. The uptick seen in 2020 is likely a result of use in severe COVID-19 patients which we expect to normalize in 2021 as cases and hospitalizations are trending down in the US. Sagent is their partner in the US which commands 8% market share today.

The market is crowded with 7 players already in the market other than Gland. NSP prices were almost steady since 2015 except a significant rise in FY 2020-21 when there was Heparin shortage during COVID. We expect revenues to slowly trend down as the market shrinks.

EXHIBIT 26: Heparin



Source: IQVIA, Bernstein analysis

Micafungin (Mycamine):

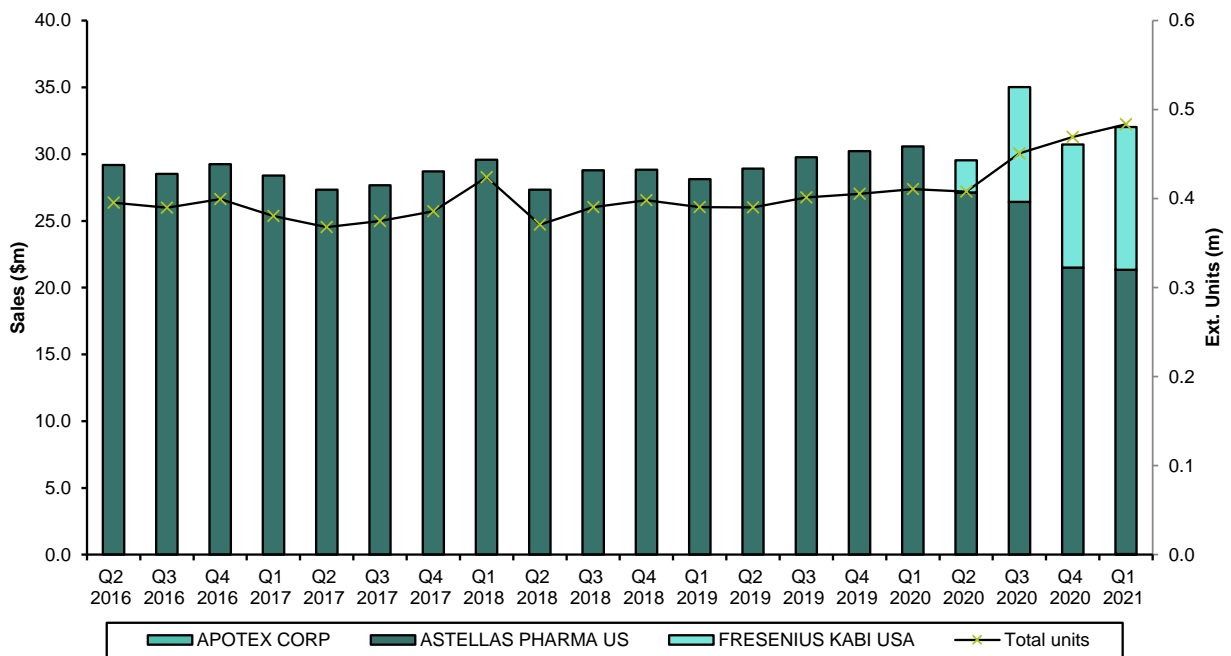
- + FY21 end market sales of Gland's partners (IQVIA): \$30.9 Mn
- + Market share: 24%
- + Currently in shortage list by the FDA: No

Micafungin is a polyene antifungal medication used to treat and prevent invasive fungal infections including candidemia, abscesses and esophageal candidiasis, Acute Disseminated Candidiasis, Candida Peritonitis. It is also indicated for prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantation.

Micafungin volumes are increasing since FY 2015. The uptick seen in 2020 is likely a result of use in severe COVID-19 patients which we expect to normalize in 2021 as cases and hospitalizations are trending down in the US. Apotex & Fresenius Kabi are their partners in the US, Fresenius Kabi being the major partner having 24% market share today.

The product has been recently launched in the market and we can expect Gland's partner to continue to gain market share. Xellia and Jiangshu are the other two with tentative approvals. We expect them to launch in 2HCY2021 but given that the market is nascent, there is ample room for growth for Gland.

EXHIBIT 27: **Micafungin**



Source: IQVIA, Bernstein analysis

Vancomycin:

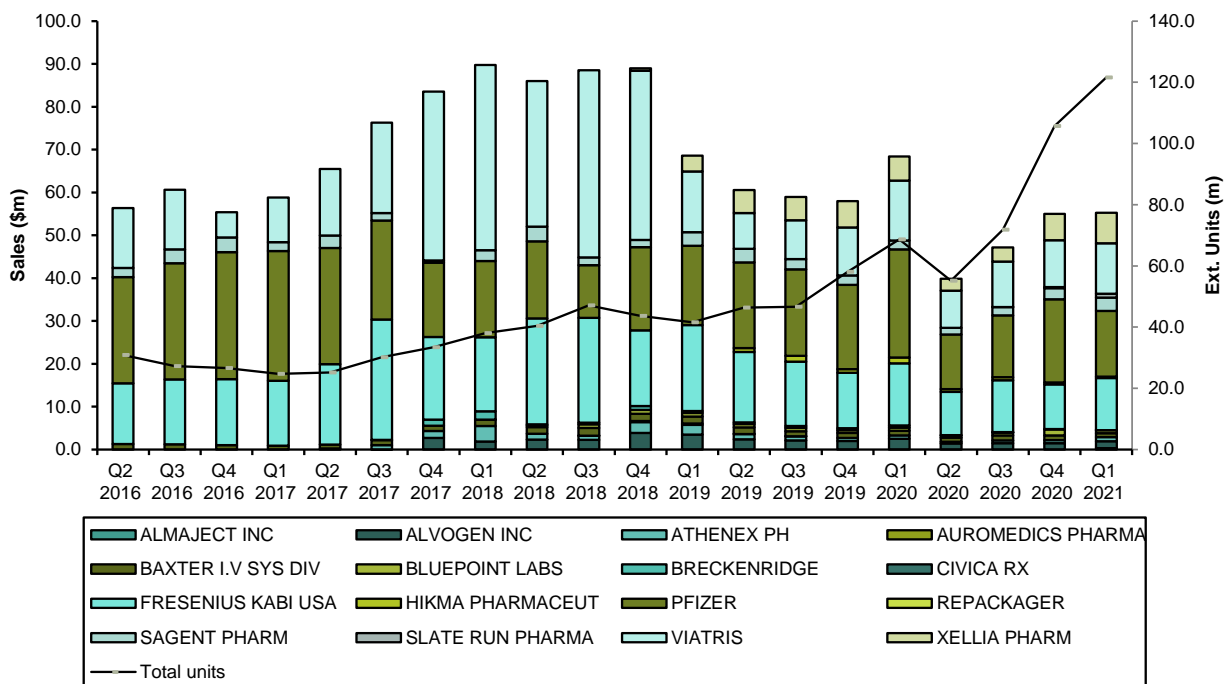
- + FY21 end market sales of Gland's partners (IQVIA): \$66.5 Mn
- + Market share: 34%
- + Currently in shortage list by the FDA: No

Vancomycin is a glycopeptide antibacterial indicated in adult and pediatric for the treatment of Septicemia, Infective Endocarditis, Skin and Skin Structure Infections, Bone Infections, Lower Respiratory Tract Infections etc.

Vancomycin volumes are gradually increasing since FY 2015. The uptick seen in 2020 is likely a result of use in severe COVID-19 patients which we expect to normalize in 2021 as cases and hospitalizations are trending down in the US. Almaject, Alvogen, Athenex, Bluepoint, Breckenridge are their partners in the US, Fresenius Kabi & Sagent being the major partners having 23% & 5% market share today respectively.

There are 7 players in the market at present. Hikma, Pharm Assoc and Sandoz also have approved ANDAs and will likely launch soon. Firvanq kit containing a powder for oral solution and a reconstituent was launched recently. Alkem is the only PIV filer so far. We are unsure of the strength of patents and there could be competition in FY24 from this new product. In the current market, Gland enjoys a dominant market share in what is a crowded market. We expect their market shares to be resilient even with additional entrants.

EXHIBIT 28: **Vancomycin**



Source: IQVIA, Bernstein analysis

Palonosetron (Aloxi):

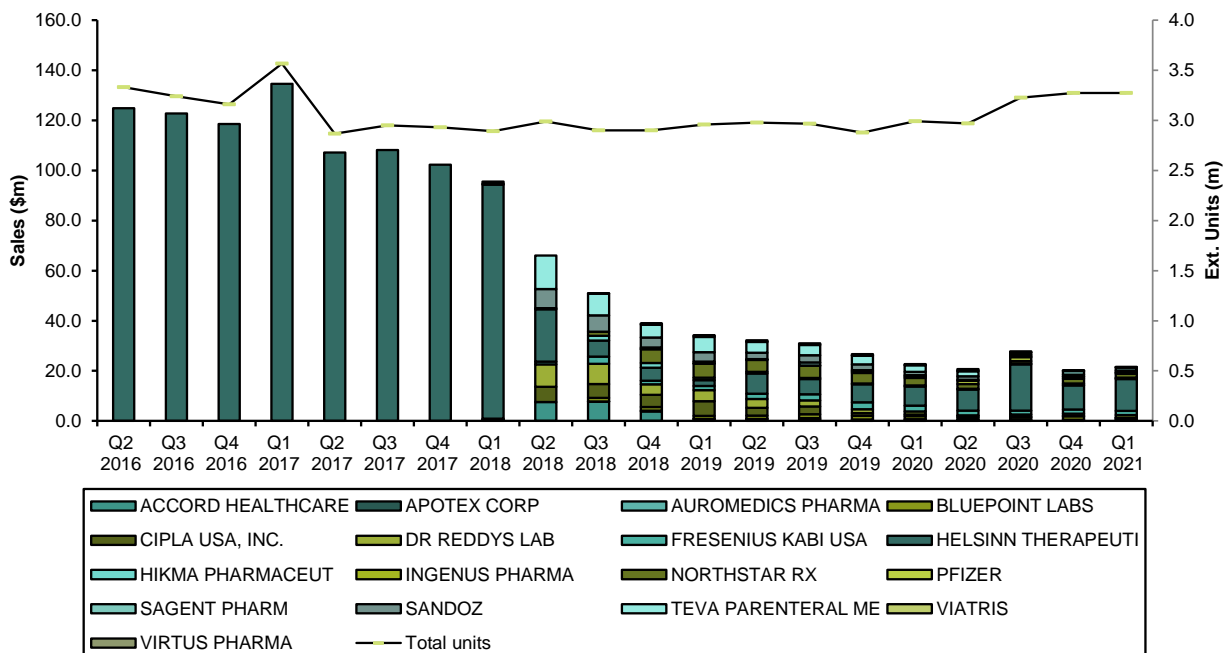
- + FY21 end market sales of Gland's partners (IQVIA): \$14.2 Mn
- + Market share: 16%
- + Currently in shortage list by the FDA: No

Palonosetron is an antiemetic and anti-nausea agent used to prevent nausea and vomiting that may occur within 24 hours after receiving cancer chemotherapy or surgery. Also, it is used for prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery.

Palonosetron volumes are gradually increasing since FY 2015. Bluepoint, DRL, Sagent are their partners in the US, Northstar being the major partner having 7% market share today.

There are 7 players in the market at present other than Gland. 7 more players have tentative approvals or have filed and are awaiting approvals. We expect revenues to slowly trend down as more players enter the market.

EXHIBIT 29: Palonosetron



Source: IQVIA, Bernstein analysis

Cisatracurium (Nimbex):

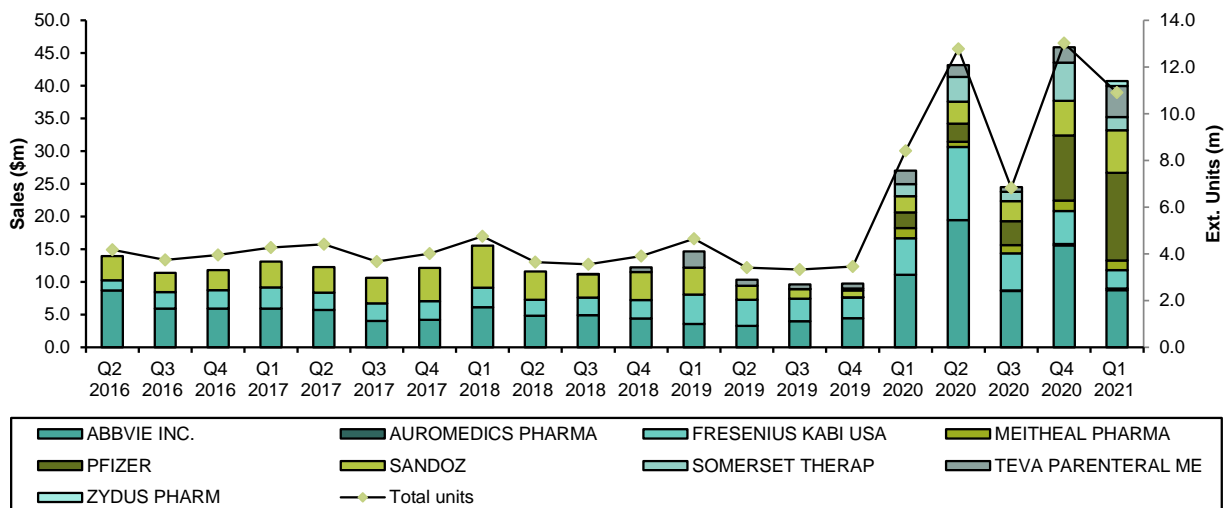
- + FY21 end market sales of Gland's partners (IQVIA): \$18.3 Mn
- + Market share: 12%
- + Currently in shortage list by the FDA: Yes

Cisatracurium is a nondepolarizing neuromuscular blocker indicated as an adjunct to general anesthesia to facilitate tracheal intubation, to provide skeletal muscle relaxation during surgery, for mechanical ventilation in the ICU in adults.

Cisatracurium volumes were stable since FY 2015. But there is significant increase in demand during COVID 19 period leading to the drug shortage (3X volumes). We expect it to normalize in 2021 as cases and hospitalizations are trending down in the US. Sandoz is the only partner in the US at present having 12% market share today. Gland was a beneficiary of the heightened demand which we believe reflected in their 1QFY21 and 2QFY21 numbers.

There are 8 players in the market at present other than Gland. NSP prices were increasing since FY 2016 with significant increase in FY 2020-21 due to increase in demand in COVID period. Aurobindo and Sagent have approved ANDAs and could launch soon. We expect the revenues to come down in FY22 and return back to normal levels 2HFY22 onwards.

EXHIBIT 30: **Cisatracuim**



Source: IQVIA, Bernstein analysis

Olanzapine (Zyprexa):

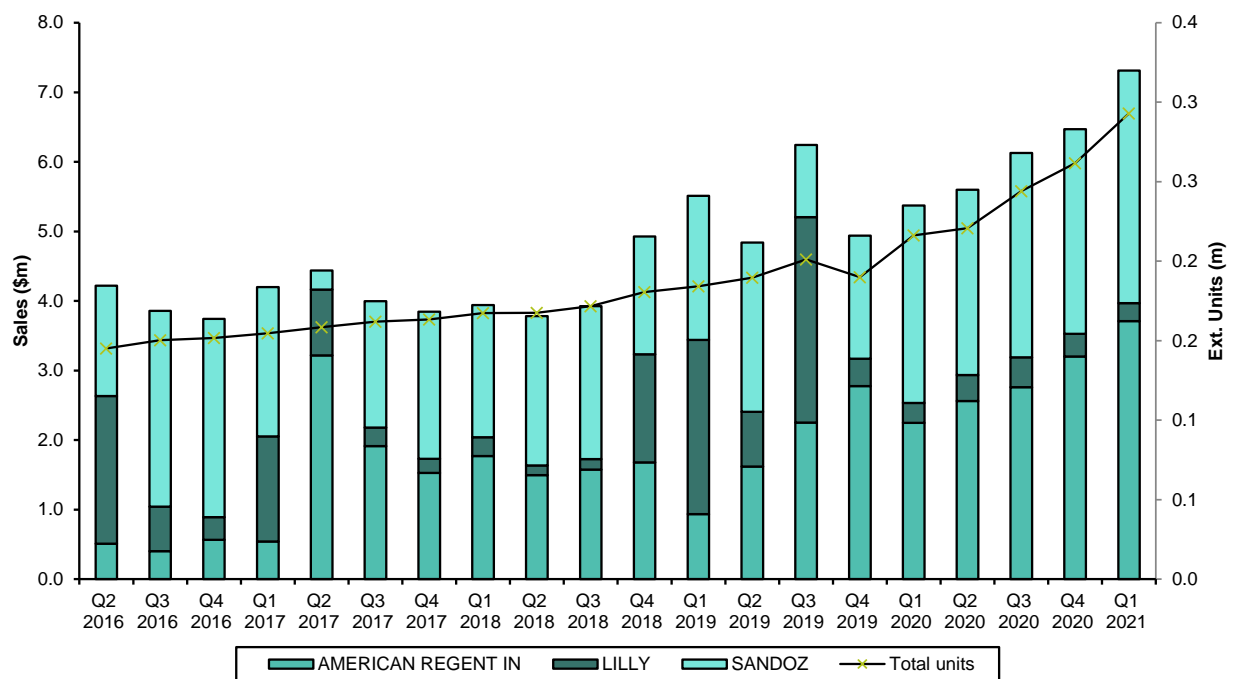
- + FY21 end market sales of Gland's partners (IQVIA): \$11.9Mn
- + Market share: 47%
- + Currently in shortage list by the FDA: No

Olanzapine is an atypical antipsychotic drug used to treat acute agitation associated with Schizophrenia and Bipolar I Mania in adults.

Olanzapine volumes are gradually increasing since FY 2015. We expect the uptrend to continue in the long run. Sandoz is the only partner in the US at present having 47% market share today.

There are only 2 players in the injectable market at present other than Gland. Aurobindo is a recent entrant in the market (3/21) and prices and market shares will trend down as they scale up. We expect revenues to trend down in FY22 for Olanzapine.

EXHIBIT 31: **Olanzapine**



Source: IQVIA, Bernstein analysis

Levothyroxine Sodium:

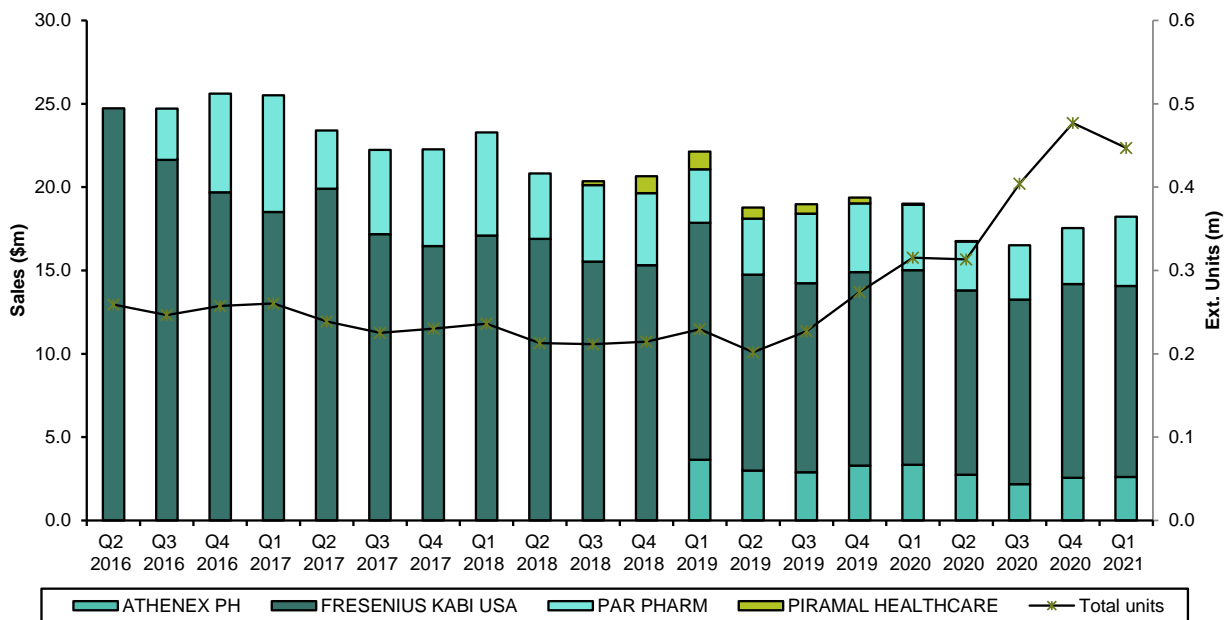
- + FY21 end market sales of Gland's partners (IQVIA): \$10.1Mn
- + Market share: 15%
- + Currently in shortage list by the FDA: No

Levothyroxine Sodium is a thyroid hormone medication indicated for the treatment of myxedema coma associated with the severe hypothyroidism.

Levothyroxine volumes were stable since FY 2015. But there was significant increase in the volumes in FY 2020-21 which is likely a result of use in severe COVID-19 patients which we expect to normalize in 2021. Athenex is the only partner in the US at present having 15% market share today.

There are only 2 players in the injectable market at present other than Gland. Dr. Reddy's has an approve ANDA and Innopharma has a file too. As they launch, market shares and pricing could trend down.

EXHIBIT 32: **Levothyroxine Sodium**



Source: IQVIA, Bernstein analysis

Bivalirudin (Angiomax):

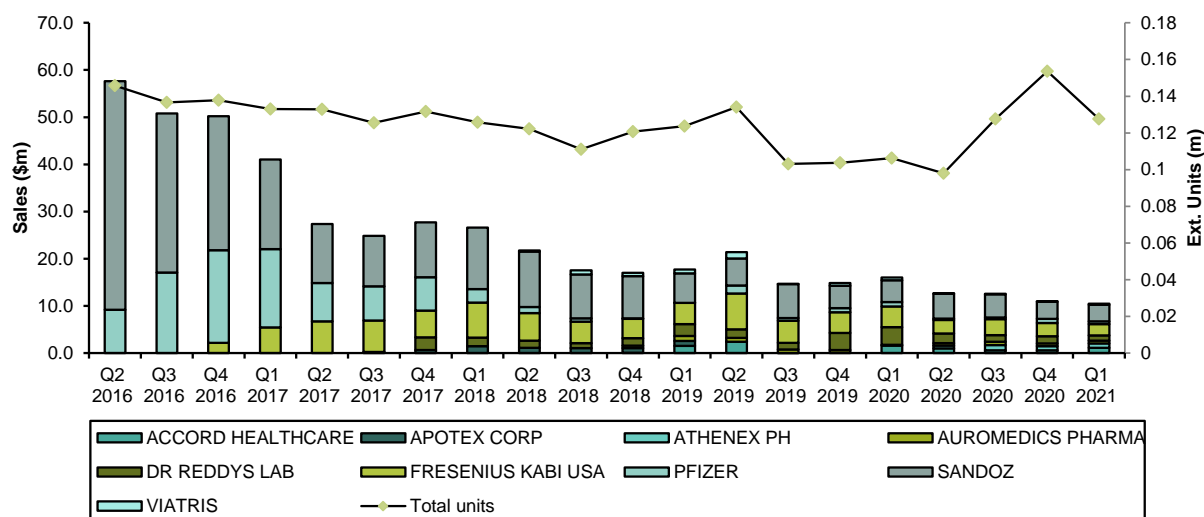
- + FY21 end market sales of Gland's partners (IQVIA): \$ 9.6Mn
- + Market share: 21%
- + Currently in shortage list by the FDA: No

Bivalirudin is a direct thrombin inhibitor indicated for use as an anticoagulant in patients undergoing percutaneous transluminal coronary angioplasty (PTCA), undergoing percutaneous coronary intervention (PCI), in patients with, or at risk of, heparin-induced thrombocytopenia (HIT) and thrombosis syndrome (HITTS), undergoing PCI. Angiomax is intended for use with aspirin.

Bivalirudin volumes were gradually declining since FY 2015 with the invention of newer anticoagulants. But there was significant increase in the volumes in FY 2020-21, which is likely a result of use in severe COVID-19 patients which we expect to normalize in 2021. Athenex and DRL are the only partners in the US at present having 21% market share today.

There are 5 players in the market at present other than Gland. Six other players with tentative approvals/files under review are waiting to launch. We expect market shares to be protected since it's already a crowded market. Gland has launched a ready-to-use (RTU) version of Bivalirudin, which requires no reconstitution. Gland is so far the only player to do so. We expect Gland to replace the old product with the new product and also gain share from other players. We expect Bivalirudin sales (lyo + RTU) to increase in the near term.

EXHIBIT 33: Bivalirudin



Source: IQVIA, Bernstein analysis

We believe a base portfolio growth of 3-4% is realistic though the company has boasted of higher growth of 6-7% in the base in the recent past. In FY23 that might indeed be true as they gain share from Kabi in Enoxaparin but in normal years we think 3-4% is more likely.

GOOD PIPELINE OF PIV FILINGS AND DMFS THAT CAN SUPPORT GROWTH

Gland has a good pipeline of PIV products where they own the ANDA. Exhibit 34 & Exhibit 35 list what could be near-term opportunities based on our understanding of the IP landscape and litigation progress. Historically, for every ANDA they file on their own they file 2x the number of ANDAs through partners. We unfortunately do not have visibility into what they might have filed through partners.

EXHIBIT 34: **Gland's PIV pipeline (1/2)**

Brand Name	Molecule	Net Sales \$Mn, 2020	First Filer	Others	Estimated Launch date
Adrucil	Fluorouracil	7	N/A	Fresenius, Gland, Ingenus, Accord/BluePoint, Sandoz, Sagent	N/A
Levaquin (Inj)	Levofloxacin	3	N/A	Akorn, Aurobindo, Baxter, Fresenius, Gland, Hikma Hospira, InfoRLife, Bedford Labs, APP	2Q22
Merrem IV	Meropenem	25	N/A	ACS Dobfar, Amneal, Aurobindo Daewoong, Gland, HQ Specialty Pharma/WG Critical Care, Savior Lifetec	3Q22
Invanz	Ertapenem	66	Merck	ACS Dobfar, Aurobindo, Gland, Savior Lifetec	1Q22
Naropin	Ropivacaine Hydrochloride	24	Navinta/Sandoz	Akorn, Aurobindo, Caplin Point/Baxter, Hikma, Hospira, InfoRLife/Sagent, Somerset, Gland, Custopharm; Wockhardt	4Q23
Nexium IV	Esomeprazole Sodium	3	Sun	Accord, Aurobindo, Deva /Akorn, Gland, Mylan/Viatris	2Q22
Optivar	Azelastin Hydrochloride	3	Apotex	Wallace, Akorn, Alembic, Gland, Sandoz, Somerset, Sun	2Q22
Paraplatin	Carboplatin	N/A	N/A	Accord, Akorn, Cipla/Fresenius, Eugia /Auromedics, Fresenius, Gland/Alvogen, Hospira, Meitheal/Sagent, Novast/Ingenus, Pharmachemie/Teva, Sandoz, Sun, West-Ward	N/A
Quelicin	Succinylcholine Chloride	20	N/A	Amneal, Amring, Aspiro, Breckenridge, Deva, DRL, Fresenius, Gland, Indoco Remedies/STI, Micro Labs, Nexus, Nivagen, Somerset, Zydus	2Q22
Vazculep	Phenylephrine Hydrochloride	21	N/A	Accord, Amneal, Apollo, Aurobindo, Caplin Point, Fresenius, Gland, Meitheal, Par/Endo, Sagent, Sandoz	2Q22

Source: IQVIA, paragraphfour.com, FDA, Bernstein analysis

EXHIBIT 35: **Gland's PIV pipeline (2/2)**

Brand Name	Molecule	Net Sales \$Mn, 2020	First Filer	Others	Estimated Launch date
Vigamox	Moxifloxacin Hydrochloride	12	N/A	Sandoz, Akorn, Alembic, Apotex, Aurobindo, Gland, Lupin, Mylan/Viatris, Watson/Teva, Teva	2Q22
Lexiscan	Regadenoson	621	N/A	DRL, Accord, Apotex, Gland, Glenmark, Hospira, International Medication Systems, Ltd./Amphastar; Meitheal, Sandoz, Sun, USV, Wockhardt	1Q23
Mozobil	Plerixafor	140	DRL, Sandoz, Teva	Zydus, Fresenius, Gland	2Q24
Bridion	Sugammadex sodium	583	Unknown	Aspiro, Aurobindo, Biophore, DRL, Fisiopharma, Fresenius, Gland, Lupin, Mankind Pharma, MSN Laboratories, Mylan/Viatris, Sandoz, Sun, Teva, USV, Zydus	4Q26
Lastacaft	Alcaftadine	2	N/A	Alembic, Gland, Aurobindo, Somerset	4Q27
Lumigan (0.01%)	Bimatoprost	256	Sandoz	Alembic, Gland, HiTech/Akorn, Actavis, Apotex, Lupin	2Q28
Pataday (0.7%)	Olopatadine Hydrochloride	N/A	Watson/ Teva	Apotex, Gland, Argentum Pharmaceuticals LLC/KVK-Tech Inc., Cipla, Lupin	2030-32
Omidria	Ketorolac Tromethamine; Phenylephrine Hydrochloride	73	N/A	Lupin, Gland, Par/Endo, Sandoz	2030
Aggrastat	Tirofiban Hydrochloride	13	Gland Pharma, Nexus	N/A	4Q23

Source: IQVIA, paragraphfour.com, FDA, Bernstein analysis

Gland has been increasing the pace of filings and share of their own ANDAs in the recent past. According to company reports, Gland has filed a total of 282 ANDAs and has received approvals for 226 with 56 pending at the FDA. These numbers include multiple partner ANDAs for the same molecule. The filing approval trends for Gland's own filings and partner filings is in Exhibit 36. Since 2015, Gland has received one of the highest number of approvals for injectable products.

EXHIBIT 36: **Gland ANDA Status**

ANDA Filing Trends

	Own Filings	Partner Filings	Total
Till CY17	71	149	220
CY18	13	11	24
CY19	14	4	18
CY20	15	5	20
TOTAL	113	169	282

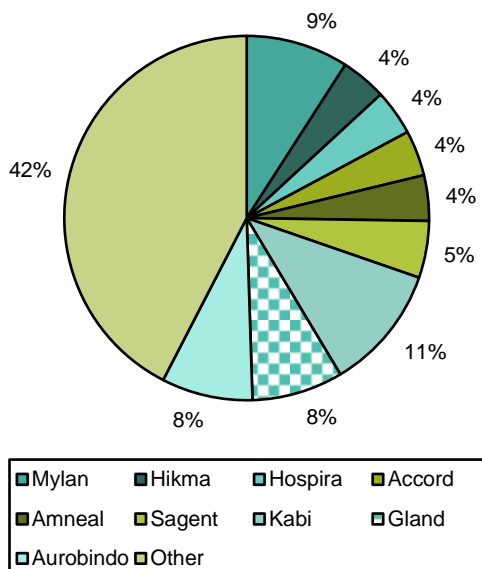
ANDA Approval Trend

	Own Approvals	Partner Approvals	Total
Till CY17	36	87	123
CY18	8	28	36
CY19	14	22	36
CY20	21	10	31
TOTAL	79	147	226

Source: Company Reports, FDA, Bernstein analysis

Exhibit 37 shows that Gland is only behind Mylan, Fresenius Kabi and Aurobindo. A wide portfolio augurs well for winning GPO contracts as mentioned in an earlier section. Every year Gland is expected to file 20-25 ANDAs though it might be on the lower end of the range with increasing number of complex generic products in the pipeline. Management commentary indicates that they will be partnering to develop complex generics and our view is that the partner is likely to want ANDA ownership in these limited competition opportunities. We believe ~50% of future filings will be ANDAs owned by Gland.

EXHIBIT 37: **Gland Share of Injectable ANDAs from 2015**



Source: FDA, Bernstein analysis

Gland has also increased the pace of DMF filings in the recent past. They have 44 active DMFs in the US. We expect them to launch ANDAs of most of these products as well. The company indicated that ~30% of their portfolio is backward integrated today which should increase going forward as they launch these products in the market. Between the PIV filings and DMF filings, we believe a healthy growth of 15-16% from new launches is possible in the near term. We believe the material ones will be gErtapenem (partnered with DRL, FY21), gRegadenoson (FY23), gPlerixafor (FY23), gPemetrexed (FY23), gEpinephrine (FY23), gCopaxone (fill-finish for DRL, FY23) (Exhibit 38).

EXHIBIT 38: **Material Products for Gland in FY22-24**

Brand	Molecule	API/PIV	Market Size \$Mn, 2020	Gland Revenues (\$Mn)		
				FY22	FY23	FY24
Invanz	Ertapenem	PIV	66	10.9	11.8	11.2
Alimta	Pemetrexed Disodium	API	1265	1.9	5.8	5.8
Epinephrine (Belcher)	Epinephrine	API	1150	-	-	3.6
Lexiscan	Regadenoson	PIV	621	12.9	12.6	11.2
Mozobil	Plerixafor	PIV	140	-	-	4.2
Copaxone	Glatiramer	API	610	13.04	16.47	15.55

Source: Evaluate, Bernstein analysis

The company has been investing in complex technologies like suspensions, hormones, peptides and microsphere products. They have also been investing in delivery technologies like cartridges and pens. As detailed in an earlier section, these are very complex products requiring significant investments in capability building and capex in R&D and manufacturing. Based on a recent conversation with the CEO (notes from our Webinar are [here](#)), we believe they are close to filing suspension products. The material opportunities in this space are gMedroxyprogesterone (\$135 Mn market), gTriamcinolone (\$159 Mn market) and gInvega Sustenna and gInvega Trinza (\$2.1 Bn). The first two are already generic and possibly Gland's first targets. Invega Sustenna has patent protection likely until 2031. We are not building revenues for complex generics till we have more visibility into their filings. These have long review cycles and approval is uncertain. For most of these products Gland is partnering with players who will support both capabilities building as well as R&D investments. The management has guided to R&D expenses being within 3-4% of sales which should be adequate as long as the heavy investments in complex generics are paid for by the partners.

One question we often get from investors is the threat of "scale" in a pure generic market like the US. In the US, all market assets are depreciating assets. Competition brings pricing down and in most cases the molecule itself starts losing share to other competing molecules since the innovator is no longer promoting it. The incremental revenues from new launches needs to meet a certain threshold so as to cover up for the base erosion and post growth on top of that. Companies find this harder to do as they scale up. Bigger the base, higher the launch run rate that is required to grow. Gland is protected from this phenomenon for now – a) their end market revenues are ~\$500 Mn and at this scale other generic companies have not had growth challenges, b) their business model allows them to actually grow their base through additional partners.

INVESTMENTS IN NEW TECHNOLOGIES TO EXPAND ADDRESSABLE MARKET

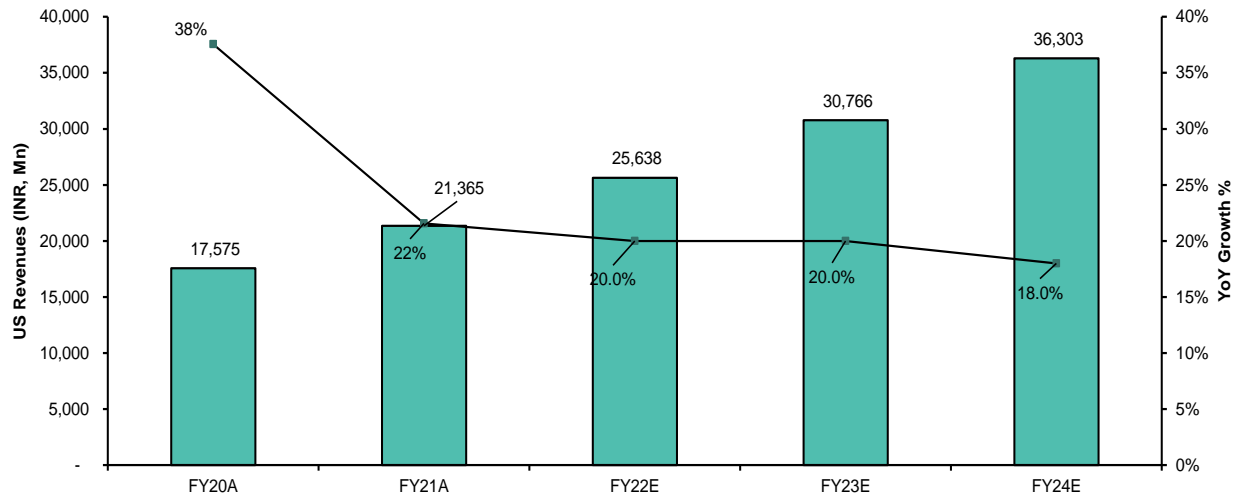
To address the opportunity in complex generics Gland has already stepped up investments in R&D and manufacturing in-house. In addition, they are keen on acquiring manufacturing facilities that can help them address the following opportunities – a) the sizeable market in controlled substances (anesthetics and pain medications) in the US where supply chain is very tightly controlled, b) fermentation API facility that can aid their objective of higher levels of backward integration in their product portfolio, and c) niche complex technologies like microspheres.

We identified a long list of controlled substances but 12 of those where market size is >\$25 Mn can potentially be targeted by Gland. gPropofol, gFentanyl, gHydromorphone, gMorphine and gBuprenorphine are all substantial opportunities and this market has been plagued by shortages in the recent past. This can be an attractive opportunity for a scale-player like Gland. Any upside from such M&As will be additive to our estimates.

WE ESTIMATE 19% CAGR IN US FROM FY21-24

With the various growth opportunities at hand including base portfolio expansion and new launches we believe Gland can grow at 19% CAGR in the US in the next 3 years (Exhibit 39).

EXHIBIT 39: **Gland US Sales**



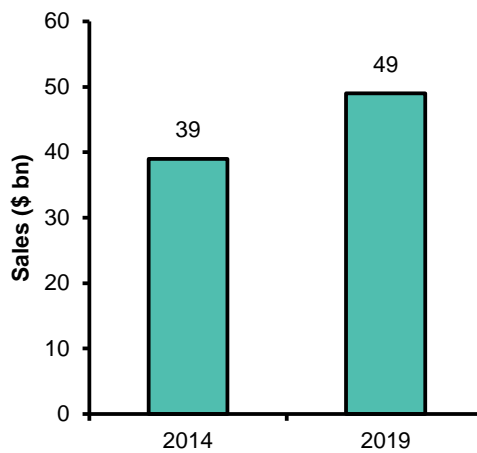
Source: Company reports, Bernstein estimates and analysis

INCREASING VISIBILITY INTO THE CHINA OPPORTUNITY

ANOTHER LARGE AND GROWING MARKET

Injectables in China was a \$49 Bn market in 2019 that has grown at 5% CAGR. Generic penetration is high at 70% (Exhibit 40).

EXHIBIT 40: **China Injectable Market**



Source: Gland Pharma DRHP, IQVIA, Bernstein analysis

China has emerged as an important medium to long term growth lever for Gland. Fosun's support in product registration and commercialization and recent regulatory changes by the NMPA (National Medicinal Products Administration) will support Gland's foray into the market, which has largely remained inaccessible to Indian manufacturers so far.

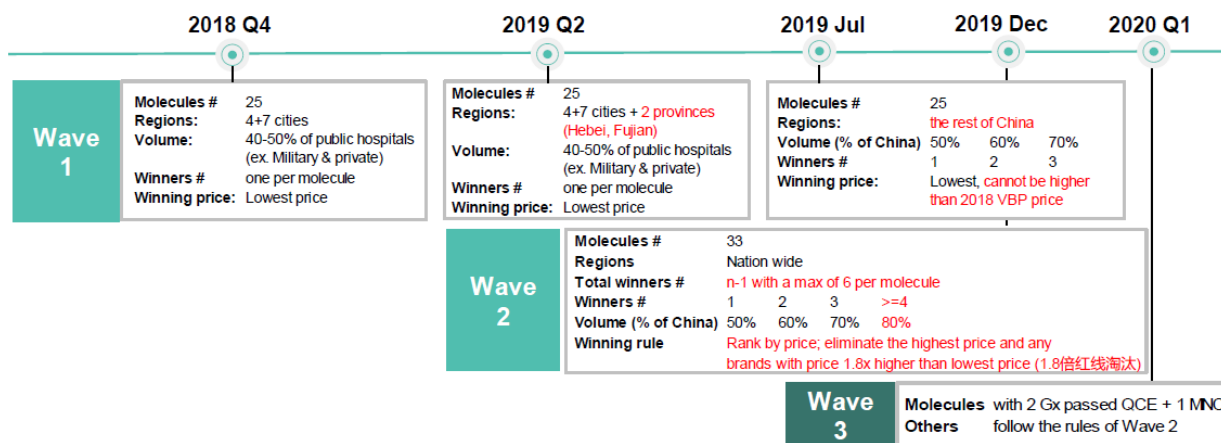
VBP WILL LEVEL THE PLAYING FIELD FOR INDIAN GENERICS

China has always remained out of grasp for Indian manufacturers due to a) a prolific and highly cost competitive domestic generic industry, b) complex market access model involving central, state and hospital tenders, c) requirement of significant

investments in sales and marketing, and d) local manufacturing requirements apart from the well-known issues of language, transparency and culture compatibility. Three recent regulations removing local manufacturing requirements, fast tracking approval for files with US/EU approval and increasing centralized procurement of off patent drugs have opened the market.

China's SMIA (State Medical Insurance Administration) announced a centralized VBP (Volume Based Procurement) model for 25 drugs for 4 provinces and 7 cities in 2018. The parameters and scope of the tender continued to evolve with the 2019 edition targeting 2 waves of drugs, 25 in wave 1 and 34 in wave 2, the entire country now in the scope and a volume promise of 50% for 1 winner, 60% for 2 winners, 70% for 3 winners and 80% for more than 4 winners of the tender (Exhibit 41).

EXHIBIT 41: China Volume Based Procurement model – progress since inception



Source: NHSA, Bernstein analysis

In the recently concluded Wave in Feb 2021, there were 45 products which included injectables and the winners were almost exclusively generic Pharma. The Top 5 winners were Yangtze River, Oilu, CSPC, Sino Biopharma and Fosun (6 winning bids). Exhibit 42 shows the latest VBP list that included 8 injectables. We expect the future waves to include more generic injectables.

EXHIBIT 42: China VBP List – Wave 4 Injectables

Batch 4 List of Products	Dose Form	Market Size (RMB, Mn)
Propofol	Injectable	1,488
Pantoprazole	Injectable	1,355
Parecoxib	Injectable	757
Ambroxol	Injectable	653
Bortezomib	Injectable	624
Doxofylline	Injectable	378
Bivalrudine	Injectable	218
Ibuprofen	Injectable	124
Total (RMB, Mn)		5,597
Total (\$Mn)		895

Source: CPA Data, Bernstein analysis
 Note CPA data underestimates actual market size by 2-3x

This procurement process has had a profound impact on pricing with cuts of 65-70% in the earlier waves and 50% in the last wave. This VBP model levels the playing field for Indian players who can now participate in the market without investing in sales and marketing teams to commercialize their products. However, the penetration of VBP is still low at ~10-15% of the total volumes of the product. This is expected to expand to 30% in 3-5 years. As the penetration increases players will need capabilities to operate in both the central tender market and the branded generic market.

Gland Pharma has 5 products under registration at various stages in China. The process is being led by Fosun who has established capabilities in the market. Exhibit 43 shows the current status of the 5 products, the competitive landscape and the addressable market. QCE stands for Quality Consistency Evaluation, which is now a pre-requisite for participating in the VBP irrespective of prior approval status. For injectables this involves generating additional data on the fill-finish and packaging processes and in some cases development work if the API and excipients do not confirm to the Chinese Pharmacopoeia. Products will be included in the VBP only after a minimum of 2 products clear the QCE process. We expect 2 products under QCE approval process for Gland to be launched by FY23 and the remaining by FY24. With Fosun's support, we expect the company to continue to invest for China and expand their portfolio.

EXHIBIT 43: Gland portfolio status in China

Molecule	Market Size (RMB, Mn)	Gland's QCE Status	Competition
Dexrazoxane hydrochloride	482	Under review	Fosun/Gland, Ansaokang, Chemo Wanbang Biopharma
Irinotecan hydrochloride	1,180	Under review	Fosun/Gland, Fresenius Kabi, Hengrui, Qilu, Vianexm, Acebright, Huiyu, Jinrui
Zoledronic acid	1,559	Under review	Gland, Emcure, Sino biopharm, CR double-crane, Qilu, Yangzjiang, Renhe Yikang, CSPC
Caspofungin acetate	1,543	Not started	Qilu, Hengrui
Tigecycline	1,902	Not started	Hicin, Sino biopharm, Fuan, Hansoh, Hisun, Kingfriend, Ansaokang

Source: CPA Data, Bernstein analysis

FOSUN'S COMMERCIAL MUSCLE TO PROVIDE A LEG-UP

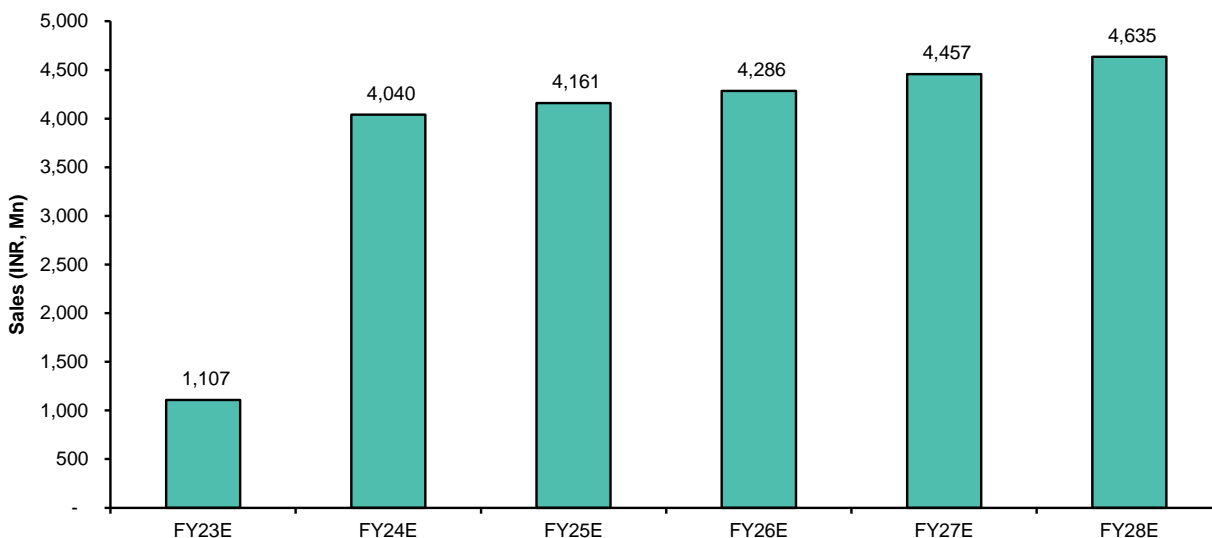
Fosun is a leading pharmaceutical player in the domestic China market focusing on both generics as well as innovative products. In 2020, Fosun had 6000 members in their commercialization team covering 2000 Class III hospitals and 1000 Class II and I hospitals. In addition to their commercial strength in generating demand, Fosun has seen good traction in the VBP waves as well. They have won the bids for a total of 17 products (out of 29 that have cleared the QCE process) across the 4 waves including 6 bids in the most recent wave which augurs well for Gland's China pipeline. Fosun is an ideal commercial partner for Gland who can help them in winning the tenders as well as generating demand for the products on the ground before VBP scales up. This sets Gland apart from other players trying to scale up in China like Aurobindo, Cipla or DRL. While participating in the VBP will be easy for these companies, penetrating the branded generic market will be difficult.

In the recent annual report, Fosun has mentioned Irinotecan, Dexrazoxane, Zoledronic acid and Ondansetron as being under registration. Gland's ability to manufacture products at scale, Fosun's commercial capabilities and leverage of Fosun's API vendor network to improve Gland's COGS can help position Gland well to gain share in the competitive China market.

WE ESTIMATE \$15 MN AND \$55 MN IN SALES IN FY23 AND FY24

Exhibit 44 shows the revenue build up in China. We expect 2 products to be launched in FY23 and the remaining in FY24. We do not have visibility into their future pipeline but expect them to shore up the pipeline on an ongoing basis.

EXHIBIT 44: **Gland Revenue buildup in China**



Source: Bernstein estimates and analysis

NEWER CAPABILITIES TARGETING THE ATTRACTIVE BIOSIMILARS SPACE

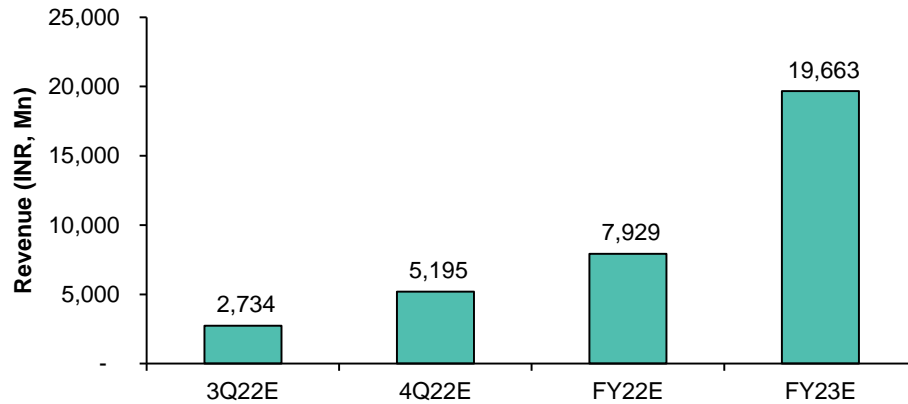
Gland has so far built capabilities only in the small molecule space. They maintained that there were enough opportunities in small molecules and that biosimilars/large molecules is something they would consider in the medium term (see our report [here](#)). COVID has accelerated their journey!

They announced a partnership with RDIF to manufacture 252 Mn doses of the Sputnik V vaccine. What was originally expected to be a fill-finish arrangement has now transformed into an end-end contract manufacturing arrangement including both drug substance manufacturing and fill-finish. Gland has recently acquired a manufacturing facility from Vitane Biologics, Hyderabad to build capabilities in drug substance manufacturing. This was for a consideration of INR900 Mn and might require additional spend to increase capacities to the required level. For fill-finish they will be leveraging their existing dedicated hormone line which will require some incremental investments in storage/warehousing since the product needs to be stored at -18 to -20C.

In order to estimate the pricing for Gland, we looked at Moderna's cost of production. In 1QFY21, they reported \$1.7Bn sales from 102 Mn doses of their mRNA vaccine and a 11% COGS which translates to a production cost of ~\$1.8 per dose. They produce their vaccines internally as well through CDMOs. The India cost benefit in biopharma/vaccines manufacturing is ~40-50%. Assuming production costs for mRNA and Adenovirus vector vaccines are similar, Gland's production cost per dose will be ~\$1.0.

Based on margin profile of other vaccines and CDMO players, we believe Gland's EBITDA margins can be in the range of 35-40% which will be EBITDA neutral in the near term. Our recent conversations with the management indicate the same. This implies a pricing of ~\$1.5/dose for Gland. The deal with RDIF is not limited to India and Gland's production can be exported. Given the large demand for vaccines now which is not being met due to India export constraints, we expect Sputnik V to retain a healthy demand right into 2022. Irrespective of the demand Gland has a "take or pay" agreement with RDIF and their revenues are secure. We estimate Gland will be ready to ship products by 3QFY21. Exhibit 45 shows our revenue estimates from this opportunity.

EXHIBIT 45: **Gland revenues from vaccine opportunity**

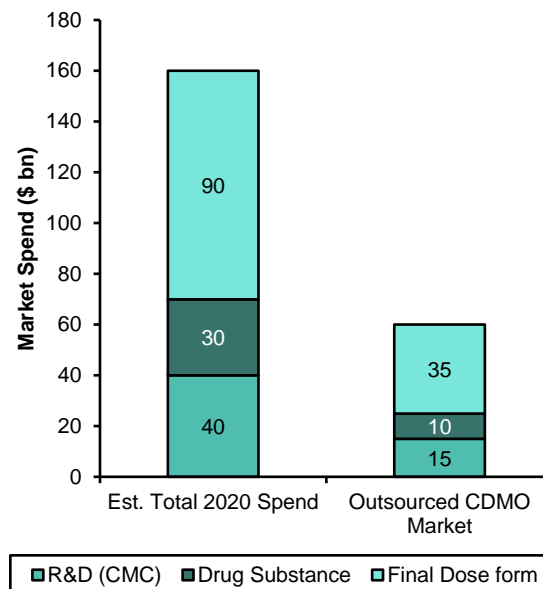


Source: Bernstein estimates and analysis

Assuming the COVID vaccine opportunity remains restricted to a one-time deal with RDIF (evidence on booster requirement is still emerging. See our perspectives [here](#)), Gland has announced its intention to repurpose these capacities to target contract manufacturing opportunity in the biosimilars market. Fosun has extensive capabilities in biosimilars which Gland can leverage. Through Shanghai Henlius (subsidiary) Fosun has 2 biosimilars commercialized in the China market and has 19 more under development. Gland could potentially contract manufacture for Fosun initially before expanding further. Their existing partners like Hospira, Fresenius Kabi, Sagent are developing a portfolio of biosimilars and we believe turning the vaccine opportunity into a recurring revenue stream will not be demanding for Gland.

The global CDMO market for large molecules is \$160 Bn growing at 7-8% (Exhibit 46). Future growth drivers are secure with steady R&D spend, increasing share of small biopharma in research who need the capabilities and capex that CDMOs bring and steady expiry of biologic brands creating opportunities for biosimilars.

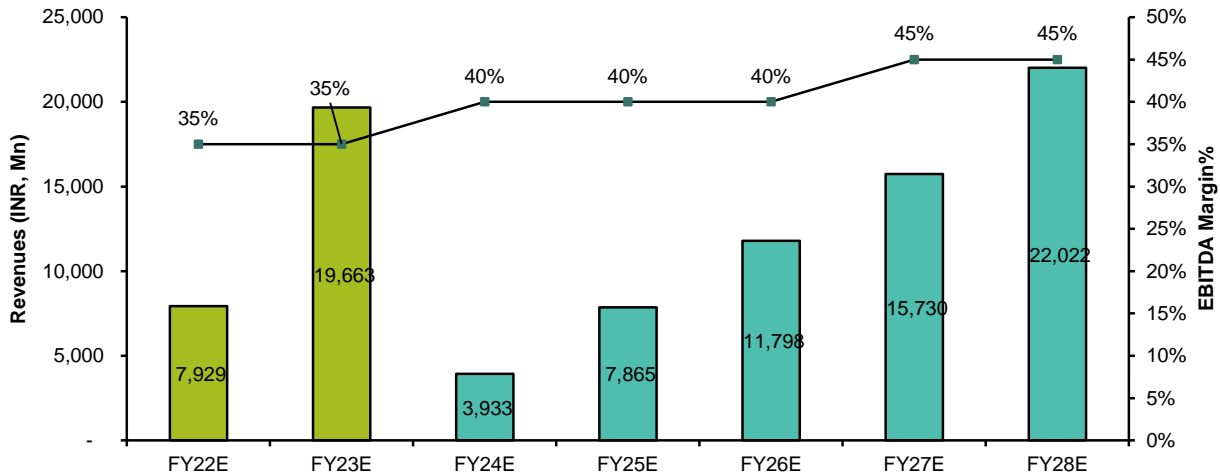
EXHIBIT 46: **Global CDMO Market**



Source: Catalent investor presentation, Bernstein analysis

Gland intends to focus on contract manufacturing initially and then expand into contract development as well. We estimate that Gland will be able to utilize the new capacity and will slowly ramp up CMO business after the Sputnik deal ends. Exhibit 47 shows our revenue and margin estimates for the vaccine/biosimilars CMO business.

EXHIBIT 47: **Gland Revenue & EBITDA Margin for Vaccine/Biosimilar Business**

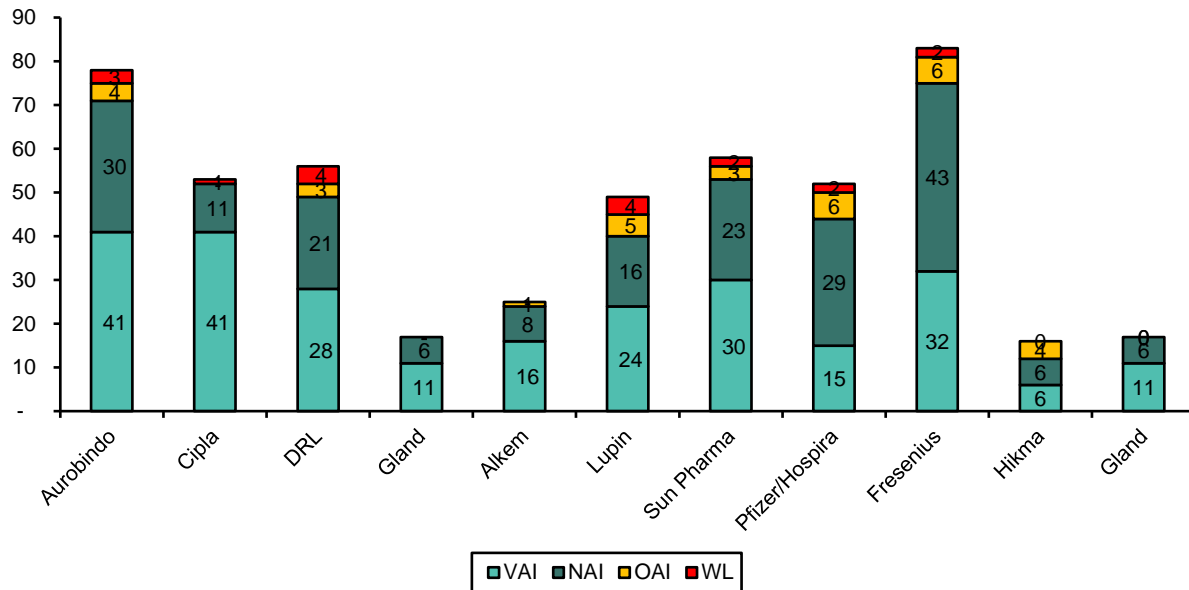


Source: Bernstein estimates and analysis

OUTSTANDING COMPLIANCE TRACK RECORD

Across markets and in the US in particular, supply reliability is key to operating in injectables. Most injectables are administered in a hospital setting and are "medically necessary". Supply issues can have irreversible consequences on patient outcomes. Gland stands out compared to peers on their compliance track record. Their facilities are inspected >30 times in a normal year by regulatory authorities and customers. In the US, Gland's received no OAI's/WLs (Official Action Indicated/Warning Letter) so far. Exhibit 48 shows Gland's track record compared to peers.

EXHIBIT 48: Gland's compliance track record compared to its peers



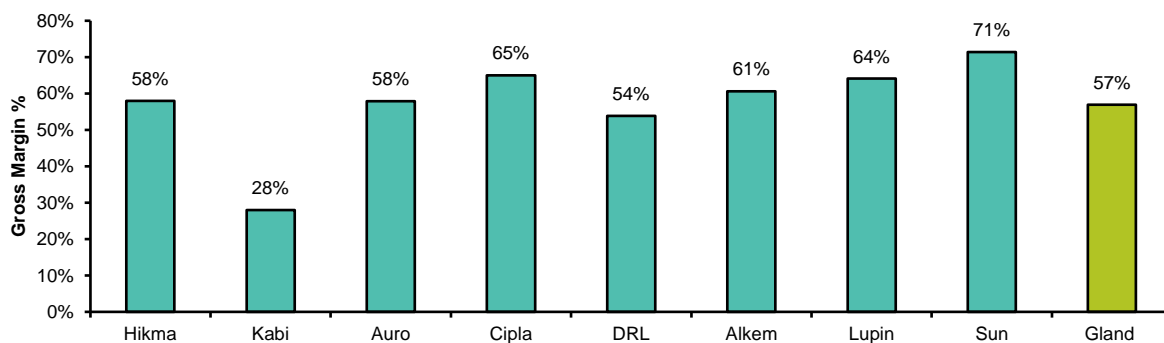
Source: FDA compliance database, Bernstein analysis

Having inspected their facilities personally as a customer (in my previous role), I can say with credibility that they have built a strong manufacturing and quality function. They have benefited from absorbing best practices from the customers and also from the high volume of audits in a year. In our view, this edge is sustainable and augurs well for their growth.

BUSINESS MODEL POSITIONED FOR HIGHER OPERATING LEVERAGE

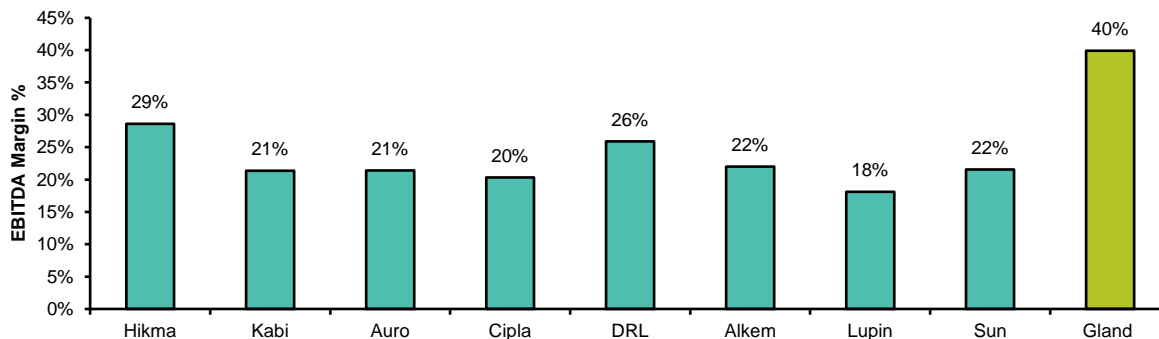
Gland enjoys superior margins and return ratios compared to Indian and global peers (Exhibit 49, Exhibit 50 & Exhibit 51).

EXHIBIT 49: Gross margin - Peer comparison 2020



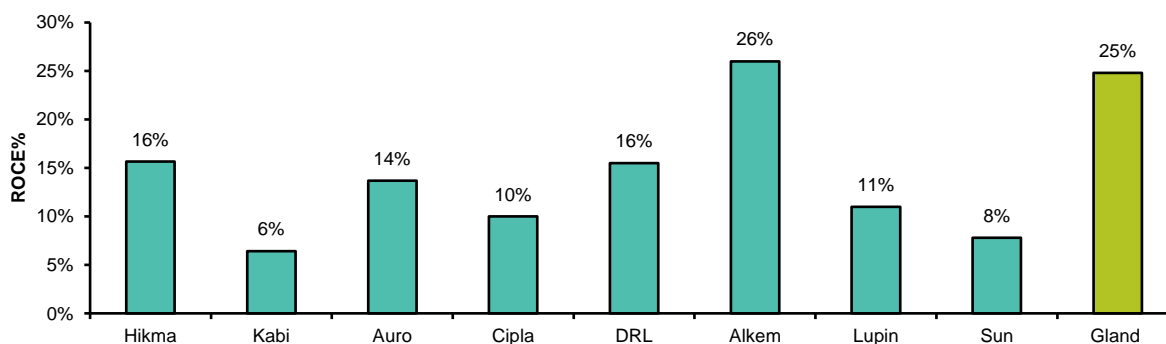
Source: Company Reports, Bernstein analysis

EXHIBIT 50: **EBITDA margin - Peer comparison 2020**



Source: Company Reports, Bernstein analysis

EXHIBIT 51: **ROCE - Peer comparison 2020**



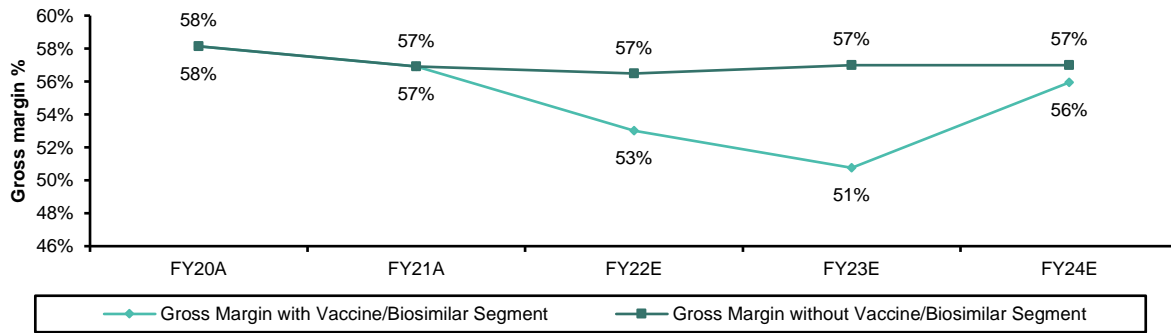
Source: Company Reports, Bernstein analysis

Gland's business model is well positioned to drive operating leverage. ~70% of manufacturing costs are fixed in injectables and utilization is therefore key. Gland is able to drive the same by selling the same molecule to multiple players and capturing higher volume share. They will be able to drive even higher utilization as they scale up presence in markets outside the US.

In addition, R&D costs are relative lower at 3-4% of sales. There is no requirement of bioequivalence studies for Q1Q2 (qualitative and quantitative sameness) injectables and in a lot of partnered ANDAs, R&D expenses are paid for by the partner.

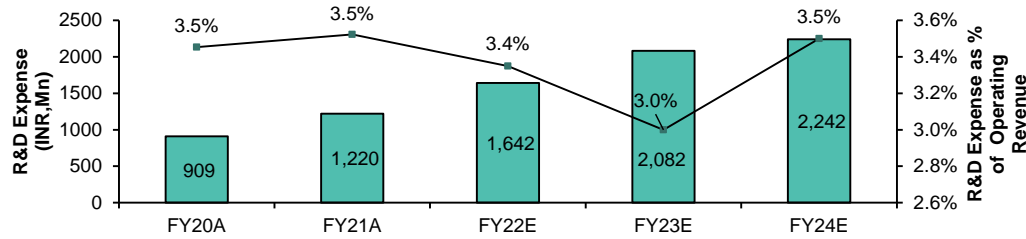
We believe Gland will be able to improve their gross margins by 100-150bps from their efforts of developing more APIs and backward integration. However, we expect a slight downward pressure from expansion into lower margin emerging markets as well as when they slowly scale up in the biosimilars CMO business. Exhibit 52 shows our estimates for gross margins. The blip in FY23 is due to the lower GM we estimate for Sputnik sales. We expect R&D costs to remain in the 3-4% range. While the company is scaling up on complex generics which require clinical trials, most of these additional expenses will be borne by the partner. Exhibit 53 shows our R&D estimates.

EXHIBIT 52: **Gland – Gross margin estimates**



Source: Company Reports, Bernstein estimates and analysis

EXHIBIT 53: **Gland – R&D estimates**

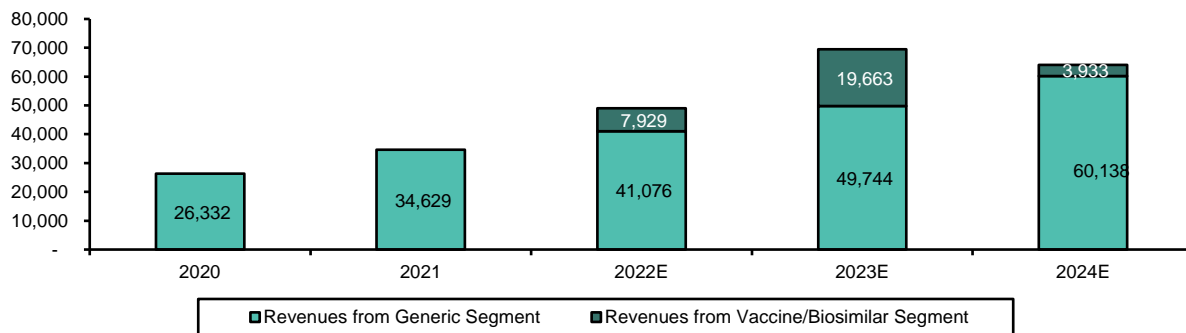


Source: Company Reports, Bernstein estimates and analysis

FINANCIAL PROJECTIONS

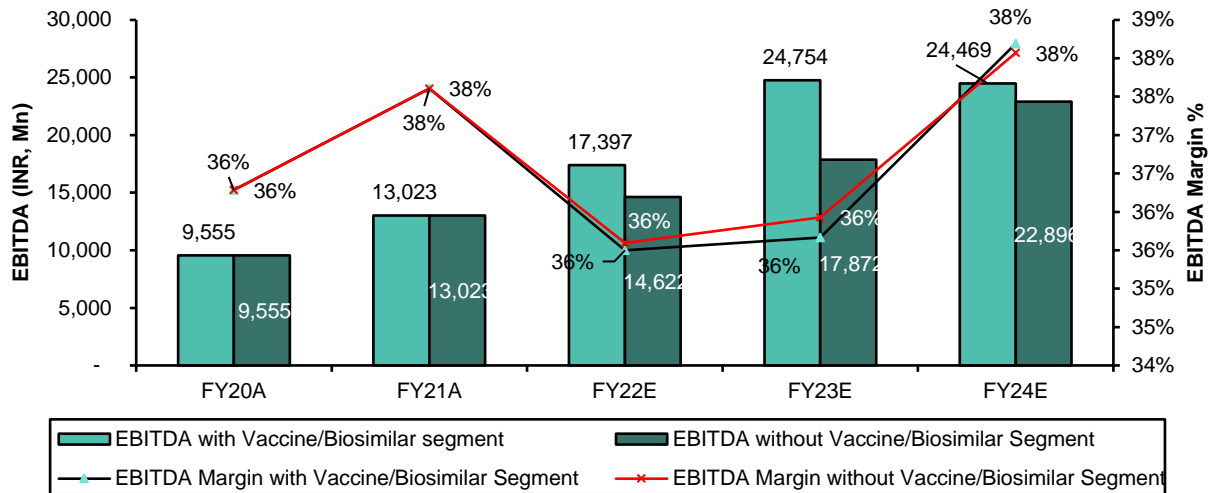
Exhibit 54 – Exhibit 58 shows our estimates for topline, bottom-line and return ratios.

EXHIBIT 54: **Gland revenue estimates**



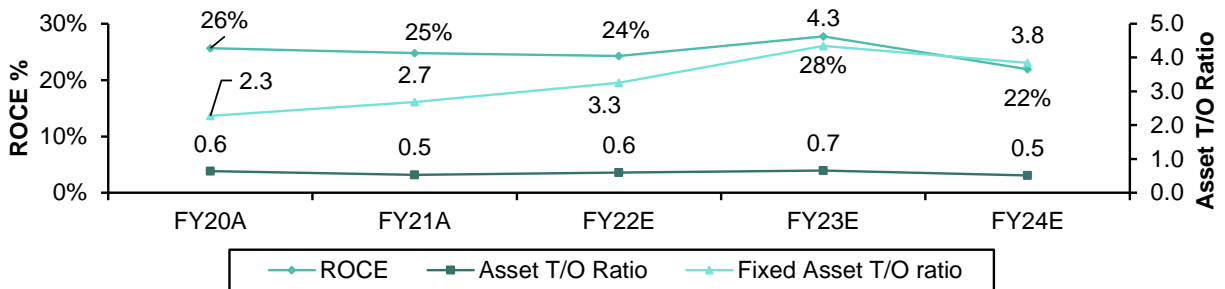
Source: Company Reports, Bernstein estimates and analysis

EXHIBIT 55: **Gland EBITDA estimates**



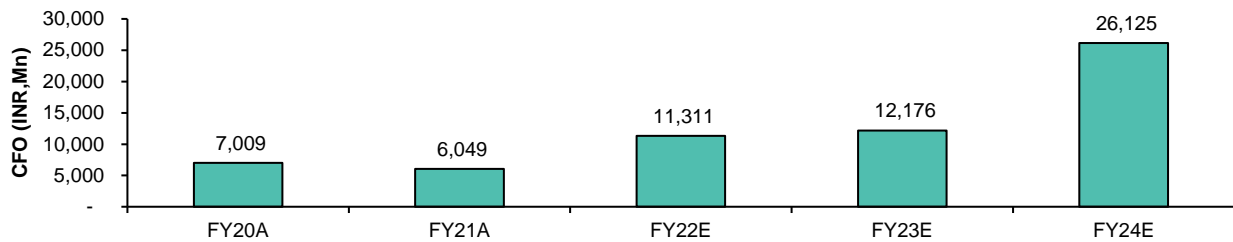
Source: Company Reports, Bernstein estimates and analysis

EXHIBIT 56: **Gland ROCE & Asset T/O ratios**

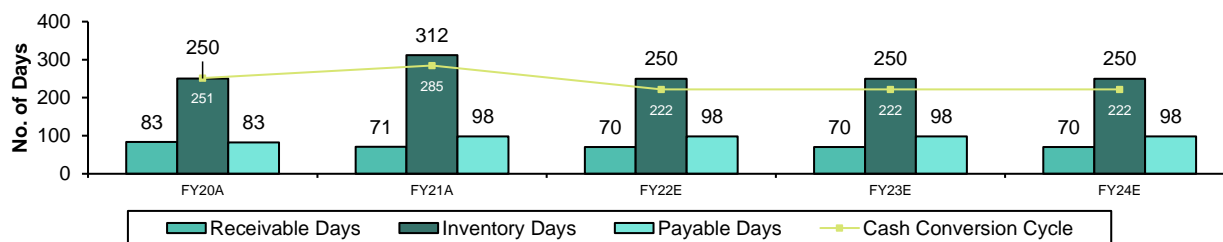


Source: Company Reports, Bernstein estimates and analysis

EXHIBIT 57: **Gland cash from operations**



Source: Company Reports, Bernstein estimates and analysis

EXHIBIT 58: **Gland cash conversion cycle**

Source: Company Reports, Bernstein estimates and analysis

Exhibit 59 shows our estimates compared to consensus. We believe our higher estimates are driven by our inclusion of the China growth opportunity and a probabilized recurring profit stream from the new investment in vaccine/biosimilars manufacturing.

EXHIBIT 59: **Bernstein estimates Vs consensus**

		FY20	FY21E	FY22E	FY23E	CAGR
Sales (₹ Mn)	BERN	27,724	35,977	52,158	73,410	38%
	Cons.	27,724	35,977	42,311	51,802	23%
	Diff.		0	9,847	21,608	
	Diff. (%)		0%	23%	42%	
Gross Margin	BERN	58.1%	56.9%	53.0%	50.8%	
	Cons.	58.1%	56.9%	57.5%	57.6%	
	Diff.		0%	-5%	-7%	
EBITDA Margin	BERN	39.5%	39.9%	39.4%	39.2%	
	Cons.	39.5%	39.9%	37.5%	38.0%	
	Diff.		0%	2%	1%	
EPS (₹)	BERN	49.88	62.99	90.95	128.48	37%
	Cons.	49.88	62.99	76.60	94.75	24%
	Diff.		0	14	34	

Source: Bloomberg, Bernstein estimates and analysis

VALUATION

We value Gland using an SOTP approach with the existing base business of injectable generics value using 1-year forward PE and the new vaccine/biosimilars business using DCF. We value the base business at 35x FY23 EPS and the DCF for the vaccine business contributes ₹ 708/share. We arrive at a target price of ₹ 3,824, an implied multiple of 29.8x FY23 EPS and an upside of 19%.

Our PE multiple values Gland at a premium to Indian peers and at a discount to Divi's Labs and Lonza. Compared to India peers Gland has a more resilient base portfolio, multiple growth avenues and higher operating leverage. But Divi's, Catalent and Lonza boast of innovators as customers and Catalent and Lonza are also targeting the attractive innovative biopharma and vaccines space.

We have also built a complete DCF model for all the businesses. We assume a WACC of 11% and 5% terminal growth which values the company at ₹ 4,269.

EXHIBIT 60: Financial summary

Income Statement					Balance Sheet				
	FY21A	FY22E	FY23E	FY24E		FY21A	FY22E	FY23E	FY24E
Revenue	35,977	52,158	73,410	69,129	Cash & Equivalents	30,052	38,059	47,976	71,973
Generics	34,629	41,076	49,744	60,138	Inventories	12,752	15,768	23,405	19,328
Vaccine/Biosimilar	-	7,929	19,663	3,933	Trade Receivables	6,710	9,398	13,311	12,288
Other Income	1,348	3,154	4,004	5,058	Other current assets	1,717	2,445	3,457	3,208
COGS	14,919	23,021	34,171	28,219	Current assets	51,231	65,671	88,149	106,796
Gross Profit	21,058	29,137	39,240	40,910	PP&E	12,913	15,069	15,983	16,691
Operating expense	6,687	8,586	10,482	16,440	Other non current assets	817	1,169	1,632	1,528
EBITDA	14,370	20,551	28,758	24,469	Total Assets	64,961	81,909	105,764	125,065
Finance cost	34	38	51	48	Payables	4,007	6,183	9,177	7,578
D&A	988	1,104	1,288	1,366	Short term debt	167	167	167	167
PBT, before exceptionals	13,349	19,409	27,419	28,113	Other current liabilities	951	1,233	1,620	1,528
Exceptional items	-	-	-	-	Current liabilities	5,125	7,582	10,964	9,273
PBT	13,349	19,409	27,419	28,113	Long term debt	9	9	9	9
Tax	3,378	4,912	6,940	7,115	Other non current liabilities	794	788	782	776
Profit share of Minority interest	-	-	-	-	Total Liabilities	5,928	8,379	11,755	10,058
Net Income	9,970	14,497	20,479	20,998	Shareholder equity	164	164	-	164
Shares O/S	159,395,581	159,395,581	159,395,581	159,395,581	Minority Interest	-	-	-	-
EPS	62.99	90.95	128.48	131.73	Total liabilities & equity	64,961	81,909	105,764	125,065
DPS	-	-	-	-					
Cash Flow Statement					Key Metrics				
	FY21A	FY22E	FY23E	FY24E		FY21A	FY22E	FY23E	FY24E
Cash from operations	6,049	11,311	12,176	26,125	Revenue growth	31.5%	41.5%	41.6%	(7.7%)
Change in NWC	(4,358)	(4,327)	(9,643)	3,713	EBITDA growth	31.3%	43.0%	39.9%	2.7%
Cash used in investments	(15,245)	(3,260)	(2,202)	(2,074)	Net Income growth	29.0%	45.4%	41.3%	2.5%
Capex	(2,288)	(3,260)	(2,202)	(2,074)	EPS growth	26.3%	44.4%	41.3%	2.5%
Cash from financing	12,385	(44)	(57)	(54)	EBITDA Margin (w/o Other Income)	37.6%	35.5%	35.7%	38.2%
Debt repayment, net of borrowings	(10)	(6)	(6)	(6)	Net Income margin	27.7%	27.8%	27.9%	30.4%
Dividend	-	-	-	-	ROCE	24.8%	24.3%	27.7%	21.9%
Net Increase in Cash	3,188	8,007	9,916	23,997	Inventory days	312	250	250	250
FCF	(9,814)	8,052	9,973	24,051	Receivable days	71	70	70	70
FCF/EBITDA	(68%)	39%	35%	98%	Payable days	98	98	98	98
					NWC days ex cash	163	140	145	135
Valuations					Performance				
	FY21A	FY22E	FY23E	FY24E		Shareholding Pattern			
Current P/E	52.3x	36.0x	25.5x	24.8x	Revenue CAGR ('18-'21)	29.1%	Fosun	58.25%	
Target price implied P/E	60.7x	42.0x	29.8x	29.0x	Net Income CAGR ('18-'21)	45.9%	FII	11.90%	
EV/EBITDA	35.4x	24.7x	17.7x	20.8x			DII	10.20%	
FCF Yield	-1.9%	1.5%	1.9%	4.6%	Revenue CAGR ('21-'24)	24.3%	Others	19.65%	
Dividend Yield	0.0%	0.0%	0.0%	0.0%	Net Income CAGR ('21-'24)	28.2%			

Source: Company reports, Bernstein estimates and analysis

DISCLOSURE APPENDIX

BERNSTEIN TICKER TABLE

Ticker	Rating	31 May 2021			TTM Rel. Perf.	EPS Reported			P/E Reported			
		Closing Price	Target Price			2021A	2022E	2023E	2021A	2022E	2023E	
GLAND.IN	O	INR	3,153.85	3,824.00	NA	INR	62.99	90.95	128.48	50.07	34.68	24.55
MXAPJ			698.55				30.46	40.01	45.79	22.94	17.46	15.26

COVERAGE INITIATION

O - Outperform, M - Market-Perform, U - Underperform, N - Not Rated

MXAPJ base year is 2020.

VALUATION METHODOLOGY

India Healthcare

We use sum of the parts valuation approach with DCF to value the specialty & biosimilar businesses and 1-year forward PE for the generics business

Gland Pharma Ltd

We value the base generic injectables using 1-year forward PE and the vaccine/biosimilars business using DCF.

RISKS

India Healthcare

Risks to the pharmaceutical industry include a) risk of pipeline products failing or getting delayed due to FDA actions, b) possibility of adverse litigation outcomes delaying key generic launches, c) cGMP non-compliance in manufacturing facilities leading to FDA actions like Warning Letters or Import Alerts to plants, d) product recalls or other product safety issues, e) pricing pressure from market factors or price control regulations, f) supply and logistics disruptions and f) healthcare regulations and reforms.

Gland Pharma Ltd

Downside: 1) Higher competition in the base portfolio 2) Adverse FDA audit outcomes

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- Nithya Balasubramanian and her spouse maintain long positions in Cipla Ltd. and Lupin Ltd. Ms. Balasubramanian was employed by Cipla from September 2013 through August 2019.

12-Month Bernstein Rating History as of 05/30/2021

Ticker Rating Changes

GLAND.IN

Rating Guide: O - Outperform, M - Market-Perform, U - Underperform, N - Not Rated
Rating Actions: IC - Initiated Coverage, DC - Dropped Coverage, RC - Rating Change

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