



“Gland Pharma Limited Q4 FY22 Earnings Conference Call”

**May 19, 2022**



**MANAGEMENT: MR. SRINIVAS SADU – MD & CEO**  
**MR. RAVI SHEKHAR MITRA - CFO**  
**MR. SUMANTA BAJPAYEE – VICE PRESIDENT,**  
**CORPORATE FINANCE AND INVESTOR RELATIONS**



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**Moderator:**

Ladies and gentlemen, good day and welcome to Gland Pharma Limited Q4 FY2021-22 Earnings Conference Call. As a reminder, all participant lines will be in the listen only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing \* then 0 on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Sumanta Bajpayee - Finance and Investor Relations, Gland Pharma Limited. Thank you and over to you, Mr. Bajpayee.

**Sumanta Bajpayee:**

Thank you. A warm welcome to Gland Pharma's Earnings Conference Call for fourth quarter and financial year ended 31st March 2022. I have with me, Mr. Srinivas Sadu - Managing Director & CEO; and Mr. Ravi Shekhar Mitra - our CFO, to discuss business performance and to answer queries during the call. We will begin the call with business highlights and overview by Mr. Srinivas Sadu, followed by financial outlook by Mr. Ravi Shekhar Mitra. After opening remarks from the management, Operator will open the bridge for Q&A session.

Before we proceed with the call, please note, some of the statements made in today's discussion may be forward-looking and based on management estimates. This must be viewed in conjunction with the risks and uncertainties involved in our business. The safe harbor language contained in our press release also pertains to this conference call. This call is being recorded and the playback shall be made available in our website shortly after the call. The transcript of the call will be submitted to the stock exchanges and made available on our website as well.

I will now hand over the call to Mr. Sadu for his opening remarks. Thank you, all. Over to you, Mr. Sadu.

**Srinivas Sadu:**

Thank you, Sumanta. Good evening, everyone. Thank you for joining our earnings call for fourth quarter and full year FY22. My best wishes to all our shareholders, analysts and their families. The industry continues to face heightened supply chain disruptions, not just delay in API supplies, but also primary packaging components. There was a considerable escalation of freight costs, utility costs and several input material costs. Efforts were made to minimize the impact of these disruptions by qualifying new suppliers as well as optimizing our production planning. We remain committed to maintain our business resilience in these challenging times. Despite the ongoing disruptions, our business performance continues to remain strong.

We closed this quarter Q4 FY22 with the revenue of Rs. 11,030 million that is a year-on-year revenue growth of 24% for the quarter Q4 FY22. Our full year FY22 revenue stood at Rs. 44,007 million, which is a growth of 27% over FY21. Our PAT stood at Rs. 2,859 million for the quarter. This is an year-on-year PAT growth of 10% for the quarter. Our full year FY22 PAT stood at Rs. 12,117 million, a growth of 22% for the full year FY22 over FY21. We have generated Rs. 7,908 million of cash flow from operations in FY22. Our broad portfolio differentiated business model, and strong execution capabilities have helped us deliver strong business performance during the year.



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I laid down four key focus areas for the company at the beginning of this fiscal year. Regrouping and consolidation, with limited physical audits, we took the opportunity this year to complete extensive knowledge sharing across our manufacturing sites and strengthen the centralized quality function. We are very well prepared to handle any upcoming regulatory audit at any of our sites.

Diversification of product portfolio; we made further investments in our R&D and we are able to make 29 ANDA filings during FY22 as compared to 20 ANDA filings during FY21. Important to note that we initiated filings for our complex portfolio during the year, we made three hormonal filings and one complex peptide filing during the year, which have market size of \$1 billion. We also focused on ensuring timely new launches in the market. To highlight a few, we commercialized our Penem portfolio during the year, we launched Ertapenem and Meropenem. We also launched other key products, including Fosfarnet, Norepinephrine and launched a total of 44 product SKUs in our core markets during the year.

In FY22, upon excluding capital R&D expenditure, the R&D expenses stands at 4.4% of our revenue for the period in line with our historical trend. As on 31st March 2022, we along with our partners have 311 ANDA filings in the US and 1,557 product registrations globally.

Our human capital was further strengthened this year. We have focused on filling any gaps in skill set and also ensuring learning from experience are well distributed across the organization.

In terms of our manufacturing infrastructure, we have not just increased more capacity ensuring debottlenecking of critical areas but have also worked on improving yields for products on existing lines. The new lines commissioned will support our complex injectables development pipeline for suspensions, hormones and emulsions-based products. We hence ensure our manufacturing cost per unit is among the lowest in the industry, despite maintaining high quality standards. All our plants continue to remain approved by US FDA.

Not taking much of your time, let me quickly run you through our business highlights across various geographies. Our Rest of the World markets accounted for 17% of our Q4 FY22 revenue and we have seen 32% year-on-year growth in revenues for the quarter. Our full year FY22 revenue for these markets stood at Rs. 8,481 million, a growth of 55% over FY21. Our key markets continue to remain MENA, LatAm and APAC. We registered our products Dexmedetomidine, Ertapenem and Tigecycline in new geographies during the quarter. Enoxaparin Sodium was a key contributor to growth for the Rest of the World Markets during the year.

Our core markets, namely, US, Canada, Europe and Australia remained strong during the year despite market challenges. Our core markets accounted for 64% of revenue during Q4 FY22 as against 74% during Q4 FY21. We have seen 8% year-on-year growth in revenues for the quarter. Our full year FY22 revenue for our key markets stood at Rs. 29,248 million, a growth of 16%



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over FY21. US market continues to surprise us with high price pressure on one side and at the same time, encountering several drug shortages.

While our US business grew by 13% in FY22 over FY21, the launch pipeline remains robust for the coming year. The key products helping us achieve this growth include Micafungin, Ketorolac Tromethamine, Heparin Sodium, Ziprasidone and Dexmedetomidine.

India market accounts for 18% of our Q4 FY22 revenue. Our full year FY22 for India stood at Rs. 6,278 million, a growth of 60% over FY21, primarily on account of volume growth of existing products. Our key launches include Caspofungin Acetate and Enoxaparin Sodium multi-dose cartridge with pen device during the year.

We faced setback on the vaccine front initially with delayed lifting of embargo on vaccine exports and later the geopolitical situation in Ukraine didn't help our cause. As updated in our last call, we have received export NOC and have also validated the commercial scale batches for Sputnik Light. Meanwhile, we have initiated work towards repurposing this facility to initiate bio-similar CDMO work. We are aggressively pursuing collaboration opportunities with established biologic players with some of the sites visits already scheduled. We are working towards complementing our existing business with new growth avenues and we are hopeful to maintain business resilience in this challenging environment.

I once again wish everyone, good health. I would like to now hand over the call to our CFO, Mr. Ravi Mitra who will share details about our financial performance for the quarter. Thank you.

**Ravi Shekhar Mitra:**

Thank you, Mr. Sadu. Good evening, ladies and gentlemen. Thank you very much for attending our fourth quarter and financial year ending 2022 earnings call. Our earnings presentation has been uploaded on the website. Let me begin with sharing the financial performance for fourth quarter and financial year 21-22.

For the fourth quarter, we have reported revenue of Rs. 11,030 million, which is a 24% growth year-on-year basis. Revenue from operations for the fiscal 2022 stood at Rs. 44,007 million, a year-on-year increase of 27%. The key drivers for this growth were increase in volume of existing portfolio and new product launches. In terms of bifurcation of revenue during the FY22 as per markets, core markets comprising of the US, Europe, Canada and Australia has contributed 67%, followed by ROW markets adding 19% of revenue. India contributed balance 14% of the revenue from operations.

Our core markets have seen a growth of 8% during fourth quarter of FY22 as compared to same period of last financial year. It has registered 16% growth during the financial year. ROW markets managed to maintain robust historical growth momentum and registered a 32% growth for Q4 FY22 and 55% growth on full-year basis. India market grew by 137% for Q4 FY22 and



60% for FY22. In domestic markets, we have managed to grow both in our B2C and B2B business.

Other income includes foreign exchange gains on operations of Rs. 272 million for the fourth quarter and Rs. 792 million for the full year ended March 2022. We have reported an EBITDA of Rs. 4,136 million in Q4 FY22 compared to Rs. 3,749 million, which is an increase of 10% compared to the same period last financial year. EBITDA margin for Q4 FY22 stood at 35% as compared to 40% for the same period of previous financial year. EBITDA for the full year ended March 22 was Rs. 17,341 million compared to Rs. 14,370 million for the previous financial year, a growth of 21%. We have reported EBITDA margin for FY22 at 37% as compared to 40% to the previous financial year. We have managed to curtail the full impact of reduction in gross margin and increase in some of the expenses due to higher operating leverage.

Power and fuel cost has gone up by 30% in Q4 FY22 and 27% in full year FY22, due to increase in power tariff and oil , gas prices. Additionally, during Q4 and FY22, we have incurred one-time legal and professional fee for our ongoing acquisition evaluation, amounting to about Rs. 55 million for Q4 and Rs. 70 million for the full year FY2.

The total R&D revenue expense for the financial year 22 was Rs. 1,932 million compared to Rs. 1,199 million of the previous financial year, which is an increase of 61%. The increase in R&D spend will help us to maintain strong future pipeline and strengthened capabilities. It stands at 4.4% of the revenue for the full year FY22. Revenue R&D expense for the fourth quarter was Rs. 443 million, which is 4% of revenue compared to Rs. 302 million in the previous financial year. The increase in R&D revenue expenses due to higher number of ANDA and DMF filings and increased expenditure on complex products. We have commissioned our new R&D facility during financial year 22 expanding our R&D capabilities.

Our net profit for the fourth quarter was Rs. 2,859 million, a growth of 10% compared to Q4 FY21. During the financial year 2022, our PAT was Rs. 12,117 million, which is an increase of 22% as compared to last year. We have reported PAT margin of 24% for Q4 FY22 and 26% for FY22. Our effective tax rate remains at about 25% in fourth quarter and for the fiscal year 2022.

Cash conversion cycle stood at 187 days for the financial year 2022, as compared to 192 days as of last financial year-end. The improvement was due to reduced inventory level. It has also helped us achieve better cash flow from operations. Total CAPEX incurred during the financial year ended March 31st 2022 was Rs. 5,221 million, used for increasing API and formulation capacities.

During the year, we have installed three liquid vial lines and four lyophilizers and one pre-filled syringe line in our Pashamylaram facility. New lines will support our complex injectables development pipeline in areas of suspensions, hormones, and emulsions. One more API block



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was completed in our Vizag plant. We are building sufficient production capacity to support our next organic growth demand.

Our ROCE on ex-cash basis as on March 31, 2022 stood at 33% and fixed assets turnover remained stable at 2.8 times for FY22. As of March 22, we had total Rs. 34,483 million of cash, which we intend to utilize for CAPEX and to fund our organic and inorganic growth strategies.

With this, I would request the moderator to open the lines for questions. Thank you.

**Moderator:** Thank you very much. We will now begin the question and answer session. The first question is from the line of the Sudarshan Padmanabhan from JM Financial. Please go ahead.

**Sudarshan Padmanabhan:** Sir, my question is, we heard a lot about needle shortages and across other companies as well some of the consignments getting pushed to the first quarter because of that, I just wanted to know, in the fourth quarter, I mean has that impacted any kind of products for us and can you quantify if at all there has been any kind of shipment delay to the first quarter because of this?

**Srinivas Sadu:** Yes, it did. I did mention last quarter as well, there is a shortage of syringes supplies and if you look at our US sales in last quarter, the growth is lesser compared to the normal run rate. That is primarily because of the syringe shortages, which we couldn't export because of the shortages. What we did was, we got some alternate source syringes, but we can't really change for the US market, so we utilized those syringes for our domestic market and other markets and that is one of the reasons you see we have larger third-party sales in the domestic market, where we have utilized syringes from other suppliers, where actually we can supply to the local market. So, there was an impact, but the end markets don't suffer because of our model. The companies do have the pipeline, but it did impact in terms of export last quarter and indirectly, it is also impacting the cost, because we are airlifting for the syringes to meet the demand and that is one of the reason, why at the gross margin level, there is an impact of that as well because the logistic costs gone up when we are importing this by air.

**Sudarshan Padmanabhan:** And sir what could be the impact of that, I mean if you can quantify it and whether this issue has been solved, because it has been running for the last two quarters?

**Srinivas Sadu:** I would say, I can't put a number to it yet, but we are catching up I think this quarter, next quarter. There is a backlog of orders, what we need to supply. Still, we are not in stage where the pipeline is dry for our partners, so but there is a backlog of orders for us. So, this quarter, there will be still shortage of about 3 million to 4 million syringes, but I think by next quarter everything will be on track in terms of the syringes they have promised to deliver.

**Sudarshan Padmanabhan:** And sir, on the cost front, I mean you talked about the gross cost as well as the cost impacting on the power and fuel and other expenses, but if I am looking at consistently. I mean, our gross margins have been coming down from 55% to 50% and so as the EBITDA margin. Now, going



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forward, I mean are we going to see in an improvement from the current levels, given that fourth quarter was a consortium of several issues, including shortage of syringes and cost escalation. I mean, can we expect some kind of retrieve in terms of some kind of price increase and some kind of normalization and basically no margins increasing going forward?

**Srinivas Sadu:**

So, in my previous calls, also I said, our gross margin, the way you look at is a little different than the front-end company and also because of a business model, a quarter where we have a larger portion of contract manufacturing, your gross margin looks better. That is one area. If you look at our business last quarter, there is lesser contract manufacturing business. Second, the US portion of our business is lower because of the impact where the margins are higher for us, but if you look at just the US business itself in fact our gross margins have increased over previous, when you look from the material point of view. The other key thing is in our gross margin, there is also a component of logistic cost, because when we bill the revenue, it includes the transfer price plus a profit share. Profit share element includes the cost of logistics that deduct that and distribution costs and then they share the profit and that is actually billed as revenue. So, unlike other companies where everything is going at the bottomline, not in the gross margin level for us, the distribution costs and also the logistic costs, what our partner is importing that also gets into the gross margin level. At least what we share, right, I mean 50% or 60% depending on our profit share model that also we are sharing, so that is deducted and then the profit share will be shared with us. That way, there is an impact on the gross margin. So, the way we look at gross margin should be different for Gland just because of the model we adopt and the margin, there is a pressure because of the logistic cost, which is actually lying for all the US market. It is also lying as part of gross margin. So, it should come back to normalized margins as well as EBITDA once I think the external environment becomes little bit better.

**Sudarshan Padmanabhan:** At this environment, I mean on the sales, you did mention that going, you are looking at 20% to 25% kind of CAGR and I mean, are we looking at any kind of a margin guidance that you would like to give, I mean from FY22 base?

**Srinivas Sadu:**

Internally, like I said, gross margin is not a criteria for us, but at the EBITDA margin level, we always look at 35%-37% levels of EBITDA margins and at the PAT level around 25%. That is how we internally always look towards that.

**Sudarshan Padmanabhan:** And we are confident of delivering 25% growth that pipeline should be there?

**Srinivas Sadu:**

It all depends on the mix. So, I can't really give a growth guidance yet, but we try to grow, like historically what we have been doing on average, we will try to do that.

**Moderator:**

Thank you. Next question is from the line of Shrey Jain from Iroha Investment Management. Please go ahead.



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**Shrey Jain:** On the vaccine, you mentioned that there is a repurpose of the facility that is being planned, wanted to ask two questions on this? One, was there any kind of write-off on the vaccine business given that we had some commercial batches?

**Srinivas Sadu:** So, we have not done any fill finished batch, other than the validation batches, so that will be very small quantities. So, as of now, there is no write-off quantities yet, whatever we bought are in terms of bags and all that, it can be used for the biosimilar production as well. So, as of now, there is no write-off of that.

**Shrey Jain:** Second question on the vaccine front was on the timeline as well as the cost for repurposing these facilities, does that entail some timeline? Or would that be immediately swappable, just wanted to visualize that?

**Srinivas Sadu:** So, when we say repurposing, whatever lines we have installed because we have not gone for commercial production, so that nothing much involved in terms of cleaning up. One line, we need to clean up because they have taken validation batches, so that doesn't involve too much of expense. So, already we have started discussing with some of our partners and a couple of visits have already been done. So, hopefully pretty soon should start some work, at least the preliminary work will be starting soon.

**Shrey Jain:** And these will be repurposed to biologics, that is right understanding, right, bio-similar?

**Srinivas Sadu:** Yes, bio-similar and biologics front, yes.

**Shrey Jain:** My other question was on the China, NMPA inspection, you mentioned in the last quarter, there would be some sort of update you would be able to give us on the exports, is there something that you could talk about?

**Srinivas Sadu:** Still because of the shutdown, we are not getting any dates on them yet, but we continue to develop products for that, and we are going to file as planned, but from the inspection perspective still because it is not opened yet, we don't have a date yet from them.

**Shrey Jain:** And my last question again from the China front as well, on bio-similar any kind of headway in terms of discussion between parent entity or any other entity to kick start bio-similar in FY24 like you had guided for?

**Srinivas Sadu:** Yes, so that has been ongoing, and I think we will be doing some kind of work as a subsidiary of the parent. So, while we are working with external companies to collaborate, we are also working with the internal subsidiaries.

**Moderator:** Thank you. The next question is from the line of Kartik Mehta from Klay Capital. Please go ahead.





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**Kartik Mehta:**

Just on the part that you mentioned at the start of the call about the shortages, which you see, I am just curious to understand the reasons which are there now in the US, is it supply of raw material, or is it due to the renewed FDA actions across as inspection start? That is the first part of the question and how much percentage of your portfolio now, if you can probably help us is under that list as per the US FDA?

**Srinivas Sadu:**

So, the shortages what I talked was nothing to do with the FDA, mostly, it is the manufacturing sites in the US, there are various reasons, for example, I was talking about components, whether it is vials or stoppers and some of the process materials like tubing, filters. So, most of the supplies were going towards vaccine manufacturing and so, it got diverted to that. That is one of the reason. So, there is a lot of backlog for them to supply to the regular injectable manufacturers. So, the lead times have really gone bad for most of these components. So, that is one of the reason we are quickly trying to identify other manufacturers who can do it. Some, it is easier to change the suppliers, but some difficult depending on the technicality of the item what we are using for a particular product. This is one of the reasons, but there also reasons around the manufacturing issues happening at sites in US, whether it is labor shortage or reduced manufacturing days, so post-COVID, there have been some disruption in that. So, the capacity is actually there but output have come down drastically. So, I think last few quarters, we have been seeing that. So, we have been holding off a pretty good last, I would say, 5 to 6 months, the lead times were also high because we were having inventories, but it starting to impact few of our products, especially and this is mostly from the US manufacturers I would say.

**Kartik Mehta:**

And just that while we are on this, is this nature you explain that it would take a quarter or so for this to resolve, but in this case, are there options in your contract where pricing can be renegotiated in terms of this? And what is the overall outlook? I am just trying to understand from your experience in manufacturing, especially in injectables, if FDA inspections across the world do start full throttle and assuming we are able to maintain our track record? Do shortages increase across on manufacturing largely on injectables? Is it the right way to look at this?

**Srinivas Sadu:**

Well, I have not seen a case where the price have gone up in recent times, it always in spite of the shortages, still the prices are kind of normal, but at least it will not go down for sure, but the volumes are increasing for certain products, which we never thought it will increase because of the shortages. So, although the competition has gone up in injectables and like always said, people are exiting some of these products and while I am on the material shortages in fact FDA is aware of these, in fact, they have sent email few weeks ago, what are the components which are having an impact on supplies and because they want to discuss with the suppliers as well, so they are actively pursuing that because they are seeing more and more products getting in the shortage situation. We are seeing at least in some areas, we are seeing some development happening, it is just going to add some cost because we can't wait for them to be shipped by sea and lose the time. So, we are airlifting most of that which we had earlier bringing by sea. So, the margin pressure is there on that, but at least we should cater to the market and at least capture the demand when it is there and some of these contracts where other companies are not able to



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meet the demand and those contracts are getting converted to the companies who are supplying. We got a couple of contracts like that as well, so it is an opportunity to do that while the cost pressure is there.

**Kartik Mehta:** My last question if I may, what is the CAPEX plan for the next 3 years and in terms of, if you could specify which lines you will be investing in?

**Ravi Shekhar Mitra:** Yes, so we plan to spend Rs. 300 crores next year and about Rs. 250 crores a year after that. So, we are currently spending.

**Kartik Mehta:** Sir, you said Rs. 300 crores is FY23, right?

**Ravi Shekhar Mitra:** Yes.

**Kartik Mehta:** FY23 and Rs. 250 crores, okay.

**Ravi Shekhar Mitra:** Yes, so currently project which is online at Pashamylaram is our suite for complex injectables and expansion of a warehouse capability and few more lines including Bags lines, including Lyo addition in Penem, so these are basically the immediate CAPEX plan and in the API side also, we are expanding for increasing the capacity of Enoxaparin production. So, this will take care of our near 2 years CAPEX plan.

**Srinivas Sadu:** So, if you see, we have added almost 4 lines in the current year, we have increased from 24 to 28 lines, but we are still not able to meet demand of Penems, so we have a shortage of that, so we are trying to invest into that. Also Bags, we are 100% capacity utilized and we are not able to cater to the entire demand, so we have planned to invest into that as well. From the API perspective, if you see about a year ago, internal APIs were about 24%, 23% was internal, now it has gone to about 33%, 34% of revenue is coming from internal APIs and we continue to invest into that because at least the risk of the suppliers not supplying will go away, so substantial investments are going into that as well.

**Moderator:** Thank you. The next question is from the line of Kunal Dhamesha from Macquarie Capital. Please go ahead.

**Kunal Dhamesha:** So, the first one, we earlier alluded that by the COVID time that product mix shifted towards, COVID products like Enoxaparin, Rocuronium like products which are used in elective surgeries took ahead, so now with COVID normalizing, are we seeing that mix shift coming back to the elective surgery portfolios like Penems and antibiotic?

**Srinivas Sadu:** So, I would say, now the COVID portfolio has gone away about 2 quarters ago, the demand for products, but otherwise, rest of it is coming back slowly. Some of the products have not caught up like before, but I think the portfolio mix is getting back to the earlier days.



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**Kunal Dhamesha:** And is it fair to assume that those products typically have better margins than the COVID products like Enoxaparin?

**Srinivas Sadu:** Well, I think if you see the margin wise, all the new products will give a better margin, so whatever we launches, I think that is the key thing, which will give better margins than the old products coming back, because the competition also increased, but I won't say that those margins will go up. So, whatever the margins that were there pre-COVID that will continue, but I think products, what we are launching recent times, if you look at our growth over 9% to 10% comes from these new products and also the volume growth rate. I mean, if you look at last year 21% growth came from that, whereas the price actually has gone down by 2% or so. So, the price is still, I would say, similar or 1% or 2% lower, but I think the volume growth and new product launch growth, that is a key for us.

**Kunal Dhamesha:** And just one more logistic question, what was the profit share contribution this quarter?

**Srinivas Sadu:** About 10%.

**Moderator:** Thank you. The next question is from line of Amey Chalke from Haitong Securities. Please go ahead.

**Amey Chalke:** First question is related to staff cost, I don't know whether we have addressed it in the opening remarks, but it has gone sequentially by around Rs. 15 crore odd to Rs. 94 crore-Rs. 95 crores, any reason for this or is it related to the plant expansion we have done or is it the new base if you can explain?

**Srinivas Sadu:** The staff costs?

**Amey Chalke:** Yes.

**Srinivas Sadu:** It is a combination of both, one is the additional lines coming in, so recruitment has happened in those lines. The other is January is the time where we get the raise, so the increment impact is also there and the incentive quarter, so that is the impact you are seeing.

**Amey Chalke:** So, we should assume this as a new base, right?

**Srinivas Sadu:** Some incentive won't be there in every quarter, so that will go away.

**Ravi Shekhar Mitra :** So, the annualized basis if you see, the increment is normal as what we have been seeing and Mr. Sadu said, there is a headcount increase, so yearly basis that can be the rate.

**Amey Chalke:** The second question is related to Enoxaparin during the year, we have seen one of our partners losing lot of market share in US and if you can highlight any reason for this and also we have



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added one more partner in the US at the end of the year, so should we see a good growth coming in FY23?

**Srinivas Sadu:** Both partners were already there, but because of the margin profile, the partners and the market shares they were getting, so it didn't make sense to continue with the low volumes. So, that is why they kind of hold off till the margins improve, but the other contract, we have a GPO contract, which I have mentioned. So, there is a ramping up is happening and they are still selling off the product, what they got from the innovator earlier and you see from this quarter and we were also a bit slow because of the shortage of syringes, we don't want to take all SKUs immediately, so we kind of limited what we can supply and from this quarter, we are seeing a ramping up and probably more ramping up will happen from June-July.

**Amey Chalke:** Also supplementary question to this, for the global supply, which we are doing for Enoxaparin, how far we have reached in terms of getting approvals in other markets and are we still expecting some more approvals from new territories or you think we have already achieved the geographic expansion in terms of supplying Enoxaparin?

**Srinivas Sadu:** Several other markets still, there is opportunities where we are looking at, because the competition for this molecule is compared to low, in fact, there were several markets where the competition is lower than the US. So, we are still there. Only geography where you are not looking at is Europe, because of the price pressure there and also the complexity of registering the product, but other than Europe, we are looking at every other country.

**Amey Chalke:** Just last question on the US market, you have talked about the launches, which are coming in FY23, so if you can highlight any color on the same in terms of the business opportunity, in terms of the complexity, anything if you can provide?

**Srinivas Sadu:** Yes, in terms of value, I think it is about, in the next three quarters, we have launches planned which is worth about \$3 billion and products about 24, 25 molecules launches are planned for the next 3 quarters.

**Amey Chalke:** So, in terms of trend, should we expect higher growth or similar growth in the US in FY23? Or it will be too early to follow?

**Srinivas Sadu:** It is too early, but because the base is high, so the percentage growth will not be same, but if you look at globally, we are trying to get at least 10% growth at a company level launching more products in Rest of the World markets also, but if you look at specifically for US, it may not meet the same percentage like earlier because the base is high, but at the company level, we are still looking at 10%-11% of growth coming from the new products.

**Moderator:** Thank you. The next question is from the line of Ankush Agrawal from Surge Capital. Please go ahead.



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- Ankush Agrawal:** So, firstly, on the growth slowdown in the core markets, so you highlighted one of the specific reason around syringes, so any other reason that you want to highlight qualitatively that has affected the performance? And similarly on the margins front as well, so is it safe to assume that the reduction in margin is primarily because of the lower share of developed markets in this quarter and the logistic and syringes that you highlighted?
- Srinivas Sadu:** So, one is of course Enox, other also and if you look at launches on an annualized basis, you should see launches, it might go up and down in a quarter. So, launches were fewer in the last quarter and also some products, we didn't launch actually because we have inventory for the launch batches, but then the followup batches, we can't make the market dry, so waiting for the components and they have to come in so that we can supply on a continuous basis, so some of the launches, which we actually plan last quarter will go end of this quarter.
- Ankush Agrawal:** And then the margins front, is it because of the market mix and no logistic and syringes primarily?
- Srinivas Sadu:** Yes, absolutely. So, one is if you look at the percentage for the year and for the quarter, US percentage has come down, that is one and then the logistic cost and if you look at the plants where our plants are located in Vizag there was issue of power supply, so we have been running on diesel for almost 40-45 days. So, that became expensive. So, on an annual basis, there was a big impact on power, diesel, utilities costs and of course, the input and logistic costs.
- Ankush Agrawal:** Sir, in your opening comments, you mentioned something about an inorganic acquisition or that some cost that was spent, so can you highlight something on what front it is like, is it development assets or if assets something what would the potential side?
- Ravi Shekhar Mitra:** See we cannot comment on the target we are currently evaluating.
- Ankush Agrawal:** Not the name, but just focus areas?
- Ravi Shekhar Mitra:** So, focus area like we also said earlier is in line with our strategic target. So, one is that of course the backward API capability we don't have, second is on products and complex injectables side.
- Ankush Agrawal:** Your focus areas are clear. I was wondering if there is any specific area attached to this inorganic acquisition or is it multiple acquisitions this year?
- Ravi Shekhar Mitra:** Yes, we cannot comment right now, Ankush.
- Ankush Agrawal:** Lastly, sir, on the vaccine, so since you are repurposing plant, is it safe to assume that the vaccine project itself, as you know, out of the box for Gland at the moment, right?
- Srinivas Sadu:** ,I won't say out of the box, because that is one line we are keeping it like that and the other line, like I said, where we have not produced any vaccine that block, we are trying to work with the



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bio space. The other line is still going to keep it for few more months because discussion is still on. So, we don't want to shut it if there is any opportunity, you want to cater to that.

**Ankush Agrawal:** So, sir, anything that we will salvage from this, in case, the vaccine project doesn't go on like earlier at the time of contact you had mentioned that, it is a take or pay kind of contract, so will we be getting anything out of it?

**Srinivas Sadu:** I can't comment on it. Now, it is ongoing discussion. I think it is in nobody's hand and that's the problem.

**Ankush Agrawal:** But it accelerates, our biosimilars opportunity, right, because we had been commenting that we will wait for the vaccine to end by end of 2022 and then Q1 of 2023 we will start, but this accelerates that, right?

**Srinivas Sadu:** Yes, so that is why we have already initiated that and some of the companies have started visiting it because we thought, why keep the entire plant as well, we can start working on one line, while the other can be used for this.

**Moderator:** Thank you. The next question is from the line of Nithya from Bernstein. Please go ahead.

**Nithya:** So, FY23 seems to be larger LOE year as there are more number of injectable brands losing exclusivity, so is it fair to assume that on a relative basis compared to, let us say FY22, your share of new launch contribution will be higher and therefore profit share will be higher? Is that a fair characterization?

**Srinivas Sadu:** Yes, at least the second half of FY23 should look like that Nithya.

**Nithya:** Quick tactical one, by when do you expect the partner volumes in Enoxaparin to entirely shift to you, what timeframe?

**Srinivas Sadu:** We are looking from June, July.

**Nithya:** By June, July all of their market share would have shifted to Gland, right?

**Srinivas Sadu:** Yes, correct.

**Nithya:** And this is a related question to what another gentleman was asking, we have been talking about M&A for the last year, year and a half, if you can just update us on where you are and are we likely to see more traction in the coming months?

**Srinivas Sadu:** Yes, hopefully, we should give something, Nithya because last year is more like the valuations were all over the place. Now, there is some sanity around the valuation. So, we are working actively on couple of things. So, hopefully we should give something in next few months..



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- Nithya:** Is there a priority between the 3 areas that you had mentioned which is controlled substances, fermentation API or complex injectables?
- Srinivas Sadu:** Priority, I would say complex injectables, advanced stage assets, I think that is priority for us while we have our own pipeline for next 3 years, which covers about 10 billion. There are several other products where we think we can expedite using cash on books, so that is our main priority and then second, of course, the fermentation.
- Moderator:** Thank you. The next question is from the line of Tushar Manudhane from Motilal Oswal. Please go ahead.
- Tushar Manudhane:** Sir, post considering these partners volume as well for Enoxaparin overall globally, what would be the market share of Gland for this product?
- Srinivas Sadu:** Globally I can't tell, because Europe is a huge market for this. China is a huge market, where we don't have the presence. So, I think globally, probably 10% because volume wise it is huge in other markets also. So, probably 10% could be my wild guess.
- Tushar Manudhane:** I mean you highlighted that Europe is not geography to look for at least for this so China would be key market to look in terms of significant expansion for this product?
- Srinivas Sadu:** Yes, China and also other markets, they are still there where, see if you look at the Chinese manufacturers presence, they are big in Europe, they are big in China and they are big in the US, but other markets still they don't have presence because of the complexity in registration in different markets. If you look from the margin perspective and the opportunity perspective, there is still a lot of value left in other markets as well, so we are focusing that also. If you see our growth of Enoxaparin as a molecule coming is mostly from Rest of the World markets. Now with the US contract coming in, you see substantial growth in US also, but China is a area also, but I would say there is a presence of Chinese players in that. So, we have to go and fight with them, where they are backward integrated.
- Tushar Manudhane:** Yes, in fact, I was just about to ask that, given that the key raw material lines in China, so there, what would be the right to win the business for this product in China market?
- Srinivas Sadu:** So, the good thing is, we are backward integrated until Heparin level, so now current procurement of crude Heparin, we are getting from different sources and there also sources available which are cheaper than China today. So, that is why we are trying to source for our ROW and India business. So, once that supply chain is secured, so our priority is, first, how to increase margins in the US, so we are trying to use whatever crude Heparin we are getting from different sources and get approved for our ANDA in the US. Once we have enough supply for that, then we will start looking at other markets. So, I think currently, our focus has been to increase the margins for the US, whatever we want to supply in next few years for this contract.



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- Tushar Manudhane:** And just on the R&D spend, annually the amount has been increasing considerably, like this year, it is almost Rs. 227 crores compared to Rs. 122 crores in FY21 and given that we have complex filings coming up over next 2-3 years, so could you just quantify like what kind of R&D spend we have in FY23, 24?
- Srinivas Sadu:** If you specifically look at this year, you have to look at the Capex R&D, right, I mean, because we are built this new R&D center and equipment's have bought. So, that is like a one-time item. So, if you remove that, the increase is about 0.6%.
- Ravi Shekhar Mitra:** Yes, 0.6%.
- Srinivas Sadu:** But 0.6% increase, which is not substantial, but on the absolute number, it will increase, but I have always said, you should always look at 4% to 5% of the revenue as the R&D spend with complex injectables coming, and number of the percentage of complex injectables going up, so the absolute number will increase, but percentage wise, it should be 4% to 5% of revenue.
- Tushar Manudhane:** And just thirdly, there have been multiple inspections at the peer side, probably the drug shortage triggering the inspection and in fact, Gland does have existing products or probably the products in the pipeline which are part of the drug shortage list of US FDA, so any inspection on the near-term side or that is not yet triggered?
- Srinivas Sadu:** So, most of the inspections are walk-in these days, so we should be ready for any day. So, we hear every second day FDA walking into some site. So, we are all prepared for that and we think even tomorrow somebody can walk-in any of our site, so that is how it is. Unlike earlier at least sounds, they were coming announced inspections, now mostly they are unannounced, so we have to just go day-by-day.
- Moderator:** Thank you. The next question is from the line of Kunal Dhamesha from Macquarie Capital. Please go ahead.
- Kunal Dhamesha:** So, slightly longer-term question, in the sense, would you ever look at consolidating the ROW product portfolio into a separate facility, because I believe the compliance costs related to US FDA which is much higher vis-a-vis, let us say, ROW market and that way you can improve the margin from the ROW portfolio?
- Srinivas Sadu:** There was debate always on this, but I think we want to keep the quality standard across the sites similar, we don't want to dilute that because at a long run that helps because from the corporate quality perspective, we want to have a common quality systems across sites, so there is no confusion and different qualities at different sites. Maybe, there will be some margin pressure in ROW, but that helps to keep your regulated market business going up and having a clean quality record with the authorities.





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- Kunal Dhamesha:** And secondly, as we said that we have increased our backward integration into API from roughly around 25% to 35%, would increasing further can it give a boost to our gross margin and if yes, what would be the extent of that positive impact on the gross margin?
- Srinivas Sadu:** Well, I can't quantify, but for sure that one is of course eliminate the risk, the other is increasing the gross margins. That is primary reason why we are expanding into this. For sure, there will be a positive impact on the gross margin.
- Kunal Dhamesha:** And would you have some products in the pipeline where you are actively looking to backward integrate?
- Srinivas Sadu:** There are ongoing, I mean every year, if you look at last year, we filed about 11 DMFs historically, we were doing like 5 to 6, but this year we did 11 DMFs and this rate we have increased. Some of the R&D spend is also going into this, right, so it is a continuous process we are identifying API, so that your margin profile will be better.
- Moderator:** Thank you. The next question is from the line of Ankush Agrawal from Surge Capital. Please go ahead.
- Ankush Agrawal:** Just one clarity like from last couple of quarters, we have seen our business where in exports to US from India has grown because the Indian partners have grown, so wanted to understand is the profitability on this business similar to if we export to a US partner?
- Srinivas Sadu:** It is similar, there is no different with that. It is such that the number of products, not what these companies have, they started launching more products and also new partners, we have added Piramal as a new partners. So, some of the partners from India, Sun Pharma is also one of our partners who are selling products, more products now in the US. So, we have more Indian partners who are selling, so the volumes have increased that way.
- Ankush Agrawal:** I mean a couple of years, we expect share of Indian partners increasing, is that?
- Srinivas Sadu:** Yes, because more products to more players who have front-end in the US, the share have also increased, so that is an increasing number. That is why you see our increasing number.
- Moderator:** Thank you. As there are no further questions, I will now hand the conference over to Mr. Sumanta Bajpayee for closing comments.
- Sumanta Bajpayee:** Thank you. Thank you everyone for joining us today for our fourth quarter earnings call. If any of the questions still remain unanswered, please feel free to get in touch with us. Thank you, and good night.
- Moderator:** Thank you very much. On behalf of Gland Pharma Limited, that concludes this conference. Thank you for joining us, you may now disconnect your lines. Thank you.