GLAND PHARMA LIMITED

November 02, 2022

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National Stock Exchange of India Limited
Listing Department
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Plot no. C-1, Block G, Bandra Kurla Complex Bandra
(East), Mumbai - 400 051
Symbol: GLAND (ISIN: INE068V01023)

Dear Sir/Madam,

Sub: Earnings call Transcript- Q2FY23

Please find enclosed the transcript of the Earnings call for Q2FY23 of the Company held on Wednesday, October 26, 2022 at 18.30 Hrs IST. This will also be available on the Company's website and the web link to access the same is https://glandpharma.com/investors/financials

This is for your information and records.

Yours truly,
For Gland Pharma Limited

SAMPATH KUMAR PALLERLAMUDI
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P Sampath Kumar
Company Secretary and Compliance Officer

"Gland Pharma Limited Q2 FY'23 Earnings Conference Call"

October 26, 2022

MANAGEMENT: **MR. SRINIVAS SADU – MANAGING DIRECTOR & CHIEF EXECUTIVE OFFICER**
MR. RAVI SHEKHAR MITRA – CHIEF FINANCIAL OFFICER
MR. SUMANTA BAJPAYEE – VICE PRESIDENT, CORPORATE FINANCE & INVESTOR RELATIONS

Moderator: Ladies and gentlemen, good day and welcome to the Gland Pharma Limited Q2 FY'23 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 from Gland Pharma Limited. Thank you. And over to you, sir.

Sumanta Bajpayee: Thank you, Faizan. Good evening, and warm welcome to Gland Pharma's Earning Conference Call for Second Quarter of Financial Year '23.

I have with me Mr. Srinivas Sadu – M.D. and CEO; Mr. Ravi Shekhar Mitra -- CFO to discuss business performance and to answer queries during the call. We will begin the call with business highlights and overview by Mr. Sadu, followed by financial overview by Mr. 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. And this must be viewed in conjunction with the risks and uncertainties involved in our business. The Safe Harbor language contain in our press release also pertains to this conference call. This call is being recorded and the playback of the call shall be made available in our website shortly after the call. The transcript of the call will be submitted to the stock exchanges and will be uploaded in our website.

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 the second quarter of Fiscal 2023.

My festive wishes to all our shareholders, analysts and their families.

Last quarter saw heightened economic uncertainty globally. After a tough start to the year, while we continue to see some supply chain disruptions, and long lead times for several processing and primary materials, we saw improvement in supplies in the second half of this quarter, and have much better visibility on our key material supplies. Our efforts on easing the supply chain by qualifying additional vendors and additional lines for manufacturing are also starting to show results. Commercial production of Insulin restarted during the second half of the quarter.

I'm pleased to announce that our new offices at USA and Singapore are now operational. This expansion is aimed at strengthening existing customer relationships, forming new partnerships in target markets to drive growth, while aligning our internal product pipeline strategy with our customers feedback and also help us in mitigating some of the supply chain disruptions in the future. This initiative will also allow us to explore partnerships to accelerate our entry into the biologic biosimilar CDMO space.

We had our first physical USFDA pre-approval inspection audit since COVID outbreak between 22nd August to 25th August at our Dundigal facility. We received one observation from the audit and our teams have already responded to the observation. I'm satisfied with the preparedness of our teams across all our sites for any regulatory audit.

We closed this Q2 FY'23 with a revenue of Rs.10,444 million as against Rs.10,805 million in Q2 FY'22 and our PAT stood at Rs.2,412 million for the quarter against Rs.3,021 million in Q2 FY'22. We have generated Rs.627 million of cash flow from operations in Q2 FY'23.

The delay in material supplies impacted volumes for certain products, and we observed impact from price erosion in some of our recent launches.

Our robust business model gives us the flexibility to onboard multiple customers for single molecule, which is helping us maintain strong market shares in key molecules. Our strength of handling manufacturing of high-volume injectable products and compliance track record has enabled us to stand out from competition.

We managed to launch six product SKUs during the quarter, which included Bumetanide in the US market and Bortezomib in the European market. We also launched other products including Oxaliplatin in the Canadian market.

We continue to make investments in R&D and we're able to complete six ANDA filings during Q2 FY'23 in line with our plan. The filings will further accelerate in the second half of the fiscal year. We are receiving encouraging feedback from China. It should help us increase our pace of China filings as well over the next year.

During Q2 FY'23, upon excluding capital R&D expenditure, the R&D expenditure stands at 3.8% of our revenue for the period in line with our historical trend.

As on 30th September 2022, we along with our partners have 322 ANDA filings in the US and 1,586 product registrations globally.

We have onboarded some senior executives during the quarter to strengthen our plant operations and human resources function. We are further looking for talent to strengthen our biotech manufacturing capabilities.

Let me summarize our performance across various geographies: Our Rest Of the World markets accounted for 21% of our Q2 FY'23 revenue similar to the contribution in Q2 FY'22. The material supply timelines have improved and we have better visibility now. We are building inventory to support the demand. We registered our products; Esomeprazole, Melphalan and Labetalol in new geographies during the quarter. Our key markets continue to remain, MENA, LATAM and APAC.

Our core markets namely US, Canada, Europe and Australia accounted for 72% of our revenue during Q2 FY'23 as against 67% during Q2 FY'22.

We continue to focus on building a niche portfolio in our core markets. Although we have seen increased competition in our new products, we remain confident of a launch pipeline that will ensure sustainable growth in the market. India market accounts for 7% of Q2 FY'23 revenue,

We have restarted Insulin dispatches during the second half of the quarter. The sales for Q2 FY'23 were lower when compared to Q2 FY'22 on account of absence of COVID-related product sales.

Increased freight cost in addition to supply chain disruptions have not only impacted our ability to compete in the RoW and India business, but also contributed negatively on our margins. Smoothening of the supplies should help us negate some of this impact in the coming quarters.

Sustainable growth has been our focus. The monetary tightening has impacted valuations globally and we continue to use this to our advantage to aggressively scout for inorganic opportunities.

On the geographic growth, China remains a key geographic focus and we expect to start receiving approvals during the current year.

On the portfolio front, we expect another two complex filings during the current fiscal and have completed installation of manufacturing lines for suspensions and hormones.

On the biosimilar CDMO business, we have completed several customer visits during H1 FY'23, and few of those have moved to the stage of commercial negotiations.

We signed up for fill finished clinical batch project and are discussing on the DS project commercials as well. Positive momentum is seen in the biologics/biosimilar CDMO space.

With this, I wish everyone good health. I would like to now hand over the call to our CFO, Mr. Ravi Mitra, who will share details about Financial Performance for the Quarter. Thank you. Over to you, Mr. Mitra.

Ravi Shekhar Mitra: Thank you Mr. Sadu. Good evening, everyone. Thank you very much for attending our second quarter earnings call.

Our earnings presentation has been submitted to the stock exchanges and is also available on our website.

Let me begin with sharing the financial performance of second quarter and first half of financial year '22-23. Revenue from operations for the second quarter FY'23 stood at Rs.10,444 million, reduction of 3% on year-on-year basis.

We have seen revenues from core markets and RoW markets has come back to normalcy and is in line with second quarter of previous year. We have witnessed 22% increase in revenue as compared to previous quarter.

Revenue from operations for the first six months of fiscal '23 stood at Rs.19,013 million, a year-on-year decrease of 15% due to various reasons impacting first quarter of current fiscal year.

Other income for the second quarter was Rs.656 million, which includes interest and fixed deposit of Rs.468 million and foreign exchange gains on operations of Rs.181 million.

For the H1 FY'23, the other income was Rs.1,400 million, of which interest on fixed deposit of Rs.844 million and foreign exchange gains on operation of Rs.523 million.

Gross margin of the company remains stable in both Q2 and H1 as compared to same period of previous financial year, but reduced quarter-on-quarter sequentially, largely due to change in geography mix and product mix.

We have reported an EBITDA of Rs.3,625 million in Q2 FY'23 compared to Rs.4,278 million which is a decrease of 15% compared to same period last financial year. EBITDA margin for Q2 FY'23 stood at 33% as compared to 38% of the same period of previous financial year.

Increased operating expenses such as higher logistic cost due to use of air shipments and certain one-time expenses impacted EBITDA margin of the company during the quarter. With normalization of inventory of certain critical items, we expect freight to come down with more sea shipments going forward.

During the first half of the year, we managed to maintain similar gross margin but EBITDA margin reduced due to higher power cost, employee cost on account of increased headcount for biologics and biosimilar CDMO facility, new commercial lines in Pashamylaram and for Vizag facility and other operating expenses.

EBITDA for the six months ended September 2022 was Rs.7,068 million compared to Rs.9,259 million for the same period last year. We have reported EBITDA margin for H1 at 35%.

Our net profit for second quarter decreased by 20% and stood at Rs.2,412 million compared to Q2 FY'22. During the quarter, we have recorded PAT margin of 22%. During the six months period of the current financial year, our PAT was Rs.4,704 million at 23% margin.

The total revenue R&D expenses for the second quarter was Rs.394 million and stands at 3.8% of the revenue as against Rs.362 million, a 3.3% of revenue and year-on-year growth of 9%. The total revenue R&D expenses for the six months period was Rs.743 million, it is 3.9% of our revenue. Our effective tax rate remains at about 26% in second quarter, and for the first half of the current financial year.

Cash flow from operation during six months period was Rs.3,956 million. Working capital increased and stood at Rs.21,436 million as on 30th September 2022 as compared to Rs.20,217 million as on 31st March 2022 due to increase in inventory levels.

Average cash conversion cycle stood at 231-days for the six months ending September 2022 as compared to 198-days of same period last financial year. Increased receivable and inventory days has pushed up the overall cash conversion cycle.

Total CAPEX incurred during six months was Rs.825 million, used for increasing capacity at our Pashamylaram and Vizag API facility and for routine maintenance CAPEX.

Our ROCE on ex-cash basis was at 21% on an annualized basis for the six months period of this fiscal year.

Our fixed assets turnover stood at 2.4x for H1 FY'23, decreased from 3.4x for the same period last year.

As on September 2022, we had total of Rs.38,200 million of cash and bank balances, which we intend to utilize for the CAPEX plan and to fund our inorganic growth strategies.

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

Moderator: We will now begin the question-and-answer session. First question is from the line of Neha Manpuria from Bank of America. Please go ahead.

Neha Manpuria: My first question is on the US numbers that we have reported in this quarter. It seems that overall the sales were pretty much flat. You mentioned in your opening remarks that we have seen competition in some of the recent launches. So, could you give us some color on what's the pricing pressure that we are seeing there and how should we look at growth in this business as we go forward?

Srinivas Sadu: Good evening, Neha. If you compare to last year, I think it remains flat, I mean, we also need to consider in last year there were sales which are COVID-related, that's kind of gone down. From the pricing pressure perspective, if we look at our gross margin level still they are intact. So, I think the EBITDA margin impact is most on the cost side, which has impacted the bottom line. So, from a growth perspective, we have launched seven product SKUs last quarter. There is a plan to launch 11 product SKUs next quarter as well. I think it's depending on the size of the molecules, which quarter gets launched, that's where the growth comes from. So, we're not committed to giving any numbers right now, but the robust pipeline what we have in terms of filings and approvals, it's there, and we think it will help grow in the business as well.

Neha Manpuria: I was looking at the numbers on a quarter-on-quarter basis given that we launched products in the US, we haven't seen as much growth in the US market. And your comment, if there was not too much price erosion, shouldn't we have seen more growth in the US given we have launched a couple of good products in the last two or three quarters? So, I'm not looking at so much on year-on-your basis, but on a quarter-on-quarter basis.

Srinivas Sadu: So, some of the products for sure, because of competition, we couldn't get to those volumes what we estimated, especially the oncology products, like Pemetrexed and Bortezomib, these didn't contribute because of too many players and I think that's why we couldn't show growth in that. But the other products what we launched still has given some volumes, but these are not larger products. So, I would say, I think the number of products launches happen also considerably lower when you look at annual basis. If you look at last year, we have launched 32 products on an annual basis. So, next quarters, we have few more product launches coming up.

Neha Manpuria: So, you should grow on the existing base that we have in the $45 million base that we have in the US, would that assumption be correct?

Srinivas Sadu: That's correct, yes.

Neha Manpuria: And my second question is on the RoW market. We seem to have gone back to the levels that we were doing last year. So, is it fair to assume that this is a sustainable number, and there is no one-offs in this and as we get additional vendors for syringes, etc., again, there should be growth on the RoW business from this base in the second half?

Srinivas Sadu: So, the issue what we're facing with RoW and India business is because of the disruptions. Most of it, we have airlifted last few quarters, and that is putting pressure on our margins and also the ability to compete. So, unless that stabilizes, and we evaluate the market, difficult to comment. But at least once the cost settles down, I think we'll have a better opportunity to grow in that business.

Neha Manpuria: But there is no one-off in the current bit, is that assumption right?

Srinivas Sadu: There's no one-off.

Moderator: The next question is from the line of Dheeresh from White Oak Capital. Please go ahead.

Dheeresh: What is the profit share number for the quarter?

Ravi Shekhar Mitra: 7%.

Dheeresh: For the quarter, revenue from new launches?

Ravi Shekhar Mitra: About 3%.

Dheeresh: On India sales, I think last quarter… I don't remember correctly, but I was under the impression that you had guided for a Rs.100 crores run rate. It is slightly lower. Any particular reason?

Srinivas Sadu: On India business, I think a few factors like I said, the import costs have not helped us, so the margins are pretty low, so we're not able to compete in the domestic market, it's a combination of the dollar going up, adding up to the cost for us, and also the importing costs have gone up. That's one reason. The other is the insulin line which contributes larger chunk for domestic business, that got started off in the middle of this quarter. Normal run rate is around Rs.25-30 crores a quarter, but I think we have billed 11 crores it's in the second half of this quarter.

Dheeresh: The US sales also like given the exclusivity we have on zinc sulfate and then there was the resumption of supply both for stoppers as well as for syringes, I was expecting a slightly better number sequentially based on the commentary from last quarter. So, the current US sales is as per expectation or you're tracking below your original expectation for this quarter?

Srinivas Sadu: So, the supply disruption is not fixed 100%. Syringes, we are good. But still the stoppers supply is not great, we are getting in tranches. So, that's impacted us. Even bag manufacturing has happened only 50% of the time because of shortage issues. So, still I think there's an impact of the supplies just contributed to this.

Dheeresh: Would you be able to quantify like how much sales you would have done if there was no disruption in US?

Srinivas Sadu: We don't want to quantify that, but I would say the bag line was running for like half of the quarter.

Dheeresh: On gross margin also, there is some deterioration it seems although the mix is not very different. In India, you're saying you did not do the lower margin business. So, if you see year-over-year and compare it to the revenue buckets, the US business, the rest of the world business, there seems to be some compression in gross margin. So, is that related to competitive pressure?

Srinivas Sadu: From gross margin level, I think in US we are pretty much stable compared to last year. So, first quarter was little exception I would say.

Dheeresh: I am comparing September '21 with September '22 quarter and I'm seeing the revenue mix in various geographies as well as the gross margin that we reported, I am seeing some compression in gross margin by about 120 bps. Is that because of US pricing pressure because if you see absolute revenue in terms of what we did like Rs.750 crores in regulated markets, Rs.230 crores in rest of the world which is similar year-over-year, but there is still some compression, is it because of lower profit share you've had this quarter or is it to do with some markets having more competitive pricing pressure?

Srinivas Sadu: Actually, if we look at Q2 FY'22 to Q2 FY'23, the US market contribution margin actually has gone up from 57% to 58%. From Q1 FY'23, to Q2 FY'23, it has gone down by 1%. So, basically it's almost like similar kind for the US market. I think where we lost margin a bit is in Canada where it has gone down from almost 88%, we were having a larger margin for Bortezomib what we sell in Canada, that has gone down to 65%.

Dheeresh: What percentage is the revenue from Canada?

Srinivas Sadu: For the quarter it's about Rs.17 crores, 2%.

Dheeresh: So, that is not that big? Okay. Any other region you want to call out in terms of contribution margin?

Srinivas Sadu: In fact, in rest of the core markets, it's better or flat. But Rest of the World market has gone down in terms of margin, if you look at from last year to this year, it has gone down from 35% to 25%. And that's mostly because of the import costs and most of it is we are importing, we are airlifting because of supply disruption, and we're not able to pass on this.

Dheeresh: Why are we not able to pass it on because others also be facing similar? Is the industry in aggregate absorbing this in rest of the world and Indian market?

Srinivas Sadu: Most of it is like a transfer price model what we have in the Rest of the World unlike US where it's a profit share. Actually, one side is the contribution margin also, the freight cost comes below the contribution margin for RoW market, so it comes under the EBITDA. So, that also has impacted our margins as a company.

Ravi Shekhar Mitra: Just to add to what Mr. Sadu was talking about is that gross contribution is largely 50%, 52% similarly in earlier quarters, Q1 was an aberration. But this time also based on the discussion we were having with the several customers on our Drug Substance project, we have taken a one-time inventory write-off of about Rs.7- 8 crores in our biologic CDMO facility basis of the feedback we got and what would be required going for the different contracts we're working on. So, this I think is about 0.7%, 0.8% and it's a one-off in nature. This would impact your gross margin. Below that in EBITDA margin, the one-time what we were explaining is of course the M&A cost is about Rs.4 crores this quarter, and we have built up the employees also for the bio similar business for both Pash and Shamirpet, these employees we have added about 500 headcounts. So, this is also impacting the margin. But once the revenue start coming, biosimilar Shamirpet facility, that would negate.

Moderator: We'll take the next question from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: Just a couple of points I wanted to check from our discussion in the previous Q1 concall. If my memory is right, if my notes are right, then you had mentioned that for the balance nine months, that you would grow 18% to 20% on a top line. This quarter, you're more or less flat, up 3%. Second, I think you'd guided on the margins as well, that you would maintain Q1 operating margin, which was 31.5% and you have come this quarter at 28.5%, so down 300 basis points. So, if you can just clarify on these two fronts?

Srinivas Sadu: One is on the estimated revenues what we thought for the large oncology didn't happen because of the competition. Second, as I mentioned to the previous question, some disruption of a couple of our manufacturing lines because of the supply issues. So, that didn't help grow the business. From a margin perspective, like Mr. Ravi said, they're like one-off items, which has impacted the margin about close to 1% on write-off of one-time materials and also the M&A cost, that's totally about 1.5% to 1.8%. If you add that it will be like close to 30% or 30.5%.

Sameer Baisiwala: I mean the numbers still don't total up, because on a sales base of Rs.1,000 crores, to miss 20% growth is like missing Rs.200 crores, that's a big miss. So, I'm just wondering what happened within three months? And what's the outlook for the second half both on the sales as well as on the margin?

Srinivas Sadu: So, we don't give a guidance because still the market is volatile. And from a number perspective, I would say, one side, the insulin didn't start at the beginning of the quarter, started late part of the quarter, and disruption in bag manufacturing as well as some delay in Lyo installations, didn't help us in terms of capacities. And of course, the oncology big products, we estimated a large chunk coming from those two products, billion dollar products, but that didn't happen. These are the factors which have impacted the numbers.

Sameer Baisiwala: I don't want numbers, but how do we model second half going into fiscal '24 if you can just help with that just qualitatively how do you see business panning out?

Srinivas Sadu: So, one other aspect what you forgot is the heparin stoppers we said in the later part of the last quarter. So, that also has impacted. So, heparin supplies didn't start yet and that's almost Rs.40, 50 crores a quarter sales for us. So, we're expecting stoppers to come in November. So, that's one other area where to bill the revenue. But moving forward, while we're focusing on growth and filing products and launching products, being the market is so volatile and the supplies are not yet 100% in line with our plan, it's very difficult to estimate the near term growth and difficult to comment on future growth or business guidance for short tenure. But we're assessing the situation and once we have better visibility of growth, I think we'll update you soon. But we are doing everything in terms of growing the current existing business and also working on the growth levers. While working on the current portfolio, we're also discussing on increasing the CDMO side of the business. Now that we have added new capacities in the line, I think there's also an increase in costs in the manpower because we have added 400, 500 people to get the lines on track last quarter. So, we are aggressively pursuing the CDMO business on those lines. So, this should add up to some revenues coming in next few quarters. I think once we have some visibility, we'll give you a growth estimate, but as of now, because of the volatility of the business and not clear indication of how supply is going to happen, we don't want to give indication for the near term growth.

Moderator: The next question is from the line of Ritesh Rathod from Nippon India. Please go ahead.

Ritesh Rathod: Can you give your outlook on the margin? I think last quarter, you spoke about some 31%, 32% margin excluding other income. So, is that intact, even you explain partly this quarter, margin has been impacted due to one-offs, or even that that needs to be downgraded?

Srinivas Sadu: If you remove the other income, it's around 28.5% EBITDA. And if you add the one-time expenses of whether the write-off of materials, it should come down to 30.5%, close to 31%. So, like we have guided should be around in that range, at least on a quarter-on-quarter basis. But if there's any change, we let you know.

Ritesh Rathod: And on the supply disruptions particularly for stoppers, has your visibility improved, I mean, you're confident of things coming by November, December end or that has deteriorated further or any uncertainty still there?

Srinivas Sadu: The two things we are doing, right, not just stoppers, but other aspects, that also has contributed to the costs. While we have added additional suppliers both from stoppers, tubing, filters , several products we have worked on in the last few quarters, that also has added costs to the company. In terms of heparin, which is a key product where we're not able to supply, we have finalized alternate suppliers. So, we're going to file that in this quarter. We're expecting an approval in three months. In the meanwhile, we are getting not 100% to meet the demand, but we are getting in tranches, so, some stoppers we will get in November, probably in the first quarter of next year, it should normalize in a combination of what we have approved in stoppers today and also the new stoppers what we have qualified.

Ritesh Rathod: Last one on this 500 employees addition, can you give some color on what you're planning to do, is there are some visibility in terms of backlog order book, which is why you have done this thing or it's more of a medium term investment?

Srinivas Sadu: So, if you look at the capacity utilization for us, the liquid vials actually we are running almost like 85%, 90% of capacity. And we're not able to take up new orders. And because of the delay of installations, it kind of pushed out. So, we have one line which got installed in last quarter where we're also planning to produce the hormone suspension products. Currently, we're taking a lot of R&D batches on that because we have complex products filings as well to do in next four months. So, once those filing batches are done, then we'll use for commercial production. So, that will bring the revenue from the commercial angle. So, we added manpower for that line and also we have added three Lyophilizers, again we are running at 80% capacity for Lyo. There are contracts where we are not able to cater to which are larger ones, especially on the CMO side. So, we can get access to those kinds of contracts. So, these three lyos will come on track in next quarter. So, this is more a near-term commercial opportunity we have. And we are also investing on CAPEX on bag manufacturing because current bags again we are not able to meet the demand what we have from the US. So, the additional CAPEX has also been planned for that as well. From Vizag oncology, we have added one more line. So, that's coming on track. So, we can leverage that to get more CDMO business side as well. So, these are more growth drivers for us in the near future.

Moderator: The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: The first question is largely relating to more of a clarification. In your presentation, you have talked about things are getting normalized specially for RoW and qualification of alternate suppliers are in the process. So, it is going to take one, two more quarters to normalize or we are done with it and from next quarter we will start seeing the growth on RoW?

Srinivas Sadu: RoW now has come back to normalcy in terms of at least prefilled syringe products. Now, it's more to do with the costs we have been incurring on that and our ability to compete in the market, so it should come back now. In terms of supplies, we don't have an issue, we also have alternate suppliers for that and we have already started supplying with alternates.

Prakash Agarwal: So, these are qualified alternate suppliers, which is other than BD, is what should we understand like that or because in the last call it will take a couple of quarters to get qualifications, so are we done that qualification yet?

Srinivas Sadu: Yes, it's already done and we have already initiated supplies with one of the suppliers.

Prakash Agarwal: In the past ,you said that because RoW having same qualification, you are using RoW supplies to cater to US. So, now with RoW resolving, at US you don't think there is any shortage as such, it's more related to pricing competition as well as portfolio less number of products launch, nothing related to shortage apart from the stoppers issue, is that the correct understanding?

Srinivas Sadu: Yes, stopper issue for Heparin, and we have three or four other products where we have tubing and filter issues where we have filed alternative sources for those products. There is also issue with bags where we have a problem with the Twist off port, which got resolved in the recent past… so in the last one month, we don't have that issue. So, I think moving forward, most of the issues will be covered except the stoppers for the heparin.

Prakash Agarwal: That commentary is that earlier was in November, but you're still saying it is coming in batches. So, maybe by Q1 of next calendar year, it should get normalized, is that understanding correct?

Srinivas Sadu: Yes, so even now the first tranche is coming in November, but it's only a partial quantity. They are qualifying the second stoppers and filing this quarter, and that might take two or three months for approval. So, if that approval comes earlier, then probably next quarter that can resolve 100%, otherwise one more quarter we have to suffer with the partial supply.

Prakash Agarwal: Last time, I think there was a product-related inspection and for the two large facilities we are due for inspection. Is there a commentary or we have a tag date, or a date where we would have the inspections?

Srinivas Sadu: So, we already had one inspection like I read in my commentary, so we had completed for one site for the product PAI, and we got one observation for which we have responded. The other sites we don't have any information on when they are going to visit. So, mostly it's unannounced inspection, so we don't know when they are going to come.

Prakash Agarwal: But that product-related means that we are done with the facility inspection also or is that check boxed or it's related to product only and then the facility inspection is still due for the first one?

Srinivas Sadu: Normally, for a PAI, it's a combination of both GMP and all that. They don't come back again, but depends on the inspector as well. But normally, whether it's a PAI or a normal inspection, they go through the site in entirety.

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

Kartik Mehta: I have a book-keeping question. Can you guys tell us what is the expense attributed to the CDMO business on the OPEX side, it would include the staff, R&D batch, etc., very specifically if you could just tell us for this quarter only for the non-revenue generating CDMO business?

Ravi Shekhar Mitra: At EBITDA level, it's Rs.15 crores for the quarter without including the depreciation.

Kartik Mehta: If you would add the depreciation also, Ravi, is it possible to quantify that?

Ravi Shekhar Mitra: Depreciation is another Rs.6- 7 crores for the quarter.

Kartik Mehta: You've spoken somewhere in the call and shared in the presentation also that you're closer to commercial negotiation. So, I am assuming everything has been charged to P&L as of now including the write-offs which you earlier spoke about. I'm not asking for a date or for the contract tenure, etc., Is it fair to assume that in calendar year '23, your revenue stream may start, assuming that these expenses obviously will continue or even in fact increase as you go near to the contractual agreements?

Srinivas Sadu: Yes, the business will start for sure. I don't know how much it will cover the total costs. It's not 100% it should cover.

Kartik Mehta: I'm not asking for revenue number. So, is it fair to assume about Rs.60 crores a year at this run rate will be the cost which you will incur, or are there any more investments, particularly above the EBITDA level, which do you expect in Q3, Q4, or even in the next three, four quarters, just operationally in terms of expense, EBITDA, etc., if that is something that you can just talk about?

Ravi Shekhar Mitra: On the overhead side, I think we are all done in terms of people or utility or consumables. So, it will not go up when the revenue starts. Of course, the direct material linked to that will be in line with the revenues.

Moderator: The next question is from the line of Rakesh Naidu from Motilal Oswal Asset Management. Please go ahead.

Rakesh Naidu: I just wanted to have your comments on yesterday's Moody's downgrade. How should we think about this entire scenario given the lineup of assets which, of course, we didn't intend to offload, how does that impact the vertical generally and are there any thoughts on India business as well?

Ravi Shekhar Mitra: To start with the issues which you mentioned is at Fosun International level, our promoter is Fosun Pharma, which is again a listed company. There is no balance sheet linkage or any dependency with them today. We have business relationship with Fosun Pharma like, for example, we sell to their subsidiary in US in other area. Last year, we did about Rs.170- 180 crores, this half year we did about Rs.100 crores. And purchase is also from some of the subsidiaries in China, which is about again last year of Rs.100 crores. So, I think other than that there is no impact in business per-se. And of course, the concern which you raise and came out is at shareholder level. So, difficult to comment from our standpoint.

Rakesh Naidu: In Q1 commentary, one of the reasons that you'd highlighted for lower US performance is shortages, and then inventory in transit is what you'd alluded to. If I just look into see how the numbers stack up, there was a pre-existing inventory and now again, there is a decent period of opinion between the system. So, how should I actually look on the ground dynamic, I mean, what exactly is playing out, I mean, is it the competitive intensity or lower optic of products or demand, what exactly is happening in the US market?

Srinivas Sadu: Yes, for sure, the competition is higher compared to earlier, but if you look at our older products are still intact in terms of margins. And if you look at the growth, it's coming from price also and also new products. But it's a degrowth of about 7%-8% by volumes. These volumes is a mix of what we're not able to supply and also the demand situation for some of the products, has not gone back, some of our key products have still not gone back to the earlier level. It should start from this quarter or the next quarter. Like I said, we were having more contracts last year and the pipeline buildup was there, that's getting used up, we should start seeing from the future. So, in that sense, I think it's volume degrowth which has impacted a bit which should come back in the next few quarters.

Rakesh Naidu: In last call, you seemed more optimistic related to incremental contracts from an existing buyer, and also seasonality, but then now you seem to be refraining from giving guidance for the second half. My understanding was that you guys had alluded to more flattish kind of FY'23. Is it fair to expect that will be delivered or it will be tough to take a call at this point in time?

Srinivas Sadu: It's tough to tell right now, because we don't want to comment on it. Like I said, while we are estimating the supplies to come on track, there were certain delays happening because of the volatility and as well most of the shipments were now making it by sea to reduce our costs. So, that will compromise a bit on our RoW sales and India sales at least to keep our margins intact and profitability higher. So, we'll keep you posted in the next few months once we get a clearer visibility and this volatility moves away.

Rakesh Naidu: You had guided for Rs.300, 350 crores of CAPEX per annum. We seem to be going a bit slow on that part. Is there any reason or what exactly is happening with regards to onboarding of new facilities?

Ravi Shekhar Mitra: It's a timing, I think it is all in track, because this 300 crores indicated earlier is all project wise, already approved budget, work is going on. It is only a timing of spend, but year-end we will end up that number. For the next year, we are looking at some more additional capacity which Mr. Sadu was explaining in terms of certain delivery format. So, in the next analyst quarter call I think we will update that for FY'24 CAPEX guidance. But for FY'23 we are on track.

Moderator: The next question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: You mentioned profit share of 7%. What is the number for the first half and also for FY'22?

Srinivas Sadu: For six months FY'22 is 8% and even FY'23 it's a same range, 8%.

Saion Mukherjee: The service income has been very high last FY'22. Has that come off in the first half compared to what it was in the previous year?

Srinivas Sadu: Milestone revenue is almost same, 7% last year, in fact, this year is 8%.

Saion Mukherjee: Next question I have is on China. How many products you have filed? You mentioned I think you will be stepping up your filings. If you can give a sense of how large these products are, any unique opportunities in terms of being driven in the first place, etc., any color, and how should we think about ramping up of this revenue in China over the next two, three years?

Srinivas Sadu: So, eight products we have filed, two are expected approval, that's what the team says, by the end of this year one I think this quarter and one next quarter, and six probably next year. This is the filing plan of six products again in FY'24.

Saion Mukherjee: So, in terms of size, opportunity, competition, how should we think about once you get these approvals, how the China revenues will ramp up?

Srinivas Sadu: We will take that offline; Sumanta will give you that information.

Saion Mukherjee: One question is on RoW. We have seen a very good ramp up over the last two years. In terms of product registration, it hasn't gone up that much, but the revenues went up a lot. It was a bit volatile and you mentioned some of the reasons. Now I understand once thing stabilize, it will probably take some time. How should we think about growth in RoW excluding China let's say over the next two, three years? The run rate has been exceptionally high for us.

Srinivas Sadu: So, one is the percentage gives a wrong indication because the base was very low a few years ago, so the percentage looks high, now the base is high. And from the registrations perspective, historically, we've been compromising on…we didn't leverage registration what we have because of capacity constraints what we're doing today. And also, the GCC market, we never explored earlier. Most of the focus was on LATAM and APAC regions. So, that region opened up because of the margin profile there is better than other markets is a lot more competition and with our quality systems we're not able to compete in some of these markets. But GCC has a better margin profile. So, that's contributing now almost 26%, 27% of the RoW revenue. So, with capacities coming on track, now with additional lines coming onboard, we continue to focus in that region. While we can't comment on the growth, but a lot of focus is happening in terms of registrations also including Mexico, we're entering South Africa as well which are not there earlier, some of the even CIS countries we are entering now. So, these are the new territories where we are trying to enter and increase the market share.

Moderator: The next question is from the line of Tarun Shetty from Haitong Securities. Please go ahead.

Tarun Shetty: Just a few clarifications from my side. Could you explain with the number of launches for this year or next year in the US market?

Srinivas Sadu: In the first six months, we have launched about 20 SKU in the US and next two quarters we have about 25 SKU launches planned.

Tarun Shetty: For FY'24 and FY'25, any visibility?

Srinivas Sadu: So, this quarter, we have about nine SKU launches happening and next quarter is about 16 SKU launches.

Tarun Shetty: I was looking for FY'24 guidance.

Srinivas Sadu: For FY'24, I don't have it on hand, but normally it's between 25 and 30 launches.

Tarun Shetty: The next one is on the inventory level quite high. So, do you see them remaining at current levels or should we build a more normalize or it might go on a downward trend in the coming quarters?

Ravi Shekhar Mitra: If you see from March level should be around this level going forward. This high inventory we explained earlier also, because of the volatile situation, we would like to have the inventory in hand.

Tarun Shetty: Last clarification was on the RoW. You mentioned the RoW margins were 25% for this quarter which was around 35% earlier or was it different?

Srinivas Sadu: 35% gross margin in the previous quarter compared to 25% of the recent quarter, yes.

Moderator: The next question is from the line of Anand Venugopal from BMSPL. Please go ahead.

Anand Venugopal: If you could describe the state of the US injectable industry at the moment. Is there a risk of prolonged price erosion due to pricing competition just like we have been seeing in generic or Oral solid dosage over the past few years?

Srinivas Sadu: The competition is intense for sure. So, all the new launches, we kind of cutting down on the forecast, especially with last few quarters. But otherwise, if you see our from our pipeline perspective, our margins are intact, I mean, I've been saying, our gross margins are still at around 52%, historically, that's been the case. But whatever new launches were happening, earlier, it used to be higher in the first year, it was like 65%, 70% and even some products, it used to be like 75%, 80%, and then it used to settle down around 40%, 50% after three years. So, that scenario, we're not seeing from last few quarters, it is going down on the first year itself, because of the competition. But we got to see with FDA coming back and auditing a lot of sites. And now we have to see whether the competition will stay intact, and how long can they sustain with this pricing what they're offering in the market. Because this is a cycle, we are in that space where we have seen that few years ago, where a lot of companies launched till the capacities get filled up and then they start exiting the market. So, we have to give that time till that happens.

Moderator: The next question is from the line of Prashant Nair from Ambit Capital. Please go ahead.

Prashant Nair: I just had one follow up question on growth going forward. Beside the near-term volatility, could you give us some sense of whether this is still structurally 20%-plus growth business that we have seen in the past or do you think given where we are in terms of base, it will be slightly lower than that, some sense on that would be helpful?

Srinivas Sadu: Yes, from growth levels perspective, there are a lot of opportunities out still there, right. I mean, whether if you look at long-acting injectable space, the ophthalmic suspension space, pen auto injector space where we have invested recently, we are investing into bags now in a big way. And also from Geography perspective, just entering some of these markets, we never grown earlier. So, the opportunities are there, it's just that I would say the consolidation phase we are going through, we also need to streamline the supply, thinking from long term perspective having several alternative sources for several aspects of products… at least for the key products. In last one year, we invested almost 20, 25 products, working around adding alternate suppliers in various areas, that also has added up to the cost. But these are all like investments we're making for the future growth and more stability for the business. So, once in five, six years where we have to consolidate the business, I think we're using that now. But from opportunity perspective, there are several areas we can grow, we have seen a lot of positive feedback on the biosimilar CDMO space, a lot of customers are approaching us. The relationships what we have with customers are intact, the large customers of the portfolio is still growing, they are the biggest customers. In spite of smaller players coming and creating some noise in terms of offering products at a cheaper price, but still we have our own place in terms of the growth. So, we are pretty confident on the growth in the future because the opportunities are there. It's just that you know we have to overcome the current tide in terms of supplies and operational issues. Because while we're talking about supply disruption directly linked to the components and all that, we have to see in expanding the lines are coming on track as the plan because people can't travel, the technicians can't travel. So, several things happen when you're running a manufacturing setup. So, with that said, once you settle, I think we have a good growth story to move forward.

Moderator: Ladies and gentlemen, that was the last question for today. I would now like to hand the conference over to Mr. Sumanta Bajpayee for closing comments.

Sumanta Bajpayee: Thank you, everyone for joining us today. We appreciate your participation during the call. If any questions still remain unanswered, please reach out to me or our investor relations team. Thanks, again. We would like to reconnect again in our next earnings call. Good night.

Moderator: Ladies and gentlemen, on behalf of Gland Pharma Limited, that concludes this conference call. Thank you for joining us and you may now disconnect your lines.