GLAND PHARMA LIMITED

November 11, 2024

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Scrip Code: 543245

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Listing Department
Exchange Plaza, 5th floor
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- Q2FY25

Please find enclosed the transcript of the Earnings call for Q2FY25 of the Company held on Monday, November 04, 2024, 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

KUMAR PALLERLAMUDI SAMPATH

Digitally signed by KUMAR PALLERLAMUDI SAMPATH
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Sampath Kumar Pallerlamudi
Company Secretary & Compliance Officer

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"Gland Pharma Limited

Q2 FY25 Earnings Conference Call"

November 04, 2024

MANAGEMENT: **MR. SRINIVAS SADU – EXECUTIVE CHAIRMAN AND CHIEF EXECUTIVE OFFICER – GLAND PHARMA LIMITED**
MR. RAVI MITRA – CHIEF FINANCIAL OFFICER – GLAND PHARMA LIMITED
MR. ALAIN KIRCHMEYER – CHIEF EXECUTIVE OFFICER -- CENEXI
MR. ANKIT GUPTA – HEAD OF INVESTMENTS AND STRATEGY – GLAND PHARMA LIMITED

Moderator: Ladies and gentlemen, good day, and welcome to Gland Pharma Limited's Q2 FY25 Earnings Conference Call. As a reminder, all participant lines will be in listen-only mode, and you will have an opportunity to ask questions after the presentation concludes. Should you need assistance during this conference call, please signal an operator by pressing star and then zero on your touchtone phone.

Please note that this conference is being recorded. I now hand the conference over to Mr. Ankit Gupta. Thank you, and over to you, sir.

Ankit Gupta: Thank you, Sagar. Good evening, everyone. We welcome you to Gland Pharma earnings conference call for Q2 of FY25. My name is Ankit, and I am Head of Investments, M&A, and Corporate Strategy at Gland. In the India office today, we have Mr. Srinivas Sadu, our Executive Chairperson and CEO, and Mr. Ravi Mitra, our CFO. We also have Mr. Alain, the CEO of Cenexi, who is connected virtually from France. We'll begin the call with business highlights from Mr. Sadu, followed by an overview of Cenexi from Mr. Alain, and lastly, the group financial overview by Mr. Ravi.

Before we proceed, I'd like to remind everyone that some of the statements made today will be forward-looking and are based on management's current estimates. These statements should be considered in light of the risk associated with our business. The call is being recorded, and the playback and script will be available on our website shortly.

With that, I hand over the call to Mr. Sadu for his opening remarks. Over to you, Mr. Sadu.

Srinivas Sadu: Thank you, Ankit. On behalf of Gland Pharma, I extend a warm welcome to our Q2 FY25 earnings conference call. As this will be the final call before the end of CY2024, we wish you and your families good health and prosperity throughout the upcoming season.

Today, we'll review our financial results and operational developments for both the Standalone entity and the Group, which includes Cenexi, our European CDMO business. At a Group level, we reported revenue of INR 14,058 million in Q2 FY25, compared to INR13,734 million in Q2 FY24, representing moderate growth of 2%. This performance is in line with our expectations, given the slower offtake in the Rest of the World markets for our base business and the impact of the extended annual shutdown at our Cenexi facilities due to the planned installation of a new ampoule line.

Let's take a closer look at our base business performance for the quarter, excluding Cenexi. We achieved INR10,659 million in revenue, a 5% increase compared to the same period last year. This demonstrates the continued resilience of our operations in a competitive environment.

Our base business EBITDA margins were steady at 34%, similar to Q2 FY24. On a consolidated basis, our EBITDA margins for the quarter were 21%, impacted mainly by Cenexi, as previously mentioned. We continue to see healthy performance in our core markets of the United States, Europe, Canada, Australia, and New Zealand. These key regions contributed 75% of our revenue in Q2 FY25, up from 74% in the same period last year.

In the U.S., our largest market, sales increased by 3% year-over-year. This growth was fuelled by both an uptick in existing products and a successful introduction of new products. During the quarter, we launched six molecules across these key markets, including four in the U.S. alone. Notably, products like Cetrolixecitate, Ephedrine Sulfate, Tranexamic Acid, and Diazepam are gaining traction with our partners, and we are very optimistic about the future growth potential.

Now, turning our attention to the Rest of the World markets, we see that these regions contributed 19% of our revenue in Q2 FY25, which is similar to Q2 FY24. While we experienced a slight delay in order pickup from Saudi Arabia, we anticipate this will pick up in the second half of the fiscal year.

We remain confident in the long-term growth potential of this important market and are actively working to strengthen our presence there. The Indian market recorded INR874 million in revenue, and this segment contributed 6% of our total revenue. In Q2 FY25, our total R&D expenditure was INR493 million, representing 4.6% of our base business revenue.

During the quarter, we filed seven ANDAs and, importantly, received approval for eight ANDAs. This brings our total ANDA filings in the United States to 363, with 304 approvals and 59 pending. Globally, we now hold 1,726 product registrations, demonstrating our commitment to expanding our product portfolio and reaching patients worldwide.

Turning to our complex product portfolio, to date, we have nine filings completed in a targeted portfolio of 19 products. Six of these complex products have already been approved and launched, with three more expected to be approved soon. Our complex products target an IQVIA market opportunity of $7.3 billion, reflecting the significant potential of this segment to drive future growth.

In the Chinese market, we are adapting our development strategy to address the evolving market dynamics. Four of the nine products in the plan for the China market are currently under development and five have received approvals.

On the Biologics CDMO business from India, while we await further developments on the previously announced potential collaborations, during the quarter, Gland entered into a binding term sheet with Dr. Reddy's Laboratories to establish a strategic Biologics CDMO collaboration. This partnership will leverage our State-of-the-Art biologics manufacturing facility at Genome Valley in Hyderabad. We are very optimistic about the potential of these partnerships to create value for both organizations, and we expect to sign a definitive agreement soon.

Lastly, on Cenexi, the business recorded INR3,399 million, which is Euro 37 million in revenue this quarter, with a gross contribution of 69%. As anticipated, the annual shutdown impacted our performance, and we reported an EBITDA of negative INR685 million, which is negative Euro 7.5 million for the quarter. However, our strategic progress at Cenexi is proceeding as planned. We also have Alain on the call with us today to provide a more in-depth update on recent developments and critical initiatives at Cenexi.

In closing, Gland has had a good first half of FY25 and is optimistic about delivering strong financial results for the entire year. We are executing our strategic priorities, expanding into new markets, and building a solid foundation for the future.

As you may have already read, we are excited to welcome Mr. Shyamakant Giri as our new CEO in January. Shyamakant is a highly accomplished leader with over 25 years of experience in driving growth and success across diverse organizations. This leadership transition is a key step in our long-term strategy, ensuring continued strong leadership and execution.

With that, I would like to hand it over to Alain for a closer look at Cenexie's performance. Thank you. Alain, over to you.

Alain Kirchmeyer: Thank you, Sadu, and good evening, everyone. Cenexi's performance this quarter is in line with what we communicated during our last call. The summer shutdown impacted the performance, during which time we invested in new capacity and performed annual maintenance.

From a site standpoint, first, in Fontenay, we successfully installed the new high-capacity ampoule line, which is scheduled to start commercial production in January 2025. Due to our strong oversight, the project progressed well and remains on track with our original plans, both in terms of investment and implementation schedule. This new line will significantly increase our ampoule manufacturing capacity, improve customer service, and generate additional revenue starting in 2025.

Secondly, in Hérouville, validation batches for a new inactivated vaccine and an ophthalmic gel are progressing well, and commercial production is expected to begin before the end of the year. The site is still operating at low volumes. However, we continue to see new business traction.

In Braine-l'Alleud, Belgium, we experienced a temporary setback caused by a lyophilizer breakdown at the site. We are currently operating at full capacity with our remaining lyophilizers. The issue will be fully resolved during the quarter, and a new backup unit will be installed in the first half of 2025 to prevent future disruptions.

While we are making good progress and our course correction plan is gaining momentum, I want to highlight that these temporary headwinds at the Braine-l'Alleud site will impact our quarterly performance. That being said, we continue to strive for achieving our short-term goals, a positive EBITDA for Q4 of fiscal year 2025.

We also maintain our medium-term goal of a positive EBITDA for the next fiscal year, driven by an increase in revenue above the Euro 200 million threshold. Thank you. I will now turn the call over to Ravi to discuss financial performance. Ravi, please proceed.

Ravi Mitra: Thank you, Alain. Good evening, everyone. We appreciate you taking the time to join us today. Let's review our financial performance for the quarter and first half of the fiscal year 2025. In Q2 FY25, our consolidated revenue from operation was INR14,058 million, a 2% increase year-over-year, driven by modest growth in our base business in the US.

At Cenexi, the revenue for this quarter was lower by 5% year-on-year due to the extended shutdown for installation of the new ampoule line at Fontenay. Base business revenue increased by 5% year-on-year. For the first half of FY25, revenue reached INR28,075 million, marking a 9% year-over-year increase. Our other income for the second quarter reached INR596 million.

This includes INR542 million from interest on fixed deposits and INR45 million in foreign exchange gains. For the first half of the fiscal year, other income totaled INR1,111 million, INR1,023 million from interest income, and INR45 million from foreign exchange gains. The gross margin for Q2 FY25 was 59%, compared to 62% in Q2 FY24, primarily impacted by lower gross margin at Cenexi.

The gross margin of our base business remained stable at 56%. For H1 FY25, it was 59% versus 62% in H1 FY24. Our Q2 FY25 consolidated EBITDA was INR2,961 million, with a 21% margin. This compares to INR3,205 million and a 23% margin in the same period last year. The increase is primarily attributed to losses at Cenexi.

Importantly, our base business delivered a strong 34% EBITDA margin, which is similar to the prior year. Operating expenses at our base business remained in line with previous quarters. The EBITDA for the first half of FY25 increased by 5% year-over-year, reaching INR3,645 million. This translates to a 21% EBITDA margin for the group.

Our base business has achieved a 34% margin. Our net profit for Q2 FY25 stood at INR1,635 million, a 16% decrease compared to the same period last year. For the first half of the fiscal year, our net profit reached INR3,073 million, with an 11% profit margin. In the second quarter, our total R&D expenses were INR493 million, representing 4.6% of revenue from operations, excluding Cenexi.

This is up from INR351 million in the same period last year, reflecting our ongoing commitment to adding new products. For the first half of the year, R&D expenses totaled INR982 million, or 4.7% of revenue. Our effective tax rate remained consistent at 26% for both the second quarter and the first half of the fiscal year.

We continue to invest in our future growth. This quarter, we incurred INR1,037 million in capital expenditures, primarily for the modular expansion of our Pashamylaram plant and Cenexi. This includes the fact that at Cenexi, we invested an additional EUR7.19 million, primarily towards new capacity and de-bottlenecking.

Our strong operational performance generated INR6,436 million in cash flow from operations during the first half of the year. We ended the quarter with INR28,201 million in cash and cash equivalents. After accounting for Cenexi's debt, our net cash position was INR25,413 million. We have also made significant progress in optimizing our working capital, which now stands at INR20,453 million.

Our cash conversion cycle has improved to 149 days, down from 196 days in the same period last year. With that, we will now open the floor for questions.

Moderator: Thank you very much. We will now begin the question and answer session. Our first question comes from Tushar Manudhane from Motilal Oswal Financial Services. Please go ahead.

Tushar Manudhane: Thanks for the opportunity. Yes. So, first, to start with the bookkeeping question in terms of this milestone income and the profit share this quarter, could you share?

Srinivas Sadu: The profit share for this quarter is 8% of revenue, excluding Cenexi.

Tushar Manudhane: Okay. And the milestone income?

Srinivas Sadu: It is 7%.

Tushar Manudhane: So, on the core market sales, in terms of the sales, has been stable for two quarters now, while there have been a few launches as well. So, when do we see the pickup in this segment? Meaningful pick-up in this segment?

Srinivas Sadu: On a year-on-year basis, the US is still growing. Now, if you see a couple of things that happened, ROW has de-grown. The tender offtake did not happen last quarter, which we were expecting in Saudi Arabia. That will happen this time. That's one aspect. And one big what we got in -- front that also will go this quarter. So, that will be a jump on the US business and the ROW business.

But basically, it's a steady growth that is happening. We are losing some products. Whatever we launched in the last few quarters, of course -- if you saw last quarter, we launched eight products. This quarter, we launched six. When we launch products, that quarter will always have a higher offtake. And then it kind of reduces to normalized numbers.

So, that's what will happen. But I think some products will go and have lesser uptake, and some will go. Overall, I think, year-on-year, it's about 9% growth.

Tushar Manudhane: So, let's say that compared to, say, INR32-INR60 crores of core market sales in FY24 and the first half, we achieved 16. So, likewise, considering these so many launches, what kind of growth can be expected in the second half for the markets?

Ravi Mitra: Are you asking what kind of growth we expect in the second half for their new products now?

Tushar Manudhane: This is for the core markets' overall sales.

Ravi Mitra: So, first half year, we grew by 9%. Considering the factors we just discussed about ROW and US, and also timing, we should be on a full-year basis, which should be around what we earlier told you about, the low double-digit kind of growth we are expecting this year.

Tushar Manudhane: Got you. And with respect to this biologics agreement, so this is first of all for which set of markets in the first place?

Srinivas Sadu: We can't really comment on that. These are basically some of the biologic products that Dr. Reddy is going to develop. So, that's a collaboration we have done. And for now, that's what we could predict.

Tushar Manudhane: Okay. And a tentative timeline to see the meaningful benefit or the commercial benefit from this agreement?

Srinivas Sadu: I think the initial financial benefits we'll get from the first quarter of next year. And then, depending on the timing of the products and the development, then we can pick up.

Tushar Manudhane: All right. So, I have more questions. I'll join back to the queue. Thank you.

Moderator: Thank you. The next question comes from Neha Manpuria from Bank of America. Please go ahead.

Neha Manpuria: Yes. Thanks for taking my question. Just extending the question from the previous participant. If I look at the U.S. revenue and strip out the profit share and milestone, it's remained at 70-odd million dollars for three quarters now, despite the fact that we have launched the number of products that we have. I didn't quite catch your comment on why you think the U.S. should pick up and how that low double-digit growth for the entire standalone business would come through, given, if I look at the ROW business, it's also been declining in the first half. So, I'm just trying to tie in your low double-digit guidance with the fact that the U.S. has remained flat for three quarters.

Srinivas Sadu: So, the milestone income and the launches are actually not that related. A portion of that may come from the launches. But most new contracts are designed for that quarter. Milestones are also related to that, and some of the CDMO contracts are signed. We also get milestones from that. So, it's not a direct relation.

Neha Manpuria: Sorry. My question is if I strip out the milestone and the profit share, the U.S. revenue for the last three quarters has been about $70 million. I'm not asking about the milestone and the profit share.

And I think you did mention in the previous comment that your U.S. business should step up from next quarter. Why do you think, given that we've already seen so many launches and we haven't really seen an improvement in the U.S., what gives you the confidence in improvement in the U.S. business, ex milestone, and profit share? And given that we've been flat in the U.S., how do we plan to achieve that low double-digit revenue that you're talking about?

Srinivas Sadu: Yes. So, one is, of course, the new launches which will happen every quarter. That's one. Second, as I mentioned, Enoxaparin, the new contract that was signed, has not been dispatched yet. That will happen this quarter. The Civica contract, which our partner signed up. And the Saudi business is not gone. So, that will start again from this quarter. So, these are substantial amounts. If you look closely, the ROW business has de-grown, primarily because much of its stock comes from Enoxaparin. So, that will keep up. Yes.

Neha Manpuria: Understood. Okay. And my second question is on Cenexi. It seemed, while the summer shutdown was well-articulated, and we understand that, I did see a very sharp decline in gross margins in this quarter. Usually, we do like a 77% gross margin. That seems to have come off fairly sharply. If you could explain that and what we should expect from a gross margin perspective? I mean, is there any one-off in this number from a gross margin that you've reported this quarter?

Ravi Mitra: Yes. So, the gross margin reduction this quarter is largely because of the mix of products, whereas on the Belgium side, there has been a lower uptake than last year. And other sites were more or less in line with Q1. But the mix of the sites will depend on, will give the gross margin overall basis. So, the mix is one of the reasons for the reduction to 69%.

Neha Manpuria: And this should normalize based on the opening comment that we have resolved the issues.

Ravi Mitra: Yes. It should go back to the earlier gross margin level.

Neha Manpuria: Okay. And so, on Cenexi, is it fair to assume that as we go back to the EUR50 million per quarter run rate in the third quarter, we should be able to achieve breakeven in the December quarter? Would that be a fair assumption?

Ravi Mitra: So, third quarter, we'll not be able to comment, but we are targeting after the new line to be up and running from January. That should definitely be achieved.

Neha Manpuria: Okay. Understood. And my last question on the CDMO that was signed with Dr. Reddy: Are there any more talks with any other partner on this, or do you think the tie-up with Reddy would be enough for us to fully utilize the capacity that we have?

Srinivas Sadu: No. So, this is a contract, so we can still get other CDMO businesses. Likewise, they can also look for other businesses. So, it's not that it's fully dedicated to just Dr. Reddy's capacity.

Neha Manpuria: Understood. And so, what would be the peak revenue potential from this CMO opportunity with Reddy? If you were to just put a number, I'm not asking for a timeline, but what could be the peak revenue in your view?

Srinivas Sadu: It's too early to comment, Neha. Yes.

Neha Manpuria: Okay. Thank you so much, sir.

Moderator: Thank you. The next question comes from Bino Pathiparampil from Elara Capital. Please go ahead.

Bino Pathiparampil: Hi. Good evening. Starting with Dr. Reddy's contract, is it for the entire API formulation, etc., or will it be just a formulation?

Management: It's mostly a drug substance. API? Yes.

Bino Pathiparampil: Okay. And would it be for the semi-regulated markets or regulated markets?

Ankit Gupta: So, hi. Hi, Bino. This is Ankit. So, they didn't specifically mention as to what market it would cover. We are developing products for the global markets, and our site is also designed to service all kinds of markets. So, at some point in time, it will be a combination of both semi-reg markets and reg markets, but let the fine print come, and we'll be able to discuss more specifics then.

Bino Pathiparampil: Okay. Got it. Second, I didn't quite understand what's the issue with Saudi business. Could you please explain what exactly happened?

Srinivas Sadu: So, we did win a tender in Saudi. Some of the products' off-take has happened. Enoxaparin, the off take has not happened. The quantities from the previous supplies, what we made with the previous tender, that was still there. The stocks were there. So, that will, off-take will start happening some end of this quarter.

Bino Pathiparampil: Okay. It's just that it didn't sell in the earlier quarter. There was no specific incident per se.

Srinivas Sadu: It's just the timing, yes.

Bino Pathiparampil: Okay. And one last question. You have tentative approval for Latanoprostene eye drops in the US. Is that a product likely to be available in the next 12 months to 24 months, or is it far out?

Srinivas Sadu: It's under – para-IV settlement, so we can't comment too much on it.

Bino Pathiparampil: Okay. Thank you.

Moderator: Thank you. The next question comes from Jinesh Shah from RSPN Ventures. Please go ahead.

Jinesh Shah: Yes. Thanks for the opportunity. So, my first question was with respect to the Cenexi business. As you mentioned, we'll probably be able to do the breakeven for the EBITDA by quarter 4. So, I would just like to know about the outlook for the EBITDA margins with respect to the Cenexi business and how we are looking for EBITDA margins next year onwards. What is our vision in that?

Ravi Mitra: So, see, we expect after the new line and some of the additional capex to be done, next year we'll end up at EBITDA neutral or low single digit. Year after that, when all the capacity is on stream, and we get all the pipeline projects commercially on, then we'll end up at the old 10% EBITDA level.

Jinesh Shah: Okay. Then my other question would be with respect to the maintenance shutdown thing, is it like the annual thing that we will expect in next year in FY26, too, that will impact one of the quarters with respect to revenue and the business or something like that? It's like the annual thing or it's like the periodic phase that we come into the maintenance shutdown?

Srinivas Sadu: It's annual maintenance. Every year, this will have just a few days here and there—more or less, it will take three to four weeks, but I think in the first couple of years, we'll try to use that time to install the actual capacity.

Jinesh Shah: So, we are expecting in quarter 2 of FY26 as well?

Srinivas Sadu: Sorry.

Jinesh Shah: So, we are expecting another maintenance shutdown in FY26 quarter 2, if I can assume correctly.

Srinivas Sadu: No, it will be in August of every year.

Jinesh Shah: Okay. Fair enough. And my last question would be with respect to the tax rate that I would just like to know the reason that though Cenexi is in like a loss making company at the moment and standard tax rate is around 25%. And how we are like charged more tax which is approximately 34% in overall consolidated business?

Ravi Mitra: Yes, because of Cenexi's negative PBT, no tax is being created for deferred tax assets. That is why you are in consolidated, which you are saying is a higher tax rate. Once Cenexi comes back to profitability, then we'll go back to our corporate rate.

Jinesh Shah: Okay. Fair enough. Thanks a lot. That's it from my side.

Moderator: Thank you. The next question comes from Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: You recently announced the appointment of the CEO Shyamakant Giri. So, can you take us through the thought process of separating your role and that of CEO, and what were the thoughts of hiring someone like Shyamakant Giri to run as a CEO here? And should we read something more strategic here? What are you expecting going forward for the new CEO to sort of focus on?

Srinivas Sadu: Yes, I think it's more to strengthen the senior leadership to grow the business, and I'll be taking the role of more strategic and long-term – mid to long-term initiatives and also a bit more time at probably Cenexi because it needs a bit more focus. And the new CEO will focus on the rest of the business. And also he brings in more experience in ROW and other markets. So that also adds to our strategy of growing business in different markets. While we continue to have that solid business in the US market. That's the basis.

Saion Mukherjee: Yes. Mr. Giri's experience of running frontend especially in ROW emerging market, is that something you are aggressively looking at going forward because you had earlier mentioned about putting up contents?

Srinivas Sadu: Yes, we are evaluating that option. I mean, there are pros and cons for that. So that's actively in evaluation, yes.

Saion Mukherjee: Okay. And secondly, on the bio contracts. I think you mentioned about Dr. Reddy's. So how have the discussions evolved? If you can give us a sense now what kind of traction we should expect, let's say from a 2 year, 3 year perspective? What are the next milestones that we should watch out for?

Srinivas Sadu: I would say this is very important what we just announced, because it also gives us the experience and learning what is required in this business. And normally a lot of companies look at what you've been doing as because it's a new area we're entering. While we're doing this we're also having some tangible discussions with some of the other players. This will only probably expedite those kinds of discussions what we're having.

So while we can't put a number to it, but it's definitely one both from - while it may not add up huge numbers in the near term, but it's a - I would say it's a foundation which we're laying for the future with smaller revenues in the beginning, but it all depends on how much of your business we can create moving forward.

Saion Mukherjee: Okay sure. Thank you.

Moderator: Thank you. The next question comes from Vivek Agarwal from Citigroup. Please go ahead.

Vivek Agarwal: Hi, thanks for the opportunity. My question is related to US business. So in first half, is it possible for you to quantify the contribution of new products in the US revenue? Basically, how many you might have launched around 10 products, so what is the current contribution in their finance revenue?

Srinivas Sadu: The next contribution for the first half I think it's around about INR60 crores?

Vivek Agarwal: So new product contribution is INR60 crores. And the second question is how the volumes have grown as far as the rest of the products in the US or the baseline products in the US?

Srinivas Sadu: From quantity perspective it is about 5% growth in the US compared to the Q1, compared to the Q1.

Vivek Agarwal: Compared to Q1 and Y-o-Y what kind of the volume growth was there?

Srinivas Sadu: Y-o-Y it's about similar 5%.

Vivek Agarwal: Okay sir. Thank you. That's from my side.

Moderator: Thank you. The next question comes from Anubhav Agarwal from UBS. Please go ahead.

Anubhav Agarwal: One I am just trying to understand your R&D. So annually your R&D is about INR200 crores. And I understand from past calls that when you report R&D, part of the R&D is spent by the partners also. So can you just help if you are spending INR200 crores a year, what would be the gross R&D spend of partner plus you put together roughly?

Srinivas Sadu: Anubhav, just give a second. Vivek, just corrected. I think year-on-year the growth based on the volume is about 13%.5% is quarter on quarter. But year on year, it's 13%, quantity increases.

Anubhav Agarwal: So my question was on R&D. So, Gland R&D annually is about INR200 crores. And my understanding was and you can correct it. For any ANDA that you submit on an average, part of the R&D is reported by you, part of the R&D is spent by your partner. So, on a gross basis, the R&D is higher. So, I'm just trying to understand, when annually your R&D is about INR200 crores, your partner and you put together, on an average what would be the gross number?

Srinivas Sadu: No, so our partner won't put anything into our R&D. It's 100% our R&D.

Anubhav Agarwal: So, I'm just trying to understand. So, you're filing about 30 products annually, and you're spending about USD25 million on R&D?

Srinivas Sadu: That's correct.

Anubhav Agarwal: I mean, you're effectively spending a million dollars per product, per ANDA, give and take, right? And that's a huge payback period. So, given your cashbook, etc, why are you not selling two times the product or three times the product? Opportunity is not small. So just trying to understand, first, versus all other companies that we trust, USD1 million per ANDA is the lowest I think that we've seen in Gland. And then I cannot understand why are you not filing 2x or 3x of the product that you are filing today, with that efficiency?

Srinivas Sadu: So, one is, of course, what is the pipeline left? We already filed 363 products. There's not much pipeline left. That's one. Second, a lot also is going into complex products. That takes a larger number of people compared to this. And we have to balance between fixed cost and also the investments that you make. So, while a lot of products also, we have to look at what capabilities our R&D have. So, whether they can actually make some of these products.

So, we have to increase the number of people to double if you have to file more. And this is not like you can hire today and then remove after three years. We have to manage; we have to balance between the filings and how we want to go with this business and then the return on those products also.

Anubhav Agarwal: But sir, can I ask you one more question on this? But effectively, if you're spending only USD1 million per product, I think you'll be easily able to recover that. There is no question about you having to fire people after two, three years, even if there is a miss on a few products. I'm not able to understand that if you're spending USD1 million per product and USD2 million as a capex per product, in the injectable field with that margin that you have, you're not even able to recoup the investment, so where does the doubt come in from?

Ankit Gupta: See, basically, if you see today, we are a purely injectable company. And as far as the generic product is concerned, we are, by and large, covering most of the opportunities that we can do from our R&D in India. We can't do certain sets of therapeutic categories because of contamination or whatever issues. But outside of that, whatever the addressable market is for us, we are doing it from the R&D capabilities in-house.

The way we want to fund the future growth is also to look at outsourcing models and maybe co-development models wherein we can partner with somebody who's more specialized in doing those developments and apportion more budgets and capital investments to that side rather than building it only on the organic R&D side. One, it will speed up the overall process of getting approvals. And second, it will also improve the overall value chain of the products that are going to come onstream for us in the future.

Anubhav Agarwal: Sure, guys. I'll take this a little offline as well. Just one more clarity on Genome Valley. What is the capacity over there?

Ankit Gupta: So, it's about 8,000 litres of DS capacity. And we have only used 30% of the site. So, capacity can actually go up very significantly. It has quite a lot of unused land. But today, the installed capacity is about 8,000 liters. And it is a mammalian capacity, single-use.

Anubhav Agarwal: And for these 8,000 litres, what will be equivalent gross block here? I mean, what kind of investment would have gone in to create this capacity?

Ankit Gupta: We have invested close to INR300 crores on the site.

Anubhav Agarwal: Okay, sure. Thank you, guys.

Moderator: Thank you. The next question comes from Aditya Pal from MSA Capital Partners. Please go ahead.

Aditya Pal: Hello. Thank you so much for the opportunity. So, a couple of questions on Cenexi. So, we're just seeing in Q2, the overheads in Cenexi P&L has come down. Anything that the management has undertaken, any strategy, downsizing, anything that you can highlight on that?

Ankit Gupta: So, Aditya, the overhead reduction is purely a function of the site running for two months instead of three. And what happens is while we have a fixed cost structure which will not be impacted by a month of shutdown, but there are certain other additional costs which come into play when the site is up and running, say the contract labor and multiple allied costs. That would not form part of the P&L because the site was not running for, let's say, three to four weeks.

Aditya Pal: So, this will again go up once we start operating in the normal period.

Ankit Gupta: Yes, probably for that, we should look at the Q1 numbers. Q1 kind of expense space is what we would have in future as well, but obviously the revenues would go up because our month-on-month run rate is now picking up significantly. In fact, September and July were very decent in terms of the monthly run rates we had from the site.

Aditya Pal: Understood. And just to double-click on the previous participant's question, there was a question about Cenexi break-even period and once the EBITDA starts to mature, that is in year 2, FY26, FY27, and you had said that this particular company will be generating anywhere between low double digits EBITDA margin. So just wanted to understand the management's thought process when we acquired this business. Even though this is a gross margin accredited business, it is being a bit dragged on the EBITDA margin. So, it's a bit of a philosophical question if you can just highlight that what is it that we are looking to get from Cenexi.

Srinivas Sadu: One is the European brand, the generics business and we didn't have any presence in Europe. That's one. Second, it's a solid CDMO business in spite of the problems and issues we face and the business is very intact with long-term contracts. And also, some of the technologies what this business has, we don't have. So, we can use those technologies to file some of our products as well. And also, they also manufacture control substances for US and Japan market.

That opens up some of the portfolio for Gland also. So, there's several areas what we looked at when we acquired this business. But we always knew that it will be EBITDA negative for us in terms of dilutive to Gland. But we also looked at how we can make it more efficient in a duration of time. But it took longer than what we anticipated because of the issues that we have there. But in the long run, I think the business is solid and we also were looking at a lot of long-term opportunities coming because of this European asset.

Because most of the time, the big pharma in Europe, they want to, we want to take the products from the European manufacturing side. This will open up those opportunities. So I would say this was a long-term plan what we looked at. And also entering European market with our own products is more competitive and very difficult to take from India. So it was like a combination of strategy of CDMO and our own portfolio, how to increase in certain areas where we can't enter. Like the control substance, we can't take it from India to US. But it's an opportunity that we can take from there.

Aditya Pal: Also, another question that I had, we currently, we have a gross block of somewhere around INR4,500 crores. How fast, how quickly can you see that we come back to a normal asset turnover of 2x, 2.5x that we used to do two years back? And if you can give me a split between Cenexi business and Gland business, ex-Cenexi, at peak revenues that I'm assuming will be 2.5x gross block?

Ravi Mitra: Yes, so on the Gland side, the new capex which we have put up in Pashamylaram site, we go upstream from next year, which is Bag line and the Microsphere dry powder line, and a few Hormones/Suspensions line also will come from next year. So that will bring us back to our old Gland asset turn rate, which is 2, 2.5. On the Cenexi, this year, we would be like EUR165 million.

But next year, we expect to reach EUR200 million, which is almost like 0.8x. And once we start commercializing the new capacity, which we are putting like one is PFS line, one Ampoule line, and a few other lines also, which we are currently planning, then we should have much higher between 1x to 2x asset turn at Cenexi as well. But that will take in a midterm basis and not next year.

Aditya Pal: Understood. This last couple of questions, sir. So in Cenexi, so what I could understand is that the Normandy side is the one that is causing the overhead to shoot up and asset turns to be low. Is that a fair understanding?

Ravi Mitra: Yes, that's correct.

Aditya Pal: Understood. And sir, a bookkeeping question. So, goodwill has gone up in September in H2 in the balance sheet. What has led to that? Because we haven't done any acquisition in this H1, correct?

Ravi Mitra: Sir, your voice is breaking. Can you repeat that question?

Aditya Pal: So, my question is Goodwill has gone up from March to September in the balance sheet?

Ravi Mitra: So, it's just an exchange difference.

Aditya Pal: Okay, understood. Understood. That's it from my side. Wishing you all the very best.

Moderator: Thank you. The next question comes from Amlan Das from Nomura. Please go ahead.

Amlan Das: Hi, sir. My question is regarding the ROW markets. How has been the performance in the ROW markets like LATAM? And what is your outlook regarding these markets?

Srinivas Sadu: I agree with that. So the APAC business has gone up and there are also several approvals in South Asia. They started exporting. Mexico business has started in there. If you actually remove Saudi and see the rest of the business has gone. But once this comes back, then I think overall the ROW business will back on track a little.

Amlan Das: Sorry, sir. I dropped in between. I couldn't hear. Could you just repeat once? I'm sorry. Are you dropped off?

Srinivas Sadu: Are you dropped off?

Ankit Gupta: Yes, your voice dropped in between. I couldn't hear. Could you just repeat once?

Srinivas Sadu: No. What I said is APAC business has gone and we also launched a new product in South Africa and also Mexico. The business started last quarter. So, this will start picking up. If you actually remove Saudi and see the rest of the business, it has grown up. It has gone up. So once we start shipping out some of the key products to Saudi, then I think overall business will be back on growth track.

Amlan Das: Okay, sir. So how is the performance in markets like Brazil and Argentina where you were quite present before, I think?

Srinivas Sadu: I think that is steady business we're having Brazil.

Amlan Das: Okay, sir. Okay. Thanks.

Moderator: The next question comes from Shyam Srinivasan from Goldman Sachs. Please go ahead.

Shyam Srinivasan: Good evening. Thank you for taking my question. Just the first one on the standalone or core costs, right? If I look at gross margins, I think are down like 50-60 basis points. So what is explaining just the core gross margins coming off? Is it mixed?

Ravi Mitra: So as compared to Q2 of last year, it has come down by 1%. And that is largely a factor of mix, which you rightly said, and also the profit share and element on that.

Shyam Srinivasan: Got it. So, this is something like any of those products which are higher in contribution today versus last year….

Ravi Mitra: But as compared to Q1, our gross margin has gone up actually from 53.

Srinivas Sadu: Correct, correct.

Shyam Srinivasan: Yes, so what is driving that Q-o-Q improvement?

Ravi Mitra: So that's the mix actually.

Shyam Srinivasan: Okay, so versus last year, the mix is inferior, but versus quarter one, it's better.

Ravi Mitra: Yes.

Shyam Srinivasan: Got it. And if I look at core margins have remained flat Y-o-Y, so and R&D has gone up 40%. So other expenses excluding R&D is actually down quite a bit. Even quarter, Q-o-Q is down 20%. So is that sustainable or is there any one-off there in terms of the lower cost, lower other expenses?

Ravi Mitra: So power and fuel has gone down at India.

Shyam Srinivasan: No, no. In the way you report your power and fuel employee, you have other expenses above EBITDA. So other expenses I'm excluding R&D, which is up 40%. So that leaves the other, other expenses is actually down 25% or something, Y-o-Y.

Ravi Mitra: So Y-o-Y, other expenses are actually same, but quarter it has come down, right? Yes. In other expenses,

Shyam Srinivasan sir, I'm just removing R&D cost. That's an okay assumption, right? That why you book R&D no?

Ravi Mitra: No, it's largely this quarter is the rate we can consider because previous year there would have been some consulting expense for acquisition and other strategic advisory you're taking.

Shyam Srinivasan: Got it. And my last question, just on guidance. Sorry, I missed it. So we earlier had a meeting growth guidance for the US, right? So you are now seeing it low double digit, is it? Sorry, I missed this.

Ankit Gupta:: That's right, Shyam. We are seeing low double digit as the top line growth expected.

Shyam Srinivasan: Yes, Ankit . And what's driving it? It seems like volume growth seems to be strong. So I'm assuming is it like because of pricing pressure or what explains that or slower, like new product launches?

Ankit Gupta : Yes. So it's going to be a combination of new launches, which are stated to be done in H2 of this year. And then at the ROW level, we did talk about the Saudi Arabia business, which is going to get back to normal. There were certain sales to Q3 and Q4, which would pick up, a combination of new launches, a steadiness in base business and the pickup in ROW would drive this growth.

Shyam Srinivasan: Understood. Thank you and all the best.

Moderator: Thank you. The next follow up question comes from Neha Manpuria from Bank of America. Please go ahead.

Neha Manpuria: Yes, just a follow up question on the CMO biosimilar business. What is the cost that we are booking for quarter in terms of the burn from this capacity? And once the contributions from Dr. Reddy starts coming through, is it fair to assume that we'll be able to achieve breakeven on the cost starting at FY26?

Ravi Mitra: So the biologics you're asking on?

Neha Manpuria: Yes.

Ravi Mitra: So the current cost is about INR3 to INR4 crores per quarter. And on the revenue side, as we mentioned earlier, it's too early to comment on that.

Neha Manpuria: INR3 to INR4 crores per quarter. That's all the cost is for the CMO business.

Ravi Mitra: That's the current running cost we are incurring.

Neha Manpuria: Okay. So depends, this is as and when the Reddy's supply comes coming through, then this cost will go up.

Srinivas Sadu: Yes, this might go up a bit, but the business should cover all those costs.

Neha Manpuria: Yes. Fair enough. Okay. And my second question is, do we have any GLP products in our pipeline or have our partner reached out to us for any GLP products given we have a requisite capacity for that, even if it's total finish?

Srinivas Sadu: Yes, we do. We have already signed a few GLP-1 contract on the CDMO side. Yes.

Neha Manpuria: This is for the regulated market too?

Srinivas Sadu: Yes.

Neha Manpuria: And supplies would start well?

Srinivas Sadu: Well, there are all patents around it, right?

Neha Manpuria: Sorry sir.

Srinivas Sadu: So we can't really tell the dates because it all client products. So it's, yes, but we have signed with, I think, three different customers on GLP.

Neha Manpuria: Got it. Thank you so much, sir.

Moderator: Thank you. The next question comes from Sunil D. Khatri, who's an Individual Investor. Please go ahead.

Sunil D. Khatri: Yes. Good evening, sir.

Srinivas Sadu: Good evening.

Sunil D. Khatri: My question is that, when is likely to be like a break-even for the Cenexi business?

Srinivas Sadu: Sorry, we lost you.

Sunil D. Khatri: When is likely, like now, for Cenexi business, we are not doing any profit. We are incurring losses. So when is likely to be like a break-even for the Cenexi business and whatever the capital expenditure you are incurring for this development. So when is to be completed and the production like your plan to give the 100 % utilization?

Ravi Mitra: So at Cenexi, a beta-level break-even will happen in Q4. And the capex cycle would complete in next one to two years' time.

Sunil D. Khatri: Two years' time?

Srinivas Sadu: One to two years. More than one, less than.

Sunil D. Khatri: Your India operations are good. Actually, they are making, the Cenexi is making a drag on the balance sheet.

Ravi Mitra: Yes. So as Mr. Sadu mentioned that this business is very solid there, and we need to invest and improve our capability and then the performance will surely follow.

Sunil D. Khatri: So you mean to say that it will take another one and a half years to two years to grow the plant on stream or 100% utilization for Cenexi?

Srinivas Sadu: No, no. Currently, some of the plants are already well-utilized. There are two plants which are not a 100% utilized. So there are several technology transfers which are happening. So by the time those get commercialized, it will take a year or so. So what we're saying is while we want to invest for the new capabilities there, of course just now somebody is mentioning about GLP capabilities also. There's also demand for that in European markets. We're also looking at investing in those new capabilities for the future growth of Cenexi business. But for the current capacity the couple of plants are already fully utilized and a couple of plants, there are projects which are getting transferred. So by the time those get commercialized, it will take for a year. And that's why we're saying, by next year, first quarter, we'll be able to..

Sunil D. Khatri: Okay, sir. Thank you.

Moderator: Thank you. Ladies and gentlemen, we will take that as our last question for today. I now hand the conference over to Mr. Ankit Gupta for closing comments.

Ankit Gupta: Thank you, everyone, for joining us today. We appreciate your participation in the questions during the call. If you have any follow-on questions to this, please feel free to reach out to us. Looking forward to interact with you in the next quarter now. Thank you.

Moderator: Thank you. On behalf of Gland Pharma Limited, that concludes this conference. Thank you for joining us. You may now disconnect your lines.