GLAND PHARMA LIMITED

February 10, 2025

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Scrip Code: 543245

National Stock Exchange of India Limited
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 - Q3FY25

Please find enclosed the transcript of the Earnings call for Q3FY25 of the Company held on Monday, February 03, 2025, 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

Pallerlamudi Sampath Kumar

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Sampath Kumar Pallerlamudi
Company Secretary & Compliance Officer

Encl: As above

“Gland Pharma Limited

Q3 FY '25 Earnings Conference Call”

February 03, 2025

MANAGEMENT: **MR. SRINIVAS SADU – EXECUTIVE CHAIRPERSON – GLAND PHARMA LIMITED**
MR. SHYAMAKANT GIRI – CHIEF EXECUTIVE OFFICER -- GLAND PHARMA LIMITED
MR. RAVI MITRA – CHIEF FINANCIAL OFFICER INDIA'S OFFICE -- GLAND PHARMA LIMITED
MR. ALAIN KIRCHMEYER – CHIEF EXECUTIVE OFFICER -- CENEXI

MODERATOR: **MS. RUNJHUN JAIN**

Moderator: Ladies and gentlemen, good day, and welcome to Gland Pharma Q3 FY '25 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 call, please signal an operator by pressing star then zero on your touch-tone phone. Please note that this conference is being recorded.

I now hand the conference over to Ms. Runjhun Jain. Thank you, and over to you, ma'am.

Runjhun Jain: Thank you, Rayo. Good evening, everyone. We welcome you to the Gland Pharma's Earnings Conference Call for Q3 FY '25.

Today, we have Mr. Srinivas Sadu, Executive Chairperson; Mr. Shyamakant Giri, Chief Executive Officer; Mr. Ravi Mitra, Chief Financial Officer from India's Office; and Mr. Alain, CEO of Cenexi, who's connected virtually from France. We'll begin the call with business highlights from Mr. Sadu followed by Mr. Giri, who will share his vision about the company. This will be followed up by an overview of Cenexi by Mr. Alain. And lastly, the group financial overview by Mr. Ravi.

Before we proceed, I would 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 risks associated with our businesses. The call is being recorded and script will be available on the website shortly.

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

Srinivas Sadu: Thank you, Runjhun. Good evening, everyone, and welcome to our Q3 and 9-month FY '25 earnings call. I would like to start by wishing you all a very happy and fulfilling new year, filled with new opportunities and achievements.

Let's dive into our financial and operational performance. At the consolidated level, our Q3 FY '25 revenue was INR13,841 million, with consolidated EBITDA of INR3,600 million, translating to a margin of 26%. 100 bps increase year-on-year.

Our base business excluding Cenexi generated INR10,123 million in revenue for the quarter, an 8% decrease year-over-year. This was due to volume degrowth in some of our key products, partly compensated by new launches. We expect to recover these volumes in the coming quarters and remain optimistic about the overall trajectory of our business.

The EBITDA margin for our base business was a robust 39%, compared to 34% in the same period last year. The margin improved in the quarter due to changes in the product mix and the measures carried out leveraging costs in various fronts.

Coming to US sales. We launched 13 new molecules during the quarter, including Chlorpromazine, Dexamethasone, Phenylephrine, Phytonadione, and Diphenhydramine. These launches strengthened our product portfolio and positioned us well for continued growth in the U.S. market.

Revenue from the Rest of the World markets increased to 21% of our total revenues in Q3 FY '25.

The Indian market generated INR562 million in revenue, contributing 4% to our total revenues.

Let's discuss the progress of our complex product portfolio. To date, we have completed 9 filings in our targeted portfolio of 19 products. 6 of these complex products have already been launched, with 3 more expected to secure approval in due course. These products target an IQVIA market opportunity of USD7.1 billion, reflecting the significant potential of this segment to drive future growth. In addition, we are very excited to inform you that 15 complex formulations, which are under co-development with MAIA Pharmaceuticals, a specialty injectable development company, have shown promising progress. These include seven, 505(b)(2) and eight ANDAs at different stages of development. We expect commercialization to begin from FY '27.

In 9M FY '25, we filed 3 RTU infusion bag products with 10 more in the pipeline. These products are part of our RTU portfolio with 14 bag products registered. These RTU bags have IQVIA of about USD530 million value in the U.S., and these filings show our commitment towards prioritizing newer technologies in infusion bags.

In Q3 FY '25, our total R&D expenditure was INR437 million, representing 4.3% of our base business revenue.

During the quarter, we filed 4 ANDAs and received approval for 8, including Latanoprost Ophthalmic solution and Phytonadione injectable emulsion. This brings our cumulative ANDA filings in the U.S. to 366, with 312 approvals and 54 pending. Globally, we now hold an impressive 1,736 product registrations, demonstrating our ongoing commitment to expanding access to high-quality medicines.

On the regulatory front, we are pleased to announce that we have received EIR from the U.S. FDA for our Dundigal and Pashamylaram facilities in Hyderabad, signifying successful closure of the large U.S. FDA inspections. We remain dedicated to upholding the highest quality standards across all our operations.

Turning to biologics. We have entered a collaboration agreement with Dr. Reddy's Laboratories. This partnership leverages our state-of-the-art biologics manufacturing facility at Genome Valley in Hyderabad and opens exciting new opportunities in a rapidly growing biologic CDMO segment. This is expected to generate incremental revenue starting next financial year.

We are happy to also inform you that we have signed a CDMO collaboration nonbinding term sheet with Shanghai Henlius Biotech as well. These aims to establish a secondary manufacturing site at Gland for some of the key biosimilar products of Henlius. These collaborations demonstrate our continued focus on investment in biosimilar CDMO space.

Coming to Cenexi. The business recorded revenue of EUR41 million in Q3 FY '25, though below our estimates, mainly impacted due to reduced manufacturing activity following regulatory audited at Fontenay during the quarter. However, gross margin improved 77%,

compared to 75% in Q3 FY '24. We have Alain on the call for a more detailed update on recent developments and key initiatives at Cenexi.

Finally, I'm delighted to introduce our new CEO, Mr. Shyamakant Giri. We are confident that his extensive experience will be invaluable as he leads the company towards continued success. You will hear more about his vision and plans for the company in his address shortly.

I want to reaffirm our commitment to driving long-term growth through strategic partnerships, innovation and investment in new products and technologies.

Thank you once again. I would now request Mr. Giri to take over.

Shyamakant Giri: Thank you, Mr. Sadu. Good evening, everyone. I'm delighted to join you all for today's earnings call, and I'm honoured to address you for the first time as a Chief Executive Officer of Gland. It is both a privilege and a responsibility to step into this role especially as the company actively pursues strategic initiatives to expand its global presence and strengthen its market position.

As I begin my journey at Gland, my immediate priority is to understand the company's current operations and improve profitability while identifying new opportunities to enhance our growth, strengthen our capabilities and expand globally in areas where we can excel.

I have started collaborating with the team to evaluate our direction and strategy from the very first perspective and build a future fit Gland. I have identified key priorities both on the demand and the supply side as we develop our overall strategy.

On the demand side, we have 4 identified priorities:

One, RoW market growth. We will improve our footprint and launch new products, focusing on high-value, high-growth countries instead of having a cluster or a continent approach.

Two, India domestic growth. We will leverage our portfolio strength in selected therapies and explore inorganic expansion within India.

Third, U.S. market expansion, new customer acquisition and value expansion from the current partners will be the crucial for our growth in the U.S.

And finally, portfolio assessment. We will continue to see strategic partnership and pursue potential M&A opportunities to incorporate more high value injectables and newer modalities into our commercial portfolio.

On the supply side, the 4 identified priorities are:

One, maintaining quality and cost leadership. We will strengthen our operational efficiencies to lead in both quality and cost.

Two, engagement with Cenexi leadership. We will ensure that the course correction measures achieve their desired profitability outcomes and provide both strategic and financial value.

Third, intensifying R&D focus. We will enhance our new product pipeline and accelerate our current projects.

And last but not the least, improving management bandwidth. We will hire top talent and more empowered leadership teams.

All our strategies will be built on the foundation of our established core values while fostering a culture of innovation, collaboration and expertise. I am grateful to the Board and its Chairman, Mr. Sadu, who are entrusting me with this responsibility, and I'm excited to work closely with our leadership team.

This is truly an exciting time for Gland, and I look forward to collaborating with all of you to chart the next phase of company's growth journey. I welcome your perspectives and ideas as we embark on this collective endeavour. Thank you again.

And now I'd like to hand it over to Alain, to provide an update on Cenexi's performance. Over to you, Alain.

Alain Kirchmeyer: Thank you, Mr. Giri, and good evening, everyone.

Cenexi's performance for this quarter was impacted due to certain factors. At our Fontenay facility, Q3 FY 2025 production was impacted by an unannounced inspection by the ANSM, the French Health Authorities. Cenexi is committed to working closely with the ANSM to address the observations raised. .

On a positive note, I am pleased to report that our new high-capacity ampoule line began production last week, right on schedule. This addition will increase our ampoule manufacturing capacity by 40 to 50 million units, allowing us to better serve our customers moving forward.

In Hérouville in France, commercial production of a new inactivated vaccine and an ophthalmic gel commenced in December as anticipated and will ramp up gradually in 2025. Additionally, we have begun installing a new prefilled syringe line, which is expected to be operational later in the year. This will significantly boost our capacity to meet the growing demand for this dosage form.

In Braine-l'Alleud in Belgium, orders from a new customer, unfortunately, had to be deferred from Q3 to Q4 FY 2025. As mentioned in our last call, earlier setbacks from the Lyophilizer breakdown continued to affect our production levels in Q3, and we expect this to get restored in H1 of FY 2026.

Given these developments, we anticipate a weaker performance for the January to March quarter, but I want to emphasize that all major projects remain on track and aligned with our strategic goals. We remain firmly focused on achieving our medium-term goal of delivering positive EBITDA in full year 2026. This will be driven by our efforts to push revenue beyond the EUR 200 million threshold.

With that, I want to thank you for your time, and I will now turn the call over to Ravi to discuss financial performance. Ravi, over to you.

Ravi Mitra: Thank you, Alain. Good evening, everyone. We are grateful for your time and presence today. Let's take a look at our financial performance for the quarter and nine months ended 31st December 2024. I'm very pleased to inform you that our EBITDA and PAT margin improved during the quarter.

The EBITDA margin increased to 26% as compared to 23% in Q3 FY '24 and stood at INR3,600 million for Q3 FY '25. For the base business, ex-Cenexi, the EBITDA margin did significant improvement for Q3 FY '25 at 39% versus 34% in the same period of last year. Improvement of gross margin and better cost management has led to the improvement.

We, however, reported a negative INR312 million of EBITDA at Cenexi primarily due to the unannounced inspection by ANSM at Fontenay site in this quarter. The EBITDA for the 9 months ended December 2024 stood at INR9,214 million, compared to INR9,744 million for the same period of last year. We have reported the EBITDA margin for 9M FY '25 at 22% at the consolidated level and 34% for the base business.

The gross margin for Q3 FY '25 also showed an improvement of 67% from 61% in Q3 FY '24 due to change in product mix. In our base business, the gross margin was at 63% as compared to 56% in the previous year. We are happy to see better margin profile of the new products launched during the year and this quarter.

Our net profit for the third quarter increased by 7% at INR2,047 million, compared to Q3 FY '24 and increased by 25% sequentially from the second quarter. During this quarter, we achieved a PAT margin of 15%, an improvement from 12% year-on-year. During the 9 months of the current financial year, our PAT was INR5,120 million at 12% margin.

Revenue from operations stood at INR13,841 million in Q3 FY '25. The gap with the corresponding quarter in the previous financial year was primarily due to lower shipped volume of certain products for U.S. market, which we expect to complete in the next quarter. At Cenexi production was impacted by unannounced inspection by the ANSM, the French Health Authorities.

Revenue of our base business, ex-Cenexi, while it showed growth of 3% in 9M FY '25 driven by our increased performance in the U.S. market, it decreased by 8% in this quarter compared to same period of last year to INR10,123 million.

Revenue from operations for the 9MFY '25 stood at INR41,916 million, a year-on-year increase of 2%. Other income for Q3 FY '25 was INR585 million. This includes INR525 million from interest on fixed deposits and INR20 million in foreign exchange gains. For 9M FY '25, other income totalled to INR1,696 million, INR1,548 million from interest income and INR65 million from foreign exchange gains.

The higher finance cost during the quarter is related to the interest on a GST different matter. The total R&D expense for the third quarter were INR437 million compared to INR530 million

for the same period of the previous financial year and stood at 4.3% of the revenue from operations on an ex-Cenexi basis. The total R&D expense for the 9 months was INR1,419 million, which was 5% of our revenue, demonstrating our continued focus in R&D. On a stand-alone basis, our effective tax rate was 25% in the third quarter and 26% for the nine months of the current financial year.

As of December 31, 2024, on a group level, we had a total of INR27,189 million in cash and cash equivalents. After accounting for Cenexi's debt, our net cash position was INR24,122 million. Cash flow from operations during the 9M was INR5,889 million and working capital stood at INR23,060 million as of December 31, 2024.

The average cash conversion cycle improved at 162 days for the nine months ended December 2024 compared to 182 days in the same period last financial year. The total capex spend during the quarter was INR1,379 million spent at Gland's Indian sites and at Cenexi.

At India, we are spending growth capex at expanding a new bag line and increasing the packing capacity. We are also in process of adding a new cartridge line at Suite 9which will be in addition to one existing cartridge line at Pashamylaram site. At Cenexi, as Mr. Alain mentioned, we are adding some additional high speed and new lines to improve the overall capability.

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

Moderator: The first question is from Neha Manpuria: from Bank of America. Ms. Neha, we can't hear you. Ms. Manpuria, I request you to may call us back maybe from a different number. We'll move to the next question. The next question is from Bino Pathiparampil from Elara Capital.

Bino Pathiparampil: My first question is on the U.S. business. We have seen a Q-o-Q decline in the run rate and Y-o-Y as well. So, you mentioned that there were some volume declines in the quarter. Could you comment on was it a quarterly phenomenon, some stock adjustment, etcetera? And what is that going forward on the quarterly run rate?

Ravi Mitra: So Bino, we had certain products which were not shipped out some of the main products like Enoxa and we plan that to ship back in the next coming quarter. On demand side, we don't have any issues here in terms of the forecast what we have received from our customers. It is just a shipping timing thing which instead of Q3, we will be probably planning for next quarter.

Bino Pathiparampil: So next quarter, we should see a significant Q-o-Q improvement in numbers. Can we assume so?

Ravi Mitra: Yes. So next quarter, this will be compensated by the some of the products which I mentioned, which would happen next quarter.

Bino Pathiparampil: Understood. And this quarter, the margin ex-Cenexi has come in strong. So, despite the top line being low, what has led to that?

Ravi Mitra: So gross margin, do you mean or EBITDA margin?

Bino Pathiparampil: Both, I think.

Ravi Mitra: Yes. So gross margin, I think, improved by a couple of percent, and that is largely a factor of the product mix at different sites. And some of the products, as you know, are high margin like vial and lyophilized products compared to ampoules. And on the EBITDA side, also the cost side, we have kind of controlled and that has showed down the benefit to the EBITDA as well.

Bino Pathiparampil: Okay. if I can ask one more question on Cenexi. So, the earlier guidance was a positive EBITDA in 4Q of this year. So, in the opening remarks, I heard that you have changed it to a positive EBITDA in FY '26. But in FY '26, if you could let us understand how the trajectory would be. So initial couple of quarters, the losses will continue and then it will pick up? Is that how we should think about it?

Srinivas Sadu: We are estimating now Q3 FY '26 could be EBITDA positive quarter. One is we mentioned about the inspection that happened last quarter. So, we lost a few weeks because of that. So that's kind of impacting the next quarter numbers a bit and last quarter numbers a bit. So that's the main reason. So, estimating I think it will move back to a few quarters.

Moderator: Next question is from Neha Manpuria from Bank of America.

Neha Manpuria: following up on Cenexi, I understand that there was an inspection, but is there more to the inspection which is leading us to delay the breakeven to third quarter? I mean, have the authorities highlighted something to us, which needs us to shut down production for longer. Just wanted to get a sense of as to why 10 days of audit is delaying the breakeven by 3 quarters?

Srinivas Sadu: So, one is, of course, the lost time, it took almost, I think, 3 weeks inspection, there are 2 inspections that happened. So, we lost production during that time. And there are corrective measures which we need to take. So, some observations which we need to work on. So that will take some loss of production time. That's why we're estimating now it could be the third quarter.

Neha Manpuria: Understood. And my second question is on the RoW business on the Saudi contract. Have you made any progress on that? We were expecting some shipments by the end of the quarter or in the fourth quarter. So, is that still on track? Or any status update on that?

Srinivas Sadu: Yes. I think that's one of the reasons we actually missed the revenue estimate this quarter. So, it got pushed out a bit and it didn't get dispatched. And also, it kind of impacted positively in the margin profile because it's a low-margin business. But on the revenue side, I think it got pushed out by a quarter.

Neha Manpuria: And should that come through in the fourth quarter? Or is there more delay expected on the Saudi tender?

Srinivas Sadu: We actually got the tender. It's just allotment to the hospitals that was delayed. So, it could be this quarter or the first quarter of next year.

Neha Manpuria: Got it. And my last question is on the Biologics bit. I think you mentioned, one, the Dr. Reddy supply would start from fiscal '26. And there was also a second CDMO agreement that you mentioned. I didn't quite catch that with whom that was and when should we expect that to start contributing?

Srinivas Sadu: So, this is an agreement with Shanghai Henlius. It's a Chinese company, which has launched biosimilars in different parts of the world, including the U.S. So, we have signed a term sheet as a second site for their pipeline of products. So that would take probably 2 years from now. Yes, once the agreement is firmed up, then it would take a tech transfer and will take time for that.

Neha Manpuria: Okay. So, this is probably FY '28 onwards.

Srinivas Sadu: Yes, sure. '27-'28, I would say. Yes.

Moderator: Next question is from Vivek Agrawal from Citigroup.

Vivek Agrawal: Just one question from my side. It is good to see that India and RoW, particularly the non-U.S. markets are seeing the kind of attention now that's being required. So, if you can just elaborate basically how we are going to do that? What has been lagging so far? What new basically we are going to do in these markets?

Shyamakant Giri: So, India, Vivek, we want to leverage our portfolio strength. We are already having a cost leadership position because of the CDMO activities. And India as a market is also growing. So, we are integrating to launch some therapies in India. And of course, we are getting various therapies as we see.

We're also evaluating any inorganic route to expand our presence. So, this is something that we're doing on the India side.

On the RoW side, we are now changing our approach. Earlier, we used to see RoW from an continent lens like LATAM or Africa, right. We have moved that lens to now focus on top 5, 6 top countries like Saudi, Mexico, South Africa and so on, okay, where we will really want to be aggressive in terms of partnership and filings and all of that. So, we have now divided the RoW into 3 groups, one which is high value -- high pharmaceutical value, and second is, of course, medium and so on and so forth. So, this approach, I think, will help us resource these markets well and put a new acceleration plan in place.

Moderator: Next question is from Aman Goyal from Axis Securities.

Aman Goyal: Sir, my question is related to the Cenexi. So, in the last quarterly con call, you said, in Q4, the Cenexi will be breakeven at EBITDA level. Can you throw some light on any estimated time that we will see the breakeven for Cenexi business?

Ravi Mitra: Like we just mentioned that we expect now to EBITDA breakeven at Q3 FY '26 next year. So, this is largely a factor of how we can push the top line to a 50 million per quarter run rate and then keep the cost under control. So that can be achieved by new high-speed lines.

So, one of the additional lines is already up and running in Fontenay as Alain mentioned in his speech.

In addition to that, there are also a couple of activities, which is going on at HSC and Belgium site, which will improve the output significantly without having more cost at manpower and other overheads. So, this will be happening at Q3 level because Q2 is anyway a summer

shutdown, and we want to also utilize like last year to build up all those new additional capabilities we are putting in.

So Q3, we estimate that would be a time where we expect the top line to touch 50 million or more and then have EBITDA breakeven.

Aman Goyal: On last call, we talked about the GLP-1 contract on the CDMO side. So, we have 3 different customers on GLP. Could you throw some light on that, like the size or revenue to be started in the commercialization?

Srinivas Sadu: So basically, it's two customers and three products contracts. And revenues, the patent landscape, it depends on which markets and all that. So, we can't really give the numbers to you, but slowly we'll start seeing some numbers in FY '26.

Moderator: Next question is from Harsh Bhatia from Bandhan Mutual Fund.

Harsh Bhatia: On biologics/biosimilar contracts for Reddy's, you had mentioned this as nonexclusive contract and you have a certain capacity, mammalian drug substance capacity. That was biologics CDMO, biologics/biosimilars contract. Is the nature of the contract with the Chinese company also very similar in terms of the contract commitment of the volumes or the size of the contract? Or is it materially different?

Srinivas Sadu: I think materially this could be different. The contract still needs to be signed up. It's a term-sheet we signed. But it's a whole pipeline of biosimilar products, what are already commercialized and also what is still there in the pipeline, which will go off patent in the next few years. And it could be a second site. So, we're already looking at expansion of the drug substance side to increase the capacity to 15 KL to meet the demand. So, it will be substantially different compared to what we have done earlier.

Harsh Bhatia: So, you already have an 8 KL capacity, and this could in the foreseeable future go to 15 KL capacity?

Srinivas Sadu: No, an additional 15 KL capacity.

Harsh Bhatia: In terms of the Cenexi contracts and the customers, your aim was to sort of move their RoW capacity from the Cenexi site in Europe to the India site over a period of time. Where are we on that as of now?

Ravi Mitra: So, we are having currently some business by customers, and it's too early to comment at this point of time. But we are seeing interest from their customers, and the work is going on.

Harsh Bhatia: Few of them must have already visited your India facilities, right?

Ravi Mitra: Yes, some have.

Harsh Bhatia: In terms of heparin. Can you explain, at a macro level, China does control a lot of capacity in terms of the raw materials as such. So, anything incrementally that you could think could be a second order derivative for the tariffs from that angle?

Srinivas Sadu: I think it's more to do with the direct imports into U.S., not to the materials what we buy from China. So, I don't think there will be an impact on that.

Harsh Bhatia: Sir, but do Chinese players, again, just very broadly this China or Chinese players directly supply these raw materials into the U.S. market as of now?

Srinivas Sadu: No. So, from a positive side, the companies who are actually competing with us directly in China. Now they might be impacted if this 10% thing gets implemented and on the pharmaceutical products, still it's not very clear. Then the people who are competing with us in heparin and some of these products from China will be more competitive against them in terms of several products. So that would be an advantage for us in terms of finished products, and probably APIs also.

But I would say, local manufacturing in China -- in U.S. anyway, is not that competitive. But I would say the Chinese players who are directly exporting finished product from China if this 10% tariff comes on to those products, then we'll be more competitive than that for sure.

Harsh Bhatia: And just very lastly, if there are, let's say, Index 200 in terms of the RN component for enoxaparin, heparin. How much of that would be China-based capital consumption and how much will be going outside of China, very roughly put, if you would have the numbers?

Srinivas Sadu: You mean within the U.S?

Harsh Bhatia: No. China production getting consumed within China and as compared to going out of China getting exported.

Srinivas Sadu: I'm not sure of that quantity, but I think globally, they control about 45%, 50% of Heparin API production, a bit more also, I think, 60%. Yes. But how much is consumed within China and outside, frankly we can't...

Moderator: Next question is from Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan: Just the first one on the U.S. business. We had 13 launches during the quarter. And despite that we have had like Q-o-Q, even in the base business, excluding Cenexi in the U.S., we have seen decline. So, could you just explain, is it price erosion that there seems to be higher?

Srinivas Sadu: No, I think the major drop is Enoxa which we expected to supply to Saudi, didn't happen, that's a major loss. And the launches that happened compared to that volume is lower, I would say. From margin profiles, the products that we launched in the last 2, 3 quarters is better margin products, and that's why you're seeing an improvement in margin profile across products.

Shyam Srinivasan: I'm just looking at just the U.S. market. And I'm assuming Saudi Arabia will come in RoW, right? Sorry, I'm getting confused. The U.S. market Q-o-Q decline.

Srinivas Sadu: Even U.S. we didn't supply Enoxa. I think there's a decline of -- I would give you a steer percentage. But 12% down in terms of quantity variance for Enoxa and Ketorolac, the other product -- 2 products. And that's the reason -- the primary reason why we lost that decrease in the volumes.

Shyam Srinivasan: Understood. We should expect Q4 that there will be a recovery there or we'll start shipping Enoxa and the other product again in Q4, right?

Srinivas Sadu: At least U.S. Enoxa, you can expect.

Shyam Srinivasan: Yes. Yes. I'm only focusing on the U.S. market.

Srinivas Sadu: Yes, correct. From price variance perspective from quarter-on-quarter, it's about, I think, 1% to 2% lower.

Shyam Srinivasan: Understood. And in terms of pricing or any of the other on the base business, excluding Enoxa and other, has there been an erosion?

Srinivas Sadu: No, no, there's not much price erosion.

Shyam Srinivasan: Understood. My second question is on the 39% core margins. So, if you could help us what was the profit share and the milestones in that number?

Ravi Mitra: So, for this quarter, profit share is 11.7% and milestone is 10.2%.

Shyam Srinivasan: So, about 20%, I'm just adding those 2 numbers is coming from at least 2, right, Ravi?

Srinivas Sadu: Yes, the profit -- yes, correct. And profit share should consider as part of the product only right. It's margin of the product.

Shyam Srinivasan: No, I'm not questioning the numbers. It's just that -- I'm just trying to look at these numbers is -- 11% for us, typically, right?

Srinivas Sadu: Yes, typically about 20% together.

Ravi Mitra: So, some quarters, it may be high, some quarter lows. So, if you say a 9-month basis, it's again 10.1% and 8.8%.

Srinivas Sadu: Also, but together, it's over 19%.

Shyam Srinivasan: 19%. Okay. So -- and we should assume that you get at least this kind of milestones and similar kind of profit share.

Srinivas Sadu: So basically, it's a simple math. The low-margin products, if you have shipped like kind of a product, it's down INR100 crores, it's like 5% to 7% margin. So that then the margin will get diluted about 36%.

Moderator: Next question is from Ritesh Rathod from Nippon India Mutual Fund.

Ritesh Rathod: How many Chinese players are active in the U.S. injectable market? Or put it other way around, how many of the front-end companies source their raw -- source their finished injectable products from Chinese manufacturing plant. If you can give some colour -- this is in context with the tariff thing which we spoke earlier.

Srinivas Sadu:: Directly it is probably 1 or 2 injectables who are selling directly front end, but people sourcing injectable finished product from China would maybe 4 to 5.

Ritesh Rathod: And when we see our top 10 or top 25 products, such kind of Chinese sourcing or Chinese competitors? Would there be -- would there be a decent -- would they have a decent volume market share, like -- and with this tariff, things can swing in coming quarters? Is that a probable scenario?

Shyamakant Giri: Yes, at least some products, especially heparin, Enoxa where the front-end player is backward integrated 100% into heparin. And the margin is low. Those kinds of products it will fill the balance, yes.

Ritesh Rathod: And in the past, we spoke about, particularly in new launches, we saw excessive competition from Chinese players spoiling the market. Do you think in your pipeline products, such kind of competition will now be much lower than what earlier you have seen for the new launches?

Shyamakant Giri: It all depends on the products because some products with the margin profile is high, then probably it's lesser impact, but wherever the margin is lower than there could be an impact. I mean there they will stay away from launching, I would say.

Moderator: Next question is from Roshan Chutkey: from ICICI Prudential Mutual Fund.

Roshan Chutkey: I just wanted to understand, going forward, if Enoxa volumes were to higher, right, one, because of like Chinese competition abating a bit because of tariffs; and two, particularly in this quarter, I guess, you have some slippage coming from the previous quarter. So, should one think that volume growth would be very high, or margins will take a knock? How should one think about this?

Ravi Mitra: If Enoxa volume goes up, then overall margin as a percentage will come down. But in absolute terms of course it will grow.

Shyamakant Giri: Yes, Roshan, there is more data point that I would like to bring in here. So, this year, if you see our new launches in the U.S., we have launched 27 molecules and 39 SKUs of which 30 SKUs are first-time launches in the U.S. and the gross margin there is upwards of 65% or so. So, if you see, what we're doing also is strengthening our new launches, which are primarily complex generics, RTUs and all of that and being very aggressive to push that agenda, push that sales in the U.S. so that we still hold on to our gross margin in spite of Enoxa going on.

And we have seen this year, for example, in quarter 3, 5% of our revenue total was primarily coming from new launches that we did in the U.S. at a higher gross margin. So, while Enoxa goes up, but we also have a plan here to improve or maintain and improve our gross margin by having a good portfolio and aggressively launching new products in the U.S. market.

Roshan Chutkey: Understood. With respect to Cenexi business, last we spoke, you mentioned RFPs are coming quick and fast. Can you just talk a little bit about that.

Srinivas Sadu: Alain, can you take that question of RFPs. We have a pipeline of RFPs, which you're addressing. So, the question is around that.

Alain Kirchmeyer: Yes. So, we have a constant flow of opportunities that we are looking at. What is especially encouraging in the last quarter is that we finalized the validation batches for 2 products that will move in Q1 into commercial production.

Moderator: Next question is from Jinesh Shah from RSPN Ventures.

Jinesh Shah: my first question was, when we talked about that we have margin improvements in this quarter due to the product mix and core business. So, I think you did mention, I just want to reconfirm that. Is it because of the new product launches that we do, we have a better margin in that and because of that overall EBITDA margins of the core business has been shifted up in this quarter. Is that the correct understanding?

Ravi Mitra: Yes. That is definitely correct. And also, the product mix we spoke about. So, both of that is responsible for this higher margin.

Jinesh Shah: Okay. So, like if I have to make a prediction for the future, then we do expect that whatever we had in past, like 33%, 34% of EBITDA margins, we do expect a better margin in the coming future, right?

Ravi Mitra: Yes, yes.

Jinesh Shah: Okay. So, my second question is, can you -- as we had unannounced inspection in one of the Fontenay site. So, can we talk about the observations of that inspection?

Srinivas Sadu: Yes. So, we do -- got some observations in that inspection and we want to finalize CAPA and submit to them. So, we'll let you know once the CAPA submission happens and what outcome of that is.

Jinesh Shah: Okay. Fair enough. And my last question would be like -- is there any like one-off in the finance cost in this part and like we have a significant jump in this quarter. So, is there any one off?

Ravi Mitra: Yes, it is one-off. See about INR18 crores is on account of GST refund matter.

Moderator: Next question is from Tushar Manudhane from Motilal Oswal Financial Services.

Tushar Manudhane: Sir, just on this, at least as far as Enoxa, heparin products are concerned, if you could share what is our market share for U.S. market in specific?

Srinivas Sadu: I think Enoxa is about 6%. I think we sell about 16 million to 18 million syringes and that's about 6%, 7%. And heparin it's around 20% -25%.

Tushar Manudhane: 6% and 25%, right?

Srinivas Sadu: Yes.

Tushar Manudhane: And how much would be the market share of the Chinese competitors?

Srinivas Sadu: They'll have higher probably, I think heparin would be 40%, I would say. Enoxa, I can't say now.

Tushar Manudhane: Sorry, sir, how much? Enoxa, how much?

Srinivas Sadu: I can't tell, but still, I think 30%, 35% should be there. But I can come back to Tushar. I can take it offline.

Tushar Manudhane: Sure, sir. Just lastly on this, is there any way to -- I mean, practically, ultimately the source of raw material is still pig slaughterhouse, which are abundant in China. So eventually when you have to depend on Chinese raw material supply, right, that time be changed as per as supply of ultimate formulation is concerned. Is that right?

Srinivas Sadu: Yes, sir, the basic growth is still in China. Otherwise, if you go to U.S., it's more expensive. But within China, we have several crudes for heparin sources so that we could be more competitive in terms of pricing. We get some volume discussion and all that. So, it's a continuous work what we do in terms of processing of the crude to heparin and heparin to Enoxa, if you consider both molecules. But still, we have to depend on China for the API.

Moderator: The next question is from Harsh Bhatia from Bandhan Mutual Fund.

Harsh Bhatia: So just in terms of, again, Cenexi part. You've spoken a bit about these capacity expansions as well as certain capabilities across ampoules and PFS in activating vaccine as such. Any of this -- anything other than this relates to in any point towards the price manufacturing capacities of -- directly or indirectly to that extent? I hope it would be too early to comment on that.

Srinivas Sadu: Can you repeat that? It was not very clear, the question. We use Cenexi capacity for Gland's, that's what you're saying?

Harsh Bhatia: No, Cenexi's capacity for customers who are looking for GLP-1 manufacturing capabilities to that extent

Srinivas Sadu: Yes. So, it's part of the plan. I mean part of the capex plan we're evaluating because there's a big opportunity out there for that -- CDMO for that also. So, it's under evaluation to install capacity for that while the -- even the syringe line what we are installing now this year that also has a capability to fill cartridges. So, it has a capability, but -- the plan is future capex, we are evaluating whether you want to invest into additional capex on the bulk cartridges, which is more economical compared to sterile cartridges, which can be done on the current syringe line. Yes, but the opportunity is there, yes.

Harsh Bhatia: Could you just sort of help us understand what would be the cartridge capacity, let's say, at one of the Cenexi level, if possible, the bulk cartridge capacity?

Srinivas Sadu: I think if you utilize the complete 100% of the syringe line what we're just installing for cartridges, it can be produce about I think 40 million to 50 million cartridges.

Harsh Bhatia: 40 million to 50 million cartridges. Okay. And what would the order book look like? I think in the first quarter of this financial year, it was somewhere around EUR 20 million, if I'm not wrong, what would the order book look like right now for Cenexi?

Ravi Mitra: Sorry, I couldn't understand what is regarding fourth quarter you mentioned...

Harsh Bhatia: Yes. For the third quarter, what would the order book look like -- the order book for third quarter Cenexi order book.

Srinivas Sadu: Alain, what's the order book for the fourth quarter

Alain Kirchmeyer: I cannot answer this question off my mind, but it must be above EUR 60 million because we have a backlog that has been carried on from 2024.

Srinivas Sadu: So, the order book is at EUR 60 million.

Alain Kirchmeyer: Keeping in mind, we have usually a 3-month confirmed order horizon with our customers.

Moderator: The next question is from Vivek Agrawal from Citigroup.

Vivek Agrawal: This is related to capex as well as investments. So, over the next 3 years, how the company is going to spend on biosimilars plus GLP-1 put together?

Srinivas Sadu: In the capex?

Ravi Mitra: So, we are on biosimilar, we are currently evaluating for the 15 KL capacity. The estimate should be around $80 million to $100 million. But currently, it's a process of calculating a project evaluation.

Srinivas Sadu: GLP-1, we have already invested into it. The line will be installed this year, next 2 quarters. So, there's no additional investment into GLP-1 in terms of finished products. But we are looking at now that the current manufacture site also kind of maxed out in terms of capacity. We are looking at a greenfield project for the next phase of growth.

Vivek Agrawal: Just a basic question. I'm just trying to understand. In terms of fill/finish as well as cartridges are concerned on GLP-1, right? So, let's say, if you want to put the capacity of 100 million cartridges, right, so how long it can take? And what kind of investments that may require. Just a rough answer would be...

Srinivas Sadu: Around I think INR200 crores.

Vivek Agrawal: And how long it can be basically, how long you can complete the project which is you start...

Srinivas Sadu: 18 months.

Vivek Agrawal: 18 months.

Moderator: The next question is from Dheeresh Pathak from WhiteOak.

Dheeresh Pathak: I'm sorry if you already answered this, but do you have capacity and capability for pen assembly in your current manufacturing setup? Pen or auto injectors?

Srinivas Sadu: Yes, we do. We do. They've already filed products from the site. We do have that.

Dheeresh Pathak: What is the current capacity sir, on the pen side -- pen assembly side.

Srinivas Sadu: About 40 million?

Dheeresh Pathak: Do you also make auto injector?

Srinivas Sadu: Yes.

Dheeresh Pathak: What is that capacity sir?

Srinivas Sadu: It's a similar common line. So, auto injector see basically, you would do syringes and then you assemble into auto injector.

Dheeresh Pathak: Okay. And are you expanding on this capacity or this is the capacity as of now? Is there a plan to expand this capacity?

Srinivas Sadu: Yes. So, one more line, we're adding this year. So, it will add another 100 million.

Dheeresh Pathak: Another 100 million. How much are you spending on that?

Ravi Mitra: Yes. So, we already spent it actually, most of it. This will come in the Suite 9) the additional one.

Dheeresh Pathak: When does it get commissioned?

Ravi Mitra: '28?

Dheeresh Pathak: Like with month wise you can tell you like calendar '28 -- first half, second half?

Srinivas Sadu: Smaller volumes will come from FY '26, where the patents are expiring from RoW market and also Canadian market. But the majority will come from end of FY '27.

Dheeresh Pathak: End of FY '27? Sorry, how much have you spent on these 100 million lines?

Srinivas Sadu: See we can't specifically this because it's part of the main site. So, it's part of the – it's one of the suites of what we have. But if I have to specific for the line, we can give a number. Offline, we can take it. It's –'not a dedicated site – we need a dedicated site for this.

Moderator: Due to time constraints, we'll take that as the last question. I would now like to hand the conference over to Ms. Runjhun Jain for closing comments.

Runjhun Jain: Thank you, everyone, for joining us today. We appreciate your participation and the questions during the call. If you have any follow-up questions to this, please feel free to reach out to us. Looking forward to interacting with you in the next call. Thank you.

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