# “Gufic Biosciences Limited Q2 FY25 Earnings Conference Call”

## November 18, 2024

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**MANAGEMENT:** **MR. PRANAV CHOKSI – CEO & WHOLE-TIME DIRECTOR**
**MR. DEVKINANDAN ROONGHTA – CHIEF FINANCIAL OFFICER**
**MR. AVIK DAS – INVESTOR RELATIONS**
**MS. AMI SHAH – COMPANY SECRETARY**

**Moderator:** Ladies and gentlemen, good day and welcome to the Q2 & FY25 Earnings Conference Call of Gufic Biosciences Limited.

As a reminder, all participant lines will be in the listen only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing "*" and then "0" on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Ms. Ami Shah - Company Secretary. Thank you and over to you, ma'am.

**Ami Shah:** Thank you, Sejal. Good evening, everyone. I welcome you to Gufic Biosciences Limited Earning Conference Call for the second quarter of FY24-25. We have with us today, Mr. Pranav Choksi – CEO & Director, Mr. Devkinandan Roonghta – CFO and Mr. Avik Das from Investor Relations team to give the "Highlights" of the "Business" and "Financial Performance" of the Company and to take questions if any.

Before we begin, I would like to state that some of the statements that will be made in today's discussion may be forward-looking in nature. It is subject to unfortunate risks and uncertainties and the actual result could materially differ. The Company undertakes no obligation to update or revise any forward-looking statement whether as a result of new information of future events or otherwise. We will now begin the call with the opening remarks from Mr. Avik followed by a financial overview from Mr. Roonghta. Thereafter, we will have the forum open for the interactive Q&A sessions. Over to you, Avik. Thank you.

**Avik Das:** Thank you, Ami. And welcome, everyone, to our Quarterly Conference Call. I will quickly update all of you all on our strategic business units. And I will begin with the Indore facility. So, the commissioning of the Indore facility marks a transformative milestone for us. The immediate focus for this facility is a carefully calibrated strategy where we aim to ramp up the production in a phased manner. So, in this approach, we try and balance operational readiness with our long-term objectives and ensuring efficiency, regulatory alignment and most importantly, quick market responsiveness. In the short term, the strategy centers on transferring select high demand products from Navsari facility to Indore. By moving these products, we aim to optimize production capacity while maintaining seamless supply chain operations. The process will involve rigorous validation protocols to ensure that the high standards of quality and consistency that we are known for are preserved. This targeted transition will allow Navsari facility to focus on backlog export orders while leveraging Indore's capacity to scale production progressively.

**.** Due to technical issues with Mr. Avik Das's audio connection, Mr. Devkinandan Roonghta provided an update on the financial highlights of the Company

**Devkinandan Roonghta:** I will just highlight the Financial Results for Q2 of 24-25 versus Q2 of '23-24:

The total revenue for the current quarter of Q2 is Rs. 204.2 crores. Last year, Q2, it was Rs. 214.9 crores. The EBITDA for current quarter of Q2 is Rs. 38.7 crores. Last year, it was Rs. 39.7 crores. The EBITDA margin for Q2 of current year is 18.9%. Previous quarter Q2 was 18.47%. Profit before tax for Q2 of this quarter is Rs. 29.3 crore. Previous year Q2 was Rs. 30.9 crore. The PAT margin for Q2 of current financial year is 14.13%. Last year Q2, it was 14.38%. Profit after tax for current Q2 is Rs. 21.8 crore. Previously, it was Rs. 23.2 crore. PAT margin for current Q2 is 10.66%. Last year, it was 10.80%.

Now, I will highlight the 6-month Result of 24-25 versus '23-24:

The total revenue for the current half yearly is Rs. 407 crore. Previous half yearly, it was Rs. 409.9 crore. The EBITDA for current half year is Rs. 79.8 crore. Last year, it was Rs. 76.1 crore. The EBITDA margin for current half year is 18.62%. Last year, it was 18.57%. The profit before tax for current Q2 with current half year is Rs. 57.4 crore. Last year, it was Rs. 59 crore. Profit before tax margin for current half year is 14.10%. Last year, it was 14.39%. Profit after tax for current half year is Rs. 42.6 crores. Last year, it was Rs. 43.8 crores. The PAT margin for current is 10.44%. Last year, it was 10.69%. Thank you. So, should we begin the question-and-answer session?

**Ami Shah:** Avik, can you continue with the business details?

**Avik Das:** I will do that. So, I will restart by giving you all an update on the Indore facility. What I was touching upon is our short-term strategy and the long-term strategy. So, our short-term strategy for the Indore facility will be centered around transferring some of our high demand products from Navsari. By moving these products, we aim to optimize the production capacity while maintaining seamless supply chain for these products. The process will involve rigorous validation protocols to ensure that we are able to sustain and maintain our highest standards, which we are very well known for. Now this targeted transition will allow Navsari facility to focus on backlog export orders by leveraging Indore's capacity to scale production progressively. Simultaneously, we will initiate audits of the Indore facility by our domestic contract manufacturing partners. These audits are intended to validate that the Indore plant adheres to the stringent quality standards required for manufacturing their products for the domestic market. Over the next 2-3 months, these audits will be undertaken, followed by a phased initiation of products or production for these partners. This collaborative approach will not only position the Indore facility as a trusted manufacturing hub for complex injectables for our partners, but also facilitate a gradual scale up of the operations. Now, as you all know, a critical pillar of our long-term strategy is leveraging the Indore facility to gain a foothold in the regulated markets. The facility's advanced infrastructure positions us as a very competitive player, capable of meeting the stringent requirements of most of the regulatory bodies. We have shortlisted high potential molecules that align with the market opportunities in these regulated markets. And we're in the process of finalizing collaborations with partners to facilitate

registrations. The production of exhibit batches for these molecules will commence shortly, laying the groundwork for regulatory dossier submissions and future approvals.

So, I was saying that the phased approach to scaling production will offer several advantages. It minimizes operational risks by allowing the facility to gradually ramp up capacity while addressing potential challenges during the transition. Additionally, focusing on exhibit batch production and regulatory preparation ensures that the Indore facility is well positioned to meet the expectation of international markets, which will be the way ahead for our long-term growth. The gradual scaling also optimizes resource allocation, ensuring that our investment in manpower, infrastructure, and materials are used effectively in the short term. The Indore facility's strategic role extends beyond its immediate operational goal. It represents a key component of our vision to establish ourselves as a leading player in both domestic and international markets. The need to ramp up production immediately with our long-term objectives of regulatory alignment and market expansion, we are hoping to set a robust foundation for sustained growth and meaningful market impact not only domestically, but also in select international markets.

Now, I will quickly update you on all our business divisions. To begin with, in the critical care division, this remains the backbone of our operations supplying life-saving injectable solutions to hospitals across India. With a strong focus on addressing critical challenges in antifungal and antibacterial therapy, this division has further made it a priority to combat sepsis, which is one of the leading causes of hospital mortality. We have done a lot of product development. We have relaunched one of our products, which is specially targeting towards sepsis. And we have definitely taken it up as a cause that we are running around to control the rise of sepsis in hospitals. For this, we have engaged more than 3,000 healthcare professionals to more than 100 scientific activities nationwide, raising awareness about sepsis management and moreover the judicious use of anti-microbials. These initiatives will aim to equip clinicians with tools and knowledge for early detection and effective intervention. This reinforces our commitment to improving patient outcomes and working with hospitals more as a partner than only a supplier.

On the product front, we are expanding our pipeline with innovative molecules in advanced antibacterial and antifungal classes. These products are uniquely positioned to address therapeutic gaps while offering complex manufacturing processes at very competitive prices. By aligning scientific education with cutting edge product development, Criticare is not just providing solution. We believe we are shaping the future of cost-effective hospital-based care. We have also given a brief of the kind of pipeline we have in this division in our investor presentation.

Coming to Ferticare division, Ferticare is addressing the rapidly growing need for assisted reproductive technologies in India, where infertility rates are rising at an unprecedented pace. We are committed to being a comprehensive solution provider in this domain, for which we are expanding our pipeline of products towards recombinant hormonal products such as rFSH and

rhCG. Additionally, we are also introducing very differentiated products like Niacinamide-based vaginal gels and Coenzyme Q10 supplements to support the reproductive health holistically. The division recently also launched Fertimax, a specialized task force focused on deepening engagement with gynecologists and IVF centers. It offers a very niche and specialized hormonal product offering. These initiatives have already begun driving market penetration and further strengthening our relationships with leading IVF chains and IVF centers and boutique practitioners across the nation.

Coming to Aesthaderm, Aesthaderm is at the forefront of creating a category for aesthetic Dermatology in India. STUNNOX is a flagship botulinum toxin brand. It aims to democratize the access to aesthetic treatments and expand the user base among dermatologists and cosmetologists. STUNNOX has become the second most used botulinum toxin in India with acceptance driven by its quality and performance. And over the past six months, we have trained nearly 300 doctors through specialized workshops and on-boarded several trainers to conduct knowledge dissemination nationwide. These efforts combined with clinical studies on new indications, such as hyperhidrosis, are building confidence among practitioners. Additionally, we are expanding our cosmetic portfolio to include solutions for concerns like melasma, wrinkles and dry skin. This comprehensive approach should position us as an early mover in the fast-growing aesthetic dermatology space, which is poised for growth as awareness increases, incomes rise, and the population ages gradually.

On the Neurocare division, the focus over here is on the therapeutic application of botulinum toxin, which is addressing an unmet need in the conditions like spasticity and chronic migraines, to name a few. Zarbot is India's first Botulinum Toxin type A of international pedigree. It has gained acceptance with more than 100 neurologists within a year of its launch. Here we are doing targeted scientific activities and interacting with user groups. We are creating a robust ecosystem of knowledge sharing and best practices. This should position Gufic as a pioneer in therapeutic botulinum toxin applications and we're also offering hope to patients with very complex neurological conditions.

Coming to Sparsh Division, Sparsh division is designed to serve a broader spectrum within the injectable market. A wide basket of essential and specialized injectables for smaller and mid-sized hospitals across India. Now, unlike Gufic's Criticare division, which targets high intensity critical care needs, Sparsh provides cost effective solutions to cater to the day-to-day therapeutic requirements for smaller hospitals and nursing homes. These include essential treatments for gastroenterology, nephrology, radiology, and even critical imaging support. We have some niche products in our basket over here, such as S-Panoriya, which is a unique alternative to the widely used Pantoprazole. We are also soon to tap. Yes, so Sparsh is direct to hospital approach enables deeper engagement with hospitals. It provides us visibility into their purchasing trends and their therapeutic requirements. This strategic advantage allows us to identify emerging needs quickly

and it also allows us to introduce relevant products, which effectively expands our portfolio, and which deepens the relationship with our hospital partners.

Now, one of the short-term challenges of this approach is an increase in the debtor days due to the direct credit to hospitals. However, the long-term benefits significantly outweigh the downsides in our opinion by fostering direct relationship with hospitals, especially in India's growing healthcare infrastructure space. Sparsh will position itself as a reliable partner in their journey. This model not only builds loyalty and trust, but also offers the ability to scale the product portfolio strategically that should ensure comprehensive coverage of hospital needs as they grow. Additionally, Sparsh's wide therapeutic coverage from dual chamber bags to niche products like contrast media soon should position it to capture a significant share of the hospital budget. And this approach aligns with our vision of becoming an indispensable partner for hospitals, offering both value and convenience.

Now on Spark, Stellar, and Healthcare Division; these divisions continue to drive growth through innovative product launches and strategic initiatives in their domains. Stellar's recent introduction of VonPHa, which is a novel PPI, has gained significant traction, reflecting our ability to capture market opportunities in niche segments. Spark's patented Stretchmark Meter is revolutionizing how gynecologists approach stretchmark prevention, boosting our brand stretchiness. And healthcare division with its Sallaki range has achieved top market rankings, cementing its leadership in orthopedic and pain management.

Now on the international business front, our international business division is seeing growth driven by a strategy of investing in regulated market registrations. We very recently received approvals in Thailand, Sri Lanka, Lithuania, and we also won a tender with UK NHS. By owning registrations, we enhance market visibility, ensure supply chain stability, and gain better control over tender participation. This strategy positions us as a reliable global player with plans to scale production at the Indore facility to support further international expansions.

With this, I will open the call up for questions. Thank you.

**Moderator:** Thank you very much. We will now begin the question-and-answer session. The first question is from the line of Bhavya from Samaasa Capital. Please go ahead.

**Bhavya:** So, just had two questions. First question is, I wanted to understand, has there been any loss of revenue because of the transfer from Navsari to Indore?

**Pranav Choksi:** Bhavya, Pranav here. So, there has been a loss of revenue as such during the transfer process. There has been a loss of revenue in the quarter because Indore started in October, October 3 to be precise. So, that's why the capacity which was not available at Navsari could not be met by Indore in the last quarter because the production started in the first week of October. So, that is the thing. Also, during the transfer also, there will be three batch validation. So, the batch size

has been kept in such a mind that the orders do not get lost. Whatever validation samples have to be removed, those will be kept on the side. So, there will be no loss in the transition process.

**Bhavya:** Okay, understood. And my second question, I think in the presentation you had mentioned that the board took a decision to do further US FDA documentation. So, just want to understand what percentage of this procedure have you already completed in terms of documentation if that's possible to answer?

**Pranav Choksi:** Yes, so what we mean by that statement that if you see a year ago in October, the facility was ready for commissioning subject to limited tests. So, at that time when we had some external audits done by, I would say experts from the pharma industry and ex-regulatory chiefs or ex-regulatory inspectors, they gave us a lot of suggestions about improvement and certain process parameters and certain utility parameters. I will just give us a few examples. Electricity, steam primarily and then water. These are the main three factors which come in the injection factory. And normally, based on the background what we have and details what we have, we had started the designing in 2021. EU Annex 1 had come up, and now also US guidelines will be changing in the next two years as per what the draft copy is available online for everyone to see. There are certain modifications which we needed to be done to ensure that we comply this not only now, but in the years to come. So, assuming there'll be no further guideline change in the next 2 to 3 years. So, to incorporate that, if we started production, it would be a little bit difficult for us to re-validate the entire process using the new guidelines. Hence, we took it on ourselves to spend those six, eight months, finish those modifications and re-qualifications. And answering your question as of now, all those things have been done. And hence, on October 3rd, 2024, we have started the production from the Indore facility.

**Bhavya:** Just a clarification. I think Amit mentioned that whichever high demand products that we had, and that's being shifted to Indore. So, did we need any approval for this? And going ahead what is the timeline and procedure for EU GMP and all the other just to start up a CDMO and also international?

**Pranav Choksi:** So, I will answer your first question. So, the FDA license of most of the products as tech transfer had already been taken in the last, I would say, 8 to 9 months side by side of the qualification studies were going on because of the R&D data and the tech transfer data which we have from Indore. We had taken some batches, like I said. That's the reason we got delayed in terms of commercial production. So, all the molecules license are in place. The EU, I mean, let's say the first thing for a CMO or a CDMO option, we have audits which started all the way in May, June, July and audits are ongoing. Even today as we speak, as Avik is there in Indore, is there where we have another big Indian MNC also getting the audit done. Plus, we have a visit from Saudi Arabia also. So, all the audits are in place right now going on. So, we assume that the Gufic's own manufacturing will happen October onwards and we foresee that the CMO, CDMO business will be initiated in November and December to start off with and then go on and so on. I mean go on. We are hoping that the EU audit will be triggered. I mean we already have

triggered the EU audit with two molecules, and we are hoping that they would come and visit us by around June 2024 to September 2024 based on their dates and we should have a EU approval hopefully before the end of next year, that is 2025. Coming to the US, like I said our focus is purely CMO, CDMO based. So, that would be depending on our clients in terms of their investments and their timelines for validation batches. So, even if they take the validation batches and then from the next month till March, when they will trigger it will be depending on their regulatory departments thing. But we are looking at a calendar year of 2026 where we see some action in the US FDA front.

**Bhavya:** Okay, understood. So, is it fair to assume there wouldn't be much of a revenue contribution from Indore at least for this year?

**Pranav Choksi:** Yes, bare minimum would be because like I say validation batches would still contribute something. Yes, the real potential of the Indore facility would be seen in the next 2 to 3 years.

**Moderator:** Thank you. The next question is from the line of Midhun James from Cupertino Investments. Please go ahead.

**Midhun James:** I think the big elephant in the room is Indore. So, I think even in the last concall also, we had given a projection of Indore starting operations and contributing to the revenue from the current quarter, which we have not seen that happen. So, my first question is, when do you see Indore contributing to some revenue? Is it from the current quarter, the running quarter, or from the next quarter? When can we see some revenues from Indore happening? Because without that, the overall revenues is like stagnant for almost 4 or 5 quarters now?

**Pranav Choksi:** Yes, so answering your first question, the revenue would be captured from Indore from this quarter itself. And already, like I said, from October 3, the manufacturing has started. So, the revenues of Indore would be seen in the books financially from 2020 for December quarter. Answering your second question, yes, if you see last year, there were multiple factors apart from the capacity constraints which we have. There were also around 20% of our revenue is contributed by around 6 to 8 molecules. Now the 6 to 8 molecules, what we had in the last 3, 4 years, they actually got eroded by almost 35% to 50%, in terms of API pricing in the last one year from China. And that's why what you see right now also, there has been a unit increase in terms of these 20% of our revenue. But yes, you're absolutely right. They are not reflecting in the value. Again, because of the reason mentioned above, because the erosion of the API and that goes through. At the same time, yes, the capacity constraint would be the reason, the primary reason, why the flat revenue is there. However, with Indore coming in is not, actually I would say Indore is not only the elephant in the room. There has to be other things like the botulinum toxin and penem and other things also start kicking in. We were a little bit more guarded in terms of our revenues in this first, second quarter, reason being also the debtor cycle we did not want to push out. So, one of the reasons that we were a little bit more, I would say, conservative, and we will continue to do so going forward without affecting the revenue or the profitability point

of it. It is something in certain institutions in India, we have taken a strategic role because if you also see other companies in our same sector, the debtor window has almost blown up like us by almost 35, 45 days extra than what was the normal norm. So, that is something which we are taking up and to ensure that not go through that level of credit, I would say credit spread out at the cost of revenue. So, that's the reason it's there. But yes, Indore definitely plays a big role apart from other factors.

**Midhun James:** My next question is regarding the botulinum toxin product. So, recently, I think there was a filing where in which there seems to be some arrangement between Dr. Balram Singh's entity. I think he has moved out from the board. So, can you give some more clarity on what has happened on that regard? And how does that impact you as a Company?

**Pranav Choksi:** So, Dr. Balram Singh was the board of director of Gufic Biosciences. And you must have also read in the news that we formed a separate subsidiary where Gufic and Prime-bio, that is Dr. Balram Singh's entity, came together to form a subsidiary of Gufic Biosciences. And in order to make the board a little bit more clean and in terms of governance, since he was also the board of Director of Gufic Prime-bio, which is the subsidiary of Gufic Biosciences, we had asked him to resign from the board of biosciences and become like a little bit more aggressive board of Gufic Prime-bio. So, relationship and the entire arrangement doesn't change. Because apart from botulinum toxin, there are some other projects which we are working on. And for that matter, we are looking at some movements happening in that sector in the next 3 to 6 months, which we will announce in due time. So, for us to make a separate clean entity for the projects which we are doing overall with Dr. Balram Singh made sense. And hence, he is still full-fledged with us. But he is just right now on the board of Gufic Prime-bio, which is a subsidiary of Gufic Biosciences. So, that is just the change that we have done.

**Midhun James:** So, meaning there is no difference in basically the working arrangement is just.., I understood the point. And next question is regarding the Selvax. Can you give some color on where are we on Selvax? What is the research going on in that front please?

**Pranav Choksi:** Right, so I think Selvax firstly just for people who might not be aware was an investment which we had done in the oncology space. I think to be more precise, immune-oncology space, which is a very interesting mechanism in terms of treating certain solid tumors, where it's combination of anti-CD40 antibodies and interleukins come together and the results, I would say, canines, that is dogs, and also another animal species has been very, I would say, promising. Currently, if you see the update as Avik has also, I would say, in our presentation, in the Company presentation we have given that, there have been some additional studies which have been done which further clarify that the product has some significant role. However, this is on a very small scale, but the dose determination studies are still pending. So, we are clear that Selvax is sort of a 5-year, 6-year window. However, it provides a very unmet need in terms of treating certain solid tumors. So, if I summarize the entire development as on today, in the last 2 quarters, there have been some additional studies done on mouse which have shown positive results. Now the

main question was the scalability. So, the initiation of the scalability of these studies have been done where, like I think I am just reading out a line from that expert that out of 24 animals, have the cure rate of 92%, which is something unheard of in oncology. However, like I said, I would not like to put our hopes very high. I have my hopes very high, but just let the data come out on a little bit single-based large study, then I think I can comment on that further. And we also have now, I mean, the Company Selvax has started working on the cell line in terms of the scalability, in terms of the production on a big scale. The expression was done on a small scale and a large scale. Now the expression of the same vector of the anti-CD40 antibodies will be done on a bigger scale to see whether this technology can be actually scaled and show relevance over making it in commercial production scale. This is where the current update as of Selvax.

**Moderator:** As there are no further questions from the participants, I would now like to hand the conference over to Ms. Ami Shah, Company Secretary. Thank you, and over to you ma'am.

**Ami Shah:** Thank you, thank you everyone. We apologize for the internet connectivity issue. I appreciate all of you joining us today, and if you have any questions which have remained unanswered, you can get back to our Investor Relations team, and we will be happy to take those separately. With that, we conclude today's call. Thank you.

**Moderator:** On behalf of Gufic Biosciences Limited, that concludes this conference. Thank you for joining us, and you may now disconnect your lines.