



“Gufic Biosciences Limited Q2 FY23 Earnings Conference Call”

November 14, 2022

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Gufic Biosciences Limited
November 14, 2022

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Moderator: Ladies and gentlemen, good day, and welcome to the Q2 FY '23 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 * then 0 on your touchtone phone. I now hand the conference over to Ms. Ami Shah - Company Secretary from Gufic Biosciences Limited. Thank you, and over to you.

Ami Shah: Thank you, Yashasvi. Good evening and a warm welcome to the Gufic Biosciences Limited Earnings Conference Call for the Second Quarter of FY22-23. I have with me, Mr. Pranav Choksi - Chief Executive Director and Wholetime Director; Mr. Devkinandan Roonghta - Chief Financial Officer; and Mr. Avik Das from Investor Relations team to give the highlights of the business performance of the company and to clarify all the queries of the investors during the call. We will begin the call with business highlights and an overview by Mr. Avik, followed by financial overview by Mr. Roonghta.

After the opening remarks, the operator will open the bridge for Q&A session, but before we proceed with the call, please note that some of the statements made in today's discussion may be forward-looking and are based on management's current expectation and this may be viewed in conjunction with risks and uncertainties involved in the business. The company assumes no responsibility to publish or update or amend, modify, revise any forward-looking statement based on any subsequent development, new information in future or except as required by the applicable laws in force. This call is being recorded, and the playback of the call has been made available on our website shortly after the call. The transcript of this call will also be submitted to the stock exchanges and will also be made available on our website.

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

Avik Das: Thank you, Ami and good afternoon to one and all, and thank you very much for joining on this call. So, I will quickly begin the call and give you all a highlight of what happened in the past quarter.

So, the past quarter, we have started gearing up to take our Indore facility live and in view of that, we have started investing in R&D for new molecules and drug delivery systems, which will eventually smoothen our entire process of going live at Indore. With respect to that, we have already started taking validation batches to create the data and build up dossiers for the pipeline products and this will definitely help us reduce our time to market significantly once our plant is up and ready at Indore. So, this has been the broad theme for the last quarter for us.

And now diving into our divisions, Critical Care division. We have an update over here, where we have launched a subdivision within this flagship division by the name of Sparsh. This division will use the most advanced technology and smoothen the supply chain process for

delivering 100 plus high-quality injectable products, primarily to untapped hospitals and nursing homes, which include not only the suburban, but also the rural market. And as per our initial estimates, the addressable market size of this market is roughly Rs. 9,500 crores and it is growing at a CAGR of 12%. We are also very pleased to inform you all that Gufic has received the DCGI approval for manufacturing and marketing Biopenem in dual chamber bag which is our proprietary technology and as we all know, given the industry trends, the Critical Care segment by and large faced headwinds due to reduced hospitalizations and excess inventory in the trade channel and we have taken some strategic decisions to mitigate that and we will touch upon that as the call progresses.

We are also very glad to announce that we are planning to launch Ceftazidime-Avibactam soon and Gufic will be the only Indian company to launch this product other than the innovator with an in-house manufactured API. So, this is again in line with our strategy to go backwards for all our critical products and new products and have the API manufactured in-house. We are also launching the novel once-a-week anti-infective Dalbavancin for the first time in India in Q4 in FY23 and we are very much on track to achieve our target date for the launch. We have also received the DCGI approval to conduct Phase III clinical trials for Thymosin Alpha injection for sepsis.

Now coming to Ferticare division. This division has done phenomenally well for us this year, and it continues to register double-digit growth and especially some of our flagship products like Puregraf, which is HMG and Puretrig, which is HCG. We continue to have dominant market share in these products. We have received DCGI approval to conduct Phase III trials with Thymosin Alpha for endometriosis and as we had updated last quarter as well, we have launched Dydrogesterone with our own API and this is a vibrant market and it has gone above Rs. 800 crores now and growing at a healthy pace of 60% year-on-year. So, our initiative to develop the recombinant alternative to derisk geopolitically is also going on track and within the next 18 months, we should be able to launch the recombinant product as well. Another update over here is that we have increased our market penetration with Enoxaparin in the Infertility segment and we created a good brand within this molecule in this segment and we have also come up to second rank in the high-growing Cetrorelix market.

Now coming to our other divisions. Some key updates over here is, we have launched a Cannabis extract-based topical solution for muscular and arthritic pain and we have also initiated development of a unique liposomal iron formulation in this division.

Now coming to our International Business. I would like to highlight that we have received 2 new product approvals from regulated markets and we have also received one product approval from Health Canada and as informed earlier, we are gearing up for many more approvals to come, primarily for our Indore and our EU approved plant at Navsari. And in order to further our alliances with our partners globally, we very recently participated in CPHI, which was held in



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Frankfurt and in the coming quarters, we will make announcements of the developments that happened there.

And with respect to Arisia, our Center of Excellence targeting toxins and new-age therapies, we are very happy to inform that we have developed 20 plus combination therapies, which are unique to Arisia only. And these will be used for skin and body transformation using FDA-approved technology.

So, coming to our Aesthaderm division. Here, we partnered with the ICCG in the field of cosmetic vaginal tightening and rejuvenation and we have organized training camps to use Botulinum toxin for these indications.

Now with this, I will hand over the call to our CFO, Mr. Devkinandan Roonghta, to quickly take you through the highlights of the numbers of the past quarter and H1.

Devkinandan Roonghta:

Thank you, Avik. Good afternoon, everybody. First thing I would like to inform you that the quarterly results of Q2 of 2022-23 versus Q2 of 21-22 is not comparable because last year Q2, we are having a COVID-related sales. The total sale for last year, Q2 was Rs. 194 crores, out of this, Rs. 47 crores was related to COVID-related sales. If I delete the COVID-related sales, the sales for last year was Rs. 147 crores against this year's sale of Q2 is Rs. 175 crores, which is 19% higher than the last year's COVID sales. EBITDA of last year was Rs. 36 crores. This time the EBITDA is Rs. 33.4 crores. Basically, this quarter, we have conducted a lot of validation batch for our Indore plant and therefore, the R&D expense is slightly higher as compared to the previous 2 quarters. EBITDA margin last year was around 18.6%; this year, 19%.

Profit before tax was Rs. 30.4 crores; this year, Rs. 27.3 crores. PAT was 15.6%. This quarter, it was 15.5%. Profit after tax was last year Rs. 23.3 crores. This year, it was Rs. 20.2 crores. PAT margin was last year 12%; this year, it was 11.5%. Thank you.

Moderator:

Thank you. We will now begin the question-and-answer session. Any one who wishes to ask question may press "*" and "1" on the touchtone telephone. To remove yourself from the question queue, please enter "*" and "2." Participants are requested to use hand set while asking questions. Ladies and Gentlemen we will wait for a moment while question queue assembles. We have our first question in from the line of Keshav from RakSan Investors. Please go ahead.

Keshav:

Sir, it is very fascinating to see so many things Gufic has been trying to do, so we are a substance manufacturer, in that we are expanding our capability to biologics or expertise in NDDS and injectables, we have a branded portfolio, so we need to be reasonably agile on marketing spends as well as on manpower for that and on top of that, we are doing innovation as well, so we have clinical trial management capabilities and so lastly, we have a portfolio that is predominantly injectables and we are intending to get into regulated markets such as US, which puts in even more quality burden on us and our quality control will then have to be top class. So, is it not that

we might be spreading ourselves too thin because all of this has a monetary bearing and all sorts of R&D spends after all come within ROI? So, if you could help understand the overall vision as to what puts us in a position to succeed in such a wide array of endeavors and why not have a limited, but more focused approach instead of that?

Pranav Choksi:

Keshav, Pranav here. Thank you for the question. I think very well put, I think, summarized our company in a nutshell, but I will tell you the reason why we are a little bit going wide and more than going wide, if you look at the core competency of the company is still injectables and new drug delivery systems and innovation, which has been there in the past, but what we feel, if you see in the last 5 years, and this is what I have felt since the last decade, actually, pharma is getting more and more commoditized and that is why if we keep on sticking to the same thing day in and day out, then there will always be an economic of scale or there might always be an erosion. There always might be some people who are ready to do it at a much cheaper rate and that is the thing which will always affect us. Today, what you have seen, US was always an attractive market before, but if you see the way erosion has happened not only in India, Europe or rest of the world, US do also want to see this very soon. The reason we are getting into a little bit of biological line is because, first of all, the entry barrier for anyone to get into, what was the entry barrier of pharma, maybe 10, 15, 20 years ago, the biological will be a little bit tougher and more complex to get into. At the same time, the core competency of the people working in this company, including me and my team, is also doing complex molecules and biologicals where we feel that it is more of a capital cost initially to be taken care of and I agree, we are still not doing NCE. So, let me please clarify that the R&D work which we are doing, it is capital intensive, yes, for sure, but it is not like a 50-50 or maybe like there has more than a 50% chance of failing in this because this is doing something which has already been proven, but it is not much more efficient way and much more organized way and plus we have the Board of Directors like Dr. Balram Singh who have more than 35 years experience in handling it. It is something which we are doing as proof of concept. So, sorry, I am using all these fancy words. In a nutshell, if I tell you, we are doing mostly biological R&D work which uses our core competency, but it will be still a big entry barrier for others to get into because we foresee that the margins in the future. Since we are into injectables as a core competency, we will get affected more and more and we have to be in other things, which not only offset then but also give us more fodder and more revenues down the line, which will help us to invest further in line. So, just to give you a nutshell, our Botulinum toxin might have taken 4 years for us to get invested, but the margins which we achieved in Botulinum toxin and the level of penetration which we go through can easily fund our foray into biologicals going forward. Right now, what you see, like I think what Roonghta sir also said, apart from the validation cost, which we see right now onetime for the Indore facility which whenever we go for any regulated market there is, of course, 3-batch validation to be done on an R&D level, then there is a tech transfer, then the scale of batches happen. So, initially, for the next 8 to 12 months, you will see a cost increasing of validation, but once the validations are done, they are basically your dossiers, they are basically your assets, which you can use for the next 5, 10, 15 years until that molecule has that relevance in the

geography area. So, what we are investing right now in validation, the same thing we are doing in biologicals and what are you call in other things. We are doing something, we are creating data, we are creating relevance which can either be encashed at any moment or moment if we can drive the entire way of regulatory post development, then we can get a much bigger share out of it. We sometimes definitely feel that we maybe biting on things which are a little bit on a higher side, but that has been always the DNA of Gufic from day 1. Today, I think in 2008-2009 when we were maybe around Rs. 40 crores-Rs. 50 crore company also, we were doing complex molecules and working on R&D comps and working on NDDS, which was not even companies of our size were not doing and hence, today, also a lot of big companies or even companies from abroad look to us for innovative products and look to us for new things which they can out-license for certain geographies also. So, I feel that the DNA is something which we don't like to change, which has been a success mantra. At the same time, of course, we have Roonghta sir and we have the right thing that we should not go overboard. Sometimes there is always going to be a pressure for us in terms of allocating the resource, I would not say managing the issue. It is mostly allocating the resources, when and when, the timing is the most crucial, but be rest assured, that we will not go so out of box that there will be a big chance for failure. So, we feel for long-term sustenance. We have to be into something which is more unique and which gives us better margins, which can sustain the next cycle of growth also. So, this is what I feel and this is what we all feel and we should continue to do so.

Keshav: Just one clarity, so when you say that we have the capability to get into biologics, is lyophilization a critical factor because the rest of it, we are in-licensing, right?

Pranav Choksi: No. So, I will explain how. So, if you see when the Botulinum toxin also came, the strain of the Botulinum toxin was in-licensed from US, but the entire development work in terms of lyophilization, in terms of formulation, also was done in-house. Also, when I see right now, once the strain comes, there is a master strain, you have to work on a reference strain. The first step of stabilizing the strain is lyophilization, but then when tomorrow, we are working on the topical format, that is topical linings, like cream or a lotion or a gel, then that also involves some sort of a unique formulation, core competency, which we possess. Third example, we are working on, let us say, tomorrow we are working on oral form of a vaccine. Now, the formulation development capability is in-house. The entire work on the genome and the entire work on the thing is something which is a collaboration between Gufic and Prime Bio, by which we do most of the work in our R&D center here. So, because of the background we have in biotechnology, it is not that we are in-licensing the technology. We are in-licensing the strain, getting the right strain and the right genetic core is important for us. How do you then express this in the right vehicle and then you, what you call, scale it up in a more efficient way that is the strength of Gufic as a company. So, strain is in-license. I am saying, the genetic strain is in-license. The remaining development is done in-house by the company.

Keshav: And sir, secondly, can you help understand the nature of relationship with Selvax? Are we development partner? Would we be playing a CRO role in clinical trials? Or if you could help understand?

Pranav Choksi: So, Selvax, I think is a little bit different of a model. Selvax where the product has already been developed by them, it is not something where we have contributed in the development part of the concept, which is about this inter-looking too. The thing we have collaborated with them that we are working on certain PD-1 inhibitors of our own and then we saw the technology, which is used by them, which is a combination of anti-CD40 antibodies that inter-look into. So, that technology which they are working on is very unique, which can also complement our development going forward only on the condition that it results certain milestones that they have committed to us. So, Selvax is basically, I would like to say, a product developed by them for solid tumors and if that works with certain milestones which we need to see in the next 1 year or 2 years, then we will be using that as a platform to combine the PD-1 inhibitor to go for a much more superior option.

Keshav: Sir, I am not very much aware of how clinical trials work over here, what the timelines are like and so if you could elaborate and also brief a bit about where we fit in the Thymosin Alpha Phase III trials that are happening for a couple of indications, so are we handling the clinical trial management bit of it? Or are we the innovator for the repurposed indications?

Pranav Choksi: If you see Thymosin Alpha, we are the innovator for the repurposing factor of it by tweaking the peptide in different kind of the formulation. We did it for COVID initially. Now, we have tweaked it in a separate way for sepsis management because sepsis, if you see, severe patients or moderate patients had the same, inflammatory parameters getting flared up plus something else, which happens only in sepsis. That is why we are doing for the repurposing part of it. To answer your question, we are actually the company who is working, who got the molecule done and then we outsource third-party agency to run this, so there is a CRO basically, a Clinical Research Organization, which gets the mandate from us and then they coordinate with either private or public institutions all around India based on the permission of the honorable DCGI. So, they are under trials. We are just the company whose molecule is being tested and eventually, we wait for the results.

Keshav: And sir, what are the timelines like?

Pranav Choksi: It depends on, so you are asking about sepsis or endometriosis? So, if you see sepsis is something that a patient is there around 10 to 14 days and then there is a monitoring of another, totally it comes around 28 days to 45 days depending on the patient's health. So, endometriosis is for a longer time because we not only have to see, at least the 3 cycles of the women has to be seen post administration, so that is kind of 4 months. So, based on that, depending on the recruitment, it was depending on the patient's size, the patient pool, it takes time. It can be anything between

a minimum of around 15 months to a maximum of 24 months, I guess, depending on the patient's size, the recruitment and the catchment area and also the duration of treatment.

Keshav: So, if it is indeed succeeds, so we cannot expect anything for the next 3 to 4 years, is that correct?

Pranav Choksi: For sepsis, we already have started earlier because we did the independent trials also. I hope for sepsis, that should be obtained by mid of next year, and we should see the product being sold post, I think, October 2023. For endometriosis, definitely, we will be able to see visibility of the commercialization of that indication in 2024 end or maybe early 2025.

Moderator: Thank you. We have our next question from the line of Rajat Setiya from iThought PMS. Please go ahead.

Rajat Setia: First of all, thanks to the management team for taking in the feedback that we gave last time and for the quick initial remarks in the beginning. Thank you so much for that. So, first question on the Sparsh subsegment that we have recently launched under the Critical Care segment, so this basically segment is different in the sense that it will be focusing on the untapped hospital segment, right, but it will still be selling the same products and sales team will be the same? Or how will that be?

Pranav Choksi: Rajat, so Sparsh is a little bit different. What we realized in the last 7 years in Critical Care, our most of the business comes from class A markets, that is from tertiary hospitals or maximum secondary hospitals. Our presence into small nursing homes, or even I am saying, forget the class B or class C towns, I mean now in India, you see a lot of development happen. I cannot say anything is class B or class A. You get my point. I am saying any city beyond Mumbai, beyond Bangalore, beyond Delhi and those 8-10 metros what we have now, are considered to be a tier 2 or tier 3 for us. So, getting there, we were mostly, if we have a team of 180 people in Critical Care, we had so many molecules coming in, first went into specialty differentiation, first it was Critical Care, then microcare came, then separate task force came for Zarbot even in Critical Care, they were divided into Critical Care Live, which was handling around a good set of antifungals and the other division was handling separate antifungals, but if you see we have primarily around 64 molecules, which was handled by this 180 team. Now with Indore coming in and with the existing channel what we have, we have more than 103 molecules, which we are working on, which we also want to take on the international markets also. Now, if I have to take out to the international markets, again, keeping in mind we did a subset of A and B, where international market potential and in domestic market potential. And then in this subset, we came to know these 103 molecules, which then work from these factories going forward, which will be having a good market and good growth in either of these geographies. So, we thought that why don't we take them in a different way, where we already have a pipeline and/or basket setup for Critical Care division in the next 2 to 3 years, where I am seeing, we have these dual chamber bags and we have Ceftazidime-Avibactam, then we have Ceftazidime and others. As these new molecules are being loaded up, the older molecules either are getting neglected or maybe the

erosion in margin is happening so much that Critical Care cannot sustain their PCPM in terms of keeping these I would say tail-end brands also. So, we created this Sparsh, which will be a unique way by which we don't want to be dependent on the channel for our business. That is normally, you have CNI when you have a stockiest, then you have a retailer and sometimes beyond stockiest, you don't have control, we tell them to give it to the hospital, but they will also buy some goods from us and they can sell it anywhere in the open market also, which might be maybe a small percentage, but still, it is substantial when I consider 20% of Rs. 200 crores. So, we thought that we will cover the possibility little bit more on the lines of an international approach, where we directly have only 4 to 5 companies and then we have only 4 to 5 distributors all around India. And then we go for the last mile approach, where we not only integrate in a system in an IT setup, each and every pin code-wise hospitals or nursing homes or even doctor having his own setup of 5 ICU beds also, maybe just a basic ward also. And these unique primary centers are being tracked on a pin code basis on all-India basis, by which we track them by a system in terms of what is the purchase on a monthly basis and then we know, so the distributors work is only to buy from us and make it reach there. How much to sell, what to sell and what rate to sell is all determined by us end-to-end, by which we can control the margin much better. Otherwise, there is always a scope of more erosion because of the channel getting more greedy in the entire process, plus there is less chance of substitution also. So, when in particular we are handling high-end products and new edge products, the old products, which can be easily substituted because of XYZ reason, it is not related to quality or pricing, it is something which we want to get into. And that is where the Sparsh has come up in a way which is mostly electronically guided. We have a team in HO who will be running this along with, of course, a team in the field, but here, we can talk about higher PCPM where we have a target of, every person has to handle minimum 300 centers, the PCPM target is around 12 to 15 lakhs in 1 to 1.5 years, where it is more of a availability of the entire 103 SKU baskets in a much more efficient way, using a very lean and mean channel in the middle. So, it is just Gufic, a single distribution point and directly the hospital and that is how the birth of Sparsh has come and we are trying to monitor electronically on a daily basis. So, every transaction, every purchase can be tracked on a minute-by-minute basis and see that can we come up with the business productivity model also and then also a lot of new molecules which you want to launch, we can get more active directly to the trade because of this.

Rajat Setia:

Now moving on to the 2 launches that we have done, one in the anti-infective side, Dalbavancin and then the other one, Ceftazidime plus Avibactam, just wanted to understand how much time did it take us to come up with these 2 products in terms of R&D and efforts that have gone into coming up with these products? How much money have we spent in the R&D here? How big is the market? And what kind of growth rate for these 2 particular products? And at what price differential are we going to sell this product vis-à-vis competition? I mean we are the first ones, I think, in terms of generics here, right?

Pranav Choksi:

Yes. So, I think, firstly, just to clarify, we will be launching Ceftazidime-Avibactam in the month of November. We have built up the inventory from the last 6 to 8 months to keep all the APIs and all the formulation side because the patent expires in January 27, 2023, but we are coming with a unique potassium salt **upsurge** by which we can launch it 3 months before anyone else can launch. That is what Avik has mentioned Ceftazidime-Avibactam's innovator is Pfizer in India. They have the brand name as Zavicefta and they are the only one who are selling it in India right now. And like you rightly said, we are the first generic for that molecule in India, and we are going to launch it on our own and then maybe offer it to 3-4 of our associates also in terms of CMO also. So, just to answer your question, yes, the work on this molecule started around 2 years ago because we knew that it was going off-patent in 2023. We first worked on the API. If we have to sustain this on a longer version, it is always better to work on the API because keeping in mind the antibiotic market, price erosion is inevitable and especially for Cephalosporin, it can give you also high revenue, but if you are not good enough, strong enough in the backward integration of Avibactam, then it would not make sense for us. The Avibactam and Ceftazidime is just 1 combination. We are going to work on multiple combinations of Avibactam down the line. That is why we worked on the API on our own. That is why it took us 2 years and then, of course, first, we started developing the API. Then we worked on a different salt to differentiate ourselves at the innovator to start up with by which we can get 2-3 months headway to launch it before the other competition and thirdly, we also came up with a pricing, which is much more unique. I cannot share the strategy with you, how much we are going to launch it and all that because it is going to be launched next month and I don't want to make it public right now. And the next one, in the month of November end, we are going to launch it and December, it is going to be in the market. So, of course, maybe in the next call, I will give you more insights, and I will give you the feedback also of the launch by then.

Coming to Dalbavancin. Dalbavancin is a product which is not available in the Indian market. It is very unique, 2 injections on the first day and then followed by maybe, if required, a third injection on the fifth day or seventh day depending on the patient. This is the only molecule available internationally. The innovator has also not brought this molecule into India because they feel that, right now it is being sold internationally at around \$1,400. We want to launch this molecule in India at a fraction. Here with this molecule, it is not going to give us the volume, but it is going to give us a bit value, it is also going to give us a good reputation because in the entire basket, what we have, we have almost all antibiotics, antifungals in our basket and we feel down the line when the resistance is going to come up for other brand-positive options like Teicoplanin, Vancomycin, Linezolid, it can be very unique proposition advantage for certain patients where these other molecules are not responding. And getting them at a fraction cost for the Indian market always makes it much sweeter in terms of affordability. More importantly, this molecule is going to be a big focus for us for the international market because we see in India, more than Gram-positive, Gram-negative is more of significance. Dalbavancin for us next year will be a very important product for Indore because we see the markets in US and Europe and other countries being taking this product in a much more gung-ho manner. So, Dalbavancin

is more of an international product in the short-term and then coming to India on a long-term. Even though we launch it next year together, I think you will see the actual numbers and values coming up maybe in the 3 to 4 years once you get Teicoplanin, Vancomycin and Linezolid is taken care of.

Ceftazidime-Avibactam, of course, will be a product for short-term where you will see a better volume growth and revenue growth also because Cephalosporins being broad spectrum for Gram-positive, Gram-negative and Cephalosporins normally also for the Indian market has always preferred for various reasons. Do I answer that properly? Or I hope I did not miss any point.

Rajat Setia: Yes, just 1 or 2 followups here, so how big is the market for Avibactam which we are going to sell in India?

Pranav Choksi: So, the Ceftazidime-Avibactam market, again, IMF numbers are not in my mind. But if you know, Cephalosporin a whole is around a big way. This molecule, if priced properly, can almost take a big share of the entire Cephalosporin market. Again, I may be wrong. I don't want to give any wrong answers. I know that Cephalosporin for the fact is more than Rs. 1,200 crores thing. Ceftazidime-Avibactam might not be more than around Rs. 80 crores-Rs. 90 crores, I don't know, I will just give you exact numbers in the next 5 minutes, plus or minus. But just to give you a feedback, the reason that Ceftazidime-Avibactam in India has not grown because you still you have the cheaper Cephalosporins available. Our foray will be there to make this molecule more affordable because doctors need this molecule much more and we foresee that this market of Ceftazidime-Avibactam will at least go to at least a multiple of Rs. 100 crores in 2 to 3 years itself. That is our projection for the molecule. I will just come back to you with the current market size of Ceftazidime-Avibactam. Only one player is there and that is Pfizer, where the product is imported into India and with a patent protection. So, until now, the market is quite limited.

Moderator: Thank you. We have our next question from the line of Rohan Aggarwal from Loop Capital. Please go ahead.

Rohan Aggarwal: I had a couple of questions. My first question is, I am not sure if you have discussed this already, about the commissioning of the Indore plant, could you just give us a bit more color on when it will start impacting our P&L?

Pranav Choksi: It has already started impacting our P&L in terms of salaries which are being paid right now to the people there, but the revenue impact on the P&L should come by around first quarter 2023. We have started the construction in December 2021. We have finished the construction, I think the main building and the R&D building being has been done by October 2022. The machines are under the process of getting installed. We feel the installation should be mostly completed by around February and there will be parallel installation and validation happening, but we feel

the entire validation and entire commissioning should be completed by March or April 2023 and then we should see the revenue coming in by May or June 2023 for us.

Rohan Aggarwal: And another question I had was, earlier you mentioned about dual chamber bags, could you just tell us more about it? And what sort of market size are we targeting with regards to that?

Pranav Choksi: So, dual chamber bag is basically a drug delivery system by which, I don't need to explain the product as such? You just want me to talk about the market addressing, is that right?

Rohan Aggarwal: Sure. I believe it is a mechanism by which the transmission mechanism for the medicine?

Pranav Choksi: Yes, it just make the entire thing very administrative as well as patient compliant in terms of, more than the patient, it is more compliant for the nursing staff and the hospital staff while they save almost at least 3 to 5 minutes depending on their efficiency on every administration of every injection. So, it is a single bag where the IV bag and the powder is in the same bag and you can just press it and it mixes. There is a good video on our website. If you have time, please go through that, I think that is a very self-explanatory video, which shows about the dual chamber bag. Answering your next question, we were supposed to launch dual chamber bag in this quarter. That is, I think, maybe around September itself and October, where we already have the permission, everything was in place and then the government came up with NLEM in terms of putting Meropenem also in this list. Our target was Meropenem and then Dori and then Imi and of course, we have got a Biopenem license also. So, we just have now decided to launch the product maybe in December or January to get more clarity from the government that even though we know for the fact that the pricing will not have any impact on the margins or in our strategy we launched, but now since we come to the schedule, we just have to go to them and now we have to get an NOC from them that since your normal vials are under NLEM, we are going to come up with a dual chamber bag approach, so why don't you give an exception and allow us to put the MRP, which we desire. So, that process is there. The market addressable thing is penem as a market is close to, we are going to start with penems and then we are going to go with other antibiotics also like Fosfomycin, caprolactam, and even product like we explore into other antibiotics like Vancomycin on an export base, not in India. India, it won't work. Even Ceftazidime-Avibactam which are going to launch right now will be eventually launched in a dual chamber bag once we get the necessary permission. So, this approach can be applied to all these molecules, which are a little bit expensive than the routine ones as well as it is something which you have the right administration, I think volume of 50 mL-100 mL to guide them. So, we hope that we can get this in multiple products, but starting off, you want to start with Meropenem, Biopenem entire Penem range, which should be around, I think, Rs. 800 crores to Rs. 1,000 crores market size.

Rohan Aggarwal: And my last question is just regarding the Center of Excellence that you have started, just wanted to know how it will help fulfill our business objectives?

Pranav Choksi:

So, the reason we went for is also something which we thought about was when we see the toxin market, you have a toxin when you have fillers and you have the different machinery available, which are mostly noninvasive, which mostly help for body and face contouring. Internationally, the toxin market is close to US \$7 billion to US \$8 billion. US is around to \$5 billion to \$5.5 billion, I believe. I am talking about numbers, which are in the outer line. There is somewhere mentioned \$4 billion to \$5 billion that is 2017-18, now it has come to almost 5 and I saw the Indian market, which is still very small. I think it is the fraction of what we have. If you see the US market, around 0.4 billion people, India market 1.4 billion people, still the market is in fraction. So, what we thought the reason we went into the market, it was already decided and why we wanted to get in the Center of Excellence. A lot of doctors want to use it. They aspire to use a toxin or a filler or these things, but they don't know how to use this in a combination. At the same time, a lot of people, and we have amazing doctors in India, but we have very few, lot of few doctors have the power and have the expertise by which they can use this in a much more efficient way. You don't want any body drop to go bad also. So, there is a particular way and there is particular SOP, by which we can use the toxin or a filler and also using some machines like Ulthera or use certain machines like Radio Frequency, ultrasound or something. We can actually mold a face or a body depending on what you desire, if you do it in the right way and that is something which we thought is something maybe Gufic as a thing because we have a doctor working with us who had earlier worked in Allergan, who has worked in Merck and we have a big team who has worked in these specific therapies and that is what Avik mentioned. There are almost 20 plus and we are in the process to getting around close to 35 different techniques by which you can use toxin, use these machines, and use maybe in some cases, fillers; not in all cases, fillers; but toxin in some cases, most of the cases toxins and some cases fillers and machine, where you can uniquely go for a body and face contouring, which you desire. This can also involve in terms of getting rid of some excess fat or getting rid of pimples, getting some depressions or some defects, I mean, some undercuts taken care of, but this is something which has to be trained and that is the Center of Excellence has been created with a single vision that we want to actually train the doctors. We want to handhold them. We want to actually give them we have invested a lot of money on Center of Excellence. We want people to come, see it for themselves, see how it can be done, also handhold them. Even our team will go back to them and make them, train them for around maybe 5 days, 7 days and then once they know, they are free to work, then we will certify them also with a particular thing, which we have tied up with not only Indian about training some AIMS, we have tied up with a doctor from Germany, we have tied up with a doctor from US and then now we are getting someone from Australia to work specifically on some cadaver training also we want to do, by which the hands of these doctors in India. So, we get a lot of inquiries from the dermatologists and these other doctors who, "I wanted to use the filler, I want to use the toxin. It is something I would add in my arsenal, which I can give to my patient and things, but who will train me, who will hold my hand." And that is the thing we have come up with, with the Center of Excellence, which, of course, eventually, it will help us to sell our toxin, our fillers and our entire cosmetic range.

Moderator: Thank you. We have the next question from the line of Bhavya Sonawalla from Prime Asset Source Private Limited. Please go ahead.

Bhavya Sonawalla: Just 2 questions, with regard to the dual chamber bag, I just wanted to understand how different is the international market, what we are envisaging the domestic market to be in terms of dual chamber bags in terms of usage, if you can throw some light on that?

Pranav Choksi: Sorry, Bhavya, so you mean to say the market size or?

Bhavya Sonawalla: Not the market size, but how well accepted is it? And how is it in use, I just wanted to understand how the international market is in terms of dual chamber bag?

Pranav Choksi: Yes, what is the response of the bag internationally? And why do I feel confident that we can a better job or we can do anything at all that is the question, right?

Bhavya Sonawalla: Yes. That is right.

Pranav Choksi: So, basically, there are 2 companies who are talking on this. One is, of course, B. Braun and second one is, I believe, Baxter, but if you see the price difference between a vial and their bag is almost 3 to 5 times. So, internationally, the costing is the big impact what I feel for them and also it's a good registration process, which has to be done in each and every country, which might be of anything. So, again, I will not comment on how they are doing and what they are doing, but I feel the pricing difference between a vial and a bag, if it crosses a particular percent, it doesn't make any relevance for them to do that. Why would, anyway these are anti-infective and mostly where the products are being used, where price is always a big factor. What we have done right now, we are trying to get the product launched right now almost close to the current MRP which is relevant for maximum around 50% to 20% above that for the penem market. For Ceftazidime-Avibactam, we are asking for a little bit more of higher pricing because product is anyway NPPA control. So, we feel since the current pricing for us is not as high, forget 1 times, 2 times, we are talking about only percentage over the current thing and this economic of scale, we have a clear-cut roadmap. In the next 2 years, we will have to manufacture these bags also in-house because once we reach critical mass. So, at that time, we have already done our homework and we have done our research that eventually in the next 2 years, we foresee that the bags and the vials should be at the same size once we reach that critical mark and at the same price is what I mean. So, again, I don't know if internationally, I know there is no relevance of the international for us to get into this market in India. We saw a good solution and we saw that the current pricing supports our strategy and in the next 2 years, if the critical mass is achieved, then we are almost seeing that whether can it replace the vial overall as such also.

Moderator: Thank you. We have our next question from the line of Saurabh Beria from Axanoun Investment Management. Please go ahead.

Saurabh Beria: My question was, over the last 5 years, our contingent liability as a percentage of net worth has been very high, it majorly comprises of letter of credit and bank guarantee, can you elaborate more on both of these types, like the nature and the purpose of this activity?

Pranav Choksi: I will request Roonghta sir to this question, but just to understand, most of our raw materials sometimes which we use in a unique way is imported. So, that is how a lot of our RM, which is coming, which we are trying to get back to the recombinant form and that is why maybe in the next 2 years will be a little bit derisked from us, but if I understand it correctly, a lot of material comes from Korea, from Italy and of course, from China and for that, we open LCs and then buy, I think is this the thing. Roonghta sir, can you throw some light. Whether I understood the question right or wrong?

Saurabh Beria: Can you elaborate on the nature of these transactions?

Devkinandan Roonghta: Yes. Basically, we import our raw material from China, Europe and other countries against the LC and sometimes the LC period buyer gives us a credit period of 30 days or 70 days or 180 days. And accordingly, if he is given a credit period of 90 days, for the remaining 90 days, sometimes we take a buyer's credit because it is cheaper and we are also having a export and because of our export it is auto hedging so we do not require to pay raising costs. So, our borrowing costs will be 3% to 4% compared to 7% to 8% that is the reason we are purchasing a buyer credit for the bank.

Saurabh Beria: And my next question was our R&D expense as a percentage of sales has been quite low when compared to the other pharma companies, so is this because of the nature of the business or any other reason?

Devkinandan Roonghta: Basically, there are 2 types of R&D expenses. One is, we call as validation bags. The validation bag is basically consumption of raw material and packing material that basically goes under the head of raw material consumption. Then there is the second type of expenses, which we are giving to doctors for conducting the trials, that is going on other expenses and on the R&D expenses as we incur a third party is we are showing under the R&D expenses. So, therefore, overall, our R&D expenses are in the range of around 8% to 10% of the turnover, whereas the direct payment of R&D expense was hardly around Rs. 4 crores to Rs. 5 crores.

Moderator: Thank you. We have our next question from the line of Nitya Shah from KamayaKya Wealth Management Private Limited. Please go ahead.

Nitya Shah: Pranav sir, congrats on the DGCI approvals and entering so many niche segments in the sector, so my question is regarding Botox. I saw in your presentation that the market size for Botox is between Rs. 150 crores and Rs. 200 crores, which is very miniscule, so I want to understand from you, where do you see this market size and demand reach in the next 5 years, especially in

the cosmetic application of Botox and since the cost of treatment is lower in India in comparison to all the other countries, so do you see this as an export opportunity for Gufic?

Pranav Choksi:

As you have seen, along with cosmetic, neurological conditions and medicine use also will be equally important for Botulin toxin. So, Stunnox and Zarbot are our brand names. So, Stunnox has been strategically launched for cosmetics and Zarbot has been launched for medicinal uses. So, yes, the current market is small and that is what I feel that at least we hope that we can contribute and also not only minimum our target is in the next 3 to 5 years, the growth will take time to gain momentum, but like you see, even countries like Thailand, forget US and Europe and other things, but countries like Thailand and Vietnam and even our neighbors who are surrounding in the Southeast Asian market and even in South America or even in Middle East, the penetration has been due to this. Just to give you an indication. We were in a seminar some time ago. A market like Iran has a consumption of around 800,000 vials. A market like Russia has a consumption of around 1 million vials. A market like Thailand, again, what I have been told, but of course, these are all data from the IMS there, whatever is there, is it more than around anything between 800,000 to 1 million vials with that population as such. Again, I feel it is not the question of affordability. I think affordability is always there. This is the question of accessibility and the more options available and one is awareness, of course, people should be aware that why don't you do it, but I think awareness is building up quite faster than what we see. More importantly, if I know about it, how do I get it done from, and who can help me to do this particular procedure in a very confidential manner or in a clandestine manner or a secret manner, because still, I don't want to go out and talk about that I have got this one. That is the normal Indian psychology what I feel, I may be wrong and that is where we feel that if we can get more and more people trained to have this treatment available in their regional or in the neighborhood, trusted medical space, then we will have reached the penetration. So, if I give you the numbers of 800,000 or 1 million vials, the market has a potential to become even Rs. 2,000 crores or Rs. 3,000 crores for India from the current market at 150, but someone has to do the hard work of starting that initiative and that will be tough, but we will work on that.

Nitya Shah:

And my second question was on like the last candidate asked about Avibactam, so I wanted to understand that what is the R&D cost and the market size for Avibactam?

Pranav Choksi:

So, market size, again, like I said, I didn't get time to see the ORG IMS data as of now, but I will ask my team member if they can do that, but I think it should be around anything between Rs. 60 crores-Rs. 80 crores, but again, I will reserve my comment until I actually give the number. But it has a bigger potential very frankly, because the cheaper Cephalosporin is available as such. So, I just feel that Avibactam, coming to your first question, I cannot give you a specific number as of now, but if you can give me time, you can send us a query, once again I will specifically try to give you numbers. Every molecule has much overlapping cost of manpower in terms of batches, in terms of things, so maybe R&D and consumption is something I can tell you much easily, but how much growth has happened, how much trial has been done, clinical

data has been done because we did also a certain sort of not only in vitro, but now we are in the process of doing some in vivo study also that our product is matching the innovator's one. So, there are sort of many different factors which come on it, but on an average, we see any molecule which has to be launched, specifically injectables, from a commodity product to around Rs. 3 crores to maybe a specialized product like Dalbavancin around Rs. 13 crores. This is a normal range which happens for any R&D development for any molecule. So, this, of course, includes the dossier cost and the clinical data also is required. So, this is a normal average cost which goes behind each and every molecule which we work on.

Moderator: Thank you. We have the next question from the line of Aman Vij from Astute Investment Management. Please go ahead.

Aman Vij: My question is around Ferticare and Critical Care segment, so first on the Ferticare segment, you had talked about we have an aspiration to reach the top 3 players in the next 3 to 4 years, so could you talk about what is the sales of say, third player currently in this segment?

Pranav Choksi: So, Aman, if I understood your question right, you are asking me the actual crores of value what the third player you are saying? Again, I think what I suggest, is all the numbers, I reveal, if you want, please write to us and we will give you specific numbers, but yes.

Aman Vij: An estimate is okay, even rough estimate.

Pranav Choksi: So, again, I will just tell you that I am around maybe Rs. 30 crores-Rs. 40 crores away from them. I will just give you that indication. So, I think with the HMG what we have and on HCG we have, coming with the entry of Dydrogesterone and also the entry of recombinant molecules coming in, I think we can achieve that very easily. Again, the reasons are because we have the backward advantage of manufacturing, which is something which will take us a little bit faster. So, again, I think that is the gap, what I see right now and of course, there is a bigger gap with the top 2, but which we foresee that in the next 24 to 36 months, it can help us to compete that in a much more efficient way.

Aman Vij: One clarification on this and then Critical Care question, so you had talked about our current market share roughly offset market is around 3% and you have talked about taking it to 10%. So, that means we are talking about Fertility segment becoming like 4 to 5x, so are you expecting this kind of growth in the next 2-3 years for us? And if yes, then in terms of molecule launch because one of the big molecule we have launched is Dydrogesterone, but there you are talking about we are only targeting very less sales compared to the core market, so we will require like Rs. 50 crore plus kind of product, so if you can talk about your thinking, how will we reach this 4 to 5x sales of Fertility segment in the next 3-4 years?

Pranav Choksi: Aman, Dydrogesterone is, of course, one of the products, but I would not say the main product to get it through. If you see the actual Infertility segment which you talked about, we normally

talk about the stimulating hormones and we normally talk about down-regulation or up-regulation of these different body cycles. So, more than that there would be more of even the HCG, HMG, FSH and the recombinant molecules of, again, FSH and HCG coming in, which would become a game changer for us. Dydrogesterone, like I said, they are already players in the market and that is why we are a little bit guarded on that estimate because Dydrogesterone, I think 2-3 companies have done a wonderful job. We are actually a little bit late in that, and that is why we are being a little bit conservative because you don't know how much we will save, but more importantly, to answer that thing, why they are looking from 3% to 10% is because of the hormones, the peptides and the recombinant molecules coming in and the scale which we are getting into manufacturing and the backward integration once the recombinant molecules come, that we will foresee. The market as such, if you see, has already consolidated much more in the Infertility segment, but there are a lot of players who are actually just buying from a manufacturer and then trying to sell it in the market and take the share. So, we see a lot of penetration of these buyers, sorry, intermediary companies happening in the next 2 to 3 years and that is where we feel that there will always be a scope of much better penetration going forward. So, I would say recombinant molecules, expansion of efficiencies of our hormones and peptides plus the launch of certain peptides for endometriosis, along with the combination of orals, plus some unique molecules we are working on reoccurrent implantation failure and also on, again, endometriosis, which already we have spoken in the past. These are the things which will help us to take that market share much more.

Moderator: Thank you. We have our next question from the line of Keshav from RakSan Investors. Please go ahead.

Keshav: Sir, in your presentation, there is a mention of us building capabilities for Peptides and Cyclopeptides and earlier, you had also alluded about Vancomycin, so are we currently sourcing the drug substance and we are just formulating, is that the correct understanding?

Pranav Choksi: So, Vancomycin is not the peptide I was referring to. Vancomycin is normally, even though it is a peptide derivative, but it is more of a fermentation thing. That is something which we are outsourcing only because it is for the regulated markets and there are already players who have better efficiency in terms of fermentation in that. It is not our trend. On the peptide, I was referring to is mostly these biological peptides, which are going to be used for infertility, also we are going to be used for sepsis management, also we are going to be used for female sexual drive also, which are going to replace certain oral things also. So, these are mostly peptides, which we are working, which are different from that for which already some trials are going on in terms of endometriosis. Then it will be something for sepsis. And down the line, we are also trying to work on peptide for some other indications, I cannot disclose right now, but that is what I refer and then we are looking at new drug delivery systems by which we are trying to get these peptides in the form of these implants or specific methods, which have a international market where you have once in a month or once in 3 months or once in 6 months options available. You

could just take a simple depo intramuscular or subdermal implant, which are much more longer term.

Moderator: Thank you. We will take our last question from the line of Narendra from Whitehouse Capital. Please go ahead.

Narendra: My question is on Ceftazidime-Avibactam, as I understand, this is basically used as an alternative to our existing antibiotics that is Carbapenem and drug-resistant organisms, but does it mean once the Ceftazidime-Avibactam is more easily available, our existing Carbapenem sales will be impacted to some extent?

Pranav Choksi: Very good question. I think, sir, you already have background knowledge about the pharmacology part of it. So, I feel more than they get affected, there are a lot of conditions where people are using a cocktail of products going forward. So, instead of that cocktail, this will be a little bit more of a drug-of-choice in certain cases where you don't want to go and try and error. I mean you don't want to go for trial and error. Yes, penems in the market is so huge that I don't think much impact will come. If the affordability of Ceftazidime-Avibactam becomes more cheap, which will take some time and we are all trying to work on that and definitely, we will see some dent happening in the penem market, but right now, because of the pricing difference between both, I still think there is enough space for both and they will survive.

Narendra: Sir, the next question is on Thymosin Alpha and sepsis, so as I understood, there is already reasonable data over the last 10 years to suggest that this may not make much impact in sepsis treatment as such, are we doing something different here? Why are you going ahead phase 3 trials when there is already some evidence?

Pranav Choksi: So, if you see that on the contrary, we went through almost 200 publications where we have seen that the Thymosin Alpha, if used in a much more efficient manner because Ulinastatin always have the issue of working and not working depending on the timing when it is used and it is a big debate, I will not get into the debate right now, but if you talk about Thymosin Alpha, we have seen the results in COVID and even the 200 plus publications of sepsis has shown that when used in the right time initially, it can really help to suppress the infinity parameters, which we have seen in COVID also like certain cytokine storm and certain CD4/CD8 or even specific of course infinity parameters were taken care of. So, we feel like that it still has a role to play because if you see our Immunocin Alpha was the only product which was approved in moderate-to-severe patients during the COVID thing and that is mostly because of infinity parameters where we see in a normal case, maybe 3 people who are dying out of 4. In case of Thymosin Alpha, only 1 patient died of 4. So, that is a big, right now, we feel still 1 patient died, but 2 people survived on the contrary. So, that way, we feel we are still quite bullish and the data, what we did independent trials before also via some doctors who have tried it in the past, they are quite gung-ho and we still feel, I think what if you need, we will try to send you some publications which we have, and maybe I would like to understand for me what publications you

have also to actually go through this data and maybe you can teach us something which we are not aware about. I will be more than happy to see what you are looking into.

Narendra: Sir, in the presentation, it was mentioned that Q2 sales were impacted because of low hospital occupancy, but the channel checks do suggest that Q2 impact was one of the highest for hospital admissions and occupancy, can you throw some more light on it, sir?

Pranav Choksi: So, your question is that in Q2, we have mentioned that the Critical Care sales in the Q2 were impacted because of less hospitalization and channel, what do you call, channel stocks, inventory levels, right? That is what we have written, but you feel that hospitalization has gone up in Q2? That is what you feel? Or that is what you have read?

Narendra: Yes, that is what I feel, sir.

Pranav Choksi: So, what we feel, I think, Narendra, very frankly, there were 2 issues in a lot of cases, what I feel and what we have worked in the thing. What were pre-COVID conditions in terms of planned surgery and other hospitalization that still has to come and, even if it has come to same year I don't deny, but there is a lot of inventory in the channel, which is blocked. So, a lot of people post COVID has also had maintained very high inventory, not only everyone but including some hoping that being prepared for if something comes back again and that high inventory has led to a lot of inventory in the channel. And that is also one way which is affecting us. That is my opinion because right now, so many companies had these anti-infectives, antifungals, so it was not only COVID, but even mucormycosis has also led to a lot of increase in antifungal inventory also and then we spoke to doctors and all that, we have it, but in the hospital stock, in the distributor level stock and other, we have so much stock, but even if hospitalization is happening, firstly, we are trying to use that inventory first and then we will go to the new one. So, that is what we got the feedback. And that is what we felt that our Critical Care could have done much better. So, even though Roonghta sir said that from, one, if I remember the COVID sales last year and I do a normal Critical Care or 2 Critical Care, we have still seen not that much growth, which we have seen in other divisions' part of it. So, that is why we feel that our Critical Care should have been much more, but we do feel it was affected because of these 2 factors.

Moderator: Thank you. I would now like to hand the conference over to Ms. Ami Shah for closing comments. Over to you.

Ami Shah: Thank you. Thank you everybody for joining this call. I hope all your questions and queries are satisfactorily answered by us and in case if there are any further questions that have remained unanswered, you can reach out to us or Mr. Deven Dhruva from SGA, our Investor Relations partner. The contact details are already provided on the last slide of the presentation uploaded on the website of the stock exchange and also on the website of the company. Thank you once again. Hope to reconnect in the next investor call.



Gufic Biosciences Limited
November 14, 2022

Moderator:

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