Transcript

Biocon Limited Q3 FY19 Earnings Conference Call
January 25, 2019

Participants from Biocon's Senior Management Team

- Kiran Mazumdar-Shaw: Chairperson & Managing Director
- Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon
- Siddharth Mittal: Chief Financial Officer - Biocon
- Shreehas Tambe: Chief Operating Officer - Biocon Biologics
- Paul Thomas, Chief Commercial - Biocon Biologics
- Suresh Subramanian: Head - Branded Formulations India – Biocon
- Nehal Vohra: Head, Global API – Small Molecules - Biocon
- Saurabh Paliwal: Head, Investor Relations - Biocon

Prepared Remarks session:

Saurabh Paliwal: Good morning, ladies and gentlemen. I welcome you to Biocon's Earnings Call for the Third Quarter of Fiscal '19. Before we proceed with this call, I would like to remind everyone that a replay of today's discussion will be available for the next few days about an hour following the conclusion of this call. The call transcript shall be made available on our website in the coming days.

To discuss the company's business performance for this quarter and future outlook, we have today with us the leadership team at Biocon comprising Ms. Kiran Mazumdar-Shaw -- our Chairperson and Managing Director and other colleagues from the senior management team.

I would like to take this opportunity to remind everyone about the Safe Harbor related to this call. Today's discussion may be forward-looking in nature, based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces that would cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements. After the end of this call if you need any further information or need any clarifications, please do get in touch with me. With this, I would like to turn the call over to Ms. Kiran Mazumdar. Over to you ma'am.

Kiran Mazumdar-Shaw: Thanks, Saurabh and good morning, everyone. Considering that we are still in January I would like to start by Wishing Everyone a Very Happy and Prosperous 2019.

I would like to start with key highlights for the quarter:

- European Commission accorded approval to our biosimilar Pegfilgrastim, Fulphila® and to our biosimilar Trastuzumab, Ogivri® which have been being jointly developed by Biocon and Mylan.

- Semglee®, our biosimilar Insulin Glargine, also co-developed with Mylan was launched in the EU during the quarter. Mylan also commercialized biosimilar Adalimumab, in-licensed from Fujifilm Kyowa Kirin Biologics, in the EU in which Biocon receives economic benefit.

With this we now have received three biosimilar approvals in the EU and have an indirect economic interest in a fourth molecule.

- Our biosimilar Insulin Glargine was also launched in South Korea through a local partner as 'Glarzia'.

- As part of our generic formulations foray into the United States, Biocon launched Atorvastatin calcium tablets in the US market during the quarter.

I will now present key financial highlights for Q3 FY'19.

- Total consolidated revenue for the quarter was Rs.1566 crores, up 43% as compared to last year.

- Revenue from operations were Rs.1541 crores, which grew 46% as compared to last year. This includes licensing income of Rs.7 crores this quarter as compared to Rs.12 crores in Q3 of last fiscal.

From a segment perspective,

  - The Small Molecule segment revenue was Rs.469 crores, up 27%;

  - Biologics segment reported revenue growth of 136% to Rs.449 crores;

  - Branded Formulations revenue was at Rs.212 crores in Q3, up 36% and

  - Research Services revenue was at Rs.467 crores, reflecting a growth of 20% compared to last fiscal.

- We incurred gross R&D spend of Rs.106 crores during this quarter, corresponding to 10% of revenue excluding Syngene. Of this amount Rs.77 crores is reported in the P&L. We capitalized an amount of Rs.29 crores related to our biosimilars and insulin analog development expenses. The gross spends are higher than last year primarily on account of increased spend in biosimilars and insulin analog development programs.

- We booked forex loss of Rs.28 crores this quarter as compared to Rs.7 crores gain last fiscal. This loss is reflected in other expenses of the profit & loss statement.

- Based on strong operational performance, EBITDA grew 59% to Rs.406 crores. EBITDA margin for this quarter was 26% as compared to 23% in the corresponding quarter last year. The improved performance was driven by a higher contribution from the Biologics segment driven by high margin biosimilar sales. The growth in margins is despite of a forex loss, underlining strong operational delivery. Core margins, i.e. EBITDA margin net of licensing, forex, and R&D improved from 27% in Q3 last year to 32% this quarter.

- Net profit for the quarter increased from Rs.92 crores last fiscal to Rs.217 crores this quarter. This includes an exceptional gain arising on account of change in fair value of anti-dilutive rights in our investment in US-based Equillium. Adjusting for the exceptional gain and associated tax, Net Profit for this quarter was Rs.211 crores reflecting a gain of 130% with the Net Profit margin at 14%.

Thus, as you can see we have had a strong financial performance this quarter and I am pleased that we have delivered the highest ever revenue and profit growth in absolute terms.

Now coming to analyzing our businesses on a segment basis:

Small Molecules grew 27% over last year, led by strong sales of core APIs and continued growth in our Generics Formulations business. A better product and customer mix resulted in robust API sales in various global markets. We

successfully launched Atorvastatin calcium tablets in the US market this quarter, and this launch along with traction in previously launched Rosuvastatin and Simvastatin formulations have helped the generics business deliver strong growth, contributing to the overall growth of the Small Molecule business segment in Q3.

Coming to **Biologics**, - This segment was the strongest performer with revenue more than doubling from last year, growing 136% year-over-year. Segment margins saw huge improvement year-on-year, from a negative single digit percentage last year now transformed to a solid 30% during the quarter, thereby contributing to the consolidated margin improvement.

Our biosimilar Pegfilgrastim, Fulphila® launched by our partner Mylan in the US continued to gain traction and along with continued performance of Trastuzumab in key emerging markets led to a strong performance for this segment. The performance of Insulin was led by sales in Malaysia and markets in Latin America.

During the quarter, Fulphila® which is our biosimilar Pegfilgrastim received a notice of compliance from Health Canada Biologics and Genetic Therapies Directorate. With this Fulphila® is now approved in the US, EU, Canada and Australia.

Ogivri®, a biosimilar Trastuzumab also received regulatory approval in Australia. Additionally, we received regulatory approval for biosimilar Trastuzumab in various other emerging markets.

As you can see, our biosimilar strategy is beginning to pay off with the launch of our biosimilar in the US and EU and we are greatly encouraged by the recent regulatory approvals of our biosimilars in global markets. We are committed to play a significant role in enhancing access to high-quality affordable biologics for patients across the world.

Now coming to **Branded Formulations.** The revenues for this segment which comprise products sales both in India and UAE, increased 36% as compared to last year. However, this was largely on account of higher sales in the UAE due to channel stocking. Going forward we expect growth in this segment to be in the mid-teens. Performance in India was led by the Metabolics, Nephrology, Immunotherapy and Market Access division. During the quarter, we introduced our biosimilar Trastuzumab under the brand name CANHERA in UAE, which is also expected to contribute to growth in the future.

Research Services had another strong quarter reporting a growth of 20% over last year. The growth during the quarter was driven by good growth in Discovery Services and increased traction in the Biologics business. During the quarter, Syngene commissioned a new dedicated facility for Baxter and extended its collaboration with Merck KGaA with a widened scope of engagement, till 2022.

Now, let me give you some **Product Development Update** on the Novel Molecules portfolio. Our partner Equillium received Fast Track Designation from the US FDA for EQ001 or Itolizumab, which is our out-licensed anti-CD6 molecule for the treatment of acute graft versus host disease. Equillium is planning to initiate a Phase-1b/2 clinical trial in early 2019 called the EQUATE trial which will evaluate EQ001 for the treatment of patients presenting with acute GVHD.

So, in conclusion, I would like to say that we have delivered a robust financial performance year to-date. We have witnessed all round growth across our business segments with Biologics segment revenues doubling year-on-year while the core segments of Small Molecules and Research Services also have registered robust growth. Year-to-date earnings have more than doubled led by the Biologics segment driving high margin growth, demonstrating significant improvement of our quality of earnings. We expect to continue this momentum across all our business segments into Q4 and end FY19 on a strong note. With this I would like to open the floor for questions-and-answers.

Q&A session:

Ronny Gal, Bernstein Research: *If you do not mind I have three of them. The first one is on the Herceptin Biosimilar Trastuzumab. Your US label does not include all the indications of Trastuzumab. I am assuming that this has to do a little bit with IP issues. Would you be able to market the product for all indications when your settlement approaches or is it something that we should expect to come to market more gradually one indication at a time the patent expire?*

Second, I was wondering if you can break for us the sequential growth you had between September quarter and the December quarter in your Biologics segment between Europe, United States and rest of the world, it kind of helps to think about where the growth might be.

And third question, Kiran, if you do not mind, a bit more specific question, we heard few companies suggest the US market for biosimilar is not worth developing the drug for and indeed we have seen reduction in number of programs pending before the FDA. From a perspective of Biocon, is the US market still viable, are we in a way to see position how it all develop for committing to further clinical development, where do you stand on developing more and novel biosimilar in the US market?

Kiran Mazumdar-Shaw: Ronny, let me start by answering your last question. As you know, Biocon is very committed and encouraged by the kind of noises and voices we are hearing about the absolute need for developing biosimilars to help the US with balancing its own healthcare spend and I think they do see biosimilars as a very integral part of health economics as they did with generics. So I do not see any headwind for us in terms of developing biosimilars for the US market and we continue to remain very, very committed to increase and expand our pipeline of biosimilar products under development both with Mylan and with Sandoz and of course we will also have our own portfolio going forward. So, I do not think we are seeing any kind of negative signals from the US market.

Biocon is also focused on a few novel programs and I think this is something that we have always adopted strategically to have different kinds of business. Novels is still a very nascent business for us, but as you can see, biosimilars is an extremely strategic market segment for us and we will continue to invest in this and we believe that we have some early mover advantage. Why other people are opting out of this business is something I cannot comment on, but as far as we are concerned we remain firmly committed. So I hope that sort of answer that part of your question.

Now coming to your first question on indications, I think I should remind you that ODAC actually has approved the drug for all indications, extrapolated from the clinical data that we have done. So, as far as we are concerned, we are approved for all indications.

The Q2 to Q3 obviously is about sales that we have made not just in Europe, but also, I think we had some really good upsides from some of the emerging markets sales and that is why I think you are seeing this big jump. Equally I think you are going to see moving forward as you know Trastuzumab now is ready for launch in Europe. We have of course launched our Semglee® in Europe this quarter. So, these are some of the reasons why you are seeing the jump in performance between Q2 and Q3.

Prakash Agarwal, Axis Capital: *Ma'am, first question on the biosimilar sales, you mentioned that across line items we will continue to see the growth momentum. So, understanding this biologics piece growth better, so during the quarter would we have significant amount of the insulin which we have launched and for the ongoing quarters, it is coming from the insulin and Trastuzumab in Europe?*

Kiran Mazumdar-Shaw: Let me answer your question by saying that we have a biosimilar portfolio which of course straddles insulins, mAbs and Pegfilgrastim, and Pegfilgrastim as you know has already been launched in the US and it continues to sustain its momentum. When it comes to Trastuzumab you will start seeing numbers being reflected in

Q4 and onwards and then you are going to see of course the Semglee® sales also being reflected as a part of the Biologics business. It has already reflected last quarter, but it will also continue to get reflected as we go forward. In addition to that, as you know we have a very large insulin business in emerging markets and we have a growing presence in terms of our monoclonal antibody biosimilars as well. So, all this collectively is really boosting sales. So, as new regulatory approvals come in, we are able to enter new markets. So, overall we are seeing very good traction in our Biologics biosimilars business.

Prakash Agarwal, Axis Capital: *I was trying to understand on the gross margin side, since Europe launches and emerging markets also picking up significantly, Q2 that we saw 66% plus gross margin due to Pegfilgrastim in US, would it be a function of profit share which keeps coming on say quarter or two and we see improving gross margins from here or this is the gross margin one should look going forward as well?*

Siddharth Mittal: Gross margins were quite stable in Q3 when compared to Q2. On a go forward basis, as we have more launches in the developed markets, the gross margin would improve for the Biologics segment, which in turn would have a positive impact on the consolidated gross margins.

Prakash Agarwal, Axis Capital: *From this base also, we are expecting some improvement is what you are saying?*

Siddharth Mittal: That is right.

Prakash Agarwal, Axis Capital: *Lastly on the R&D and tax rate, so R&D we are expecting it to inch up, but it has been flat. So, is it a timing issue and we do expect any ballpark guidance on the R&D for the year and next year and for the tax rate also?*

Siddharth Mittal: The R&D expenses would definitively phase up. We have said that R&D spend tends to be lumpy and is dependent on how the programs are progressing and on the number of programs we pursue. So, on an overall basis, the R&D expense at a gross level for the nine month period has been Rs.314 crores. I would expect the full year number to be around Rs.450 crores. For the next year, the expenses would go up as some of our Sandoz pipeline molecule related expenses start inching up. While we will see benefit of some of the expenses on Mylan collaboration products going down, we will also have expenses for our Novel programs and our Small Molecule ANDA programs. So, from an overall perspective next year, we should have over Rs.500 crores spends in R&D at a gross level.

Prakash Agarwal, Axis Capital: *In tax rate sir why it is particularly low and this is a new normal?*

Siddharth Mittal: I would not say it is a new normal. On a cumulative basis we roughly are at 19% tax rate for the group against our guidance of 23% to 24%. We drew 35 (2AB) benefits on the R&D capex we have done and have also benefitted from some of the carry-forward losses we had in our UK entity, which has now turned profitable because of the profits that we are receiving from launches in the emerging and developed markets. I would say that for the next year you should factor in 22% to 24% as the tax rate at group level.

Damayanti Kerai, HSBC Research: *My question is regarding Fulphila®. So, if you can indicate the progress in the US market in terms of like how much market share we have gained so far and how we are looking for strategies to grow further from here?*

Arun Chandavarkar: So, in terms of Fulphila® market share, we can say that we are tracking to plan. There has been good growth month-on-month in terms of the market share gains, so, I think it is going exactly as we had anticipated it to.

Damayanti Kerai, HSBC Research: *Sir, any number which you would like to share?*

Arun Chandavarkar: The numbers are there in the public domain from whether it is IQVIA or Bloomberg and I would direct you to use those publicly available numbers. I think we had indicated that of the covered market or syringes, we are seeing traction month-on-month and I think at this stage we are somewhere in the mid-teens.

Damayanti Kerai, HSBC Research: *My second question is regarding our launch preparation for Ogivri®. Has there been any change from our previous strategy given that now we have three approved biosimilars for Herceptin in the US?*

Arun Chandavarkar: The launch in the US will track as per plan and the plan is determined by the settlement between Roche and Mylan.

Damayanti Kerai, HSBC Research: *But now like with two more additional approvals we are not changing any strategy compared to what we have earlier indicated or taken on?*

Arun Chandavarkar: The competition in the biosimilar landscape has been known to everybody for quite some time. So it is easy to track that based on the progress in terms of Phase 3 trials and FDA approvals. So the competitive landscape in terms of who the key players are in key geographies is known and baked into our strategy and plan.

Damayanti Kerai, HSBC Research: *Last question will be on small molecule growth. So, one of the reasons we mentioned in the press release is that it is due to increase in API phase to India-based customers who are delivering to the US market. So, what kind of products are these which would increase in demand -- is it like more commoditized or bit niche kind of products and are these mostly short-term contracts or we have something in sustainable way also?*

Arun Chandavarkar: If you look at Biocon's product portfolio, it comprises products where the competitive landscape from an API perspective, because our focus is largely on fermentation derived molecules like the immunosuppressants and few of these statins and products like that. Of course it also has a few key synthetic products and differentiated complex products. So, clearly the growth has come across both our portfolio of statins and immunosuppressants, both through India-based clients who then formulate and have their ANDAs in the US as well as to other customers. So, our Small Molecule strategy is anchored very much to our product portfolio strategy of carving out differentiated portfolio based on immunosuppressants, fermentation based-API and the like. Clearly, we see this as continued business and we continue to see strong traction both in our older APIs as well as in our newer APIs.

Harith Ahamed, Spark Capital: *On the US Trastuzumab launch that you have talked about, now there are two other players with approval, would you expect competition at the time of your launch or does your settlement give you some kind of exclusivity for a certain period in the US for Trastuzumab?*

Arun Chandavarkar: Whilst we are privy to the Mylan-Roche settlement in terms of the timing, we are not privy to the timing of our competition. So, clearly I cannot answer that question. But in response to a previous question I mentioned that our assumption is that we know who the competition is for quite some time, that exact timing of their approval and launch depends on their progress and development, but clearly competition is baked into our strategies and plans.

Harith Ahamed, Spark Capital: *The biosimilar insulin glargine launch in Europe, can you talk a bit about the progress so far and the early response, how many the countries you have launched and what is the kind of market share that we are targeting?*

Arun Chandavarkar: No, at this stage we cannot give you color in terms of the specifics except that we had a recent launch of the Semglee® in Europe. We cannot be specific at this stage in terms of specific countries and specific market shares in those countries.

Harith Ahamed, Spark Capital: *Can you give the CAPEX number year-to-date excluding Syngene and the guidance for full year FY'19?*

Siddharth Mittal: The year-to-date capex for Biocon (ex-Syngene) has been roughly Rs.400 crores and we expect to end the year little over Rs.500 crores for all the projects that we are currently working on. Obviously, spends would continue in the coming fiscal year.

Shyam Srinivasan, Goldman Sachs Research: *First question is on the strategy. Like you said mid-teens now market share on Neulasta biosimilar. If I look at for the other biosimilars in the US so far, they have been struggling at 7% or so especially for the say Remicade Biosimilar, so what explains our success of having getting much higher share in a shorter period of time, these Biosimilars Remicade have been there since 2016, so is there something different about the drug or the innovator response which is helping us so much?*

Arun Chandavarkar: #1, I think any such early gains and all are clearly due to Mylan's strong presence in the US. Mylan drives our commercial strategy and I would attribute it to Mylan. The second thing I would point out is that when you compare and contrast launches for different products, I think there are specifics around each product that innovator defense strategies maybe different, the therapy segment maybe different, something maybe diabetes, something maybe immunology, something maybe oncology. So, all of these dynamics play in terms of the channels through which you market this product, the segment which you are operating in and of course the innovator response.

Shyam Srinivasan, Goldman Sachs Research: *Would there be one overarching thing that is overriding in the case of Neulasta is more acute setting versus chronic settings in Remicade, is there something that explains this in one factor or you think it is like a combination of many things?*

Arun Chandavarkar: Certainly the fact that acute settings do not depend on switching to gain, helps make rapid progress in terms of market share in the segments which are more in the acute therapy. That is certainly a factor in favor.

Shyam Srinivasan, Goldman Sachs Research: *My second question, I do not know whether I heard Kiran wrong, was saying Trastuzumab in developed markets we are preparing in 4Q'19 or did I miss hear that at all?*

Arun Chandavarkar: I think Kiran was referring to the EU.

Shyam Srinivasan, Goldman Sachs Research: *So there is a potential EU launch soon.*

Arun Chandavarkar: Yes.

Shyam Srinivasan, Goldman Sachs Research: *This could be ahead of whatever the global. I thought the global settlement was…?*

Arun Chandavarkar: It is tracking to global settlement.

Shyam Srinivasan, Goldman Sachs Research: *My last question is on the Lantus in the US. Some of the patents have now expired. Can you just refresh on what the timelines on Lantus would be – would it still be post-2020?*

Arun Chandavarkar: Yes, we are on track. There is no change in the stated guidance in terms of the 30-months stay as well as in terms of our timing to respond to the FDA's queries on the bridging study. We are tracking to the timelines previously stated.

Shyam Srinivasan, Goldman Sachs Research: *Other Expenses, even if I strip out Rs.28 crores of FX losses, have sequentially jumped significantly to about say Rs.200 crores or so. I am looking from the fact sheet. So, what explains our non-FX jump in Other Expenses?*

Arun Chandavarkar: While Siddharth can give you color on this, I think at a high level as you know Other Expenses would have the forex component in it, the selling expenses as well, and there is a component of wherever we have cost and profit share relationships with partners, there is an element where we remit profit share in the markets we market, to the partner. So it is a combination of all three.

Surya Patra, Phillip Capital: *Sir, just wanted to have a sense on the future biosimilar pipeline. In that one of the long awaited products, rh-insulin, what is the progress there for US market and what is the timeline that you can indicate now?*

Arun Chandavarkar: So clearly I think if you look at the commentary on insulins, especially in the US, all been extremely favorable and supportive for the need for affordable insulin in the US. And we are clearly very much an active participant in this whole discussion about how do we get our rh-insulin fast track in terms of regulatory approvals and launches in the US. You know that we had previously announced that we are in partnership with the Mexican company Lab PiSA for the US rh-insulin and clearly our development is tracking to that. Whether this development can be accelerated in light of the favorable commentary from the US government and the regulator, is something that we are closely watching and actively participating.

Surya Patra, Phillip Capital: *But is there any timeline to 2020 opportunity or beyond that?*

Arun Chandavarkar: Baseline model might be about two to three years but if anything gets fast tracked, we can see if that is possible, but right now what is the baseline I would say it is about two to three years.

Surya Patra, Phillip Capital: *Regarding Adalimumab, so what one should really believe about US launch per se, anything on that it would be great?*

Arun Chandavarkar: Mylan has a settlement with AbbVie where the US launch of Adalimumab will not happen before somewhere in the middle of 2023.

Siddharth Mittal: July 2023.

Arun Chandavarkar: So, nothing will happen prior to that.

Surya Patra, Phillip Capital: *A couple of this book-keeping I wanted to know. Sir, this Branded Formulations business the way that we have witnessed strong traction here. So here I just wanted to understand how the revenue is booked since that is a JV, so just the profit share should be coming is one line item that is one? Also, we are seeing traction in the revenues. So how is that booked sir? That is one about the accounting part. Secondly, the economic trend from Adalimumab for European market, which line item that is getting factored?*

Siddharth Mittal: Surya, even though this quarter the growth was 36% as compared to last year and 29% compared to previous quarter, we have reported 13% growth in Branded Formulations in the nine months. I think Kiran alluded to that for the full year we would still track to mid-teen kind of growth. This quarter we had higher sales to the channel in UAE which resulted in a one-time kind of increase. So you should not really take that as a new normal and look at the overall growth level. Now, in terms of the revenue recognition, when our UAE entity sells to its customers, the top line is booked in our revenues for the segment.

Surya Patra, Phillip Capital: *It is a manufactured and supplying revenue that we book here and the profit share that come for the revenue what they sell there?*

Siddharth Mittal: The profit share comes through the JV line.

Surya Patra, Phillip Capital: *Regards that economic interest about Adalimumab answer?*

Siddharth Mittal: It is booked in the Biologics revenue line.

Surya Patra, Phillip Capital: *Sir, can you give some sense about the Malaysia plant -- whether it has achieved a breakeven? So considering that what is the behavior of the other expense that is going to be in the subsequent period let us say next year?*

Siddharth Mittal: We had said at the beginning of the year that while we had a small loss last year, this year we expect to breakeven. We will not break up the entity level P&L on a quarterly basis. Once the full year numbers are published, the numbers will be on our website where you can see them. So given that we have one more quarter to go, Mylan has recently launched Semglee® in Europe and the fourth quarter numbers are still to come in, I would say, we are on track. In terms of the expenses, we have mentioned that the fixed expense including depreciation and interest for that facility is to the tune of $50 million. Next year, obviously the fixed expenses would go up in line with the cost increases that would happen for all of the operating expenses there.

Surya Patra, Phillip Capital: *That would be much lesser than the revenue growth that we can see from that base?*

Siddharth Mittal: Absolutely.

Surya Patra, Phillip Capital: *Given about $200 million kind of capex of Syngene and our own growth capex that we are planning, so, next year what is the consolidated capex that it could be, about Biocon, put together on consolidated basis?*

Siddharth Mittal: I would say that the last two fiscal years Biocon's capex has been approximately Rs.600 crores (ex-Syngene). On a go forward basis, I would expect let us say for the next fiscal, the same level of spends to be there.

Nitin Agarwal, IDFC Securities: *Sir, two things: One is on the biosimilar sales in emerging markets, like typically they are in the developed markets. Should we assume like a linear progression in this business or there is going to be a large-ish component of tender sales so there could be lumpiness from quarter-to- quarter on an overall basis?*

Arun Chandavarkar: Yes, there are some businesses where you can expect a fairly linear progression, for example, we have the offtake agreement in Malaysia which has a far greater degree of predictability. So, wherever the markets have a component of strong proportion of retail business, it tends to be far more predictable. Our current revenue mix is a mix of both tenders and retail in emerging markets. So, there is that element of unpredictability in tenders but the tenders are not like for short duration like three months or six months. If you get a tender or you do not get a tender, it usually translates to a full year or two year period.

Nitin Agarwal, IDFC Securities: *What will be typically qualitatively a split – it is more skewed towards emerging markets towards tender in general or it is more towards regular linear sales?*

Arun Chandavarkar: But what happens is that since we have diversified the risk by being present in multiple countries, the granular level of lumpiness does not reflect in the emerging markets sort of consolidated number. Because we have multiple products and across countries and some countries have more than one tender.

Nitin Agarwal, IDFC Securities: *On the point of the scale-up that we have seen in the Biosimilars business, obviously Peg in US would have contributed and there has obviously been pickup in momentum even in the emerging markets over the last couple of quarters. But largely from a product perspective, it is largely Trastuzumab in emerging markets which has driven up the numbers, contribution of emerging markets or there are more other biosimilars apart from Trastuzumab also contributed meaningfully over the last two quarters?*

Arun Chandavarkar: I think rh-Insulin, Insulin Glargine and Trastuzumab is where our biosimilars portfolio in emerging markets is currently focused on. So clearly, all of these are doing well across all the three molecules. So, I would say there is a contribution from all molecules, specific molecule may contribute differently in a specific country but at an aggregate emerging market level, all three have contributed significantly.

Nitin Agarwal, IDFC Securities: *Siddharth, on the Other Expenses issue that we have talked about earlier, is it fair to say that increase in Other Expenses is kind of linked to the increase in Biologics sales and as these sales sort of keep picking through, we will keep having a proportionate or kind of some sort of linked increase to our other expenses also?*

Siddharth Mittal: That is correct. Other than forex, the selling expenses and profit share will be directly linked to the sales increase, not necessarily linearly linked but yes, as the sales go up in the coming quarters and coming years, we would see an increase in Other Expenses.

Dheeresh Pathak, Goldman Sachs Asset Management: *Just understanding the Other Expenses again. So the forex element is how much and this is in Biocon book, right, not Syngene?*

Siddharth Mittal: The consolidated forex loss during the quarter was Rs.28 crores and all of it did come from Biocon.

Dheeresh Pathak, Goldman Sachs Asset Management: *The nature of this is forex debt or it is current liabilities, what is…?*

Siddharth Mittal: It is the restatement of Current Assets and Liabilities at the December exchange rate. As you know that in September end, the dollar was tracking around Rs.74 compared to almost Rs.70 in December, so that Rs.4 movement led to a loss. You will see that we had also gained in the first two quarters, as the rupee had weakened then. On a cumulative basis, we have had Rs.35 crores forex gain.

Dheeresh Pathak, Goldman Sachs Asset Management: *Sir, you also said that profit share you are showing in other expense, can you just expand a little bit more on that like which markets are these?*

Siddharth Mittal: We cannot break up the profit share by markets. As Arun said, we have multiple partners in emerging markets, including Mylan, wherein we lead the sales and share profits with our partners. The shared profit is booked in the Other Expense line.

Dheeresh Pathak, Goldman Sachs Asset Management: *My understanding was wherever we have entered into partnership it is mainly for marketing expertise of the partner, but you are saying you are sharing with the partner for what because manufacturing is done by Biocon as I understand, typically partners are front end partners if my understanding was correct?*

Siddharth Mittal: Mylan is a major component of this. In certain emerging markets where we sell, we share profits with Mylan.

Dheeresh Pathak, Goldman Sachs Asset Management: *The intangibles under development, if my understanding was correct, they were mainly linked to Herceptin and Glargine. Now, you have commercialized both in certain markets*

not obviously the largest market which is US. So have you allocated certain cost and you are depreciating them or the full cost is linked to US and you will amortize when you get the US approval?

Siddharth Mittal: To correct you, it is Glargine, Trastuzumab and Bevacizumab costs that are capitalized. We have started amortizing cost for Glargine in Europe since Mylan has launched the product there. We have also started amortizing our share of amount paid out to Fuji for in-licensing Adalimumab. For Trastuzumab in Europe, since the launch is planned in this Q4, the amortization will begin in Q4. For the US, once the launch happens, the amortization would begin. But I should also say that while the depreciation or amortization is one aspect, you should understand that we continue to incur costs on the programs even after they are approved in the US and Europe because of the commitments given to the regulator and certain additional trials we need to do, post approval, to generate data.

Dheeresh Pathak, Goldman Sachs Asset Management: *But bulk of the costs if you allocate let us say on a molecule wise region wise, they would have been to the US market, right, is that fair understanding?*

Siddharth Mittal: Absolutely. The way we split it up between US and Europe is basis the market size of the drug. Typically you will see 2:1 or 3:1 allocation between US and Europe for most of our biologic drugs.

Charulata Gaidhani, Dalal & Broacha: *My question pertains to the outlook for price erosion as more and more players enter the biosimilars market with Trastuzumab already having three approvals.*

Arun Chandavarkar: What I would say is that clearly our strategies in terms of pricing, in terms of strategy to gain market share factor in this. I cannot give you an outlook other than saying that yes, in the biosimilars or generic space, prices do not tend to go up, but it is a fact that overtime prices would come down. If your question is how rapidly they will come down, I think it really depends on markets - tenders or retail and number of competitors out there and the psychology of the competitors; whether people are keen to gain volume at a cost of eroding value or whether people want to sustain market share. So, it is a very dynamic play. It is too early to hazard a guess in terms of specific guidance. I do not think there is enough experience out there unlike the ANDA witnessed to say exactly what the trend would be.

Siddharth Mittal: One thing that I would like to add specifically for Pegfilgrastim in the US. As you know, when Mylan launched the product, they had launched the product at a certain discount to the innovator. Coherus, which recently got the product approved and has launched the drug in the US, has also publicly announced, that their WAC for Pegfilgrastim will be at the same level as Mylan. In the initial years, no two molecules would have a similar level of pricing dynamic. Each molecule with different number of players might behave very differently.

Charulata Gaidhani, Dalal & Broacha: *Can I have the sales and PBT from Malaysia?*

Siddharth Mittal: I had mentioned earlier that we do not breakup the P&L at an entity level on a quarterly basis. Once our annual accounts are audited, the annual accounts are published for standalone subsidiaries on our website. So by end of May of 2019, you will get the detailed financials for Malaysia on our website.

Charulata Gaidhani, Dalal & Broacha: *Just like you mentioned for BFI mid-teen growth on annual basis, what would be a sustainable growth for Small Molecules?*

Siddharth Mittal: The Small Molecules nine months growth has been 20%. Kiran in her closing remarks had alluded that the performance we have witnessed year-to-date is something that we can expect going into Q4 for Small Molecules. Beyond Q4, giving a guidance for next year would not be possible at this time.

Ranjit Kapadia, Centrum Broking: *My question relates to Pegfilgrastim. What is the market size in US and how many players are there? Second question relates to in-licensing of products in UAE. How is the scenario for Januvia and Janumet?*

Paul Thomas: On Pegfilgrastim, this is a $4-5 billion market overall with most of it in the US. Currently, in addition to the originator product, that is ourselves and one more biosimilar in the market.

Siddharth Mittal: In terms of in-licensing products from Novartis, you mentioned Januvia and Janumet, our brand is Jalra.

Kiran Mazumdar-Shaw: I want to clarify that our product that we are marketing in UAE is not Januvia. We have brought Vildagliptin, under the brand name Jalra and that is doing fairly well. We will continue to look at in-licensing products for the UAE market.

Ranjit Kapadia, Centrum Broking: *Any possibility of increasing this business in the UAE?*

Kiran Mazumdar-Shaw: I mentioned that we have launched Trastuzumab under CANHERA brand name and we expect it to have a good contribution to our UAE business growth.

Sameer Baisiwala, Morgan Stanley Research: *Arun, can you again refresh us on the Glargine for the US market? You mentioned about addressing the CRL as well as completion of bridging studies for the site switch.*

Arun Chandavarkar: Sameer, what I mentioned is that whatever we had stated in our previous quarter, continues to remain true. We are on track in terms of the bridging the manufacturing site from Bangalore to Malaysia. The information requested by the FDA, we are on track in terms of developing and timing of submitting that data and of course as you know in parallel the 30-months stay that also continues to track as per previously stated timeline.

Sameer Baisiwala, Morgan Stanley Research:*Arun, what I am asking I guess is, when you say it is on track, are you looking at one quarter later or two quarters later to submit the data for both CRL and bridging study?*

Shreehas Tambe: Sameer, the 30-months stay extends into March 2020. So, we are tracking to that. We have been working with the FDA under the agreed guidance and our bridging studies are tracking to finish in time so that we can be in time as soon as the 30-months stay is over.

Sameer Baisiwala, Morgan Stanley Research: *When you say that you mean to say you will get the approval at the end of 30-months?*

Arun Chandavarkar: That is what we are tracking for.

Sameer Baisiwala, Morgan Stanley Research: *Second question is on Bevacizumab. When do you expect this market to open up in the US? And do you think you could be in time for the first wave of launches?*

Paul Thomas: I would not want to comment very specifically on that.

Sameer Baisiwala, Morgan Stanley Research: *Third question is on Humira. For your own product, have you developed both the low concentration and the high concentration product, 40 mg by 0.4 ml, is the one I am specifically asking for?*

Paul Thomas: Right now the launch is with the lower concentration product.

Sameer Baisiwala, Morgan Stanley Research:*But do you intend to develop the higher one as well or?*

Paul Thomas: I think that would be in development but we would not give specifics of timing about that now.

Sameer Baisiwala, Morgan Stanley Research:*On the capacity side, I think in general the company has mentioned that you aim for 25% market share; that is what your capacities are geared for. Now that for Fulphila® you are hitting mid-teens or maybe high-teen market share. Do you think you can take it above 25% or your capacity could be a constraint there?*

Arun Chandavarkar: I think what we said is that we always dovetail our capacity to our market plans and we do not build further capacities upfront across our portfolio, we build them in a modular way and that applies to all our programs and we continue to track to ensure that our capacities come online as we gain market share or as we get approvals in other countries. So we cannot be more specific than that due to competitive reasons.

Sameer Baisiwala, Morgan Stanley Research:*Which means you will not get capped at 25% market share for Fulphila® if there is a market opportunity?*

Arun Chandavarkar: As I said, I do not want to give a specific answer. All I am saying is our capacity plans dovetail to our anticipated market plans.

Sameer Baisiwala, Morgan Stanley Research:*On the new MAb facility, when do you expect that to get commissioned?*

Shreehas Tambe: We would be looking at commissioning the facility in the year 2021.

Rohit Shah, Individual Investor: *In 2014, you guys have put up a five year plan with target for FY'19. I was just wondering, are you guys going to do the same thing again in terms of sharing your guidance for the five years coming up?*

Siddharth Mittal: We have not yet made a decision. We will let you know once we close this fiscal year if we are going to give number guidance for the next five years period.

Nitin Agarwal, IDFC Securities: *Sir, in the past we talked about value unlocking in the biosimilars business. There are two things: One is, a), with the biosimilars revenues and profitability sort of contribution picking up and at the same time our R&D expenses likely to go up, do we still see a need for value unlocking in this business as a means to fund for our future growth in biosimilars?*

Siddharth Mittal: Yes. We are in investment mode. We have been investing heavily in capex and R&D for this business. As our collaboration with Sandoz and also our own pipeline develop, the investments on a go-forward basis would go up. Though we have room for debt on our balance sheet, we would also look at equity for our Biologics business, either in the form of a private equity or in the form of an IPO at a future point in time.

Nitin Agarwal, IDFC Securities: *Siddharth, just a bit of housekeeping. In the segment, now you carve out your business into segments and give us some sense on the EBIT number which is pretty helpful. Just one thing, in the current quarter, there is a pretty large amount sitting in other unallocable expenses. What would that be?*

Siddharth Mittal: That has Rs.28 crores of forex expense. If you take that out, the expenses on a quarterly basis is somewhere between Rs.45-50 crores at a consolidated level. If you actually look at Q2, it was Rs.13 crores because we had a forex gain of Rs.29 crores. So when you add back that you will have the same numbers of Rs.45 crores of

unallocable expenses which primarily has expenses like depreciation, corporate cost, and other unallocable cost specific to any other vertical.

Surya Patra, Phillip Capital: *Just wanted to have some sense on the Small Molecule API opportunities. So, given the kind of a development that we are witnessing from the China side and on the wake of that what opportunity that is feasible for whoever is there in that Small Molecule APIs, that seems quite strong and seems sustaining also. You have also seen that progress in terms of inspection and all that for your plant. So, now considering the pipeline or activities that you are doing there, and the growth potential what you are anticipating there, can you please share anything on that front?*

Nehal Vora: We certainly see this region but it is too early for us to comment. I think if we want to get into this region, it is going to be a long drawn process for us. So we will comment at an appropriate time.

Surya Patra, Phillip Capital: *So as of now how big is that opportunity in the overall small molecule business for us currently?*

Arun Chandavarkar: Are you talking about an opportunity in China?

Surya Patra, Phillip Capital: *No, that is anyway is a driving force that I see, but currently in the revenue small molecule revenue this API piece, the plant what we acquired sometime back and what is the kind of contribution?*

Arun Chandavarkar: No, let me step back. If your question is about outlook generally for APIs and not specifically about China, I think our focus in the API business is clearly around technologically differentiated products, whether it is fermentation, whether it is complex, whether it is potent, as you know, we have previously announced commissioning of our potent oral solids formulation facility, clearly that will be serviced by in-house APIs. So, this differentiated portfolio of API is something that we will continue to invest in and grow our pipeline and I think there is quite a bit of headroom for growth based on our selected portfolio. Second comment I would like to make is that I also said that from an API perspective there is a certain part of the business opportunity but increasingly going forward the Small Molecules division would also focus on growing the generic formulations opportunity. So rather than leaving a large chunk of the value on the table, if Biocon can capture a big chunk of that for specific APIs, that will be another significant opportunity for growth for Biocon.

Surya Patra, Phillip Capital: *Please correct me. My understanding was that the plant what you had acquired, it was not about fermentation API capacity, it was the other …?*

Arun Chandavarkar: Those are the potent APIs.

Prakash Agarwal, Axis Capital: *Just one clarification; on the profit share that we get from the partner especially for Peg, since we launched and got some share in Q2 and Q3 now, so are these with a lag and do we expect higher numbers going forward as the market share is increasing in Q4 and onwards?*

Siddharth Mittal: When we supply the material, obviously we get the profit share at a lag because we book profit share once Mylan sells to its customer. Would it go up or down? That is dependent on the number of launches. As we have mentioned that there have been some recent launches in Q3, there will be additional launches in Q4. So the profit share would go up.

Prakash Agarwal, Axis Capital: *It would be a function of gaining market share and obviously the pricing?*

Siddharth Mittal: Absolutely.

Prakash Agarwal, Axis Capital: *This is applicable for the partnered Humira launch also in Europe. So, that is not one-time, it will continue in that bucket?*

Siddharth Mittal: Absolutely.

Prakash Agarwal, Axis Capital: *With more launches which you mentioned, Trastu in Europe and maybe Peg, so this momentum what you mentioned or Kiran mentioned in opening remark, that is leading to a higher growth even QoQ?*

Siddharth Mittal: In addition to increased sales in emerging markets.

Saurabh Paliwal: Thank you all for joining us today. If you have any further follow ups, please do get in touch with me. Till next quarter have a wonderful day

- Ends -

Note: The contents of this transcript have been edited to improve accuracy and readability. It includes corrections to statements/ numbers.