Biocon Limited Q3 FY18 Earnings Conference Call
January 25, 2018

Participants from Biocon's Senior Management Team

- Kiran Mazumdar: Chairperson & Managing Director
- Arun Chandavarkar: CEO & Jt. Managing Director
- Siddharth Mittal: President (Finance) & CFO
- Prasad BSV: Sr. Vice President & Head - Small Molecules
- Shreehas Tambe: Sr. Vice President & Head - Insulins
- Paul Thomas: Vice President & Head - Biosimilars
- Suresh Subramanian: Sr. Vice President & Head - Branded Formulations India
- Naren Chirmule: Sr. Vice President & Head - R&D
- Saurabh Paliwal: Head, Investor Relations

Conference Call Participants during Q&A

- Prakash Agarwal, Axis Capital
- Ritika Jalan, Narnolia Securities
- Nitin Agarwal, IDFC Securities
- Charulatha Gaidhani, Dalal & Broacha
- Cyndrella Carvalho, Dolat Capital
- Sameer Baiswala, Morgan Stanley
- Harith Ahamed, Spark Capital
- Shraddha D'Souza, Wealth Managers
- Vipul Shah, Sumangal Investments
- Anubhav Aggarwal, Credit Suisse
- Vikram Agarwal, Individual Investor

Presentation Session

Saurabh Paliwal: Thank you, Margaret, and good morning everybody. I welcome you to today's earnings call for the third quarter of fiscal '18. Before we proceed with the call, let me remind you on the Safe Harbor. The discussion today may contain forward-looking statements that may involve known and unknown risks, uncertainties and other factors. . It must be viewed in conjunction with the risks that our business faces that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements. Please refer to our 'Conference Call Invite' for the same.

A reminder to all of you - a replay of today's discussion will be available for the next few days post the conclusion of this conference call. Further, if there is any further clarifications or information needed from us, please do get in touch with me.

To discuss the quarterly performance and the future business outlook of the Company, we have on the call today, Dr. Kiran Mazumdar – our Chairperson and Managing Director along with the senior management team. I will now hand the call over to Dr. Kiran Mazumdar. Over to you ma'am.

Kiran Mazumdar: Thank you, Saurabh. Good Morning, everyone. I welcome you to Biocon's Earnings Call for the third quarter of Fiscal '18.

Let me start with 'Key Business Highlights for this Quarter:'

- I am very proud to say that US FDA accorded approval for Ogivri™, our partnered Biosimilar Trastuzumab with Mylan. We thus became the first company from India to get its Biosimilar approved by US FDA.
- Biocon also received approval from the Brazilian regulatory agency, ANVISA for Biosimilar Trastuzumab through its partner Libbs Farmaceutica. It is the first Biosimilar Trastuzumab to be approved in Brazil.
- ANVISA also approved Biocon's Recombinant Human Insulin drug product under the new non-originator biologicals pathway which will help us compete in the country's Ministry of Health tender market in addition to the retail market where our partner has significant presence.
- Biocon launched KRABEVA®, a biosimilar Bevacizumab product in India, indicated for the treatment of patients with metastatic colorectal cancer and other types of lung, kidney, cervical, ovarian and brain cancers.
- Last week we announced our global collaboration with Sandoz, a Novartis division and a global leader in biosimilars for developing a set of next-generation biosimilar products. The collaboration aims to help patients worldwide to gain access to range of high quality affordable immunology and oncology biologics which complement our existing portfolio. It will boost Biocon's existing global biosimilar portfolio comprising biosimilar antibodies and insulin analogs which we are developing in our global partnership with Mylan. We are targeting opportunities that are expected to open up in the next decade thereby addressing some of the biosimilar opportunities beyond the near-term opportunities being addressed with our very successful global partnership with Mylan.
- Syngene expanded its ongoing collaboration with Bristol-Myers Squibb through 2026 that will see the addition of a new facility to support Bristol-Myers Squibb's future R&D operation and allow for expansion of the team of scientists working exclusively for them in Syngene. Syngene operates the largest research and development facility for Bristol-Myers Squibb outside the United States. It is certainly playing a very integral role within the global research and development network of Bristol-Myers Squibb.

I would now like to move on to "**Financial Highlights**"

- Consolidated revenues this quarter were Rs.1092 crores,
- Revenues from operations were Rs.1058 crores which grew 1% as compared to last fiscal. This includes licensing income of Rs.12 crores as compared to Rs.79 crores that we booked in Q3 last year.
- From a Segmental perspective -
  - The Small Molecules segment revenue was Rs.369 crores, down 9% from Q3 of last year.
  - The Biologics segment revenue was Rs.190 crores, down 15% over last year. However, when adjusted for licensing income, products sales grew 16% as compared to last year with growth seen in both insulins as well as biosimilar antibody sales.
  - Branded Formulations showed strong growth of 27% at Rs.156 crores against Rs.123 crores last year.
  - The Research Services segment represented by Syngene was up 17% at Rs.388 crores compared to Q3 last fiscal.
- We incurred gross spends of Rs.94 crores on R&D this quarter, and of this Rs.53 crores is reported in the P&L corresponding to 8% of revenues excluding Syngene. We capitalized an amount of Rs.41 crores related to our Biosimilars and Insulin Analog development expenses.
- We booked a FOREX gain of Rs.7 crores this quarter.

- Group EBITDA was at Rs.256 crores with EBITDA margins of 23%. Core margin that is EBITDA margin, net of licensing, impact of FOREX and R&D stood at 27%. The reduction in EBITDA margin as compared to last year is on account of lowering licensing income which was compounded by fixed and operating costs related to the Malaysia facility.
- Our reported Net Profit for the quarter was Rs.92 crores which represent net profit margin of 8%.

Now coming to Individual Business Segments:

Small Molecules segment continued to face headwinds as a result of continued pricing pressure and channel consolidation in the US, impacting the statins business. This was led by decline in Rosuvastatin API pricing as compared to last year. Continued demand for immunosuppressants helped to offset some of this pressure. We anticipate this trend to continue in the near future.

When it comes to **Biologics**, financial performance of this segment was impacted on account of plant requalification activities undertaken at our fill-finish plant which led to production disruption. We also booked significantly lower licensing income resulting in lower revenues as compared to last year. Lower licensing income coupled with fixed and operating expenses related to the Malaysia insulins facility impacted segment margins. Given that the drug product plant is now back on line and producing commercially, we expect Biologics production to normalize in Q4 thereby furthering sales growth. The Biologics segment is expected to bounce back in a robust manner in FY19 on the back of expected regulatory approvals and product sales in emerging markets.

Branded Formulations: The growth of this segment was led by the UAE business driven by new and in-licensed products with momentum in Branded Generics. The Oncology and Comprehensive Care franchises in India led growth in the Indian domestic market.

Syngene grew 17% driven primarily by the chemical development verticals reflecting good underlying performance. Biologics and Biological Discovery have also seen good traction. We expect Syngene to close FY18 with strong momentum primarily driven by Biologics.

When it comes to **Product development and Regulatory updates –**

Biocon and Mylan have submitted a response to the US FDA on the complete response letter issued by the agency for Biosimilar Pegfilgrastim.

The European Medicine Agency or EMA has accepted our resubmission of marketing authorization applications for biosimilars of Trastuzumab and Pegfilgrastim.

As regards our Insulin Glargine, our market authorization applications are under advance stages of review in the EU, Australia and Canada. The application for this drug is also under review with the US FDA.

I would also like to mention here that our global Phase-1 clinical trial for Insulin Aspart has recently been initiated.

The global Phase-3 trial for biosimilar Bevacizumab is progressing well in various sites in the EU and India as first line treatment of patients with stage-IV non-squamous small cell lung cancer.

In terms of the **Novel Biologics** pipeline, we received DCGI approval to conduct Phase-2/3 study in type 2 diabetes patients for our oral insulin candidate, Insulin Tregopil in India. Dosing has commenced and we expect the trial to be completed in about two years.

Before I conclude, I would like to summarize as follows.

The financial performance this quarter was muted. Pricing pressure and channel consolidation in the US has impacted our Small Molecules API business while reduction in licensing income and supply constraints due to plant requalification activities have affected the performance of the Biologics segment. While challenges remain in Branded Formulations India business, the Branded Formulations segment as a whole has shown good growth this quarter driven by the UAE business. Syngene performance is beginning to not only normalize but gain traction. The regulatory advancement in Biologics business made during the period augurs well for our future. We are hopeful of recovery in our consolidated performance in the coming quarters led by the Biologics and Research Services segments.

I would now like to open it up for question-and-answer. Thank you.

Question and Answer Session

Prakash Agarwal: **First question trying to understand gross margin movement specially QoQ. YoY I understand why the Biologics sales have been lower, but QoQ also it has marginally dipped and if see the segmental performance I think the Small Molecules have done better QoQ. So if you could highlight what has really led to the decline QoQ on the gross margins please?**

Siddharth Mittal: We will have those minor fluctuations. The quarter-on-quarter move is a very nominal 70 basis points at a gross margin of ~56% percent. I would not say there has been anything one-off, not in the normal that has impacted the margins. It depends on the product mix within the various segments and also which segment has given how much growth.

Prakash Agarwal: **The question I ask because sales mix actually improved if you see Research Services QoQ has improved, your Branded Formulations marginally dipping, but Biologics of QoQ improved. So, is it largely due to the licensing income or that also has improved? I am just trying to figure out what has really happened.**

Siddharth Mittal: When you see the segment results, it is after taking into account R&D expenses. As I mentioned the gross margin has not significantly changed, but the segment results consider after all the other expenses and R&D costs.

Prakash Agarwal: **Secondly, update on Pegfilgrastim, since we have submitted our data what would be the next steps going forward and when are we expecting the approvals?**

Arun Chandavarkar: In terms of Pegfilgrastim, as Kiran mentioned in her opening remarks Mylan has submitted a response to the complete response letter that we had received. Obviously, now the FDA would review that response and give approval in due course. We cannot at this moment give a definitive timeline but suffice to say that we expect decision from the regulator hopefully in the first half of FY'19.

Prakash Agarwal: **Lastly, we saw Kiran ma'am on TV talking about the potential listing of the Biosimilar assets. So if we could know which markets probably we are looking at and what is the timeframe here that would be very helpful?**

Kiran Mazumdar: I had commented that we will be looking at opportunities to unlock value from our Biologics assets in the foreseeable future. It is too early for us to give you any timeline in

terms of when this listing would happen, but suffice to say that at some stage in the near future.

Ritika Jalan: **I just have some house-keeping question like what is the CAPEX guidance for FY18 and FY19?**

Siddharth Mittal: FY'18 is almost over, but what we have said directionally is that on an annualized basis, we have roughly Rs.100 crores of maintenance CAPEX in Biocon (ex-Syngene). In addition to that we have started construction of our second antibody plant where we are going to invest somewhere between $150 million to $175 million with the facility expected to be commissioned over a period of two years. Therefore, you can expect large part of CAPEX payout in the next two years towards this.

Ritika Jalan: **Do you expect margin to grow further from this level or do you expect to maintain the margin?**

Siddharth Mittal: We cannot give any guidance on margins. What we have said in the past is that when we have ramped up sales of biosimilar products in the developed markets, intuitively the margins should go up.

Ritika Jalan: **What is the reason for decline in the licensing income, can you brief?**

Siddharth Mittal: Licensing income is inherently lumpy. It all depends on what deal is done during the quarter. Sometimes you also have milestone payouts depending on the approval of the products. So, there is no trend that can be really looked at.

Ritika Jalan: **Do we have products scope of more licensing income in other emerging countries or something like that?**

Siddharth Mittal: Licensing income this year has been low. If you look at nine months of this fiscal, licensing income that we booked is Rs.21 crores as compared to Rs.129 crores for the nine months of last fiscal. The licensing income is derived mostly when you out-license these drugs in the emerging markets. Since we have already struck partnerships in large emerging markets for most of our existing biosimilar drugs, the licensing income would start going up only when we have newer molecules that we can start to license in these markets.

Ritika Jalan: **Little bit of outlook on when it will start like when your deal will be finalized and all?**

Siddharth Mittal: It is in various stages, we cannot give an outlook exactly in terms of the timing and the amount. As you heard that we recently got approval for our Biosimilar Bevacizumab in India. So, that is a good licensing asset for us and we would start discussions with our existing and new partners in emerging markets. This should result in increase in licensing income over the next few fiscals.

Ritika Jalan: **On the Malaysian facility, a couple of questions are there; what are the expenses related to the Malaysian facility?**

Siddharth Mittal: We have fixed expenses for this facility which are around $48 million per year or $12 million a quarter. This quarter we have $12 million of expense including interest and depreciation in the P&L.

Ritika Jalan: **Will it continue going ahead or what?**

Siddharth Mittal: These are fixed expenses, so they will continue, the depreciation, the interest, the employee cost, the utility cost, by very nature these are fixed, they are not going to fluctuate or go down.

Nitin Agarwal: **On the commercialization of biosimilars in regulated markets, what is your own take on the differences you see in the very early days in the way pickup has been in US versus Europe, we have seen still challenges even Pfizer is facing with Inflectra, how do you see this commercialization bit in the US market, any development going forward?**

Kiran Mazumdar: As you know, Mylan is front ending the commercialization in both Europe and US markets. I think this question is better addressed to them, because it is not appropriate for us to comment. But having said that I believe that as you very rightly said these are early days, and as you know that the uptick of biosimilars in Europe has been very strong and we expect that in many segments in the US, especially in the area of Oncology drugs, I think there will be a positive response to biosimilars is what our take is. We will have to wait and watch.

Nitin Agarwal: **Secondly, the question is in this business, whilst it is a very-very limited competition opportunities would be there across products, how important is being first-to-market in these products in your assessment?**

Kiran Mazumdar: I think it is important to have an early mover advantage. Having a partner like Mylan who understands the market very well, I think it definitely is advantageous.

Nitin Agarwal: **Thirdly, in terms of emerging markets roll out of our Pegfilgrastim and Glargine, how do you see FY19 in terms of progression on that front?**

Kiran Mazumdar: I real opportunity for Pegfilgrastim is obviously the highly regulated markets of Europe and US. When it comes to Glargine, we are represented fairly well in many emerging markets. So really the next big opportunity for Biocon and Mylan is the European and US markets; and the European review for Glargine is fairly advanced. So hopefully, we will get into the market in this calendar year.

Nitin Agarwal: **I am sorry, Trastuzumab also for the emerging markets?**

Kiran Mazumdar: Trastuzumab for the emerging markets as you know we have received approval from ANVISA and we are obviously positioning ourselves to look at many other such big emerging markets opportunities. So we will look at emerging markets very seriously in the near-term.

Nitin Agarwal: **Do you think the goal for us in the emerging markets across Trastuzumab and Glargine, will it be FY19 be a sort of inflection year or is it more like 20 where we will probably see critical contribution coming from…?**

Kiran Mazumdar: Obviously FY19 is going to focus a lot on emerging market opportunities for these biosimilars. I believe that we will the see the big opportunities once US and European markets open up. While they will be big opportunities, they might take a bit of a ramp up. So FY19 certainly is definitely emerging markets play in the near-term.

Siddharth Mittal: Nitin, I would like to add one more thing, which was there in our press release we have mentioned about receipt of approval for our Insulin Glargine in Russia, which for Glargine is amongst the top three emerging markets. So that again in addition to Brazil and some of the other emerging markets will also reflect in our growth in FY19.

Nitin Agarwal: **How big would the Glargine market be for Russia?**

Shreehas Tambe: Glargine is a sizable opportunity in Russia as well. While the market has been moving from Glargine towards Toujeo, the numbers for Glargine were pretty strong in FY17.

Nitin Agarwal: **Would you give any specific number, just to help us more a little bit?**

Shreehas Tambe: Let me just come back to you on that number.

Charulata Gaidhani: **Hi, my question pertains to the profitability of Small Molecules. There is a lot of volatility in the margins. Can you throw some light on that?**

Siddharth Mittal: Segment margins are sales minus cost of manufacturing and other expenses. Some of these other expenses tend to be lumpy which would have resulted in reduction in the margin in Q2 as compared to what we have in this quarter. You should really look at margins on a nine months basis to see what would be the normalized margins. If you look at nine months, PBIT for Small Molecules is roughly Rs.200 crores which means the average profit per quarter is ~ Rs.65 crores.

Charulata Gaidhani: **My second question pertains to growth in Branded Formulations. What has led to this growth and how sustainable is this?**

Siddharth Mittal: Kiran's mentioned in her opening remarks that growth in Branded Formulations was driven largely by our UAE business. She had also mentioned in terms of the guidance that there are challenges which remain for our Branded Formulations India business; however, in our UAE business we have and will continue to see good growth in the coming quarters.

Charulata Gaidhani: **Have we commenced Insulin supplies from Malaysia to EU?**

Siddharth Mittal: Not yet, we have not yet got the EU approval. Only after we receive the EU approval and then subsequently are ready to launch, the supplies would commence.

Cyndrella Carvalho: **Ma'am just wanted to understand Insulin Glargine update for the EU region. Where are we right now? What is our tentative expectation on that approval?**

Kiran Mazumdar: As I mentioned in my opening remarks, we are in a very advanced stage of review with the EMA and we expect to receive positive news from them very soon. Once that happens, we then expect to receive marketing authorization shortly thereafter. We hope that we will enter the European market with Insulin Glargine in this calendar year.

Cyndrella Carvalho: **Ma'am just understanding we have received rh-insulin, human insulin approval also we received approval in Russia. All these supplies will start from Malaysian plant, is that correct?**

Kiran Mazumdar: Between Malaysian and Indian operations we will balance the supplies across the markets.

Cyndrella Carvalho: **Any color that you can provide in terms of utilization from the Malaysian site whenever we get Insulin Glargine, how should we look at it over two to three years from here onwards?**

Kiran Mazumdar: We cannot give you exact color on that kind of opportunity until we basically start seeing ramped up sales. But suffice to say that it is in our interest to see how we can quickly fill up capacity in Malaysia and that is what our objective is. But having said that I think we are also very pleased that we got the 'Offtake Agreement' signed with the Malaysian Ministry of Health, which obviously has taken up some capacity of the Malaysia facility. So with added opportunities kicking in from EU and other emerging markets, we hope that the Malaysian operations will be optimally utilized.

Cyndrella Carvalho: **Ma'am on Trastuzumab, we expect the entire emerging markets and the other developed markets approvals to come by, we already have ANVISA with us already and more approvals to come. How do we see FY19 not from the developed markets but from the other markets point of view?**

Kiran Mazumdar: We will map out all the opportunities and make sure that we actually address the really lucrative opportunities in the emerging markets. We do need to make sure that we are prepared to cater to the developed markets opportunities as they emerge. Therefore, we will map and make sure that we have a sizable presence in the emerging markets opportunities, but equally, we need to ensure our readiness for the developed markets as well.

Cyndrella Carvalho: **Like earlier guidance of around $200 million from the Biosimilars kind of so, are we closer to that or it will be going a little next year, what is the sense?**

Kiran Mazumdar: We have had a setback in Biologics because of some of these inspections last year. But having said that, once we cross that hurdle, we are very confident that although we might have been delayed by a few quarters, but we will actually be able to hit that target next fiscal.

Cyndrella Carvalho: **Taking discussion to the Small Molecules part, ma'am, any outlook over there, we have our first Rosuvastatin also in the US market now and some other markets also we are getting in. So like how should we look at the entire Small Molecules business because US market in terms of pricing scenario still remains not that so good, so what is the outlook, and if you can help us with little more of color in terms of earnings in the Small Molecules segment?**

Kiran Mazumdar: In the next fiscal, I think the contribution from generic finished formulations will begin to appear, but the real opportunities will only kick in thereafter. I think from 2020/21 you can start seeing our specialty generics that we are developing to start contributing. At this point in time, I do not want to be too hasty in saying that these are going to be big ticket opportunities next fiscal. I think next fiscal you will start seeing our generic molecules contributing to the Small Molecules segment. APIs will continue to be the bread-and-butter. But thereafter we hope that vertically integrated approach and the forward integration approach that we have pursued through the ANDAs and generic formulations will obviously then help us to bolster growth in volumes and revenues of this business.

Cyndrella Carvalho: **What is the update on the EMA re-inspection, any schedule that we have on mind or we shall wait?**

Kiran Mazumdar: We do expect re-inspection shortly.

Sameer Baisiwala: **Any thoughts on when should you expect US FDA to inspect the Malaysian facility?**

Arun Chandavarkar: At this moment we do not want to comment on timing of any inspections. Suffice to say we got our application for Glargine in the US, and that would certainly trigger an inspection. But I do not want to make any comment on the specific timing of the inspections, but clearly, the inspection would happen in due course. As you know, the timing for approval is still some time away, because it goes through the 30-month stay, so I do not think the US inspection is on a critical path.

Sameer Baisiwala: **Any thoughts on the timing of commercialization of Neulasta in the US?**

Arun Chandavarkar: I think that is the decision that Mylan would take based on approval timings as well as other situations around IP. Previously Mylan has guided that they do not expect a launch until either end of 2018 or early 2019.

Sameer Baisiwala: **Just a question on Copaxone. Earlier line was that by end of this fiscal you will be resubmitting, are you on track of that?**

Arun Chandavarkar: We are more or less on track on that, I think we are confident of submitting it in Q1 of next fiscal, but we are still targeting to see if can do it end of this fiscal.

Sameer Baisiwala: **Does that then tie up with the Kiran's earlier remark about ramp up in the US specialty sales in fiscal '20, is that …?**

Arun Chandavarkar: Glatiramer is one such opportunity. As you know we are working on a pipe line of ANDAs where we are trying to create a portfolio and this portfolio has been done in a measured way. So every year we are just filing a few ANDAs. So as they cumulatively add up to a sizeable portfolio in the next few years, and as the patent expiries happens, because many of the ANDAs we are filing now, the patent expiries happen only sometime two years later or three years later. That is why from a commercial standpoint it may stack moving the needle only at that point in time.

Sameer Baisiwala: **Any update on Adalimumab BLA filing**?

Arun Chandavarkar: No, we do not have any comment on that this point.

Sameer Baisiwala: **But it is in late Phase-3 if I am not wrong?**

Arun Chandavarkar: That is right.

Sameer Baisiwala: **This is for the emerging markets. What is the competitive landscape over there is a very general question, but if you have to be little specific, the Glargine Russia or Trastu Brazil, are there several local players who may not qualify for US or Europe and therefore we do not see them, but they are there in these emerging markets or do you think it is a pretty low competition two or three player markets as is the DM?**

Arun Chandavarkar: I will just give a brief comment and then may be have Shreehas pitch in. By and large that the competition we have seen in the insulin space globally, still emanates from the innovators, that is your Lilly, Sanofi and Novo. As you know when it comes to some of these molecules, some of these innovators are also developing biosimilars. By and large, we have seen competition predominantly come from the innovators themselves. Some markets do have local players, but the dominant competition still happens to be the innovators.

Shreehas Tambe: This is Shreehas. Thanks Arun. Just to add a little bit on that particular aspect. I think there was a previous question even on Glargine in Russia. I think Arun is absolutely right, major competition does come from the innovator companies in these markets. Russia specifically we have seen that we are the first biosimilar to be approved, and the strategies have been to move patients from Lantus to Toujeo. The real impact we would be having to make with our partner in Russia would be to actually see how we can create the disruption by actually bringing in the first Biosimilar Glargine in that space and to kind of bring the market back towards Glargine. I think these are the challenges we would see although the market itself has been pretty large, almost $80 million in the previous year.

Sameer Baisiwala: **Brazil Trastu, is yours the first approval there or are there any more players?**

Arun Chandavarkar: I think ours is the first approval.

Harith Ahamed: **On the R&D spending this year, it appears that we are more or less flat versus last year. How should we look at this number over the next two to three years in terms of absolute number from the current Rs.400-odd crores gross spending?**

Siddharth Mittal: R&D spend should go up. We had guided that it should be around Rs.450-500 crores and as some of our novel molecules progress in clinic, we would see an increase in the R&D. We also announced the collaboration with Sandoz. The broad contours of the deal were discussed in the investor call wherein we had said that the expenses would be shared 50:50. Even though these are in very early stages of development, but since you have asked about next two to three years, as these molecules progress, we obviously will have R&D expenses increase reflecting our share of Sandoz collaboration assets.

Harith Ahamed: **Given our potential to be the first biosimilar launch in the US for both Trastuzumab and Pegfilgrastim, how do you look at the capacity situation given the exclusivity that we may enjoy for both these products, will capacity be a constraint for us to capture significant share in these markets for these two products? In the context of some of the competitors having disclosed the kind of investments which they made in capacities which are significantly higher scale and our own capacity newer facility in Bangalore will take at least two to three years. Based on the capacities that are available now, how much share can we capture or will capacity be a constraint when it comes to capturing market share especially during the exclusivity phase?**

Arun Chandavarkar: I will just add color to it; of course, my standard disclaimer would be that we would not be able to share competitive information linking capacity to market share and grabbing the opportunity. Having said that, clearly, our assumption is that we would plan our capacities in such a way that we would cater to the market as the market share ramps up. I think we mentioned earlier that we have already triggered capacity expansions in our antibodies

facilities and all of them would come into play as we launch and ramp up market shares in the developed markets.

Shraddha D'Souza: **Just a question on the timelines. Would it be a fair assumption to make that we expect Trastu and Peg approval from the EU sometime around late first half of the next fiscal or H2 in the next fiscal?**

Arun Chandavarkar: If you look at European approval for Trastuzumab and Pegfilgrastim, I would say my expectation would be that it would be sometime in the later part of this calendar year or towards the middle to second half of next fiscal.

Shraddha D'Souza: **How about the US approval for Glargine and Pegfilgrastim?**

Arun Chandavarkar: Similarly, I think in comment to an earlier question I mentioned that Mylan had previously talked about the potential to launch Pegfilgrastim in the US, say in early 2019. So clearly, the expectation is the approval should be before that. Glargine is still sometime away.

Shraddha D'Souza: **Secondly, based on the nine month numbers that we have got, how confident are we of achieving the FY19 target especially in the Branded Formulations and Biologics because if we see the numbers then we will almost need to double the Branded Formulations sales and very high growth in Biologics and with the background of Biologics sales more is coming from the emerging markets and also the impact we had to face during the year due to the remediation process, so how confident are we achieving the target for FY19 and what would be the drivers for achieving that?**

Arun Chandavarkar: I will just make a comment and then also has Kiran comment on that. So the quick comment I would have is that it is certainly our endeavor to meet the long-term guidance that we issued in 2013…of course, some of the things you mentioned around Branded Formulations would be risk to this guidance, but clearly if you look at our growth drivers or the growth sectors which would be our Biologics segment and Research Services segment represented by Syngene, we would definitely expect to either meet or even exceed the segmental guidance that we had provided for these segments for next year.

Shraddha D'Souza: **That is Biologics and the Research also?**

Arun Chandavarkar: Yes, but certainly there are headwinds in the Small Molecule and Branded Formulations businesses. In Small Molecules we alluded to the rapidly changing competitive landscape in the US which impacts our API customers, resulting in sort of cascading pricing pressure on us and clearly on the API segment as well. For Small Molecules and Branded Formulations India, when we provided a guidance, of course, that was in dollar terms and the rupee has of course moved since then. These two segments which have a significant rupee-denominated revenue component to it, do not benefit from that rupee depreciation. So I do accept that in growth segments like Biologics and Research Services, we are confident that either meet or even exceed the guidance. Small Molecules and Branded Formulations we will do our best.

Vipul Shah: **Can you give any color on the current capacity utilization of our Malaysia plant and what should be our cash breakeven in terms of capacity utilization for Malaysia?**

Siddharth Mittal: We cannot talk specifically in terms of what will be the breakeven capacity utilization but needless to say at this stage we have not achieved the optimal capacity utilization. Since this facility is going to be used for Glargine sales for US and Europe, large part of the capacity has been reserved for Mylan as and when they get the approval in these markets. So right now the sales we are doing is for emerging markets and it is not going to be a significant utilization of the total available capacity until Mylan gets those approvals.

Vipul Shah: **I missed your concall on Sandoz deal. Can you give me brief contours of that deal?**

Siddharth Mittal: It is a collaboration to develop the next-generation biosimilar pipeline. It is for a number of molecules, the number and names of the molecules have not been disclosed. What we have said is that both the parties would be responsible for developing the molecules on an end-to-end basis which would mean that the entire clinical, regulatory would be managed for the specific molecules by the respective partner; however, the commercialization in Europe and US/Canada would be front-ended by Sandoz while for all other developed markets as well as ROW would be front-ended by Biocon. In terms of commercials, it is a cost and profit share in the ratio of 50:50.

Anubhav Aggarwal: **My couple of questions on Small Molecules segment. One, when you have seen a revenue decline of almost about high single digit in this quarter on YoY basis, how the volumes would have done in that revenue decline?**

Siddharth Mittal: Anubhav, volumes either would be at the same levels of last year would have gone up. The major reason for the drop is the pricing challenges. I think one of the specific examples I can take is Rosuvastatin. Rosuvastatin volumes are doing quite well but the pricing has gone down significantly as compared to last year. So generally, if you look at whether it is the statins portfolio or the immunosuppressants portfolio, the volumes continue to do well and our plants continue to manufacture full steam. It is the pricing which is impacting the revenue growth.

Anubhav Aggarwal: **Just one clarity on this; how frequent is the repricing of the contract, let us say, you are supplying API to a partner and in the Formulations level the pricing has gone down. So immediately in the same quarter you have to reduce the pricing or there is a lag which get impacted?**

Siddharth Mittal: It is a combination of both, at times the impact is immediately during the quarter, in certain cases the price negotiations happen on annualized basis.

Anubhav Aggarwal: **But would you say which is more predominant between the two?**

Siddharth Mittal: I would say most of our contracts would be on annual pricing. However, even in those circumstances when we have annual price agreements, if the market pricing changes drastically, then we have seen our customers come back even during the term of the price agreement to get a lower pricing or higher discounts.

Anubhav Aggarwal: **Based on the financials that you give out on profitability, capital employed on Small Molecules, roughly we still make very-very healthy returns of (+20%) on the segment and Kiran ma'am talked about in terms of outlook pressure continuing. Is that very high return that you think can come down at a certain point of time to high single digit or low double digits versus (+20%) we make right now?**

Siddharth Mittal: We do not expect that. As I mentioned in response to one of the earlier question that segment results when you look at even on an average say Rs.65-70 crores a quarter, that takes you to annualized profits of roughly Rs.300 crores and the total capital employed for these businesses were roughly Rs.1300 crores, we are still looking at +20% ROCE. The only caveat I should add is that this is all dependent on the pricing. This year we do not expect any significant change but next year again if there is a big impact on the pricing then it could come down a bit.

Nitin Agarwal: **Initially you mentioned about the value locking in the Biologics segment. If you can probably help us given the fact that our debt-equity is pretty okay and will be running into serious cash flows from next year onwards once commercialization starts for our developed markets biosimilar portfolio. What would be the motivation for value unlocking in this business now?**

Kiran Mazumdar: We have recently entered into a second partnership with Sandoz. This partnership also requires Biocon to develop certain assets from end-to-end. So we do expect much larger spend on R&D as we progress and advance these assets. We will also be looking at various cash requirements for CAPEX needs of our biosimilars in the future. All these as you know are gestational requirements because each of these require at least two to four years before you can actually commission such plant. I think all in all we are assessing our capital requirements and based on that we will basically raise capital in the capital markets.

Siddharth Mittal: The other thing I would also like to add is that in additional to raising funds, we also go to the capital markets for unlocking of value of a business.

Nitin Agarwal: **Secondly, in your experience, if you can probably share what has been the total cost which is there for developing a biosimilar product?**

Kiran Mazumdar: I think we have indicated that depending on what the biosimilar is, it takes anywhere between upwards of $100 million to $150 million per molecule.

Nitin Agarwal: **For us that would be captured to extent in the gross R&D spend that we indicate.**

Kiran Mazumdar: What we indicate is our share of R&D spends. This quarter I had already explained that at a gross level we incurred an R&D spend of Rs.94 crores, of which Rs.53 crores is reported in the P&L and the balance of Rs.41 crores has been capitalized.

Nitin Agarwal: **Lastly, on Trastuzumab in the emerging markets where probably we have the marketing rights in lot of these emerging markets, how do you see the subcutaneous version that Roche has is impacting our positioning there?**

Kiran Mazumdar: When you look at biosimilars, I think it is about affordable access. In emerging markets the number of patients who can afford these very expensive treatments that really is about different mode of delivery - I do not think these are what the Ministry of Health and others and the larger part of the population would be able to afford or access. So we believe that in the emerging markets, biosimilars certainly have a major role to play. So we remain confident that Biosimilars will be big opportunities in the emerging markets.

Vikram Agarwal: **As you have a partnership with Mylan and also now a new partnership with Sandoz, it is key that you take in both the partners and grow the business successfully. So**

how would you manage the relationship between the two – would there be any conflict or something? My second question is I missed the Syngene concall yesterday is that they mentioned in the results that state-of-the-art Biologics facility has been set up. So how large do you think that opportunity is and how fast can you ramp that up?

Kiran Mazumdar: So let me answer your questions as follows: First and foremost, Mylan is a very valuable partner and so is Sandoz. As I explained in our call regarding the Sandoz partnership, our partnership with Mylan is centered on first wave of biosimilars and these are all near-term opportunities which we are confident will enable both partners to create a lot of value. Our partnership with Sandoz is for the next wave of biosimilars that come off patent post-2025. There is no conflict of interest. We believe that both these partners are extremely important and valuable to us for our future growth and for our biosimilars endeavors. So I believe that these are important partners and we know how to manage both these partnerships in the way it should be done.

In terms of the next question about "Research Services" and you asked about their "Biologics Facility". As you know they are actually dealing with a large number of pharma companies and in many of these big pharma companies, pipelines are now moving towards biologics. Amgen is one of the recent big customers and partners and they have a very strong biologics focus, they also have certain biologics R&D contracts with other companies like Zoetis and others. I think there is a need for Biologics supply right from the clinical to the commercialization stage and that is what Syngene is addressing in a big way.

Vikram Agarwal: **So could you share how quickly could you ramp that facility, some thoughts on that?**

Kiran Mazumbar: I think Syngene is beginning to get very confident that it can have a very strong business built on Biologics manufacturing and development and they have entered into various contracts which has given them head start.

Prakash Agarwal: **I did hear Siddharth talking about R&D being around Rs.450-500 crores, current nine months about Rs.300 crores. So just a clarification here; do we maintain that kind of run rate? Since you also mentioned Sandoz collaboration will pick up, so what kind of R&D run rate will look for '19 & '20 please?**

Kiran Mazumdar: So let me start the comments and then Siddharth will add to it. As I always maintained, I think R&D is a very integral part of our growth and we need to invest in R&D which unlike the generic pharma sector requires huge investment dollars. Not only is it expensive to develop the kind of products we are developing, but it also is gestational in that, it takes several years before you can actually complete the lab to market journey. Therefore, the R&D spend should be an indicator of pipeline expansion. Actually, it should be viewed positively rather than one of concern.

Siddharth Mittal: Prakash, specifically to answer your question, for the nine months, the gross R&D spends were Rs.283 crores, for the full year let us say give or take we will be at Rs.400 crores; that would be the guidance for this year. For next year we do expect the numbers to go up to Rs.450-500 crores.

Prakash Agarwal: **Secondly, positive development on Aspart. What broad level time frame required for clearing the Phase-1 and Phase-3 and what is the very broad level timeframe that we can see for approvals and commercialization for Aspart?**

Arun Chandavarkar: Prakash, I cannot give you specifically but you can see the timeframe in terms of doing if we have to do like Phase-1 trial, Phase-3 trial, depends also on whether one needs to do type-1 study and a type-2 study or just a type-2 study and things like that. So suffice to say right now we believe that this is an opportunity that will pan out in the next few years and we are working closely with the regulators to see how we can accelerate the paths to approval. So it is too early to comment on specific timelines at this stage.

Prakash Agarwal: **Is my understanding correct that typically takes two to three years for clearing Phase-1 and then typically two to three years for Phase-3?**

Arun Chandavarkar: Phase-1 should take lesser time. If Phase-3 is required in two population sets, then it takes longer. If it is just one population, it would take shorter.

Prakash Agarwal: **On Bevacizumab, so would we still be in the first wave, we started seeing some approvals, so just wanted to understand what could be the broad level timelines here?**

Arun Chandavarkar: We have progressed well on our Phase-3 trials and whilst there are other companies also out there, we are certainly amongst the set of companies that are ahead in this.

Shraddha D'Souza: **Our Malaysia plant is currently approved by how many authorities?**

Arun Chandavarkar: In terms of the emerging markets approvals for Malaysia, we have already talked about approval from the Malaysian authority itself and Brazil. I do not want to give a color in terms of how many of the countries have approved it but suffice to say that Malaysia will be an important contributor to our emerging markets story in the insulin space in FY19.

Shreeehas Tambe: Just to add to what Arun is saying, this is of course in addition to the European authorities approving the Malaysia plant.

Shraddha D'Souza: **So there are more emerging markets which have approved our Malaysia plant?**

Arun Chandavarkar: Yes.

Shraddha D'Souza: **Are we satisfied with the way the approvals have been progressing for the Malaysia plant from the time we had commercialized the plant?**

Arun Chandavarkar: For Malaysia, we had always received approvals in the first cycle. So that does satisfy us. We got EU GMP in Malaysia for both drug substance and drug product. We had the Malaysian authorities approve the product as well as the GMP. We had ANVISA out there and a few other regulators. So I think it has been going well.

Shraddha D'Souza: **Could you provide an update on the cumulative ANDA filings?**

Arun Chandavarkar: It has been a small number right now, because as you know that we have been operating through an outsourced model in terms of manufacturing until our own in-house capacities

get qualified. So our in-house facility has now been commissioned and in use for some of the early trials. As that happens, we will ramp up our filings from our in-house capacity.

Shraddha D'Souza: **Kiran ma'am said in one of the previous questions that we see meaningful contribution from the Complex Generics starting from maybe 2020 or 2021. So in between this period from now till then and in the light of the pricing pressure that we are seeing in the Statins business and also the consolidation, what is our outlook on this business keeping aside the ANDA in Small Molecules?**

Arun Chandavarkar: If you look at our long-term growth that we had even given as guidance sometime back, the growth was either high single digit or the low double digits kind of a range. That is what we expect to see until some of these new product approvals and ANDA launches happen.

Shraddha D'Souza: **My last question is what is the reason for the sequential drop in the Branded Formulations business this quarter?**

Arun Chandavarkar: I think we mentioned in the last quarter call that there was a one-time rebound because of the GST, remember Q1 was very low. So this is now more normalized.

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