Biocon Limited Q2 FY18 Earnings Conference Call
October 27, 2017

Participants from Biocon's Senior Management Team

- Kiran Mazumdar-Shaw: Chairperson & Managing Director
- Arun Chandavarkar: CEO & Jt. Managing Director
- Siddharth Mittal: President (Finance) & CFO
- Shreehas Tambe: Sr. Vice President & Head - Insulins
- Paul Thomas: Vice President & Head - Biosimilars
- Saurabh Paliwal: Head, Investor Relations

Conference Call Participants during Q&A

- Prakash Agarwal, Axis Capital
- Sudharkar Prabhu, Span Capital
- Dheeresh Pathak, Goldman Sachs Asset Management
- Charulata Gaidhani, Dalal & Broacha
- Nitin Agarwal, IDFC Securities
- Shradha D'Souza, Wealth Managers
- Cyndrella Carvalho, Dolat Capital
- Kritika, Narnolia Securities
- Sangam Iyer, Subhkam Ventures
- Sameer Baisiwala, Morgan Stanley
- Surya Patra, Phillip Capital
- Rakesh Naidu, Haitong Securities
- Mansi Shah, Research Delta Advisors

Presentation Session

Saurabh Paliwal: Good morning ladies and gentlemen. I am Saurabh Paliwal from Biocon Investor Relations team and I would like to welcome you to Biocon's earnings call for the second quarter of fiscal '18. Today to discuss the business performance and outlook for Biocon, we have the leadership team at Biocon comprising Dr. Kiran Mazumdar, our Chairperson and Managing Director and other colleagues from the senior management team. Before we proceed to this call, I would like to remind everyone that a replay of this recording will be available for the next few days immediately following the conclusion of this call. The call transcript shall be made available on the website in the coming days. I would like to take this opportunity to remind everyone about the safe harbour statement. 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 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. After the end of this call, if you need any further information or need any clarifications, please do get in touch with me. Now, I would like to turn the call over to Dr. Kiran Mazumdar. Over to you ma'am.

Kiran Mazumdar: Thank you Saurabh and good morning everyone. I welcome you to Biocon's earnings call for the second quarter of fiscal '18.

I will start with the key financial highlights for this quarter.

- Total consolidated revenue for the quarter was Rs.1019 crores, which was a modest 3% higher compared to last year.
- Revenue from operations was Rs.969 crores, which grew 2% compared to last year. This includes a modest licensing income of Rs.1 crore this quarter as compared to Rs.33 crores in Q2 last year.
- From a segment perspective -
  - Small Molecules segment revenues were Rs.351 crores, down 13% from Q2 of last year.
  - The Biologics segment was essentially flat at Rs.156 crores.
  - Branded Formulations showed strong growth of 29% at Rs.176 crores as against Rs.137 crores last year.
  - Research Services revenues were up 11% at Rs.335 crores compared to same period of last fiscal.
- We incurred a total spend of Rs.93 crores on R&D this quarter. Of this, 54 crores is reported in the P&L corresponding to 9% of revenues excluding Syngene. We capitalized that amount of 39 crores related to our biosimilars and insulin analog development expenses.
- We booked a forex gain of Rs.18 crores this quarter, majorly coming from Syngene. This is reflected in the 'Other Income' line.
- Group EBITDA was at Rs.233 crores, reflecting a decline of 16%, with EBITDA margins at 23%. Core margins, i.e. EBITDA margins net of licensing impact, forex and R&D stood at 27%. Lower revenues, which includes lower licensing income compounded by fixed and operating costs related to Malaysia, and increase in staff costs, have resulted in the margin decline this quarter.
- Interest and depreciation cost increased 44% to Rs.107 crores for this quarter largely attributable to Malaysia costs impacting our P&L statement.
- Reported net profit for the quarter was Rs.69 crores, which represents a net profit margin of 7%.

Now, coming to individual business segments –

Small Molecules - This segment was impacted by lower offtake of certain products as a result of pricing pressure faced by our clients in the US. This coupled with an adverse product mix resulted in degrowth and impacted segment margins. Further we witnessed a higher decline in Rosuvastatin pricing in the US, which was in line with generic pricing of the molecule.

Biologics - The performance of this segment was flat as compared to last year primarily on account of plant modifications undertaken to comply with regulatory requirements that led to production disruption. Additionally, there was significantly lower licensing income as compared to last year. And lastly we continue to experience regulatory and tender delays in some emerging markets, which have impacted revenue growth. These factors coupled with our Malaysian facility expenses has impacted segment margins. The growth of the Biologics segment in the second half of the year is dependent upon regulatory approvals and certain tender outcomes. We

are optimistic about some of these. We are hopeful that we should be able to bounce back strongly in FY19 once we overcome the production and regulatory hurdles that we have been challenged with this year.

Branded Formulations - The performance of this segment was strong this quarter showing a growth of 29% as compared to last year. Channel restocking this quarter post the GST-related disruption in India in Q1 and a strong performance of the UAE business led to this growth. Major verticals in the India business, namely metabolics, oncology, comprehensive care, and the institutional business showed good traction, while the performance in UAE was driven by our diabetes portfolio and contribution from newly launched Glaricon, which is the brand name of our Insulin Glargine. With impact due to GST largely behind us, we expect a more normalized growth from this segment in the remaining quarters of the fiscal year while we continue to remain optimistic about this segment.

Research Services (Syngene) announced its results yesterday and continues to show signs of recovery. Sustained growth in the dedicated centers and strong performance in their chemical development verticals reflects good underlying performance, with some catchup seen from projects that were delayed in the first quarter. Syngene expects the growth momentum to continue in the second half of the year.

Now, let me touch upon certain **R&D and regulatory developments**. Let me start with Insulin Glargine. During this quarter, our partner Mylan has made regulatory submission for our insulin glargine under the 505 (b) (2) pathway with the US FDA. Our dossier for this product is also under advanced stages of review in some other developed markets. With respect to our EU marketing authorization application, our Malaysia site received EU GMP certification for the Glargine drug substance and drug product. Our marketing authorization application for Glargine is in the last leg of the review process in the EU. We will inform you of relevant development as they come to bear.

Earlier this month, FDA issued a Complete Response Letter or CRL for our proposed biosimilar Pegfilgrastim, being jointly developed by Biocon and Mylan. The CRL relates to the pending update of the BLA with certain CMC data from facility requalification activities post recent plant modifications. The CRL did not, and I must emphasize this, did not raise any questions on biosimilarity, pharmacokinetic/pharmacodynamic data, clinical data, or immunogenicity. The application for Pegfilgrastim will be resubmitted after it has been updated with the relevant data from the ongoing facility requalification and we are committed to work with the FDA to resolve these issues raised in the CRL expeditiously.

The US FDA also notified our partner Mylan that they will extend the target action date for our biosimilar Trastuzumab submitted under the 351(k) pathway from 3rd September to 3rd December 2017 in order to review some of the clarificatory information submitted to them as a part of the application review process. As a reminder, we received unanimous approval recommendation from the FDA's Oncologic Drug Advisory Committee or ODAC in July and we do not believe that this extension affects FDA's positive opinion about the product - be it biosimilarity, PK-PD data, clinical data, or immunogenicity.

Biocon is on track to complete all CAPAs, i.e. Corrective and Preventive Actions as per plan submitted earlier during the year to FDA and EMA for the sterile injectable fill-finish facility in Bangalore. We have nearly completed requalification of the facility and will expeditiously update our BLAs filed with the FDA with the required data.

On the EU side, we are engaged with EMA on next steps, and will seek to refile our applications for Trastuzumab and Pegfilgrastim and request for re-inspection of the drug product facility at the earliest.

A brief update on Novel Biologics - we continue our efforts in progressing our nascent novel Biologics pipeline. In Q2 we announced the collaboration with JDRF or the Juvenile Diabetes Research Foundation, the world-leading organization supporting Type 1 diabetes research, which has extended its support to Biocon's study of novel Insulin Tregopil to treat patients with Type 1 diabetes.

So, let me now end with my concluding remarks where I would like to say that lack of licensing income, more importantly regulatory challenges and pricing pressure have significantly muted our earnings in the first half of this fiscal. Plant modifications undertaken to comply with regulatory requirements have led to product disruptions. Additionally, we have experienced delays in getting certain regulatory approvals and tenders in some emerging markets for our biosimilars, which have certainly impacted revenue growth. This has been further compounded by Malaysia carrying costs and pricing pressure in our API business. We expect these headwinds to ease by the end of this fiscal and are hopeful of a strong recovery in FY19. Until then, we expect modest growth across our businesses, bolstered of course with strong growth from Syngene.

With this I would like to open the floor to question and answers.

Question and Answer Session

Prakash Agarwal: **Ma'am, first question on the P&L actually, just trying to understand this other expenses line, which has moved Q-on-Q by 30%, so is it due to the remediation measures taken…is there any one off impact, which has had pressure on margins or this is the run rate that we saw Q2 '17 and is the run rate and there is no one off on that?**

Siddharth Mittal: Prakash, on a sequential quarter basis, there is a 31% increase. Of the Rs.24 crores increase in other expenses, there is approximately 6-7 crores of that increase coming from Syngene. Apart from that, as you rightly said, there were expenses towards implementation of the CAPA measures where we engaged consultants and incurred expenditure to remediate the observations received from EMA and FDA. There was also an increase in expenses on account of our Malaysian operations. As you are aware, we cross-charge Malaysia fixed costs to our partner depending on the activities that happen in the facility. During the quarter, given that the activities in Malaysia were lower as compared to the first quarter, there was an increase in expenditure which reflects in Q2 'Other Expenses' numbers. From a future perspective, I wouldn't say that this is the trend you should expect. Clearly, the one-time expenses which we have had in this quarter would not be there on a repeat basis.

Prakash Agarwal: **Okay. And just a clarification that remediation is done and the Biologics sales should also come back from Q3 onwards, because you mentioned that these are done.**

Kiran Mazumdar: I would say that yes, most of them are, you know, have been completed, and we do expect some uptick in the Biologics sales starting from next quarter. But, as I mentioned, the real strong growth in Biologics will start in FY19.

Prakash Agarwal: **Understood, thanks for that. And second question is on the filing for your insulin glargine, which has happened now. So, which facility is it and I mean, broad level if you can share what kind of timelines we are looking at, because my understanding is, it has triggered a 30 months stay. So, does it, I mean, would it be a fiscal '20 kind of opportunity for us?**

Arun Chandavarkar: So, coming to the Glargine filing in the US, Sanofi has filed litigation against Mylan on certain patents. So, in terms of the IP strategy there, we will defer it to Mylan, but yes it follows the normal course of a 505 (b) (2) timelines since the Glargine filing is under 505 (b) (2). Coming to your question on the facilities that have been used for filing, we have already mentioned that in the context of the EU filing that we received the EU GMP certificate in Malaysia for the Glargine drug substance and cartridges. The same facility is being used for the US as well.

Sudhakar Prabhu: **Yeah, good morning. I have three, four questions. So my first question is on this Bangalore facility. Have you completed all the plant modifications things and all or do you need to spend couple of more, quarters for completing the same?**

Arun Chandavarkar: We have completed all the plant modifications and are in the process of requalifying the facility and updating the relevant dossiers with the requalified data.

Sudhakar Prabhu: **So this requalification thing would require only for the emerging markets or also for the developed markets?**

Arun Chandavarkar: This is mainly for the developed markets.

Kiran Mazumdar: I just want to remind you that these plant modifications have been done because of the regulatory requirements post the EMA and the US FDA inspections. If you remember, EMA had sought a reinspection and FDA gave us certain observations; based on that we have completed the plant modifications. When you make plant modifications, you are required to requalify the facility after the modifications. So this is what we are talking about. It has got nothing to do with emerging markets. This is to do in response to these audits.

Sudhakar Prabhu: **Okay, that's clear. So, would the plant require additional re-inspection by these developed markets regulators?**

Arun Chandavarkar: What we have already mentioned that the European authorities have requested for a reinspection of the facility. As far as the US FDA is concerned, there has been no such request for re-inspection. We have already mentioned earlier in the context of the Pegfilgrastim CRL that we received, that the US FDA has also not made any additional observations as part of that CRL that we received.

Sudhakar Prabhu: **Okay, thank you. And my second question is on your Branded Formulation business. So, this quarter we saw a very good growth of 29%, 30%. So what kind of growth can we expect in the second half?**

Arun Chandavarkar: The growth this quarter has partly been on account of the bounce back from the GST turbulence that had affected us the previous quarter. Certainly we expect to see sustained growth in a more normalized manner minus the one-time impact of the GST bounce back.

Sudhakar Prabhu: **Is it possible for you to quantify what was the one-time impact in this?**

Arun Chandavarkar: No, we cannot provide specific guidance, but we can certainly say that both our Research Services segment Syngene and Branded Formulations segment are back on the track of growth. In the case of Branded Formulations, all we can say is that the one-time impact due to GST is largely behind us.

Sudhakar Prabhu: **Right sir. And my last question is on your FY19 guidance. Couple of quarters back you had guided for $1 billion revenue guidance by FY19. So seeing the current run rate, do you think the $1 billion is on track or you see it being delayed by one or two years?**

Kiran Mazumdar: We remain committed to this particular target and the only thing that could make it challenging to meet this target are some of the opportunities that we have built in our numbers in terms of tenders, in terms of certain regulatory approvals. If they get delayed, we will let you know. But, as of now, we believe that we are on track to meet the stated numbers.

Sudhakar Prabhu: **Ma'am the reason why I am asking you this is because out of this $1 billion, around $200 million is supposed to come from biosimilar business and another $200 million from branded formulation business. But looking at the current run-rate of these two businesses are around $100, $110 million, so do you expect it to double within a period of one year?**

Kiran Mazumdar: Well the Biologic business really has the biggest potential because once you get these regulatory approvals, hopefully next year, we are in a good position to actually quickly address those very robust revenues. It will involve getting into the market which means pipe-line filling kind of opportunity that will obviously then raise your revenues.

Siddharth Mittal: **I** wanted to add one thing to what Kiran mentioned. I should remind you that when we had given the guidance of $200 million for our Branded Formulations business, this was in early 2013. Over the last 2+ years we have rationalized lot of our brands. The non-profitable brands have been discontinued. So to that extent, while we still maintain an overall $1 billion dollar target, there will be some re-adjustment. As we had mentioned last quarter, if there is a reduction in Branded Formulations, it would be made up by the other divisions.

Kiran Mazumdar: For instance we have just entered the US market with our generic Rosuvastatin and that is showing some good signs of growth. So we will be looking at the whole ANDA generic business also to probably offset some of the potential inability to reach that

$200 million-dollar Branded Formulations business through some of these new opportunities.

Sudhakar Prabhu: **Right. Just to clarify, out of this$ 200 million of biosimilar business, how much would come from emerging markets? Some estimates on that?**

Arun Chandavarkar: Previously we have guided that a lot of it would be emerging markets driven and Kiran's reference to the regulatory approval delays or tender delays, uncertainties are more in connection with the emerging markets. I think I mentioned it in one of our earlier investor calls that unlike the regulated markets where there is a defined clock, like a target action date or some defined time-line, in emerging markets there doesn't tend to be a defined time line. So we essentially refer it with the regulators in the emerging markets through our local partners to seek early approvals.

Dheeresh Pathak: **Thanks for the opportunity. I just want to understand the Glargine filing in the EU market, if it has been filed from the Malaysian facility and then late stage of approval process. Can you just talk about, from the approval is there any litigation element to it like it is there in the US and can you just talk about that a little bit and market formation and when do you expect to be there in the market formation post?**

Arun Chandavarkar: I cannot comment specifically on any ligation aspects outside of what is already in the public domain and what's in the public domain is of course in relation to our US filings with the 505 (b) (2) pathway. In terms of the regulatory status in Europe, yes, the Glargine dossier is at late stage of review and we also mentioned that we received the EU GMP certificate for our Malaysia facility.

Charulatha Gaidhani: **Yeah my question pertains to the Malaysia contract for insulin. Have we started commercial supplies?**

Arun Chandavarkar: Yes we have started that a few quarters ago.

Charulatha Gaidhani: **Okay and the second question pertains to Branded Formulations growth. More of this growth was from India or from UAE?**

Arun Chandavarkar: Well the growth was in both, UAE as well as in India.

Charulatha Gaidhani: **Okay can you quantify the growth?**

Arun Chandavarkar: No, we cannot quantify the growth but clearly if you look at, when we refer to the bounce back of the one-time impact of GST, clearly GST is an India-specific issue and UAE continues on the growth track on a more normalized basis.

Charulatha Gaidhani: **The second question pertains to the CAPA. This quarter has a component of the one-time expenses. Do you expect this to continue over the next two quarters or you think this is an end to it?**

Siddharth Mittal: I think the majority of the expenses are already in the second quarter; so we do not expect a significant….I would say carry over in quarter three.

Charulatha Gaidhani: Okay fine, thank you.

Nitin Agarwal: **Ma'am on the Pegfilgrastim refilling, the plant issues for Trastuzumab and Pegfilgrastim would have been the same. So any particular reason why there is a refilling required for Pegfilgrastim versus Trastuzumab?**

Arun Chandavarkar: See, Trastuzumab, the target action date is on the 3rd of December. We are yet to reach that milestone. As you said Pegfilgrastim the target action date was 9th of October. Clearly, as of 9th of October we were not in a position to have completed all the re-qualification activities related to the facility. So we will wait for the outcome on the target action date on the 3rd of December for Trastuzumab. But clearly we have expressed our encouragement that like Pegfilgrastim, Trastuzumab also has no queries with regard to the science aspect that is the biosimilarity, the clinical immunogenicity because that was cleared as part of the ODAC committee recommendation to the FDA way back in July.

Nitin Agarwal: **Okay thanks. Secondly, on the Malaysian facility, now since we get into the 505 (b) (2) situation, for the US market which probably delays the commercialization in the US for sometime as far as glargine is concerned, how do we see the scale up in the Malaysian facility now going forward?**

Arun Chandavarkar: We are filing for approvals from Malaysia across various emerging markets as well as developed markets like Europe. So clearly while US would have linkage to the IP because of the 505 (b) (2) pathway, the other markets are more dependent on as and when we get regulatory approvals for our filing from Malaysia. Like for example, we have already commenced supplies locally through the OTA to the Malaysian government.

Nitin Agarwal: **So on the Malaysian supplies based upon the tender, are we going to be more back-ended because we haven't seen too much of that probably in H1 so far?**

Arun Chandavarkar: We have guided for an off take agreement on an annualized basis of about 300 million ringgit and that is on track. Those supplies commenced a couple of quarters ago.

Siddharth Mittal: It is roughly 20 million dollars a year, so the supply started in December 2016, and the supplies are not skewed. It is already baked in the first half numbers.

Nitin Agarwal: **So the Malaysian tender supplies are already reflecting in our numbers in H1?**

Siddharth Mittal: That's correct.

Nitin Agarwal: **Perfect. Lastly, on Copaxone is there….since one up since the generics are finally getting approved, what is our status on our filing?**

Arun Chandavarkar: I think we have previously guided that in response to the request from the FDA, we are working towards generating the required data to satisfy their queries and expect to complete some of the data generation by the end of this fiscal. So clearly our filing will be on track soon after that.

Shradha D'Souza: **Good morning and thank you for giving me an opportunity. Firstly, I would like to understand the procedural aspect in relation to the CRL for Pegfilgrastim. We are looking at responding to the CRL currently and then we will be getting a new target action date for Pegfilgrastim?**

Arun Chandavarkar: Clearly it is not a question of now a target action date. Basically when a CRL is issued, it means that the FDA has completed reviewed the dossier and any outstanding questions would have been communicated to us by the CRL. So we are clearly in the process of addressing those outstanding questions which as we have mentioned, primarily relate to updating the BLA with data from the requalification activities post the modifications. We are on track to do that expeditiously and when we do that what our partner would submit the application addressing the queries raised in the CRL.

Shradha D'Souza: **Okay so seeing that they have a target action date….**

Arun Chandavarkar: I don't think that's the process going forward.

Shradha D'Souza: **Okay thank you. Secondly, on the Bangalore plant, should we expect the re-inspection to take place in this fiscal followed by a refilling of Trastuzumab and Pegfilgrastim in the first half of next year?**

Arun Chandavarkar: This re-inspection you are talking about is more in relation to the European filing. As I mentioned earlier, the US FDA has not requested any such re-inspection to us. In terms of the European authorities, we have already mentioned that we have by and large completed all the CAPAs and through our partner are engaged with the European authorities both in terms of re-submitting the dossiers for Trastuzumab and Pegfilgrastim as well as seeking early re-inspection. From our side the CAPAs are more or less completed.

Shradha D'Souza: **Okay but we are not having the idea about when do we expect them to come, maybe this year….this fiscal?**

Arun Chandavarkar: We are hoping for an early date but we can't give you a specific time line. We are clearly engaged with the European authorities both in terms of early re-submission as well as early re-inspection.

Shradha D'Souza: **Okay. Just a clarification….have we invited US FDA for inspection of the Malaysia plant considering our filing for glargine?**

Arun Chandavarkar: There is no question of inviting them. They make a determination as to when they would come. Malaysia is not a re-inspection or something that we have to tell them that we are ready. Whenever they decide, they would inform us and they would come.

Shradha D'Souza: **Okay so we are waiting?**

Arun Chandavarkar: Yeah. We are awaiting inspection of the Malaysian facility.

Shradha D'Souza: **Right. Lastly, if I could just squeeze in one more question on the Branded Formulations, as far as the sales are concerned, it has been a good quarter post the GST; but on the profitability side we've seen a sharp improvement on the profits for this segment. So I just wanted to understand this better as to what could be the reason for this profitability and other than that have sales of bevacizumab commenced in India?**

Siddharth Mittal: Profitability for Branded Formulations depends on growth of the business given that major part of the cost is towards the field force and marketing expenses, which tend to be fixed in nature. Once you have increase in sales, you will see an incremental effect on profits. The margins in Q2 are roughly 11% for this division which is what we had aspired for. If you look at FY17 as compared to FY16, we saw margins come down because of rationalization of products. We had then guided that we aspire margins to be back in the mid-teens for this business. As the business grows, the profitability would improve.

Shradha D'Souza: **So it would be fair enough to assume it will be sustainable?**

Siddharth Mittal: At the current revenue levels it is definitely sustainable. As we mentioned some time back, we definitely expect this business to maintain its growth momentum, so with that, the profitability would remain at these levels or improve further.

Shradha D'Souza: **Okay, the second part to the question…. Bevacizumab sales…are we commencing in India?**

Kiran Mazumdar: Bevacizumab will commence shortly. We had to delay the launch because we had a plant shut down which delayed our Bevacizumab launch.

Shradha D'Souza: **Okay. Ma'am if you can provide a global update of the pipeline for Adalimumab and Bevacizumab….where do we stand?**

Arun Chandavarkar: Globally we have mentioned that Bevacizumab is placed in global phase 3 clinical trials and that trial is progressing well.

Shradha D'Souza: **Okay and Adalimumab?**

Arun Chandavarkar: In Adalimumab we are deciding the next course of action in terms of progress of the Adalimumab filings. That is also in terms of development.

Shradha D'Souza: **But that is in late stage?**

Arun Chandavarkar: Yeah, that is in late stage.

Cyndrella Carvalho: **Hi ma'am, just wanted to understand with EU, the re-submission that we would be initiating from Bangalore plant would it be considered as a fresh filing again or we would have the benefit of refilling? In the sense like we have a time-line understanding that if you file with EU, general approval time-line is 12 to 15 months or max 18 months….so just to understand on that front?**

Arun Chandavarkar: I think I mentioned that we are in close touch with the European authorities in terms of our re-submission. We are certainly as part of our engagement with the European authorities for re-submission would be engaged with them in terms of seeking an accelerated review of the dossier as well.

Cyndrella Carvalho: **Sir in the sense would it be a fresh filing….or….?**

Arun Chandavarkar: Re-submission is certainly a fresh filing but in terms of the review, whether it requires a full cycle review or accelerated review is something we are closely engaged with the authority.

Cyndrella Carvalho: **Okay that's helpful. And sir in the sense that now we understand that a plant shut down was over, we have re-qualified the plant, so for the third quarter…..I mean from here onwards should we see some impact still in the P&L coming in or should we see a normalized business from the plant?**

Arun Chandavarkar: As far as the production facility which was under a shut-down, clearly the re-qualification would be completed in this quarter, in Q3. In two, three weeks we would complete it and submit the data to the authorities. To the extent that it resulted in the disruption, it should come back to normal, beginning Q4.

Cyndrella Carvalho: **Yeah, in terms of our Branded Formulations business, just wanted some clarity in the sense there is a kind of rebound which we have seen which is really good 29%. If we look at it on a normalized basis, that is ex-GST, will you be able to share us this number? Like on the normalized front, excluding the GST impact?**

Arun Chandavarkar: So if you look for example the Q1, Q2 combined growth, the combined growth was only 4%. That shows you the negative impact we had in Q1. Whereas Q2 alone, which is post GST, the bounce back was 29%. So clearly when we say normalized, we expect it to be somewhere between 4% to 29% range.

Kritika: **Good morning. Most of my questions have been answered, just want to understand, do we expect the margins to continue at the same level for the next couple of quarters or will it be somewhat normalized?**

Siddharth Mittal: Well, I cannot give a specific guidance on the margins. It is all dependant on how each of our businesses performs. We have already spoken a bit about the margins in

the Branded Formulations segment - if the current revenues are sustained and we see growth that Arun spoke about, we should see an uptick in the margins for that business. On the Biologics side we had taken some one-time costs in Q2 which will no longer be there going forward. On Malaysia, we had earlier guided for that impact on margins due to facility costs will probably be higher in H1. As we start receiving approvals in emerging markets during the course of the year and generate revenues as a result, it will help offset costs that has impacted margins in H1. Furthermore, in Biologics we have had Rs.21 crores segment loss in Q2 on account of significantly lower licensing income this quarter as compared to last year. Licensing income forms an important part of our Biologics revenue stream and profitability. While we maintain that licensing revenue tends to be lumpy, we expect to have higher licensing revenue in the coming quarters as compared to Q2. So as the licensing revenue goes up, we will also see an uptick in the margins. Syngene had a good quarter and they would continue to maintain the margins they have seen in the first half of this year.

Kritika: **In terms of capacity utilization, could you give the breakeven for the Malaysia facility?**

Siddharth Mittal: We cannot talk about breakeven for the Malaysian facility. But, what we have said in the past that this is a pretty large facility. And this facility was commissioned with the objective of selling in the developed markets. Emerging market volumes cannot fill up this capacity in its entirety. So, we would be dependent on the sales in Europe and the US to fill up the full capacity. In the meanwhile, we will obviously endeavor to sell as much as possible in the emerging markets to offset the expenses that we have.

Kritika: **What will be the CAPEX guidance if you can give for FY18 and FY19 CAPEX guidance?**

Siddharth Mittal: Ex-Syngene, apart from the maintenance CAPEX of Rs.100 crores in a year, we have capitalized about Rs.150 crores a year of our R&D expenses. Apart from these two, we have recently started work our second antibody facility in Bangalore, with a total estimated investment of 200 million dollars in two phases over a period of three to four years. Apart from that we do not expect any other major CAPEX projects.

Kritika: **What is the progress of the antibody facility which we have started in Bangalore?**

Siddharth Mittal: The construction has just started. It will take three to four years for the two phases to be commissioned. This excludes whatever time it takes to get the facility qualified and approved.

Sangam Iyer: **Ma'am, few clarification that I wanted. One, does the in-licensing revenue get impacted because of the delays in the filing in the emerging markets due to the plant's remedial measures going on?**

Siddharth Mittal: It is the out-licensing and not in-licensing. It is not dependent on the outcome of the facility. So far we have licensed Glargine and Trastuzumab in emerging markets. The

licensing revenue formed a very important part of our overall revenue over the last two to three years. We have pretty much exhausted the major markets where we could have licensed these two molecules. So, on a go forward basis, we definitely expect that once we launch Bevacizumab in India, Bevacizumab would become a very attractive licensable asset in the emerging markets.

Sangam Iyer: **Okay. And sir, another clarification, one of the participants had already asked, the Biologics sales that you expect to pick up, you have indicated that once the remedial measures are submitted, which you are expecting it to be completed by this quarter end. Do you expect the sales to pick up post the clearance or post the submission of this thing, because there would be a time lag before the approval comes through or acceptance of the remedial measures comes through?**

Siddharth Mittal: There are two different issues here. One is that because of the facility shut down there were no supplies as in the existing emerging markets where we have approvals, we could not supply in those markets. Once the facility restarts commercial production in Q3, we can resume supplies in those markets and there will be no impact or negative impact in this quarter. The second aspect you are talking about is the product approval, which is dependent on resolution of the audit observations made by the US and European authorities. The revenue growth from these two markets will be dependent upon the timing of the approvals.

Sangam Iyer: **Okay. And sir, finally given that the next target action date has been achieved for Trastuzumab for December was because of the plant issues that was there and nothing else, because there was an unanimous acceptance of the product as such. So, if this remedial, the approval doesn't come through during this period, whether there would be an extension of the TAD that would come through or how does it work here? I just wanted to understand the dynamics.**

Arun Chandavarkar: I cannot comment on what will happen on December 3rd, but I want to clarify that the extension of the target action date for Trastuzumab from 3rd September to the 3rd of December was not related to the facility. It was to do with certain clarificatory information that FDA had requested for as part of the dossier review. We had communicated this in our issued communication at that time. The CRL for Pegfilgrastim was related to updating the dossier with the requalification data.

Sangam Iyer: **Okay. So, regarding the dossier whatever queries were there we have already furnished the required, necessary documents?**

Arun Chandavarkar You are talking about which product?

Sangam Iyer: **Trastuzumab.**

Arun Chandavarkar: No. For Trastuzumab, we are clearly in the process of discussing with the regulators. As and when queries come, we will respond to that.

Sameer Baisiwala: **Good morning. Siddharth, just on the licensing income, so you said that insulin and Trastuzumab are pretty much exhausted. And now the future would be coming from Bevacizumab, is that the right understanding?**

Siddharth Mittal: During the last two to three years, majority of the licensing revenues came from rh-Insulin, Insulin Glargine and Trastuzumab as we have done licensing deals in the major emerging markets. Therefore, there will not be any major upfront licensing income from these three assets on a go forward basis. However, as a part of our licensing deals, we also get various milestone payments. These milestones may be linked to the filing, some are linked to product approval and launch. So, for these three drugs, the licensing income would continue as and when we achieve those milestones. But from a new licensing deal point of view, we expect Bevacizumab to contribute to our revenue on a go forward basis. Pegfilgrastim and Adalimumab are more developed market opportunities given over 90% of their revenues come from the developed markets and there is not a significant opportunity to license them in the emerging markets.

Sameer Baisiwala: **Sure. And how does Bevacizumab compare with these three assets in terms of its potential to win the out licensing income?**

Siddharth Mittal: If you look at the global sales of Bevacizumab, it is as high as Trastuzumab. And the emerging market sales for the Bevacizumab are also significant.

Sameer Baisiwala: **Okay. And, just to complete this point; so, on a full year basis, how should we model licensing income?**

Siddharth Mittal: Sameer, it is very difficult to comment on the same. While we can even give a guidance on R&D, which is also lumpy, it is very difficult to give guidance on licensing. It all depends on what kind of deals are there and what is the timing of closure. Some of these deals could be complex, it could take longer time to negotiate. Sometimes the discussion may take a little longer when our potential partners in the emerging markets know that there are some regulatory headwinds that we are facing.

Sameer Baisiwala: **Okay, that is fine. And just moving on to Glargine in Europe, now that you have got the GMP certificate, what are the steps going forward? And when do you expect the approval to come through?**

Arun Chandavarkar: For Glargine, the dossier review is in late stage of progress. So, as and when queries come in, we will be addressing them. I think we mentioned that as far as GMP is concerned, for the drug substance and cartridge, which is made in Malaysia, we have got the EU GMP certificate. The pen assembly happens in Bangalore, where we have the request for re-inspection. The request was largely to do with aseptic filling line and not so much to do with the device assembly. So, that is again something that is being discussed with the European authorities.

Sameer Baisiwala: **Okay. And so all going well, middle of next year is when you can get the European approval?**

Arun Chandavarkar: Yeah, could be.

Sameer Baisiwala: **Okay. Excellent. And the second question, I am a little curious that for Pegfilgrastim, why did US FDA not give you a three month extension, because it has very, some data updation and you said that you would be re-qualifying the facility in this current quarter. So, three months would have been good enough.**

Arun Chandavarkar: I cannot really comment on the actions of the FDA. FDA you know has multiple avenues by which they can communicate their request for additional information. In this case they chose to issue a CRL, which one way helps us, because we know that it is the final list of requirements which the FDA wants, since it is a complete response. So, to that extent when we respond to a complete response, hopefully there are no further queries beyond that.

Sameer Baisiwala: **Okay. Just one final question from my side, I think someone already asked you this question. So, for Bevacizumab and Adalimumab, I understand that one is in the late stage and the other is in phase three. What are the timelines for filing them?**

Arun Chandavarkar: We have not guided for any filing date. We will discuss with our partner Mylan and then arrive at the appropriate time. As you know the filing is linked both to the approval status as well as the IP status.

Sameer Baisiwala: Okay, got it. Thank you.

Surya Patra: **Just a clarification; now, the Malaysian plant is approved by European agencies. So, we would have a regulatory market or advanced market activities there. So, will this mean there is a kind of more saving by Mylan in terms of the unabsorbed cost towards of that is there in the plant currently? So, this will mean kind of a decline on unabsorbed cost, which is currently there in the plant from the Malaysia?**

Siddharth Mittal: Surya, I am not sure what you mean. But, the facility approval doesn't change any P&L dynamics, it would be commercial supplies that would change it. So, once you start supplying to Mylan, then obviously they will pay. But, in the meantime what we have already mentioned and you will see it also in our P&L that there are some reimbursements done from Mylan towards the carrying cost for that facility. And that would continue.

Surya Patra: **Okay. So, will that increase after the supply has starting to them, let's say, after the launch of Glargine in Europe?**

Siddharth Mittal: It will not increase, because once you start supplies to Europe, your capacity utilization will go up. You receive cost plus mark up from Mylan and you also get the profit share from them. Once the facility utilization goes up, the idle time or the carrying cost will go down. So, the recovery will go down.

Surya Patra: **Okay. I am asking actually the share of Mylan in the carrying cost will increase?**

Siddharth Mittal: No, that is a fixed share. The percentage is already predetermined at that time when we signed the agreements. That will not fluctuate.

Surya Patra: **Okay. And so after this plant clearance, possibly we should be seeing some ramp up in the emerging market for the Glargine. Is it so sir? And if yes, then which are the areas or what are the kind of ramp up that we have witnessed so far for Glargine?**

Siddharth Mittal: It is not only for Glargine, it is also for human insulin. But yes, what we have said is that as the approvals start coming in from some of the other emerging market regulators, we will see an uptick in the revenues. We cannot quantify in terms of what the numbers would be. You can see that at the end of the year in the standalone financials for Malaysia.

Surya Patra: **Okay. And one clarification on the forex gain also, what you have indicated that 18 crores forex gain amount is there in the other expenses side, is it right sir?**

Siddharth Mittal: No, the forex gain is there in the other income line and not in the other expenses.

Surya Patra: **Okay fine. And lastly, on the CANMAb thing, so it is interesting to see that you have already gathered 30% kind of market share in India. And I believe that is not including the share of Hertraz again?**

Siddharth Mittal: That is right.

Surya Patra: **Okay. And sir, can you quantify what could be the kind of a revenue that you should be generating from CANMAb from India?**

Siddharth Mittal: I don't have the number readily available. But, this is available on the IMS data. So, if you have the IMS data, I think you can pick it up. Given that the IMS data only captures the trade business and not full the institutional business, you can add to the number obtained from IMS.

Surya Patra: **Okay, fine. And just one more last question. On the small molecule front, so now there is some activities, some progress on those fronts. So, already the formulation plant is also seeing some progress. And we have already launched one product in US. So, about your filings and your initiatives about the product development and the kind of a timeline when you can see some meaningful progress on those front, can you just share?**

Arun Chandavarkar: So, we have mentioned before that in terms of the Small Molecule business, there has been turbulence which I guess the entire pharma sector has been facing, because of the pricing pressures in the US market. We indirectly face it, because our API supplies to our customers get impacted, when they face pricing pressure in the US.

One of the strategies to buffer ourselves from that kind of situation and go up the value chain was to get into formulations and ANDAs. Clearly we have mentioned that our formulation facility, this is the small molecule formulation facility in Bangalore has now been commissioned. So, now once post commissioning, we will of course include our formulation facility going forward in development plans for small molecule ANDAs and that is on track. So, we will start doing the development batches or exhibit batches going forward from our formulation facility and start our filings. Considering that we will initiate filings from that facility this year and next year, the approvals and launch timings in terms of revenue impact are still a few years away.

Rakesh Naidu: **Thank you and good morning everyone. My question is on Pegfil. Now that this incremental CMC data needs to be submitted because of requalification, is there any way to know the standard timelines that one should be looking at, by which when we will be able to get in this data? And second, is the requalification of the facility over and by when can I expect it to get over?**

Arun Chandavarkar: I think we have already mentioned it earlier. We have taken a shutdown of the facility to modify certain aspects. And we have completed those modifications last quarter. We have also mentioned that in this quarter we would have completed the requalification of that facility and would be probably in a position to update those BLAs with the data required for the requalification. So, we can't guide to a specific timeline as to what happens post that. But yes, from our side, we are working to expeditiously update the required data.

Rakesh Naidu: **So, once this facility requalification process is over, data needs to be generated. And so the timeline…..is there a way to know?**

Arun Chandavarkar: That is not a long timeline. That is a very short timeline.

Rakesh Naidu: **Okay. So, will the understanding be correct that the CRL that has come to us, the query that is raised are the facility requalification among other things, there could be other issues as well that needs to be addressed?**

Arun Chandavarkar: What we have already mentioned is that whatever data that we would need, we will address that expeditiously. We have also mentioned clearly that based on the Mylan's guidance for anticipated launch, none of this are likely to have an impact on the launch timing. So, if you are looking at how in terms of revenue impact or guidance on launch timings, we have already mentioned that none of this is likely to have an impact on Pegfilgrastim launch timings in the US.

Manshi Shah: **I just had a question on Adalimumab ma'am. As you said that it is in phase three. So, are you targeting all the indications for Adalimumab or only some?**

Arun Chandavarkar: So, that depends on extrapolation. The clinical trial clearly will not be done on all indications. And you have seen from our experience in Trastuzumab that the ODAC gave on extrapolation. So, you rely on extrapolation for other indications.

Manshi Shah: **What are the chances of extrapolation for all the indications for Adalimumab?**

Arun Chandavarkar: For that we don't give guidance or chances. We work scientifically with the FDA to justify extrapolation. We don't base it on chance.

Manshi Shah: **Okay. And just one, the patent protection for Adalimumab is still mid 2020 or like can you correct me if I am wrong or is it more or is it less?**

Arun Chandavarkar: So, as I mentioned that I cannot comment on IP strategies on Adalimumab. The only data point in public domain is of course as you know the Amgen settlement. Other than that we cannot comment. The Amgen settlement guides for launch in early 2023 in the US market.

Manshi Shah: Okay, thank you so much.

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