Biocon Limited Q3 FY17 Earnings Conference Call
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Participants from Biocon's Senior Management Team

- Kiran Mazumdar-Shaw: Chairperson & Managing Director
- Arun Chandavarkar: CEO & Jt. Managing Director
- Siddharth Mittal: President (Finance) & CFO
- Prasad B.S.V: Sr. Vice President & Head - Small Molecules
- Suresh Subramanian: SVP & Head - Branded Formulations, India
- Paul Thomas: Vice President & Head - Biosimilars
- Saurabh Paliwal: Head, Investor Relations

Conference Call Participants during Q&A

- Manushi Shah, Research Delta Advisors
- Ujwal Shah, Quest Investment Advisors
- Mayur Parkeria, Wealth Managers
- Sameer Baisiwala, Morgan Stanley
- Surya Patra, Phillip Capital
- Sudhakar Prabhu, Span Capital
- Charulata Gaidhani, Dalal & Broacha
- Nitin Agarwal, IDFC Securities
- Vipul Shah, Sumangal Investments
- Ranjit Kapadia, Centrum Broking
- Cyndrella Carvalho, Dolat Capital

Presentation Session

Saurabh Paliwal: Thank you, Margaret and good morning everybody. Thank you for joining us today for Biocon's Q3 FY17 earnings conference call.

Before we proceed with this call, I would like to remind everybody that a replay of today's discussion will be available for the next few days immediately following the conclusion of this call. A call transcript shall be made available on the website in the coming days.

To discuss the Company's business performance and outlook, we have today the leadership team at Biocon comprising Dr. Kiran Mazumdar-Shaw, our Chairperson and Managing Director with other colleagues from the senior management team.

I would like to take this opportunity to remind everyone about the Safe Harbour contained in our press release. Today's discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces that 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 clarification, please do get in touch with us. Now, I would like to turn the call over to Dr. Kiran Mazumdar-Shaw. Over to you, ma'am.

Kiran Mazumdar-Shaw: Thanks, Saurabh. Good morning, everyone and welcome to Biocon's earning call for the third quarter of fiscal 2017 ended December 31, 2016. Although it's almost the end of January, let me start by wishing you a very happy and prosperous 2017.

Now coming to business performance, I would like to start with key business highlights.

- It has certainly been a very eventful quarter for Biocon especially for our Biosimilars business where we have made significant progress.

- As part of our global Biosimilar foray, our BLA for our proposed biosimilar Trastuzumab, which was filed in November 2016 was accepted by the US FDA for review with a target action date of September 3, 2017. It is the first acceptance for the Biocon/Mylan collaboration in the US and is potentially the first acceptance for Trastuzumab by the US FDA under the 351(k) pathway. We believe this is a very, very key and important milestone for this partnership.

- The Marketing Authorization Application or MAA filed by our partner Mylan for Insulin Glargine for the EU markets was also accepted by the European Medicines Agency making it another important milestone for us. And this was our third biosimilar application accepted for review by EMA in FY17, the other two being Pegfilgrastim and Trastuzumab.

- I'm also delighted to announce a very important milestone that we have just announced this morning where Biocon SDN, our Malaysian step down subsidiary, has been awarded MYR 300 million contract to be serviced over a period of three years with an option to extend for another two years for supplying rh-Insulin cartridges and re-usable insulin pens under the Malaysian government's offtake agreement initiative. This again is a very significant milestone for Biocon Malaysia. With this, the Malaysian plant has now started commercial operations and it also is very positive in terms of our financials for Biocon Malaysia.

- Our ANDA of Rosuvastatin Calcium also received FDA approval this quarter and we are gearing up for the commercial launch of this product in the US market.

Now coming to key financial highlights for Q3 FY17.

- Consolidated revenues grew 32% from 829 crores to 1,092 crores.

    - Biocon sales grew 35% from 526 crores to 712 crores while Syngene's Research Services sales grew 17% from 270 crores to 317 crores.

    - Breaking it down, our Small Molecules business recorded a growth of 24% to 390 crores largely led by statins.

    - Biologics sales were at 120 crores, a growth of 61% on account of increased sales in emerging markets including sales for Malaysia.

- Branded Formulations sales were 123 crores, a growth of 18% as compared to last year. However, on a like-to-like basis, Branded Formulations sales showed decline of 4%.

- We also booked licensing income of 79 crores in Biocon in Q3 FY17 largely attributable to continued licensing of biosimilars in emerging markets.

- Total R&D spends were 100 crores, of which 85 crores is reported in the P&L while 15 crores has been capitalized on account of Trastuzumab and Glargine development related expenses for the developed markets.

- Consolidated EBITDA was 324 crores, which actually reflects a growth of 57% with EBITDA margins at a very healthy 30%.

- Consolidated Net Profit was 171 crores for the quarter reflecting a growth of 65% as compared to Q3 last year. Net Profit Margin stood at 16%.

I will now like to comment on individual business segments.

The **Small Molecules segment** continued its strong performance this quarter as well with traction in global sales of statins, immunosuppressants, and specialty API products.

The **Biologics segment**, that comprises Biosimilars and Novel Biologics, delivered strong growth with increased sales of insulin in Q3. With supplies to Malaysia having started, continued commercial sales from the Malaysian facility will help grow our Biologics segment revenues. We expect the growth to receive a further boost with expected qualifications of the Malaysian facility by other emerging market regulators in coming quarters. Our Biosimilars pipeline continues to make good progress as we prepare for filing of Insulin Glargine in the US and Adalimumab in both US and EU. Our Bevacizumab biosimilar has also entered global Phase III clinical trials while the RoW focused Phase III is close to completion.

Now coming to Malaysia operations and its P&L impact. Given the EU filing for Insulin Glargine incorporated the product validated at Malaysia, what I mean is that our EU submission has basically incorporated Malaysia produced Insulin Glargine, and given the recent offtake agreement with the Ministry of Health in Malaysia that has resulted in the start of commercial supplies for the Malaysia plant; we plan to stop capitalizing further expenses from the plant at the end of this fiscal. Consequently starting Q1 FY18, depreciation and fixed expenses related to the Malaysia plant will be charged to the profit and loss account.

We estimate annual depreciation of approximately $18 million and fixed plant operating expenses which includes the finance cost to be approximately $30 million. A portion of these expenses will be shared with our partner Mylan. In addition to supplies for the Malaysian market, we also expect approvals from other emerging markets during FY18. And as a result of these factors, we expect a minimal loss from the Malaysia plant which is not expected to have material financial impact on the consolidated group P&L for FY18. However, the impact could vary during the quarter due to ramp up in terms of supplies and different activities every quarter. So it is going to be lumpy, but on an annualized basis, we expect very marginal loss from the Malaysia operations. And if you have any other queries relating to this accounting impact, please direct your questions to our CFO, Mr. Siddharth Mittal during the Q&A session.

Moving to our **Novels portfolio**, this continues to make steady progress with multiple molecules in different stages of development. Our Novel anti-CD6 asset Itolizumab and SiRNA candidate QPI 1007 are progressing actively in ongoing clinical trials. The Phase I study in Australia using a subcutaneous formulation of Itolizumab has completed stage-1 dose escalation and stage-2 is now being initiated. The data so far generated is very encouraging. QPI 1007 is undergoing global Phase III trials in NAION patients, which is a rare ophthalmic disease, and is recruiting actively in several regions of the world including India. A pivotal Phase III clinical trial in Type 2 diabetes patients in India under an IND has been finalized and is expected to be undertaken shortly for our oral insulin program, Insulin Tregopil. We are also looking to file multiple IND applications in the coming fiscal for other novel programs.

Coming to **Branded Formulations**, the business showed a slight decline this quarter on a like-for-like basis. Keeping in mind the loss of a key in-licensed novel asset in our portfolio last quarter, delay in launch of some products in UAE coupled with a negative impact due to pricing notifications in India, I would say that the performance of our Branded Formulations segment although disappointing was along expected lines. However, we are working very prudently to get this business back on track and expect some of these efforts to be visible in the next financial year.

Finally, our **Research Services segment** (Syngene) continues to deliver strong and profitable growth that was broad-based across its business lines this quarter.

Towards the end of Q3, there was a fire in one of the buildings of Syngene that caused substantial damage to the building. There was no loss of life and the facilities in that building remain non-operational. Syngene has implemented its business continuity plan and as part of that, ongoing projects and scientific teams have been relocated to other facilities on campus where additional capacity and infrastructure was available. Also a shift system has been introduced to make up for the lost time and also to increase lab hood capacity utilization. This has helped in minimizing the impact of the incident on client projects.

In conclusion, with three-fourth of fiscal 2017 past us, Biocon has delivered upon its stated goals of continued R&D progress, Malaysia facility commercialization, and improved operational performance. With multiple biosimilar filings accepted and under review in the EU and in the US, we continue to move further along in achieving our stated goals not only in the Biologics business through our global biosimilars pipeline, but also in making improvements in our base business. There are definitely areas we can do better, especially in our Branded Formulations business, and we remain committed to them. I remain optimistic and confident that Biocon is on the right path with a firm footing. And with this, I would like to open the session up for Q&A. Thank you.

Q&A Session

Manushi Shah: I just had one question that recently there was this biosimilar interchangeability guidance given by the FDA so in that, there was this one criteria where if the Company performs switch-over studies in the clinical trials, they can get an interchangeability status. So for Trastuzumab, have you performed any such switch-over studies or for the future like Pegfilgrastim or Adalimumab?

Paul Thomas: Thanks for the question, this is Paul Thomas. So, we have our studies that are in the public domain in the clinical trials registry and we've published results of many of those. I think as you may be aware, the importance of interchangeability varies quite a bit across therapeutic areas and so it's a molecule-by-molecule difference in how much it applies. But overall, the guidance is not a surprise

and really doesn't change our strategy. It's in line with the prior conversations that we've had with FDA on interchangeability.

Manushi Shah: So, are there chances of interchangeability like through some other means or something or is it only biosimilar?

Paul Thomas: So, the guidance is encouraging in that it does reflect FDA's endorsement of the interchangeability concept confirming that and endorsing the possibility of substitutability at a pharmacy. But FDA has also been clear from early on about the unlikely prospects for getting interchangeability with an initial approval and that it would likely be a second stage and this guidance is in line with that. There are some aspects that can theoretically be provided at an initial approval, but there is a lot of linkages to post marketing studies and things like that. So, I think that FDA has guided about not typically approving on an initial approval for interchangeability and there's no change in this guidance here.

Ujwal Shah: In terms of our R&D spend, we had initially guided for around 350 crores kind of R&D spend for the year. Do we still stand by for the full-year numbers or do we look for some lowering of that and can you provide some guidance for next year as well in terms of R&D spend?

Siddharth Mittal: Year-to-date R&D expenses were 201 crores. We expect the full-year expenses to be around or slightly less than 300 crores given that only one more quarter is left. For next year, we continue to maintain our R&D guidance of 12% to 14% of Biopharma revenue..

Ujwal Shah: And secondly sir, in terms of margins, we have seen that to be quite lumpy. I do understand this time we did have licensing income coming through. But in terms of sustained margins, any guidance that we can give? What kind of margins is Biocon looking for next year?

Siddharth Mittal: If you actually look at our EBITDA and take out the licensing, R&D and Forex gain or loss as the case may be, for the first three quarters our margins were very stable at 32-33% levels. And what we have said is we do not expect the margins to go down, we definitely expect the margins to continue at these levels. And eventually in mid to long term as we enter developed markets with our biosimilars, we expect the margins to go up.

Ujwal Shah: And lastly sir, can you talk about any steps for the efforts that ma'am did mention in the Branded Formulations space and the effects that would be seen in FY'18? So, what are the steps that have been taken and where do we see it going forward?

Suresh Subramanian: Thanks for the question. This is Suresh Subramanian. In Branded Formulations, we have taken multiple steps. One is change in structure and change in leadership of a few of our businesses. Second is we have brought in a new CRM tool to kind of improve our ability to track and manage performance. Third is we are also talking to multiple companies to get products in-licensed to Biocon. And these three I think will help kind of improve performance in the coming quarters and year.

Mayur Parkeria: Just had two questions. First is on the Malaysia facility, ma'am indicated that FY'18 the impact on profitability would be minimal as we go ahead. What I wanted to understand was is this outlook based purely from the sales of Malaysian facility which it will contribute and hence gross margin which it will generate or is it based on overall Company profitability and hence the overall profitability will not be impacted?

Siddharth Mittal: This is purely from the Malaysian facility. The fixed operating expenses are $30 million in addition to annual depreciation of $17 million to $18 million and then we would have the variable costs, which would be the raw material costs, consumables and other variable costs. These expenses are at gross level and a portion of this would be shared with Mylan. With the revenues expected to be generated from Malaysia for sales towards the OTA which we announced and also for some of the other emerging markets, we expect a marginal loss for the year. Now obviously what we mentioned is the impact of that marginal loss would be immaterial at a consolidated P&L level.

Mayur Parkeria: So this was based on purely as if a P&L of Malaysia was to be prepared, then the loss would be marginal and that marginal loss would have an even further lesser impact on the overall profitability?

Siddharth Mittal: Absolutely.

Mayur Parkeria: The second was this interchangeability, are there similar norms in the EU also?

Paul Thomas: So, in the EU it's managed on a different basis. The EMA central authority does not opine on interchangeability either way, it's left to member states or provinces within the states.

Mayur Parkeria: But based on your initial assessment, how do you see that? Will that be an area for us to ramp up or will it be more gradual?

Paul Thomas: It's a good question and the European link provides some interesting information. I think what you've seen is you've seen high levels of switching and high market share uptake in a short amount of time. That does imply a lot of switching that looks a lot like an interchangeable kind of an approach especially in many countries. So I think what it shows is that even without an official interchangeability designation in Europe, and the same will apply in other places and I think there are initial signs in the US also with some recent launches, that there are other levers that will drive quick switching outside of a specific interchangeability designation. Payers and tenders and governments can have a significant impact on driving switching. So I think this guidance is still draft, but it's a positive step to have some more clarity on that, but there's a lot of other factors in the market that are moving things in a positive direction for switching as well.

Mayur Parkeria: Just one last small question if I can chip in. I'm sorry I'm not too aware of the technicality of the biosimilar situation, but ma'am mentioned the date of September 2017 as the start date of that. Does it mean that after that we can launch or is there a procedure even after that for actual launch in the US for the actual sales to start?

Paul Thomas: So, September is the official target date that FDA has provided for their review based on the Biosimilars User Fee Act. So, they have a basic timeline there for approval. Actual approval time can vary based on case-to-case progress and then launch is a different question that comes into other factors as well.

Sameer Baisiwala: Couple of questions on the Malaysian facility. First is what would be the percentage that would be shared by your partner Mylan as far as the cost and depreciation is concerned?

Siddharth Mittal: Sameer, we can't be that specific as there are multiple moving parts and certain cost components will be shared with Mylan. When the facility is fully utilized for commercial purposes, there

would be no cost sharing. The loss or the financial impact in Malaysia would be lumpy because there will be different activities during each of the quarters.

Sameer Baisiwala: I thought that Mylan is partner for US and Europe so as far as you are using the facility for emerging market, Mylan would not be required to share the cost.

Siddharth Mittal: That is right.

Sameer Baisiwala: So then if you are commercializing for emerging markets, how does Mylan end up sharing the cost in next fiscal because you would not be commercializing?

Siddharth Mittal: Whatever portion we utilize for emerging markets, obviously Mylan does not share in that. But since the facility will not be fully utilized by emerging markets, there will be an unutilized component, which is where we will have a sharing with Mylan. We'll also be running development batches for Lispro and Aspart, the molecules which are in pre-clinical stages which we will be cross-charged to Mylan as development cross-charge.

Sameer Baisiwala: Okay. And if you expect minimal losses from Malaysia standalone, would it be fair to say that you would be required to do at least around $50-$60 million in sales to offset that?

Siddharth Mittal: Absolutely. If you look at the fixed expenses of $48 million including the depreciation without the raw material cost and when you add the raw material cost, the revenues expected will definitely be more than $50-$60 million.

Sameer Baisiwala: Okay. And based on what you have already on hand, which is the Malaysian government order, Kiran mentioned MYR 300 million over three years so which probably works out to about $80 million, which probably works out 25-30 million. So, this alone would not be sufficient. So, which are the other key markets that you need to get approvals to offset the costs?

Siddharth Mittal: As you know that our Bangalore facility has been capacity constrained for last couple of years and in some of the very lucrative markets such as Middle East or in Latin America, we were unable to supply over the last few years. Basis the Malaysian approval, we are going to approach these regulators to qualify Malaysia. And the markets would be same for Malaysia compared to India..

Sameer Baisiwala: One final from my side and that's on Copaxone. Can you update us how has been the progress for a 20 mg file with FDA?

Arun Chandavarkar: Sameer, at this point in time, we cannot give any guidance in terms of any expectation of a near-term approval of Copaxone. So I would say at this stage, it is wait and watch.

Sameer Baisiwala: Thanks, Arun for this. But are there any pending queries from FDA and it's not the near term that I'm asking about, it's more about over next 12-month period?

Arun Chandavarkar: We are in communications with the FDA.

Sameer Baisiwala: But is there any pending queries with Biocon?

Arun Chandavarkar: Yes.

Surya Patra: Sir, again on the Malaysia plant, just one clarification. That depreciation amount around $18 million what you have mentioned so that means around 10% of the CAPEX that you are charging in a year. So does that mean that over 10-year period that we would amortize I think this entire expense? And from Biocon's if you consider, then the incidence of depreciation has not been 10% of the CAPEX. So, can you please?

Siddharth Mittal: The total CAPEX value would be around $250 million, which comprises of CAPEX of approx. $200 million and pre-operating expenses that we have capitalized so far. As a total, it is expected that $250 million will be depreciated over approximately 14 years.

Surya Patra: Okay. And regards the licensing income surprise what we have seen, is it largely flowing from the fact that Trastuzumab is now out-licensed in couple of the emerging markets, sir?

Siddharth Mittal: A large component of the licensing is from Trastuzumab as we have been licensing Trastuzumab ever since we got the approval in India, about three years ago, and if you compare this with FY16's first nine months, our licensing income was 98 crores compared to 120 crores in nine months in FY'17. So, I don't think there is an extraordinary licensing income this quarter. We have always maintained that licensing income would be lumpy, it cannot be evened out quarter-on-quarter.

Kiran Mazumdar-Shaw: But having said that, I just want to add that I think these kind of assets do command a very good licensing premium. So, I think you will continue to see good licensing income over the coming years and because of the fact that these are assets being developed for US and Europe, obviously they command a much higher premium for licensing in the emerging markets.

Surya Patra: So more or less it's a kind of a run rate what we used to see like 60-70 crores kind of annual rate though it would be lumpy quarter wise, but there would be a much better stronger visibility on the licensing front that is coming from the Biosimilars portfolio what we have built. Correct, ma'am?

Kiran Mazumdar-Shaw: Yes, you are right.

Surya Patra: Okay. And on the R&D spend front, now this quarter did something like if we adjust that licensing income and consider, then it is obviously near about 14% of the Biopharma sales or Biocon's standalone sales. So that means the R&D spend is already picked out, it may remain in this level in the subsequent period?

Kiran Mazumdar-Shaw: Yes. I'm just saying that you know that R&D is a very integral part of our business trajectory and that is why you are seeing the kind of projected growth in revenues over time because our R&D is very gestational and now it is beginning to deliver. So, I think it is very important that we continue to invest because we are clearly front-runners even globally in biosimilars and the pipeline that we have. So, I think these are very important investments that we are making not just for the near term, but also for the future.

Surya Patra: Okay. And with regards to Rosuvastatin, any specific reason that we have not yet launched the formulation in US, ma'am? Obviously API is a much bigger opportunity for us and for which we are known for also. But initially we wanted to tap that API opportunity before launching the formulation, was that the reason or something else?

Arun Chandavarkar: Biocon anyway did not enjoy the 180-day exclusivity period so from a timing perspective, we would probably do it. We will launch it, but we will launch it at a timing of our choice. Right now, we are enjoying the ride in terms of our growth on the Rosuva API.

Surya Patra: Okay. Just last one question on the biosimilar interchangeability. As per the guidance, it seems that FDA is requiring a switch study between the reference drug versus the biosimilar. So if it is so, then the switching from biosimilar to biosimilar would not be allowed ever. Is that right?

Paul Thomas: I don't think that's an implication of this. I can't tell you for sure on this, but I don't think that that is an implication of that requirement.

Surya Patra: My question is that whether the first mover will have the much better mileage because of the switching aspect. So, is that correct or may not be?

Paul Thomas: So, interchangeability also does give a certain exclusivity on the interchangeability designation. There are certain first mover advantages you could say for that. But I think as I mentioned before, there are a lot of other dynamics that are playing out in the market with formularies - Express Scripts, UnitedHealth, CVS; excluding originators from their formulary and really forcing the issue even without an interchangeability designation. And so, I think the importance of this on its own as a designation or any advantage from it is much diluted from what it was I think was earlier considered.

Sudhakar Prabhu: I have three questions. So my first question is on your CAPEX guidance for next year, what would be your CAPEX for FY18 and next year FY19 also?

Siddharth Mittal: We had triggered two CAPEX projects last year, which are under construction and completion expected in the next year for the oral solid dosage facility and for the second formulation line in Bangalore. So most of the cash out has already happened, but the capitalization itself will happen next year. Now in terms of maintenance CAPEX, we expect anywhere between 75 to 100 crores per year. And in terms of new large project, it will be the second monoclonal antibodies facility in Bangalore, which as we had mentioned in the previous quarter, would be invested along with our partner Mylan. And the details of the CAPEX investment are still being worked out and as soon as the details are ready, we will let everyone know.

Sudhakar Prabhu: Sir, the CAPEX for the oral solid facility is fully done?

Siddharth Mittal: Oral solid I would say is 75% to 80% done. Formulations, the Fill-Finish biologics formulation facility, will be fully done by end of this year.

Sudhakar Prabhu: And right now you have a gross debt of around 2,100 crores and you also have cash in balance. So would it be safe to assume that your gross debt has peaked at the current level?

Siddharth Mittal: Yes. Our gross cash is 2,200 crores while the net debt is of 437 crores. We do not expect gross debt to increase significantly. From the current cash balance and operating cash flows, a large part will be invested in the CAPEX.

Sudhakar Prabhu: And my second question is on your guidance of $1 billion, which you had given for 2019. In that, you have assumed 20% to come from Biosimilars business and 20% from Branded Formulation business. So $200 million at conversion rate of 60, it comes to around 1,200 crores. So, how do you see your Branded Formulations business growing from current run rate of 500 crores?

Because if I see the Q3 numbers, the annualized Branded Formulations revenue comes to around 500 crores. So from 500 crores to 1,200 crores, it's almost a 50% CAGR. So, what will drive growth for the Branded Formulations business?

Arun Chandavarkar: So whilst we continue to maintain our overall guidance of the $1 billion target at 60, there may be slight changes in the slices of the pie that contribute to it. Branded Formulations as you know is not just Branded Formulations India, it also includes our international component elsewhere so that pie will definitely grow. As our new Branded Formulations Head mentioned earlier on this call, we are taking measures that we expect to see results from over the course of the next fiscal and we are hopeful that Branded Formulations will deliver. But if there are any shortfalls there, they will be made up in the other segments.

Sudhakar Prabhu: And Biosimilars business, you see 50% to 60% growth over next two, three years?

Arun Chandavarkar: Yes.

Charulata Gaidhani: My question pertains to the geographic breakup, can you give the geographic breakup for the Biologics?

Siddharth Mittal: In Biologics, the entire revenue comprises of exports revenue. India revenue is included as a part of our Branded Formulations revenue. Now within the exports, we cannot give a breakup of which geography it comes from, but we have said in the past that Latin America is one of our very large markets. Now Malaysia revenues are also included in this while Middle East is an important market for us.

Kiran Mazumdar-Shaw: And Southeast Asia.

Charulata Gaidhani: Is Japan also a part of...

Siddharth Mittal: Yes. In Japan we supply Glargine and the revenues are included in Biologics.

Charulata Gaidhani: Okay. How do you see the growth in Japan so far?

Kiran Mazumdar-Shaw: Well, I think it's been very positive. In fact I think the signs are very encouraging. It's a market which as you know is not very large, but it's an important market and I think that's the most critical aspect of the Japanese market. And our partner FUJIFILM Pharma are very positive about the inroads they've made in the Japanese market.

Arun Chandavarkar: And remember we have been in Japan, the launch was just in July so we've been in Japan for only about five months.

Charulata Gaidhani: Okay. So, you expect this kind of a growth to continue over the next one or two years?

Arun Chandavarkar: Yes, we expect our Biologics business to do well.

Kiran Mazumdar-Shaw: Not just one or two years. I think we are very committed to this whole business.

Charulata Gaidhani: Yes, certainly, I can see that. But my second question pertains to Small Molecules, what has attributed to the growth of Small Molecules in this quarter?

Kiran Mazumdar-Shaw: I think I mentioned in my comments that it was largely driven by statins and immunosuppressants, which continue to be important products for us. And I will also request my colleague to make a few comments, if he wants to.

Prasad B.S.V.: Thanks for the question. This is Prasad. So, we have seen across the board the growth in all our buckets like immunosuppressants and statins. So, we expect this growth to continue in the single-digits.

Charulata Gaidhani: Okay. And which markets have contributed to this growth?

Prasad B.S.V.: So, I don't think we'll be able to give the market wise distribution of this.

Arun Chandavarkar: Remember, most of the sales are ultimately to customers who then sell into the US market. So, this is for the US market indirectly. Like Rosuva is clearly the growth driver because of its opening up in the US, likewise for many of our immunosuppressants. So although we sell to clients who may be located outside the US, as APIs, our clients formulate and then sell as ANDAs into the US market.

Charulata Gaidhani: Then the next question pertains to the margins. Do you expect the margins to grow further from this level or you expect to maintain at this level?

Siddharth Mittal: Well at company level, right?

Charulata Gaidhani: Yes, corporate level.

Siddharth Mittal: I just addressed another question on a similar line that we expect the margins to continue to be at the same levels for the next couple of years. And once we enter US and Europe with our Biologics, we expect the margins to go up.

Nitin Agarwal: On the Biosimilars filing, we were looking to file four of these products across both of your geographies in Europe and US, we've obviously covered a fair amount of distance. How do you see the filing progress on the other proposed filings for which we had guided to earlier?

Arun Chandavarkar: So, we will continue to progress these filings and as and when we file, we will make announcements. You will see news flows around this over the next few quarters.

Nitin Agarwal: Okay. And secondly on the R&D spends, now that most of our key programs or the advanced programs essentially are in a filing stage so where are the areas where we would be looking to ramp up R&D? When you look at the next four to five quarters, four to six quarters, where would the major areas of R&D spends be for us now?

Arun Chandavarkar: So even though we have done our filing for example for our three molecules in the EU and those molecules, the big clinical spends are behind us, there are other assets in our pipeline which we continue to progress. As you know, we have triggered a global Phase III study for Bevacizumab, we have Aspart and Lispro coming up in future, we have other assets coming up, and plus we have our novels and ANDAs. So, our R&D spend is not just only the biosimilar clinical. We will

over the course of the year initiate clinical trials for our oral insulin program. We are already talking of the progress on our SiRNA program. So, there are multiple assets over which this R&D spend will take place and most of these spends at the moment are not being capitalized other than Trastuzumab and Glargine.

Siddharth Mittal: And even for the molecules which we have already filed in the US and Europe, it doesn't mean the R&D expenses will go away as the R&D activities continue. The expenses obviously will come down compared to what it was at its peak.

Nitin Agarwal: Okay. And on the Malaysian facility, literally for us to breakeven on the Malaysian facility next year, we are almost assuming that our Biologics business should more or less double from the current sizes to be able to achieve that guidance?

Siddharth Mittal: Nitin, if you look at $60-$70 million of Biologics revenue going to $200 million in the next two years will obviously mean it's tripling in two years. Yes, Malaysia is a very important part of our growth strategy for Biologics and that's where in the last few years we had capacity constraints. Now with this plant getting approved by the Malaysian authorities and other emerging markets in due course, we definitely think that it is going to add to our topline.

Vipul Shah: My question pertains to Malaysian facility so in terms of capacity utilization, what should be the breakeven?

Siddharth Mittal: We would not be able to disclose those numbers. As I said, there are multiple moving parts. The breakeven is not only about capacity utilization; it's also about the development, it's also about where we commercialize, how much reimbursement we get from Mylan. But what we have again said in the past is that this facility has been commissioned keeping in mind the volumes from US and Europe and emerging markets alone cannot occupy a significant portion of this capacity.

Vipul Shah: But now can you disclose what that capacity is? I think on previous calls you were reluctant to disclose the actual capacity for Malaysia plant.

Siddharth Mittal: We do not disclose capacity for any of our plants due to competitive reasons.

Vipul Shah: Okay, sir. And regarding that Trastuzumab in US, what will be the price erosion versus reference product if and when that product is approved? Can you..?

Arun Chandavarkar: That is a matter of speculation. So I think each one does their modeling in their own way so we would refrain from commenting on something and clearly the pricing decisions will be driven by Mylan.

Sameer Baisiwala: I'm just thinking about your pipeline as a whole for Biosimilars, you had four closing the filing and you had five in the early stages. Now beyond these nine, are you looking to add more products to the pipeline?

Arun Chandavarkar: See if Biocon wants to be a biosimilars company, clearly we will have a growth strategy in place and which means that we would need to create a pipeline.

Siddharth Mittal: And one of the reasons we had mentioned last year when we had restructured our legal entities to reflect our BU's (Business Units) was so we could monetize some of these BU's at an

opportune time. The reason we hosted our entire Biosimilars business in UK is because we want to enter the developed markets on our own, with molecules outside of our Mylan partnership.

Arun Chandavarkar: See if you look at it, when we struck that agreement on Recombinant Human Insulin with Lab PiSA, clearly the nature of that agreement was that Biocon would front it in the US. So, that is an example of what we have done outside of the nine assets that we mentioned. And going forward in the future, we will add to our pipeline.

Sameer Baisiwala: And how would this be, any light that you can share? I mean with three, four products every year sort of..?

Arun Chandavarkar: No, we cannot give that kind of guidance right now because unlike the ANDA space, Sameer, you know that here it's not just about selecting the molecule; but it's also about advancing it through the clinic, it's also about identifying the opportunities in terms of market formation dates, which is not always as black and white as an ANDA's.

Sameer Baisiwala: The second question is on the licensing income. I am just curious that would things such as filing with EMA on Glargine and filing Trastu in the US, these sort of activities would they not trigger payment from Mylan?

Siddharth Mittal: There are no licensing payments from Mylan for filing in any of these countries.

Arun Chandavarkar: See our arrangement with Mylan is a cost share profit share, it's not based on milestones.

Siddharth Mittal: These are all partners in emerging markets so non-Mylan.

Sameer Baisiwala: And the last one is on the Small Molecules business, anything that you can share that whether you're gaining new customers for immunosuppressants, statins or within statins whether it's a newer statin which is contributing to growth or even the older legacy products they are contributing whether its volume or whether its pricing? Any color would be very helpful.

Arun Chandavarkar: So Sameer, the broad answer is it's a mix of everything. But clearly within that, there have been new customers, there also have been new molecules which I mentioned an example of was Rosuvastatin. And clearly within the basket, the immunosuppressants and the newer statins meaning like Rosuvastatin are driving a lot of the growth. And the growth has actually been more than single-digit when you look at it. Even though long term we have guided for the single-digit, our actual performance has been much better than the single-digit growth.

Ranjit Kapadia: My question relates to Small Molecules. With immunosuppressants and statins, obviously the pricing currently and obviously the pricing pressure building up in this set of molecules?

Arun Chandavarkar: See now many of the older molecules in our basket have reached sort of steady state so there is single-digit base erosion in terms of the pricing. Rosuvastatin, it's just happened so we would see a price erosion over the next year or two at a much more rapid pace. But for the other molecules, which are more mature, I would say there's a single-digit base price erosion.

Ranjit Kapadia: And are we the supplier of Rosuvastatin after the patent expired to the patent holder?

Arun Chandavarkar: I'm saying that we supply to our customers who have ANDAs.

Cyndrella Carvalho: Ma'am, I'm trying to understand a little broader view over here, but I hope you will be able to help me on that. I want to look at Biocon beyond like when we had one or two approvals in the Biosimilar segment for the regulated market, how do you see the Company going then like if you will be able to help us with that? Thank you.

Kiran Mazumdar-Shaw: See, I think basically Biocon has clearly articulated its business strategy by saying that we want to be leaders in biosimilars and therefore we are creating a very robust pipeline on which we are delivering. I think the fact that we have been potentially the first to file in terms of our Trastuzumab biosimilar in the US and the fact that the target date has been provided by US FDA later this year is a very important signal that we are actually in a position to deliver very high quality products to the developing world. And I think this is a very important signal because up until now I think there was a lot of concern about whether a company like Biocon can indeed address these very large and lucrative market opportunities in Biosimilars and the answer is yes. I think you will also see from the JAMA publication that they have actually validated Biocon's ability to develop such products. So, I think you have to look at it very positively from that point of view. You also know that globally it is accepted that the next bolus of growth in terms of the pharmaceutical area is going to come from biosimilars. And I think you can clearly see that Biocon is amongst the front runners and we clearly see that Biocon and Mylan are in a very strong position to address these very large opportunities because of the fact that we believe we have a very strong cost competitiveness and we have invested in this at the right time. So, I think you have to look at it in that context. And going forward, obviously we are going to invest very strongly in a growing pipeline of biosimilars and we want to be very strong in this segment. Now you can also see that Biocon is very unique because we are the only company that actually have straddled both insulins and biologics. So, I think again this puts us into a very prime position in making ourselves very strong and large in this whole context of biosimilars. And then Biocon has also been very prudent in investing in some very important novel biologics and we believe that the next few years will also show you that we will build credibility in these novel biologics as well. So, I think it's a very exciting opportunity for Biocon and for investors to invest in such a unique growth story. So, I think that's what it's all about if I hope I've answered some of your questions.

Mayur Parkeria: Our Malaysia facility now that we have visibility of filing in US, Europe, we have got the initial start date also; there is some better visibility than where we were let's say six, seven months back. So, are we crystalizing any plans for the Phase II expansion? That was first. And now since that would be mainly driven by the developed market sales, will Mylan also share the expansion and the CAPEX on that side? So, that was the first part?

Arun Chandavarkar: So I would say if you look at our Malaysian facility, yes, we have designed that facility so that at any time we feel it is required we can trigger a Phase II expansion of that facility. We have not made that decision yet. We will make it at an appropriate time because at the moment our capacities are adequate for our immediate needs and we will time it such that it's ready by the time we get the market share that we expect in the developed markets for our insulin basket.

Mayur Parkeria: Will it be fair to say that even the decision and the other details would be at least a year away from now?

Arun Chandavarkar: Roughly, yes.

Mayur Parkeria: The second was on again the licensing income. Do we have further scope of more licensing to other emerging countries which are there or more of the basket is now broadly being addressed and the licensing income will be a function of continuous income from the existing markets which we have done or is there more scope for that and an outlook on that?

Arun Chandavarkar: See, we don't give guidance on licensing because the nature of licensing is lumpy, it may happen in a quarter, it may not happen.

Mayur Parkeria: No. Yearly basis, do we see that increasing meaningfully by addressing more emerging markets still left or is it that we have broadly addressed the pie and now it will be a more gradual?

Arun Chandavarkar: If you look at it, our early assets have been partnered but we have additional assets in our kitty, which are yet to be progressed in terms of partnering.

Mayur Parkeria: And just a clarification, Biologics sale even from other than Malaysia facilities also there right some portion?

Arun Chandavarkar: Yes.

Mayur Parkeria: What would be that portion? So currently practically most of that would be from the Indian facilities, right?

Arun Chandavarkar: Yes.

Kiran Mazumdar-Shaw: Please understand that Malaysia is only for insulins.

Siddharth Mittal: If you look at Q2 Biologics revenues of 100 crores was from the Indian facilities. Only during this quarter we had revenues commencing from Malaysia.

Mayur Parkeria: There we had scope of capacity, more utilization and ramp-up of sales possible from that?

Siddharth Mittal: The insulin facility from India was fully utilized, but the monoclonal antibodies facility from India, there is capacity available to service the emerging markets as well as the launches for Europe and US.

Saurabh Paliwal: Thank you, everybody for joining us today for this earnings call. If you have any further questions related to these results or anything with regard to the Company that you need, please feel free to reach out. Have a good day.

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