Biocon Limited Q4 FY17 Earnings Conference Call
April 28, 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
- Ravi Limaye: President - Marketing
- Prasad B.S.V: Sr. Vice President & Head - Small Molecules
- Paul Thomas: Vice President & Head - Biosimilars
- Saurabh Paliwal: Head, Investor Relations

Conference Call Participants during Q&A

- Prakash Agarwal, Axis Capital
- Ujwal Shah, Quest Investments
- Surya Patra, Phillip Capital
- Sameer Baisiwala, Morgan Stanley
- Abhishek Sharma, IIFL
- Nitin Agarwal, IDFC Securities
- Sandeep Baid, Quest Investments
- Charulata Gaidhani, Dalal & Broacha
- Vipul Shah, Sumangal Investments
- Ashi Anand, Allegro Capital
- Harshil Gandhi, JHP Securities
- Harith Ahamed, Spark Capital
- Shraddha D'souza, Wealth Managers

Presentation Session

Saurabh Paliwal: Thank you, Janice and good morning everybody. I am Saurabh Paliwal from Biocon's Investor Relations team and I welcome you to today's earnings conference call for the fourth quarter and full year of fiscal 17. Before we proceed, I would like to remind everybody that a replay of the recording of this call would be available for the next few days immediately following the conclusion of this call. We shall be posting the call transcript on our website in the coming days.

To discuss the company's business performance and outlook, we have today with us the leadership team at Biocon comprising Dr. Kiran Mazumdar-Shaw – our Chairperson & Managing Director and other colleagues from the senior management team. I would like to take this opportunity to remind everyone about the safe harbor related to this call. Today's discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces that 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 get in touch with us. Now, I would like to turn the call over to Dr. Kiran Mazumdar. Over to you, ma'am.

Kiran Mazumdar-Shaw: Thanks, Saurabh. Good morning everyone. I welcome you to Biocon's earnings call for the fourth quarter and full year of fiscal 2017. It was certainly a very eventful year for all of us at Biocon as we crossed many important milestones. I would like to start with some of the key highlights for the year.

- Our marketing authorization applications for a proposed biosimilar of pegfilgrastim, trastuzumab, and insulin glargine were accepted for review by the European Medicines Agency;
- US FDA is reviewing applications for our proposed biosimilars of trastuzumab and pegfilgrastim for which we have received the target action dates for September and October respectively in this calendar year.
- Biocon's Malaysian insulin plant started commercial sales where our subsidiary Biocon Malaysia SDN. BHD. was awarded a 3-year 300 million Malaysian Ringgit contract for supplying recombinant human insulin cartridges and reusable insulin pens under the Malaysian government's offtake agreement or OTA initiative.
- The commercial launch of biosimilar insulin glargine in Japan through our partner FUJIFILM Pharma commenced in July 2016 and we see this event as a strong endorsement of our product quality as well as our manufacturing facilities. Our disposable pen was also highly appreciated for its unique features.
- We received our first ANDA product approval for Rosuvastatin Calcium from US FDA. This we believe is the first step in our endeavor to forward integrate and add value to our API business.
- I am also delighted to share with you that Biocon was again ranked amongst the top 10 biotech employers as per the 2016 rankings released by Science Career Magazine. We are the only Asian company to be featured in this list and we believe this is a great testament to our work culture and the opportunities our scientists get within the company, ultimately resulting in successful outcomes.

Now moving on, let me present the key financial highlights. I will first discuss the highlights for the quarter and then follow it with the full year numbers.

- Consolidated revenues for Q4 FY17 were Rs.974 crores which is flat compared to last year.
  - Biocon sales were at 653 crores which represents a modest growth of 4%.

  Within this,
  - Small Molecule sales were 387 crores for Q4, marginally down from Q4 last year.
  - Biologics sales were also flat at 119 crores.
  - Branded Formulations grew 25% to 131 crores as per the accounting standards adopted from April last year. However, on a like-to-like basis, the segment was flat.
  - We booked licensing income of 16 crores this quarter as compared to 10 crores in the same period last fiscal.
  - Syngene contributed sales of 272 crores in Q4, down 14% as compared to Q4 FY16. These numbers on a consolidated basis adjusted for intercompany transactions and other income. On a standalone basis, Syngene reported revenues of 315 crores, EBITDA of 124 crores and net profit of 78 crores.
- We incurred a total spend of approximately 98 crores on R&D this quarter. Of this amount, 65 crores is reported in the P&L corresponding to 10% of our sales when you exclude Syngene. We capitalized an amount of Rs.33 crores related to trastuzumab and glargine development expenses.
- We have booked a forex loss of 17 crores this quarter. The losses are on account of restatement of foreign currency denominated assets due to the recent rupee appreciation against the US dollar. The amount appears under other expenses in the profit and loss statement.
- Group EBITDA was at 231 crores for Q4 reflecting a growth of 5% with EBITDA margins at 24%. Core margins, i.e. EBITDA margins net of licensing, impact of forex and R&D expenses, stood at a very healthy 31%.
- Reported Net Profit for the quarter was 127 crores which represents a net profit margin of 13%. Adjusting for exceptional items, the net profit would be Rs.135 crores reflecting a growth of 75% over Q4 of last year.
- The effective tax rate for the quarter appears lower than last year due to recognition of deferred tax asset for the full year and utilization of R&D incentives.

I must emphasize here that investors should not look at our performance in Q4 in isolation, but we would like you to look at how we have performed on an annualized level for FY17 which shows strong growth over the previous financial year.

So let me take you through the financial highlights for the full year.

- Consolidated revenues grew 18% over FY16 to 4,079 crores.
- Biocon sales were at 2,738 crores, representing a strong 20% growth.

  Within this,

  - Small Molecule sales were 1,587 crores, a growth of 14%.
  - Biologics grew 34% to 458 crores; while
  - Branded Formulations clocked sales of 549 crores which is a growth of 24%. On a like-for-like basis, however, this segment was down marginally compared to last year.
  - Licensing income for the year was 144 crores as compared to 108 crores last year.
  - Research Services (Syngene) sales grew 7% over FY16 to 1,138 crores on a consolidated basis. However, on a standalone basis, Syngene reported sustained revenues of 1,272 crores, EBITDA of 478 crores and a net profit of 287 crores.
- Our gross R&D spends at Biocon for the year were 402 crores. Of this, 267 crores is reported in the P&L representing approximately 10% of Biocon sales excluding Syngene**.** This is in comparison to 427 crores last year. Total amount capitalized during the year was 135 crores. We project gross R&D spend to remain in the 12%-15% range in FY18.
- Group EBITDA was at 1,137 crores with EBITDA margins at a very strong 28%. Core margins for the full year stood at 32%.
- Reported Net Profit for the year was 612 crores with net profit margin of 15%. Adjusting for exceptional items, net profit was Rs.620 crores reflecting a growth of 54% over FY16.

Now before I move on to discussing individual segment performance, I would like to share with you that the Board of Directors has recommended for approval by the shareholders a bonus issue of shares to the shareholders of Biocon in a 2:1 ratio that is 2 bonus shares for every one share held by an individual on the record date. The board has further recommended for approval a final dividend of Rs.3 per share pre-bonus for the year FY 2016-17.

Now coming to discuss individual business segments, let me start with **Small Molecules**. Small molecules performance was down marginally in Q4, but showed a robust 14% growth for the full year. Growth was largely led by rosuvastatin, pravastatin and immunosuppressant API sales during the year. We are working on certain niche API and generic formulation opportunities to sustain long-term growth for this segment.

Now coming to **Biologics**, the biologics segment continued its strong performance in FY17. Insulin sales for the Malaysian OTA and trastuzumab sales in certain emerging markets drove growth in this segment in FY17. We also saw strong licensing income this year, bulk of it as a result of partnerships for trastuzumab in emerging markets. I must take this opportunity to remind our investors that partnering in emerging markets is integral to our business and any licensing income resulting from such partnerships is inherently lumpy. Overall, we expect the Biologics segment to continue its strong growth trajectory as we begin to receive approvals.

The performance of our **Branded Formulations** as a whole has been flat on a like-for-like basis. Increased competition from low price biosimilar mAbs and introduction of price caps in some key brands by the government in India along with the loss of key in-licensed oncology brand Abraxane, which was withdrawn by the licensor from India and UAE market has impacted our growth in this fiscal. Biocon is one of the strongest companies in India in the insulin space while our oncology products - both novel and biosimilars command high market share in their respective categories. Our focus and commitment on having a specialty portfolio remains unchanged and we have benefited from this strategy with an increase in prescription shares for both our insulin brands Insugen and Basalog in FY17. We are working to overcome challenges faced by our business especially in India by

modernizing our to-market approach, focused execution, expanding our reach to adjacent markets and by making organizational changes. Through these changes, we hope to deliver a better performance from this segment in FY18 and beyond.

A brief comment on **Research Services (Syngene)** - Standalone revenue recorded a sustained growth of 14% on back of overall robust performance across its businesses as well as higher interest income. Revenue growth this quarter and for the full year has been impacted by the fire incident that happened in December; however, operational performance has been solid with reported EBITDA and PAT margins at 38% and 23% respectively for FY17.

Important developments during this fiscal included among others; 1) the commissioning of the first phase of the Syngene Research Center, 2) a signed strategic deal for setting up a dedicated R&D center for Amgen which represents Syngene's fourth dedicated R&D center, 3) Syngene added new capabilities in Bioinformatics and, 4) a strategic partnership with Herbalife Nutrition was also announced as their first dedicated nutrition research and development lab in India and the fifth dedicated center for Syngene.

Syngene continues its investments to expand its service offerings and building capacities which among others include the commercial manufacturing API facility at Mangalore and a new biologics plant in Bangalore.

Now coming to **R&D highlights -** FY17 was a significant year in terms of progress made by our various biosimilar programs, with five regulatory filings across the U.S. and EU for a few of our products. Further, we completed the ROW-focused Phase III trial in metastatic colorectal cancer for our proposed biosimilar bevacizumab. We have submitted a Marketing Authorization Application for the same with DCGI in India. An additional Phase III global trial has also commenced in non-small cell lung cancer. For Adalimumab, we continue to make progress towards regulatory submission. As part of our insulins portfolio, we expect to file our Marketing Authorization Application for Insulin Glargine with the US FDA very shortly. Other molecules from our insulin analogs portfolio, Insulin Aspart and Insulin Lispro are also advancing.

Coming to our **Novel Molecules** portfolio - In diabetes, Biocon's lead program is Insulin Tregopil, a first-in-class oral prandial insulin molecule for post-prandial glycemic control. A clinical trial application for Insulin Tregopil has been filed with DCGI, the Indian regulator, for a pivotal Phase III study to clinically validate its promise as an orally delivered rapid-acting prandial insulin in managing type 2 diabetes. A multiple ascending dose study in type 1 diabetes patients is also planned in FY18. These two studies combined in different diabetic populations will form the foundation of a broad global program envisioned for Insulin Tregopil.

Clinical developments of our novel anti-CD6 monoclonal antibody, Itolizumab, continues in Australia. Stage 2 of a Phase I clinical study using a subcutaneous form of Itolizumab is scheduled to start very shortly.

QPI-1007, a novel SiRNA molecule to treat non-arteritic ischemic optic neuropathy or NAION, which is based on Quark Pharma's SiRNA technology platform continues to make progress following the initiation of a pivotal global Phase III study by our partner, Quark Pharma in FY17. The trial also includes patients randomized in India, a country with a high incidence of this disease.

Fiscal year 2017 was an exciting year for Biocon. It marked the beginning of the new growth journey for the company led by our Biologics segment, with commencement of insulin glargine product sales in Japan followed by the initiation of commercial supplies of recombinant human insulin from our Malaysian facility. Progress of our biosimilar pipeline with multiple filings across various developed markets was also an important event this fiscal, while Syngene continues to make investments to expand its capacities and service offerings. All combined, these events and activities provide good visibility for us to deliver long-term growth to all our shareholders.

Now as we move into FY18, we have a cautiously optimistic outlook. As stated in the Q3 call, we have now stopped capitalization of further expenses at the Malaysia plant at the end of Q4 FY17. Consequently, depreciation and fixed expenses amounting to approximately $48 million annually, which is related to the Malaysian plant will now be charged to the P&L account starting Q1 FY18. The impact, as we said, would be offset among other things by product sales in emerging markets, which we are cautious about as it is highly

dependent upon getting local regulatory approvals. The approvals are expected in the second half of FY18, but the exact timing is hard to predict unlike the US where we receive target action dates. Any shift in these timelines and hence impact of the same on our margins remains a risk to our guidance. That coupled with GST impact and currency headwinds due to the recent appreciation of the rupee keeps us cautious for FY18. We hope that the headwinds will reduce. But in the meantime, we will work and endeavor to deliver whatever we can in a strong and robust fashion in FY18.

And with this, I would like to open the floor for question and answers.

Q&A Session

Prakash Agarwal: First question on Trastuzumab, congratulations on the settlement. Trying to understand the patents relating to `213 which expires June 2019. So would it be fair to understand that if approvals come through, we would be set for 2019-20 launch in the U.S.?

Arun Chandavarkar: Prakash, this is Arun. I think we issued a comment on the press release that was issued by Mylan when they reached the global settlement with Roche. And as stated at that time, due to confidentiality reasons, I am unable to give specific comments in terms of specific patents and specific timelines in any of those countries. Any information request on this should ideally be directed to Mylan. So bear with me, I will not be able to give you any specific comments other than what was confirmed in that stock exchange notification issued at that time.

Prakash Agarwal: Sure. I understood. And secondly, on Insulin Glargine, just trying an understanding what has caused marginal delay? I mean, in the past we have maintained that by fiscal '17, we would be looking forward for filing. I know these timelines can be here and there. But as per our understanding, is it a 1H event or can it push ahead?

Arun Chandavarkar: We expect to file that very shortly.

Prakash Agarwal: Okay. And lastly, on the Malaysia facility. Ma'am did speak about the commissioning and expense being started. So if you could just give a broad split between the operating expenses and depreciation. Ma'am mentioned $48 million, which, I guess, includes both elements?

Siddharth Mittal: Depreciation is $18 million approximately and the fixed operating expenses, which primarily comprises of salaries and utilities amongst other expenses are roughly $30 million. It does not include raw materials and other variable costs.

Ujwal Shah: Just looking at your 4Q Biologics numbers, the segmental numbers that you have given. The PBIT that came in from Biologics was only about 5.9 crores if I'm not mistaken. So can you throw some light were there any onetime expenses that impacted that segment? And how do we see about it?

Siddharth Mittal: Two large components when you look at the Biologics segment from a profit perspective comprise of R&D expenses and licensing income. The licensing income during the quarter was 16 crores which on a run-rate basis has been one of our lower quarters while the R&D expenses were in normal range. However, the operational performance continues to be at the similar levels as compared to previous quarters.

Ujwal Shah: Okay. And sir, secondly, considering that emerging market approvals are seen in second half and the timeline cannot be determined about the same. Do we still stand by our FY19 targets for the Biologics segment because we would be required to grow at a much faster pace to achieve the same?

Arun Chandavarkar: Yes, we continue to stand by that guidance. As I said and as Kiran mentioned in her opening remarks, the uncertainty is not about the approval. The uncertainty is more related to the timing because unlike some of the developed countries, which because of either GDUFA or BSUFA, the FDA gives target action dates; very often in emerging markets such specific dates are not specified. So there is always a couple of months shift this way or that way, based on how long they take to review or secondly, how long they take to

schedule a cGMP inspection of the facility. So from an emerging market perspective, there will definitely be approvals later this year. So from an FY19 perspective, we are quite okay. The cautious outlook that Kiran mentioned was specifically for FY18.

Ujwal Shah: And sir, lastly on the Small Molecules business. You have been gaining a lot of sales as well as the margins have been very robust in FY17. Do we see the momentum continuing in FY18 even in terms of the margins, the strong margins that we have seen in FY17?

Siddharth Mittal: The Small Molecules vertical is a high-profit vertical. The margins are very healthy. However, I should mention that R&D expenses for our ANDA portfolio also sit in the segment results for this division. And what we have mentioned in the past that we will continue to look at filing 5 to 6 molecules every year. We have had lower number of filings this fiscal, but we do expect to have higher R&D expenses for this vertical on a go-forward basis.

Ujwal Shah: And sir, CAPEX guidance for next year?

Siddharth Mittal: CAPEX should be approximately 700 crores for Biocon. Syngene has given separate guidance for their CAPEX.

Surya Patra: Sir, I just wanted to know whether we have seen the full quarter benefit of this Malaysian government insulin supply during this quarter?

Siddharth Mittal: Yes, that's right.

Surya Patra: Okay, but on the Biologic revenue front that we are seeing sequentially, it is slight flattish to negative kind of growth sequentially on the Biologic revenues. So any specific reason despite incremental revenue flowing from this? And annually, I think 150 crores kind of an annual run rate for your businesses should be getting from there?

Arun Chandavarkar: So the OTA supplies to the Malaysian government actually had initial launch quantities in the previous quarter, I mean, in Q3 itself. So that was one thing. And of course, there are always phasing issues because currently, the nature of our Biologics business is still based on few products and few markets. I would be more comfortable looking at an annualized basis at this phase of our filings and approvals.

Surya Patra: Okay, fine, sir. And another question is on the margin performance this quarter, which seems relatively lower than expected. Possibly that is flowing from the fact that the weaker revenue mix because of the weaker performance in Syngene this time. But if you see the standalone Syngene performance, surprisingly their margin is much better than the normal trend, 34.5% kind of Syngene margin. So despite that you're in the consolidated levels, the margins are lower. So is it that the margin pressure is coming from the commercialization of the Malaysia plant in this quarter that we are witnessing?

Siddharth Mittal: The Malaysian plant has been capitalized at the end of the year and the expenses will be in the P&L from quarter 1 of next fiscal. But answering your specific question on the consolidated margins, as Kiran mentioned in her opening comments that the core margins, which is EBITDA margins less the licensing, forex and R&D stood at 31%, which has been the historical range as well. Now when you compare Syngene standalone margins, it was also mentioned that we had a forex loss of 17 crores during this quarter. When I break it up between Syngene and Biocon, Biocon actually had a forex loss of 33 crores, while Syngene had forex gain of 16 crores. So Syngene's income is higher because of forex gain on a standalone basis. At the consolidated level, it was 17 crores loss.

Surya Patra: And regards to R&D outlook, we are raising our R&D budget to 12% to 15% of the biopharma revenues for FY18 whereas that is for this FY17, it is around 10%. So whether the spike in the R&D spend is because of the biosimilar projects or is it also getting enhanced because of the novel project what we have initiated?

Siddharth Mittal: R&D expenses for the full year in the P&L were 267 crores on total Biopharma revenue of ~2,740 crores, which is approx. 10%. The R&D guidance of 12% to 15% which Kiran mentioned was at the gross level. Including R&D expenses capitalized last year, our gross expenses were 402 crores on Biopharma revenue of ~2,740 crores, which is 14.7%. Additionally, on an absolute basis, our R&D expenses would go up on the back of all the novel development programs and also some of our other biosimilars and insulins, which will progress further into the clinic.

Surya Patra: Okay. Can you split the R&D spend into biosimilar and novel also?

Siddharth Mittal: We do not give a break up, but roughly more than 50% is for biosimilars and insulin. And I would say 30% to 40% would be for combination of novels and ANDA.

Surya Patra: Okay, just last one question, sir. So whether we have got any target action dates for this biosimilar approval or filings in Europe?

Paul Thomas: So I think in Europe, as you know, the fillings are under review now for the two products and we've said 12 to 18 months kind of a review period is what we expect. And the review process is going on well as far as we can see now. So no update to that.

Surya Patra: Okay, fine. So officially there is no target action date, what ma'am had indicated in the opening remarks. Is that correct?

Paul Thomas: So there is a target action date that is there for U.S. We mentioned September and October for the two products - trastuzumab and pegfilgrastim.

Sameer Baisiwala: Kiran, you mentioned the outlook for fiscal '18. I think, it was more to do at the margin level. But on the topline, how do you see the year pan out?

Kiran Mazumdar-Shaw: Yes. I would say that we are obviously focused on growing topline. And as I said that we feel that if we get all the regulatory approvals in time, we are very committed to driving a good growth at topline. Obviously, this will also reflect in the bottom-line. So I'm just really staying a bit cautious only because of all the regulatory delays that we have seen at this point in time where certain regulatory approvals that we were expecting during this part of the year have been delayed to the next few months. These are the kind of things that make us give a little bit of caution about the guidance. If things happen as we hope, then obviously, we will be able to deliver on what we want to.

Sameer Baisiwala: Okay, that's fair enough. But if I just keep a few of these EM approvals out, the balance part of the business, which is Small Molecules, which is Syngene-related, which is Branded Formulations for India etc. So if you put all of those together, are we looking at a double-digit sort of a growth?

Kiran Mazumdar-Shaw: Yes.

Sameer Baisiwala: And second question is on the filing for Insulin Glargine in Australia and Canada. What's the expectation over here in terms of timelines for getting to market, and are these sizable markets?

Arun Chandavarkar: Well, I can't give an expectation because, again, this year we don't have target action dates. So I don't have a precedent in terms of a biosimilar application review and approval in these markets. So at this stage, I can't give you any specific guidance on Canada and Australia.

Sameer Baisiwala: And how big are these markets?

Arun Chandavarkar: The market size of Canada and Australia are $140 million and $93 million respectively as per IMS year end 2016 data. (Added post the call)

Sameer Baisiwala: Yes, sure, fair enough. And just one last one. On Copaxone file, how is it progressing for 20 and 40mg?

Arun Chandavarkar: As you know that what we stated last time that we would be responding to the FDA in due course. And we are not factoring that into our revenue guidance for FY18 anyway. So because my sense is that by the time we respond, it will still be a few months away and then how long the FDA will then take to review the file. So right now, we are not baking any revenue numbers related to that in FY18.

Sameer Baisiwala: Okay, that's fine. And can you qualitatively tell us what is it that's been asked for on this specific file? I mean, is it gene expression data, is it API related or is it something else?

Arun Chandavarkar: Well, a lot of it has to do with some of the information that the FDA asked for subsequently, which we are in the process of responding to. I can't give you specific information around the data. But rest to say, we don't look at them as being potential showstopper. It's just going to be a question of taking the time to generate the requested information.

Abhishek Sharma: Just one question around the fact that you have got target action dates for two of your biosimilars in the U.S. Is your facility due up for inspection? And any specific dates that you have? And if it has been inspected, then what is the outcome?

Arun Chandavarkar: So in terms of the U.S. filings, yes, that has triggered an inspection of our facilities in Bangalore. And as a policy, we do not comment on the specific outcomes. Rest assured, we believe there is nothing to be concerned about. We are optimistic about the outcome and we hope our approvals come in due course as per the target action dates.

Abhishek Sharma: So the inspections have happened already?

Arun Chandavarkar: Yes.

Nitin Agarwal: On the Biologics, as we go forward, apart from the ramp-up of the Malaysian facility and the emerging market approvals, what are the major drivers that you're seeing for this business in the next, say, 12 to 18 months, because I presume the regulatory market approvals are revenue commercialization will take still some more time to come through?

Arun Chandavarkar: So in terms of the emerging markets, as you know, our business model in emerging markets is not a direct presence, but typically by partnering with very strong local players. And so there are two aspects to it. If you look at most emerging markets, many of them are driven through bulk procurement by governments or government tenders. So that's one aspect. And there are, of course, some markets where our partners would enter as a retailer and get incremental market share over a period of time. When it comes to markets which are tender-oriented, it really depends on the tender cycle. If our emerging market approvals come in that time cycle where we can participate in a tender in the period that it's open, yes, the opportunity opens out. Otherwise, we have to wait for the next tender cycle. So that's why, sometimes, the revenues do get impacted at this stage of our evolution where we are still not present in all the countries say for example, with trastuzumab and glargine, the way we are present in many countries with our recombinant human insulin. So that is the nature; we work through local partners in both markets, whether it's retail or tender in emerging markets.

Nitin Agarwal: In your experience, Arun, trastuzumab, there won't be too many options which are there in emerging markets for the branded alternative and I guess, government should be keen to take on also absorb this or uptake the biosimilar option, the lower cost of biosimilar option that we're representing. So why are there delays in some of these markets?

Arun Chandavarkar: I won't call it a delay. In their perspective it may not be a delay. From our perspective, it looks like a delay because we are comparing it to the experienced developed markets where the regulators in the

developed markets have a great deal of experience in terms of how to review, how to inspect or how to schedule the inspection or how to adhere to target action dates. Within emerging markets, I feel it is still, maybe, an evolution in terms of their own experience in terms of reviewing some of these information because if you look at the quality of the dossier, the quality of the product and the robustness of our trials and data generation, clearly, it's the same that has been accepted in the regulated markets. So we believe it's more to do with their comfort level in terms of reviewing some of these dossiers and scheduling these inspections.

Nitin Agarwal: And if I can sneak a last one on this one, what's your experience been with the innovators? How have they sort of responded to your entries in some of these markets, have they been aggressive with the pricing?

Arun Chandavarkar: I don't want to make a very specific comment in terms of the innovator responses because the innovator responses are not necessarily linked to only Biocon. Innovator responses are linked to other biosimilar competitors who would be present in some of the emerging markets as well. So from a pricing perspective, yes, there is always competition, and we are prepared to respond to the price competition quite effectively because we have been responding to such price competition historically in our insulin and glargine businesses and trastuzumab, which is relatively recent we are prepared for that sort of price competition should it materialize. Clearly, our cost base here in India helps us.

Sandeep Baid: Ma'am, you mentioned that licensing income is quite lumpy, and that's what we have seen in the last few quarters. I just wanted some guidance for the full year FY18 and FY19 on licensing income, if it is possible.

Kiran Mazumdar-Shaw: We don't give guidance on licensing because these are event-based and we cannot actually make such predictions. So I don't think we will be able to give you any guidance on licensing. Suffice to say that we have many opportunities for licensing in FY18, which you will get to know about once we get into those licensing deals.

Sandeep Baid: And with regard to the Malaysian facility, is interest expense also included in the $48 million figure you mentioned?

Siddharth Mittal: Yes.

Charulata Gaidhani: Yes, my question pertains to the Biologics. So there is a 7% growth in the quarter. Is there any seasonality involved in this or if you compare it with Q3, is there some products which have gone out or which have not been sold, because of which, the growth is lower?

Siddharth Mittal: 7% growth includes licensing income. Excluding licensing, Biologics revenues were at 119 crores compared to 120 crores in the same quarter last year. And as Arun had mentioned sometime back that some of the business is also dependent on approvals and timing of the tenders. And you should really look at our Biologics business on a full year basis rather than on a quarterly basis.

Charulata Gaidhani: My second question is pertaining to there is an increase in the share of profit. Is this from NeoBiocon?

Siddharth Mittal: Yes. We consolidate our share of profit in the joint venture which for the year stood at 16 crores.

Charulata Gaidhani: And relating to Biologics, going forward, can we expect a 25%, 20% increase in the business on an annual basis?

Siddharth Mittal: Definitely. Revenues during the last fiscal year was approximately $75 million while our guidance for FY19 is $200 million. This guidance has been reaffirmed during this call and also in our past releases which would imply that our growth will be at a much higher level for the next two years. However, the

outlook that Kiran had mentioned is dependent on the timing of the approvals some of this could be in later years and hence the growth could be back-end loaded to reach to the $200 million revenue number.

Vipul Shah: How should we look at the revenue potential of the Malaysian facility at a reasonable capacity utilization?

Siddharth Mittal: We cannot give a guidance on the revenue from Malaysia. At this stage, it's too early because there are various moving parts; first is the timing of approvals and launch, second is the market share and the; and third is the pricing that we will get in the U.S. and Europe. Also, as you know that for the emerging markets and for the developed markets, we have partners to whom we sell at different commercial terms. So to put everything together and to say what the revenues would be is difficult.

We have also mentioned in the past that one should also look at our Biologics business from a bottom-line perspective as well, because for the developed markets, we will receive profit share from Mylan which will be accounted in the topline and will flow directly to the bottom-line.

Total investment that we have made in Malaysia is roughly $250 million. What we have said is that from a margin perspective, the insulin business has high margins and when you take out the R&D expenses, is above company average margins. And once we are in the developed markets, those margins would go up.

Vipul Shah: So then any update on oral insulin?

Kiran Mazumdar-Shaw: Yes, I think I mentioned that we are likely to start a pivotal Phase III study in India this fiscal on type 2 diabetes patients. We also expect to commence an important type 1 patient study as well.

Prakash Agarwal: Just trying and understanding this forex loss which you mentioned of 30 plus crores. What does relates to, obviously, it's a P&L loss, but what does that relate to, sir?

Siddharth Mittal: It is the restatement of our net USD positive balance sheet position primarily comprising of export debtors and USD bank balance. During the previous quarter, USD/INR exchange rate was around Rs.68 and with recent appreciation of rupee to 64.5 level, it has resulted in a translation loss of ~Rs.4 per USD. We also have a dollar debt, the exchange gain on that restatement was accounted in the balance sheet and not in the P&L. On a net basis, actually, there is not much of an impact. And also, on a full year basis, our forex loss at a group level was just 3 crore.

Prakash Agarwal: So these are balance sheet items in the P&L for the particular year, so this has been restated. So if rupee remains stable versus other currencies, unlikely to see this recurring, right?

Siddharth Mittal: Absolutely. If rupee depreciates back to the earlier levels, we'll see the gain in the P&L.

Prakash Agarwal: Okay, understood. And second on the tax rate. So you mentioned deferred tax adjustment. So what this pertains to and what is the outlook for next year, sir?

Siddharth Mittal: The full year deferred tax benefit for Biocon Research Limited was 27 crores while for the quarter, it was 12 crores. After adjusting for the deferred tax benefit, adjusted effective tax rate, at a group level for the full year, was 22%, which is in line with the effective tax rate for the last year. Going forward, we expect this rate to go up to around 24% to 25%.

Prakash Agarwal: And what would lead to that change, sir?

Siddharth Mittal: Many of the Biocon facilities are completing 10-year SEZ tax holiday during this year. And also the government is slowly phasing out of 35(2AB) benefit where until last year, all the companies were eligible for 200% weighted deduction, which has been reduced to 150% for FY18. And it's going to be completely phased out on a go-forward basis. So that would definitely impact our tax benefit and accordingly the Effective Tax Rate.

Ashi Anand: The first question I have is with relation to the $200 million of revenues we're looking at Biologics in FY19, how much of this do we expect to come in from the developed markets?

Siddharth Mittal: Will be a very small number. What we have said is this is primarily from the emerging markets. And if at all developed markets, it would be supplies of initial launch quantities to our partner, Mylan.

Ashi Anand: Okay. So in FY19, we're not really expecting large numbers coming in?

Siddharth Mittal: Yes. But we also mentioned that we could have an upside if the regulatory approval starts coming in earlier than expected.

Ashi Anand: So in terms of how we'll be accounting for the revenues from Mylan, given the fact that it's a profit share, are we primarily getting the profit share in the revenue number, so the margins on this would be very high?

Siddharth Mittal: That's right. When we supply to Mylan, we will be recognizing revenue on a cost-plus basis and the profit share will come in after few quarters. Only after Mylan sells, we will know what our profits are. And the profits would be accounted, as you said, in the topline and will flow directly to the bottom-line as well, net of tax.

Ashi Anand: And just lastly, in terms of if you look in the biosimilars in developed market. What kind of price declines do we expect at this point in time? Is it possible to give some kind of indication what kind of pricing declines we expect in these molecules?

Siddharth Mittal: I would say it's too early to comment, and will be dependent on how many players are there at that time of launch. The pricing strategy would be decided by Mylan, very close to the launch.

Harshil Gandhi: My question is EBIT margins have been on a slide for Branded Formulation business for many quarters. In Q4, we have seen an improvement, so will the margin improvement sustain?

Siddharth Mittal: Well, we will obviously endeavor to get the margins higher. For the last fiscal year, the margins have actually not been at par with our expectations and we would look at improving the same as we go into FY18.

Harshil Gandhi: Okay. And sir, what would lead to improvement in margins?

Arun Chandavarkar: Obviously, the biggest improvement in margins will come when our revenues go up, disproportionate to the overhead and selling cost. So that will clearly drive margin improvement going forward. But historically, in the year before, we had already taken steps to improve margins in terms of rationalizing our product portfolio and focusing on sales effectiveness or operational excellence initiatives. So the combination of product portfolio rationalization, which we have done about a year ago and focusing on greater revenues and operational excellence is what's going to drive the margin growth. Clearly, the growth will come predominantly from our anchor products, which are all either the biologics or differentiated or in-licensed molecules.

Nitin Agarwal: Siddharth, on the CAPEX, the 700 crores CAPEX that you mentioned of Biocon, I mean, what would be the major driver for this CAPEX amount, because it seems to be large?

Siddharth Mittal: Well, there are multiple things. First, it includes the capitalization of R&D expenses, which in the last year was around 150 crores. Second, our maintenance CAPEX has been around 100 crores for the last many years, so that will be there. Third would be the commencement of our new Biologics facility in Bangalore. And fourth is the balance CAPEX from the oral solid dosage as well as the second formulation line for Biologics that we had started building last year in Bangalore. And lastly, some of the other additions in Malaysia as a part of our Phase I CAPEX.

Nitin Agarwal: So do you see a tapering off of CAPEX in the outer years or you see, given that way we're looking at things, it will probably stay around these levels for some more time to come?

Siddharth Mittal: It would, I would say, stay at these levels or probably go up a bit because, just from a projects perspective, I would say there are two large CAPEX projects, which are going to be there. One is obviously the new Biologics facility, which will be constructed over a 2 to 3 years period. And second is at the right point in time, we would also trigger the Phase II of Malaysia. So I would say, for the next 4 to 5 years, our CAPEX levels would continue to be high.

Nitin Agarwal: And how do you sort of read that back into our return ratios in terms of ROCE? We still have a fairly subdued return ratio levels with CAPEX being where it is. And how do we look at pickup in the same?

Siddharth Mittal: I would recommend that you look at the ROCE at the segment levels. Small Molecule ROCE is around 25% to 30%, Branded Formulation ROCE is around 60% to 70% while Syngene continues to be around 25% to 30%. So obviously, we have subdued ROCE in the Biologics segment where we have a great opportunity in front of us with significant progress in terms of the clinical filings and all these facilities that we are creating is going to augur the growth that we are looking at beyond 2019 as well.

Biologics ROCE, when you look at, let's say, FY20 and beyond, should definitely look very healthy once we are in the developed markets and have penetrated at the market share that we are targeting, given the advantage we have in terms of being amongst the first three players to launch in these markets.

Harith Ahamed: My question is on Itolizumab. Now looking at the efficacy data you had released at the time of your India launch and comparing it with some of the newer Biologics for psoriasis that have been launched since then by other companies, it seems the newer drugs score higher on the efficacy front. So just wanted to check on your thinking with respect to how you'll position this product, given that the competition in the space has gone up significantly? And you have challenges in terms of licensing this product for partners in the U.S.

Arun Chandavarkar: So just the second question first. The challenge of partnering was not necessarily linked to data. It was linked because this molecule had an origin from Cuba and because of the OFAC approvals needed, it was creating certain hurdles in terms of licensing too. I will say not only in the U.S., because most partners, even if they are a European company or ex U.S. companies, would want U.S. rights. So to that extent, that was what was historically proving to be the bottleneck. But coming to your specific question on psoriasis, as Kiran mentioned, that we are doing further studies in Australia to basically address not just the positioning of the product, but also looking at, for example, dose range finding in terms of also the subcutaneous formulation which will then move to a self-administered way of delivering the drug rather than an IV way of delivering the drug. And of course, there are opportunities for this drug in many other indications. CD6 is a novel target. If you look at all the others, many of the other psoriasis drugs on the market, none of them are towards CD6. Conventionally, they have been TNF- alphas, and the more recent ones are either the IL-17s or IL-23-type, then we have a few IL-6s out there. So this is really a unique positioning in terms of the target. And I would say we have not scratched the surface yet in terms of what this specific CD6 target means in terms of disease modification across different segments, not just psoriasis, but other diseases as well. Kiran wants to add something.

Kiran Mazumdar-Shaw: Yes, I just want you to understand that CD6 is something that we are very advanced in. We are forerunners in this particular target. And I can tell you, if you were to actually follow what is happening in this whole autoimmune space, suddenly, CD6 is something a lot of companies are now looking at. So we believe that we are really ahead of the curve. It is unfortunate that we have had a bit of a credibility challenge because we are an Indian company doing a lot of work in India and because of the Cuban origin of the molecule. But I have no doubt about it that it's a very unique molecule. It has a very interesting profile and mechanism of action, which is now gaining a lot of attention in the U.S. Suddenly, we are seeing a lot of companies now looking at CD6 as a target, and we are right ahead. I am very confident that in the years ahead, this molecule will actually do very well for Biocon. And I'm very confident that when you look at even the data that we have generated in India thus far, no one has matched the remission rates that we have seen in this molecule. It's a matter of concern that, basically, we need to have a much greater engagement with our medical community and research, and that will actually make this molecule be what it deserves to be.

Sameer Baisiwala: Any update on Adalimumab filling both for U.S. and Europe?

Arun Chandavarkar: I think right now we can only say that we are looking at filing that in due course in FY18.

Sameer Baisiwala: Okay. And just one question from the previous speaker. See your European approvals will take 12 to 18 months and that probably takes us to the end of fiscal '18 for all the three products on the outer side. So would fiscal 19 not be a meaningful year for monetization for the three in Europe?

Arun Chandavarkar: Yes. But for that to happen, the markets need to open up in terms of not just the approvals, but also the pricing to get reimbursements. Right now, we are not necessarily baking in any upsides should those markets open up earlier than our current expectations. We're assuming that our $200 million guidance in FY19 is predominantly emerging markets.

Sameer Baisiwala: Fair enough. And just one final, and this is just a general question because we're not too used to that. So once the target action date happens for the U.S. market for the two filling that you have done, what would be the expectation, I mean, that you get approval in the first review cycle or how should we think about it?

Kiran Mazumdar-Shaw: Let's hope we get it in the first review cycle.

Shraddha D'souza: So as you just mentioned about the Phase II of Malaysia plant, just wanted to understand if you could give an approximate idea of the total CAPEX outlook for the Phase II. So would it be similar to the $200 million that we spent on the Phase I? And secondly, is this again going to be insulin-dedicated facility?

Siddharth Mittal: Yes, it's an insulin only facility. While it's too soon to give an exact number, the level of $200 million you mentioned looks reasonable.

Shraddha D'souza: Yes, okay. Because I think we had once mentioned in one of the previous calls that we already taken the land for the plant, so why would it still be as high as the Phase I?

Siddharth Mittal: In Phase I, we invested over $250 million with not only the land, but also on admin and R&D related CAPEX which will not be duplicated. Excluding these, the CAPEX in the drug substance and the drug product facility, will be duplicated in Phase II.

Shraddha Dsouza: Okay. So it's again going to be an insulin facility?

Siddharth Mittal: Yes.

Shraddha Dsouza: Okay. And secondly, I want to understand our outlook on the ANDA filings over the next 2 years and when do we expect it to meaningfully contribute to our sales?

Arun Chandavarkar: I think we will continue to guide for a single-digit approach. And right now, strategically, we are looking at moderating our filings so that we do more and more filings from our own facility, which will be commissioned later in FY18 rather than completely depending on an outsourced model, which currently we are, in the absence of our own facility.

Prakash Agarwal: Just trying to understand the PM's statement of proposing generic-generic for the so-called specialty and from branded generics. And I understand the specialty portfolio is likely to get more hit if that is implemented given higher pricing versus the generic pricing. So any views, comments would be appreciated.

Kiran Mazumdar-Shaw: I think there's a lot of confusion about what this whole generic policy is about. First and foremost, I think there has been a concern that companies have almost been giving the impression that unbranded generic and a branded generic made by the same company are different, which cannot be the case. Now I think, basically, what is being proposed by the government also is very complex because unless you have a very uniform regulatory ecosystem across the country, unless you have the quality of generics all of the same type, you cannot be actually going ahead with a generic policy. Right now there is no clarity on regulatory

harmonization because the DCGI or CDSCO has one set of regulations -- I mean, is approving drugs based on BE/BA studies. The state regulators do not require BE/BA studies. This is untenable. I think doctors themselves are very worried about how do they prescribe a generic drug that has not gone through BE/BA studies versus one that has gone through BE/BA studies. And I think the impression being created is that the branded generics are the ones that have gone through BE/BA studies and the unbranded ones are that haven't gone through, and that is also not true. So I think there is a lot of confusion out there. I think there is going to be a stakeholder consultation. I think this has got nothing to do with specialty or non-specialty. This has really got to do with drug pricing and parity of drug pricing. And therefore, I think all stakeholders, whether they are manufacturers, whether they are prescribers, and whether they are regulators, we all need to be harmonized in what we want to achieve. I completely agree that we need to get better parity amongst the drug pricing because patients should not be suffering from these kind of false understandings and perception. But I think it is a very complex issue, which the government itself is now beginning to realize it's not that simple.

Saurabh Paliwal: Thank you, everybody. Ladies and gentlemen, I will see you again next quarter. Have a wonderful day.

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