Biocon Limited: Q2 FY17 Earnings Call Transcript
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Participants from Biocon's Senior Management Team

- Kiran Mazumdar Shaw: Chairperson and Managing Director
- Arun Chandravarkar: CEO & Jt. Managing Director
- Siddharth Mittal: President, Finance
- Ravi Limaye: President, Marketing
- Narendra Chirmule: Sr. Vice President, R&D
- Shreehas Tambe: Sr. Vice President, Insulins
- Paul Thomas: Vice President, Biosimilars
- Bhavesh Patel: Vice President, Generic Formulations
- Saurabh Paliwal: Head, Investor Relations

Conference Call Participants during Q&A

- Surya Patra, Phillip Capital
- Prakash Agarwal, Axis Capital
- Dheeresh Pathak, Goldman Sachs Asset Management
- Vipul Shah, Sumangal Investments
- Sameer Baisiwala, Morgan Stanley Research
- Nitin Agarwal, IDFC Securities
- Karan Doshi, Subhkam Ventures
- Ujwal Shah, Quest Investment Advisors
- Ranjit Kapadia, Centrum Broking
- Manoj Garg, Bank of America Merrill Lynch
- Charulata Gaidhani, Dalal & Broacha

Presentation Session

Saurabh Paliwal: Good morning everybody. I am Saurabh Paliwal from Biocon Investor Relations and I welcome you to Biocon's earnings call for the second quarter and first half of fiscal 2016-17 which ended on September 30th.

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. The 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 with us the leadership team at Biocon comprising Mrs. Kiran Mazumdar-Shaw – our CMD along with the people from the senior management team.

I would like to take this opportunity to remind everyone about the Safe Harbor regarding today's discussion. Today's statements 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. I would also like to add that today's discussion will be based on the new Ind-AS framework, as adopted by the Company starting this fiscal year. After end of this call if you need any further information or clarifications, please get in touch with us. Now, I would like to hand over the call to Mrs. Kiran Mazumdar-Shaw. Over to you, ma'am.

Kiran Mazumdar-Shaw: Thanks, Saurabh. Good morning everyone and welcome to Biocon's earnings call for the second quarter of fiscal 2017. Let me start by wishing all of you a very happy Diwali for next week. I hope that the year ahead is filled with prosperity for all and now I will start with key business highlights.

- As a part of our global Biosimilar foray, our partner, Mylan filed the Marketing Authorization Application or the MAA for Biosimilar Trastuzumab for the EU markets in Q2, which has been accepted by the European Medicines Agency for review. This is our second biosimilar application accepted for review by EMA, the first being Pegfilgrastim and it is a proud moment for us as this is the first application for Biosimilar Trastuzumab accepted for review in any developed market.

- Earlier this month, we presented data from the pivotal pharmacokinetic and pharmacodynamic or PK-PD (global phase 1) and confirmatory efficacy/safety and immunogenicity studies (global phase 3 study) for our Pegfilgrastim biosimilar candidate at the prestigious European Society of Medical Oncology or ESMO annual congress in Copenhagen, Denmark. The phase 1 study involved a 3-way pivotal PK-PD where our Pegfilgrastim Biosimilar demonstrated clinical equivalence versus both US and EU-sourced reference products. The phase 3 study was conducted in breast cancer patients receiving new adjuvant or adjuvant chemotherapy and was completed earlier this calendar year. The data presented demonstrated clinical equivalence versus the EU-sourced reference product. We are preparing for the US filing for this molecule.

- In continuation to the Trastuzumab Biosimilar phase 3 data from the HERITAGE study which we presented at ASCO earlier this year, 48-week data from the same study was presented at ESMO, as I mentioned earlier the European Society of Medical Oncology which was very well received at the conference. The encouraging clinical progress of our biosimilar programs puts us on track for regulatory filings for some of these advanced molecules in the developed markets of US and Europe in FY17. We continue with expansion of our emerging markets footprint in terms of our biologics business striking licensing deals in many of them. This bodes well for the business in the coming years.

- Our ready-to-use prefilled disposable Insulin Glargine pen that was launched by our partner FUJIFILM Pharma in Japan earlier this quarter, has been very well received by patients and doctors. The device has been appreciated for its ease of use and it certainly augurs extremely well as we move towards filing and later commercializing Insulin Glargine in larger developed markets of EU and US.

- We received our first generics formulations tentative approval for Rosuvastatin Calcium this quarter. Though the product is already heavily genericized with multiple players, it would be our first step towards making a foray in the US generics market with a finished dosage. We

are gearing up to launch this product later this financial year once we receive the final approval from USFDA.

Now coming to key financial highlights for Q2 FY17;

- Consolidated revenue grew 21% from 819 crores to 993 crores.
    - Biocon sales grew 17% from 533 crores to 622 crores while Syngene, the research services business grew 14% from 250 to 286 crores.
    - Small molecule sales were at 389 crores, a growth of 15% which we attribute to higher volumes in statins.
    - Biologics sales were at 96 crores, a growth of 26% which we attribute to increased sales in emerging markets of many of our biosimilar molecules.
    - Branded formulation sales were at 137 crores, a growth of 15% as compared to last year. However, on a like-to-like basis, branded formulation sales were disappointing and showed decline.
    - We also booked licensing income of 33 crores in Biocon in Q2, largely attributable to licensing of biosimilars in some emerging markets.
- Total R&D spends were 113 crores, of which 65 crores is reported in the P&L while 48 crores has been capitalized on account of Trastuzumab and Glargine development related expenses for the developed markets.
- Consolidated EBITDA was 278 crores, reflecting a growth of 45% with EBITDA margins at 28%. Gross margin improvement this quarter was aided by a good product mix.
- Consolidated Net Profit before exceptional items was 147 crores for the quarter, reflecting a growth of 51% compared to FY16 the same quarter. Net profit margins stood at 15%.

Now discussing the business on a segmental basis -

I would like to start with **Small Molecules** which saw good traction this quarter with increased sales of statins led by Rosuvastatin supplies to key customers targeting the US market. However, this trend can be lumpy based on the pricing of the end products in the respective markets. We continue to work towards bringing newer API products to the market and benefit from them in the future.

Now coming to **Biologics**, our current portfolio products which include Recombinant Human Insulin, Insulin Glargine and Trastuzumab which we sell in emerging markets showed good growth this quarter attributable to increased sales of Trastuzumab. In the coming quarters, we expect to receive more approvals for our products in various markets which should help us deliver strong growth for this segment.

Branded Formulations had performance below par this quarter on a like-to-like basis. This was reflected both in India as well as in our UAE business. There are many reasons ascribed to this poor performance. Firstly, we will no longer be offering Abraxane®, an in-licensed oncology product for sale

due to a decision taken by the licensor to discontinue supply. This impacted both markets in India as well as in UAE and we have estimated the annualized impact of this discontinuation is approximately 75 crores. Secondly, there was impact on our government institution business due to facing issues in tender timelines both in India and in the UAE resulting in lower than expected sales this quarter. Lastly, we were also impacted by drug price control or drug price reduction mandated by DPCO, NPPA on certain drugs.

Suresh Subramanian has recently come on board as head of our India Branded Formulations business. Suresh with over 30 years of experience in the pharmaceuticals industry has a proven track record of delivering robust business growth and will provide the much needed credible leadership that this division lacked until now. This we believe will address various challenges that the BFI segment has witnessed in the last few quarters and we are confident that it will put us back on sustainable growth.

The outlook for the segment for the remainder of this financial year is cautious given the challenges the business has seen in Q2; however, we remain optimistic to achieve our FY19 guidance of 1000 crores which will be driven by visibility we have on new in-licensing opportunities. We also expect a number of new product launches both in India and UAE and we also expect to expand into other geographical markets.

Our **Research Services segment, Syngene** continues to deliver strong and steady growth while maintaining its profitability. During the quarter, Syngene commissioned its fourth dedicated state-of-the-art R&D center exclusively for Amgen with over 100 highly qualified Syngene scientists engaged in several Amgen projects. It also acquired the bioinformatics platforms of Bengaluru-based Strand Life Sciences to complement its existing integrated services platform and also meet its customers' growing needs for bioinformatics and data analytic support.

So in summary, I would like to conclude by saying that in the first half of FY17, Biocon has delivered a strong operational performance. With our two biosimilar filings accepted and under review in the EU and other planned filings for our other advanced biosimilar candidates, we are on track for filings later this fiscal year both in the US and Europe. We should continue to build upon our performance seen thus far as we move into the second half of this financial year. I would now like to open the floor for question and answers. Thank you.

Q&A Session

Surya Patra: Just in the opening remarks what you mentioned about the Abraxane® discontinuation of the licensing arrangement, so what was the reason for that ma'am and I think that was one of the important asset for us in the oncology portfolio which was a much profitable product also and this 75 crores kind of annualized impact on the revenue that we have indicated whether the current quarter number is already reflecting that or what is the kind of outlook that full year Branded Formulation business that we are currently having, can you just..

Arun Chandavarkar: This is Arun responding to your question. In terms of the Abraxane as you know, it is an in-licensed product from Abraxis BioSciences and subsequently Abraxis got taken over by Celgene. So clearly Celgene has taken a strategic call to in terms of discontinuing supplies of Abraxane® and as a consequence since we were just an in-licensee, we would no longer be able to offer Abraxane® in our markets. It is a decision taken by Celgene in terms of their business analysis.

In terms of the impact, yes, the impact is already reflected in Q2 and the full year impact will continue. Kiran mentioned in her opening remarks that on an annualized basis, the impact could be 70-75 crores in terms of the topline which she mentioned that we would over the next few quarters try and make up for through other opportunities. But in this current financial year, yes, there would be some impact which is why we have given a cautious guidance for this year, but in terms of the long-term guidance, we continue to maintain that.

Surya Patra: And sequentially or even continuously for some time we have been seeing, though there is a growth in the topline on the Branded Formulation, but the profitability growth is not there, the margins are challenged. So that will continue in the subsequent quarters I think.

Arun Chandavarkar: I think last year we had alluded to the efforts we were undertaking to rationalize our product portfolio and focus on many of our either core biologics kind of products or core in-licensed products which definitely have a higher margin than some of the more commoditized products in our portfolio. So that rationalization is now behind us. The impact you see currently is largely on account of 3 things which Kiran mentioned in her opening remarks. One is of course the discontinuance of Abraxane® which was clearly one of our core and profitable products. The second impact has been more the fact that there has been a phasing of some of the institutional business where we continue to incur the overhead, but the commensurate revenue has not triggered. It is more a deferment rather than a loss in some cases and lastly, of course there has been some minimal impact due to lowering of prices for products that are under the price control. So all three have to some extent impacted our profitability this quarter, but as we continue to grow our Biologics businesses and core brands, as we continue to both expand access as well as product portfolios through internal products as well as in-licensed products, we do hope to restore profitability because certainly under cost side, we are very cautious in terms of costs and so we have not greatly added any numbers to the head count for example.

Surya Patra: And if you can just update us about the biosimilar molecules that we have already filed, you have already indicated that what progress that so far we have seen as Trastuzumab and Pegfilgrastim is concerned after filing with the European regulators, but what are the milestones that those are likely before the approval of the product and any clarity that we are currently having for the approval of the product sir?

Arun Chandavarkar: When you say milestones, I am not very clear, are you talking about financial milestones or progress milestones?

Surya Patra: No, about the progress of the molecule means what are the key things that we may hear before getting a final approval of those products by those regulators or before the real actual commercialization of the product?

Arun Chandavarkar: As you know, we filed our Trastuzumab and Pegfilgrastim and these filings have been accepted for review. Clearly as the review process progresses with EMA, there could be having certain set of queries which we would address as and when we receive them. Clearly, this would also trigger cGMP inspection of the manufacturing facilities at some point in time. So it is basically awaiting queries or responses to those queries and awaiting cGMP inspection and cGMP clearance of our manufacturing facility. Looking at the data we have generated and submitted and looking at the track record on cGMP compliances, we are fairly confident on both fronts.

Surya Patra: It is the Malaysia plant where the inspection if it happens, then that will be there, right sir?

Arun Chandavarkar: Trastuzumab and PEG-GCSF are both out of our Bangalore facilities.

Surya Patra: And regards the Malaysia plant, how many countries that so far have approved Malaysia plant for launch of the insulin products and any more clarity about the commercialization of this unit in the near future?

Arun Chandavarkar: In terms of the Malaysia facility, we have received local approvals in Malaysia for our product manufactured in Malaysia and we hope to commercialize these products by the end of this calendar year in Malaysia. We have of course in parallel have filed for approval outside of Malaysia, in the emerging markets and as and when we receive approvals there, we would commence sale of products.

Surya Patra: So this is Malaysia only?

Arun Chandavarkar: At the moment yes, but we have also filed for approvals in other emerging markets.

Surya Patra: Okay, just last one question sir. So what is the margin trajectory over next 2 years that we are anticipating considering the fact that our biosimilar progress that we would be seeing in the addressed market, this Malaysia plant commissioning might happen and there is a progress also that we have seen in the small molecule front. So considering all this aspect, what is the margin trajectory one should expect for Biocon?

Siddharth Mittal: Surya, as you know we do not give margin guidance, but qualitatively what we have said is that the core operating margins would remain at the same levels over the next two years and as we launch our products in the developed markets, they should improve. The core operating margins would be defined as the reported margins adjusted for R&D expenses, licensing income, other income and the expenses that we will have from our Malaysian facility.

Prakash Agarwal: Question on the update on other molecules Glargine and Itolizumab. So we are on track to file both in Europe and US in this financial year?

Arun Chandavarkar: I think you are mixing up two molecules, nevertheless I will answer the question. Glargine as you know comes under our generic biologics category where Itolizumab is a novel monoclonal antibody.

Prakash Agarwal: Adalimumab, not Itolizumab.

Arun Chandavarkar: So in terms of the current guidance, we continue to maintain that we are on track for filing these molecules inside the developed markets this fiscal.

Prakash Agarwal: And secondly on the licensing income, we have seen some good traction here. So what I understand is these are entry into newer markets and going forward, this will culminate into revenues in the biologics front. Is that right understanding?

Arun Chandavarkar: That is correct.

Prakash Agarwal: And this licensing income as you progress with more markets, this we can see an incremental momentum or this is likely to remain at these levels?

Arun Chandavarkar: Licensing, I think historically we have mentioned fluctuates quite a bit because licensing will not be like a recurring income. Once you license a molecule in a country, that licensing opportunity has been extinguished. So it is only some other molecules that get licensed for some other countries. So licensing is not going to be like perpetual income generating opportunity, it is there for a limited time as market entry. But what we certainly depend on as a sustainable opportunity is revenue from product sales which will be an outcome of these licensing. Therefore the licensing triggers should be viewed not so much in terms of the amount of licensing income, but as opportunities that are opening up for Biocon in terms of market penetration with this portfolio.

Prakash Agarwal: Understood and currently these are coming from the licensing of Trastuzumab and Glargine if I am not wrong?

Arun Chandavarkar: It is licensing of a biosimilars portfolio but also of course there is a small element of licensing related to small molecules as well, but predominantly it is our biosimilars portfolio.

Prakash Agarwal: Okay understood and sir the CAPEX plan since you mentioned last quarter you already starting the small molecule formulation facility and then there was a talk of another MAb facility. So what is the CAPEX plan for this year and next year sir?

Siddharth Mittal: The work on the small molecule facility started last year and it is on track. We should commence operations in the next year though not the commercial operations. We will start the exhibit batches and various other operating qualification activities. In terms of the new MAb facility, this is under works and we should be in a position to give more details hopefully by next quarter.

Prakash Agarwal: But any number you can give for CAPEX, we should build in our model for this year or next year?

Siddharth Mittal: Well, at a very high level we have given an estimate of around $150 million though what we have not communicated is how much of the capex is funded by us versus Mylan.

Prakash Agarwal: And this is over two years?

Arun Chandavarkar: 2-3 years.

Prakash Agarwal: Okay and there will be Mylan contribution obviously because of the partnership?

Arun Chandavarkar: Yes.

Prakash Agarwal: Understood and lastly on the R&D front, so we have seen uptake Q-on-Q and I think in the last commentary there was a mention that it is going to be higher given extra study is still on and the filing cost will be there. So we are on track with the 12% kind of guidance that we had given?

Arun Chandavarkar: Yes.

Dheeresh Pathak: The Abraxane® impact was there for the full 3 months for this quarter?

Arun Chandavarkar: Yes.

Dheeresh Pathak: Also you talked about two other reasons for the impact, one was government institutional business and one was price control. So can you just quantify that what percentage of revenue in branded formulations come from government institutions and how much is under price control now?

Ravi Limaye: Basically a large chunk of it was in Middle East. This is the Sheikh Khalifa fund. So that was significant. I would not give you the percentage, but it was quite significant.

Dheeresh Pathak: Okay, but on an annual basis like what percentage of…

Ravi Limaye: As was mentioned in the opening remarks, this is a deferment. We believe that this will come in the second half.

Dheeresh Pathak: Okay, but I just wanted not just specific to this quarter, I just wanted a sense like on an annual basis if you are doing…

Ravi Limaye: It is significant and you cannot put a number to the government tenders because it is also lumpy.

Dheeresh Pathak: And what percentage of the branded formulation business is under price control now?

Ravi Limaye: Based on FY16 sales, it is over 30%.

Dheeresh Pathak: Okay and in the comments I think it was mentioned that like-to-like it was a decline but reported numbers are about 14% growth, so what will be, when you said like-to-like decline what was…

Siddharth Mittal: Dheeresh, if you look at the Indian GAAP numbers, last year we had reported revenues of ~160 crores against this years of 137 crores reflecting a decline of 14%. Because of Ind-AS, the reported numbers last year was adjusted to ~120 crores while the current quarter remains same at 137. That is why the reported number shows a growth of 15%. The Ind-AS adjustment is because of de-consolidation of our NeoBiocon JV in UAE.

Vipul Shah: Can you give what is the total CAPEX incurred for Malaysian facilities till date and when will the commercial production start and what type of revenue annually we can generate when it is operational?

Siddharth Mittal: Well, the total CAPEX is roughly $250 million which includes the plant cost as well as the validation cost. We expect the commercialization to start latter part of this fiscal year and at this stage, we cannot give any revenue guidance from this facility.

Vipul Shah: Can you give any capacity guidance, what sort of capacity we have created?

Siddharth Mittal: We do not disclose our capacity; however, what we have said is this facility is significantly larger than our Bangalore Insulins facility.

Vipul Shah: So 250 million is what we have incurred till date, if I have understood correctly?

Siddharth Mittal: Yes.

Vipul Shah: Sir any update on oral Insulin?

Kiran Mazumdar-Shaw: Yes, maybe I will just make a mention that we have actually decided to conduct a Type 2 diabetes study, we have had a meeting with the investigators who will be conducting the study. It is something that will start next fiscal. We also have a proposal to do a Type 1 diabetes study which has been accepted by an organization called JDRF which also gives us confidence that there is lot of interest in this molecule.

Sameer Baisiwala: Last concall, you mentioned that you were expecting the approval for Copaxone 20 mg by the end of this fiscal, can you update us on that?

Arun Chandavarkar: Sameer, as you know that we got into the whole Glatiramer Acetate business because it offers use of our strong R&D capabilities and you have seen the kind of complexities around the approval. It is very hard for us to give you an exact timeline in terms of when the approvals come. You have seen how long it has taken for the other companies in terms of approvals, it is very difficult for me to commit to any kind of a timeline. Suffice to say that as and when we receive queries from the FDA, we would be in a position to respond to them.

Sameer Baisiwala: Are there any pending queries right now?

Arun Chandavarkar: Yes, we need to respond to some queries as such.

Sameer Baisiwala: Does it mean that you would no longer expect the approval by the end of this fiscal?

Arun Chandavarkar: We cannot give you any guidance is all we are saying.

Sameer Baisiwala: No, you had said that last call.

Arun Chandavarkar: Yes, I don't want to commit to any timeline at this stage because we really have to wait and see how long it will take for the FDA review process to complete.

Sameer Baisiwala: Just separately on the 40 mg, the recent favorable ruling by PTAB on 3 patents. Do you think it will have an implication for the underlying court case in the district courts?

Arun Chandavarkar: I would not want to comment specifically on the IP situation. For us, what we believe is that our initial focus is to make sure that we get the 20 mg approval because that means all the technical aspects would be behind us and I think by the time we get into the cycle for the 40 mg, we would have lot more clarity in terms of the IP situation as well. Lot of the IP situation we will also

end up to some extent, piggybacking on what all the other companies are also doing because the issues are the same across all of those applicants. I do not think there are issues specific to Biocon or specific to a company, we have common issues across us.

Sameer Baisiwala: When you say IP issues, you are referring to the court case or you are referring to the FDA review?

Arun Chandavarkar: I am referring to the court.

Sameer Baisiwala: Is the understanding correct that once you get the approval for 20 mg, then the hurdle to get the approval for 40 mg, this is FDA action, would be a lot simpler or lot easier?

Arun Chandavarkar: That is our expectation since the API is the same.

Sameer Baisiwala: And separately on the 2 filings that you have done so far Biologics in Europe, is the data requirement or the dosage requirement between US and Europe significantly different and given that for those to that you already done in Europe, I think in July and August, you still haven't done for the US. So would Europe always be ahead of US?

Arun Chandavarkar: Well to answer your last question to the first if not always necessary that Europe is ahead of the US, but except that to say that to answer your first question, yes the data requirements and expectations do tend to be different and this difference goes beyond just the use of the reference product. So basically how much time it takes us to gather the data for requirements for each jurisdiction really impacts the filing date, but however for both the filings that we have done to date in Europe, we continue to maintain that we would file these products in the US during this fiscal.

Sameer Baisiwala: Just one more question with your permission, for the Biologics revenues this quarter which is about 96 crores, it is a fair bit low if I compare with the preceding 2 quarters which were over 121 crores, 125 crores each in Q4 and then Q1. So anything specific about this quarter or this would remain a little lumpy?

Arun Chandavarkar: I think if we look at some of these revenues, as I think Ravi mentioned in some of the earlier comments, some of this is also gets linked into institutional businesses, global opportunities, but there is some degree of lumpiness in that. It is a phasing issue but if you look at it from a half year to half year perspective or at the end of this fiscal if you look at it from a full year to full year perspective, we are confident of seeing a significant double digit growth.

Siddharth Mittal: Sameer, I would just like to add one more thing. In the first quarter even though the numbers reported were 123 on a like-to-like basis, it was 107 because we had a one-time benefit of 16 crores coming from the 4th quarter on account of the cut-off because of the transition to the new accounting standards.

Nitin Agarwal: On the domestic business, what was our sales for the domestic businesses this quarter on a Y-o-Y basis and what kind of growth it had in the quarter?

Siddharth Mittal: This quarter revenues were 137 crores and last year same quarter was 120 crores.

Nitin Agarwal: So that is across UAE as well as the India businesses, can you share data just on India part of the business?

Siddharth Mittal: This is UAE as well as India. We have not broken up India and UAE.

Nitin Agarwal: Secondly, on start you mentioned that $150 million would be the CAPEX spend for the MAbs plant, but in general what will be the consolidated CAPEX spend you are looking at for the next couple of years, this year and next year?

Siddharth Mittal: Well, I will give you overall CAPEX guidance. At the India level, we typically have maintenance CAPEX of ~100 crores a year. Apart from this, there are 3 projects which are under works. The first is the insulin formulation line of which a large part of CAPEX is already behind us and we expect 40 to 50 crores in the coming quarters. Second is the oral solid dosage facility with CAPEX of 150-160 crores of which approximately half of cash has already been spent and the remaining half should come in the next one year or so. Lastly there will be the new MAbs facility with CAPEX of ~$150 million. These numbers do not include the capitalization of R&D expenses and the Syngene CAPEX, which itself will be significant in the next couple of years.

Nitin Agarwal: So, our CAPEX spends have been about 800 to about 1000 crores over the last 3 years, right, on a consol basis, so do we see a material change in the CAPEX numbers as we go forward?

Siddharth Mittal: I would say that we will continue to invest at least that much given that the MAbs facility would be a large one and also Syngene would be investing $200 million over the next 2 to 3 years, as per the guidance provided by them.

Nitin Agarwal: So I guess from a free cash perspective, we continue to be free cash negative for some time I guess right, to the time the big scale-up in the regulated markets begin to happen for us?

Siddharth Mittal: Correct. If you look at the cash balance as of September, the net debt was ~250 crores at the group level. However, we do have gross cash of almost 2300 crores on our balance sheet.

Nitin Agarwal: Secondly on the Biologics business, at the run rate about 100 odd crores that we have for the quarter, prior to the approvals in the regulated markets, where do you see, what kind of growth do we see in these numbers or it is going to be largely a function of the kind of scale which happens in the regulated markets?

Siddharth Mittal: Well, as Arun mentioned sometime back, 100 crores is not really a run rate. We do expect double digit growth and expect this even without the developed market approvals.

Karan Doshi: Sir, what would be your R&D expense for FY17?

Siddharth Mittal: Well, at a gross level we have given a guidance of around 450-500 crores and in the P&L, year-to-date has been 117 crores, we would expect this number to be closer to 300-350 crores.

Karan Doshi: So around 150 crores would be capitalized?

Siddharth Mittal: Yes.

Karan Doshi: Sir, when we talk about core R&D margins of 25% and 26%, can you please repeat what are we including and excluding in it?

Siddharth Mittal: Reported profits adjusted for R&D expenses, licensing income and other income to the extent these are one time in nature and the expenses relating to the Malaysian facility which are currently being capitalized.

Karan Doshi: Sir at operating level, can we expect once if we include R&D and everything, expenditure and Malaysia expenses also going forward, around 22% kind of a margin, around 300 basis points hit?

Siddharth Mittal: We cannot provide this specific guidance but you can look at the core operating margins guidance that was given in terms of maintaining core operating margins. We have also given guidance for the R&D expenses to be ~10-12% of our revenues ex-Syngene. Licensing income was would continue to be lumpy and that could also impact. So for H1, our operating margins were 22%.

Karan Doshi: Sir when we talk about Malaysian facility becoming commercialized by this year end, we are talking from a local market perspective so when can we see it coming on our P&L, our depreciation and everything?

Siddharth Mittal: We will be in a better position to give guidance on when the depreciation would start and what kind of expenses would be there in the next quarter.

Ujwal Shah: Sir, I just wanted to get some clarity about our existing Bangalore MAbs facility, does it have enough capacity to cater to both developed markets and emerging markets and what the timing of the new MAbs facility coincide with the approvals that we are expecting from the MAbs, from the developed markets?

Arun Chandavarkar: Our existing MAbs facility in Bangalore is adequate to cater to our near-term needs. As we gain market share in developed markets, clearly we need to trigger expansion of our MAbs manufacturing facility and that is what I think my colleague, Siddharth, was referring to when he was talking about the future CAPEX requirements.

Ujwal Shah: Secondly in terms of our Rosuvastatin approvals, with so many players already in the market and it is being highly competitive scenario being there, what kind of an opportunity do we see for this product from the developed markets?

Arun Chandavarkar: As Kiran mentioned in her opening remarks, this will be our first ANDA launch in the US once we receive the final approval from the FDA. From a commercial perspective, this is also a vertically integrated opportunity where of course we manufacture the API as well as have the dossier. So from that perspective, we do expect to be competitive. Clearly we are looking at this as the opportunity to get into the market and as we add additional products to this portfolio, the size of this opportunity and business and the nature of this opportunity and business would change. At this point it is just one product, so I would say it would be misleading to talk of the margin contribution from a product because clearly the overheads are loaded on to just one product.

Jayesh Parekh: My question was on timeline for FDA review and Europe Medical Agency, I think you have answered that question, only point if you can clarify, what is the past record of USFDA and Europe Medical Agency for giving such approval in terms of timeline, if you had done any study on these of other companies?

Arun Chandavarkar: I think we have in the past mentioned that our expectations of EMA timeline are anywhere from 12 to 18 months and in the US, it is tough to predict the timeline because in the US the regulatory approval is also interlinked with the IP whereas that is not so in Europe. So in US, it is very hard to give a timeline for that kind of a review and approval, we might just have to go by the couple of precedents that exist on other molecules and that is just, it is too hard to extrapolate from that because there are not enough data points but in Europe the expectation is that it will be somewhere between 12 to 18 months.

Ranjit Kapadia: My question relates to Glargine Insulin pen, what is the competitive scenario in Japan as well as the other regulated markets if you can highlight and who are the major players?

Kiran Mazumdar-Shaw: The major players are Sanofi, Eli Lilly and FUJIFILM Pharma - our partners in Japan. Our device has been very well received**,** FUJIFILM Pharma is very pleased with performance of the device, it has been well accepted by both patients and doctors and they are very optimistic about garnering good market share.

Ranjit Kapadia: What is the timeline for the other regulated markets when you are likely to enter the regulated market of US and Europe?

Arun Chandavarkar: I think we have guided for filing for approval later this fiscal and approval timelines depend on the review timelines. For Europe, I have mentioned that the expectation is that the review timelines will be 12 to 18 months post filing. In the US, it would be a filing through the 505(b)(2) pathway. At this point in time, we do not want to give a specific response in terms of approval timelines there.

Manoj Garg: I would like to understand 2 things Siddharth, one is like you indicated in the BIOMAb facility, so obviously Mylan will also be a contributor, had they also contributed for this Insulin facility in Malaysia?

Siddharth Mittal: Yes, a small portion of that facility because that facility was triggered even before Mylan had come in when we had partnered with Pfizer.

Manoj Garg: Okay and this $250 million is a combined investment or it is only a part of Biocon?

Siddharth Mittal: It is combined investment.

Manoj Garg: The second question Siddharth, you indicated about BIOMAb facility which may take 2 years from now and assuming that it may take another 1 or 2 years for regulatory authorities to come and inspect the facility, so do we think that for next 3-4 years' kind of requirement even expecting European launch somewhere in fiscal year 2018, our existing facility would be good enough to cater that kind of requirement?

Siddharth Mittal: That is what we anticipate basis the volume uptake that we are expecting. However, if we have an upside since we will be amongst the first to file in EU as well as the US for Trastuzumab and we get better than expected market share, then we might have capacity issues.

Manoj Garg: And this question is for you Kiran - When you look at in the US market, clearly the two of other biosimilar guys or bioinsulin guys are basically pursuing the pen device while we are the one who have both pen as well as vial. How do you see trends going forward over the next 3 to 5 years, do you think that entire market will shift towards pen and vial will be miniscule and what is the incentive for us to go for vial as well?

Kiran Mazumdar-Shaw: As you know, we have all presentations. We will look at various markets and look at where we can play in both these presentations. I do not think Biocon is in troubled spot, I think we are very well positioned to take advantage of markets in any shape or form.

Manoj Garg: And the last question from my side. When you reporting this Biologics sales, is it only for outside India or even India sales also included as a part of Biologics sales?

Siddharth Mittal: Only outside India. The India sales are included under Branded Formulations.

Charulata Gaidhani: I wanted to check about Rosuvastatin, have you launched the product in EU?

Arun Chandavarkar: No, we have not yet launched the product.

Charulata Gaidhani: Okay, you plan to launch it soon?

Arun Chandavarkar: We plan to launch it when more the western markets of EU open up, they are still under patent.

Charulata Gaidhani: So that would be to 3 quarters from now?

Arun Chandavarkar: I think it is end of next calendar.

Charulata Gaidhani: Okay and regarding the other comprehensive income in the accounts, can you elaborate on what it pertains to?

Siddharth Mittal: The other comprehensive income is on account of transition from the old accounting standards to the new accounting standards. As per the new accounting standards, there are certain transactions which are not routed through the P&L during the interim period and these adjustments tend to be typically on account of the mark-to-market gains or losses on hedges. These are routed through the OCI and are accounted in the P&L only upon actual settlement of the underlying transaction.

Charulata Gaidhani: And there was a remark regarding deconsolidation of NeoBiocon JV, what is this pertaining to and how much is the impact?

Siddharth Mittal: Under the old accounting standards, we used to consolidate the revenues of NeoBiocon. However as per the new accounting standards, we cannot consolidate revenues from that JV since we hold 49% stake in that entity. This impacts the earlier reported number of ~160 crores in

Q2FY16 for Branded Formulations. We had to reduce the earlier reported number by ~40 crores as part of the restatement of our financials under the new accounting standards.

Charulata Gaidhani: Okay and this is included in the share of profit, right?

Siddharth Mittal: Yes, it comes as single line consolidation of profits.

Prakash Agarwal: Just trying to understand the comment you made on Europe starting to give revenue for the filing that you are doing now in next 12 to 18 months, so practically fiscal 2019 this will be largely somewhat baked in our guidance right, of $200 million?

Arun Chandavarkar: Yes, a part of it.

Prakash Agarwal: And this we should read a billion dollar guidance of fiscal 2019 at Rs.60 to a dollar?

Siddharth Mittal: Well, the dollar revenue will obviously get readjusted. However the rupee revenue, I mean if you look at our last fiscal year, ~45% of Biocon ex-Syngene revenues were rupee denominated and 55 were exports. The dollar revenues would get readjusted to whatever the exchange rate is in that year and rupees will get some benefit, I would not necessarily said there will be no benefit of rupee but 60 should be a fair number as of now.

Prakash Agarwal: So we are looking at a $1 billion at 60 for fiscal 2019 and that implies a very good 45%-50% kind of growth on the biologics segment itself from this space?

Siddharth Mittal: Yes and I would like to clarify one more thing in previous questions regarding the European launch. Even though the timeline that we have indicated of 12 to 18 months is for the centralized approval from EMA, we need to get pricing approvals from each country subsequent to the EMA approval. Therefore it will not be a next day launch in Europe. The $200 million guidance as Arun mentioned factors early launches in Europe given the timing difference between EMA approval and commercial launch in various EU countries.

Arun Chandavarkar: As I mentioned, it is not the full thing but it does include part of it.

Prakash Agarwal: No, sure it will be a part of it.

Arun Chandavarkar: Largely because the approval does not mean launch because after approval you have to get country by country pricing.

Prakash Agarwal: Which is another 6-9 months phenomena right?

Arun Chandavarkar: Yes may be.

Siddharth Mittal: Some might be faster, some might take more time to negotiate.

Prakash Agarwal: Understood and is there any update on your other molecules like Lispro and Aspart, where are they in terms of expectation of entering clinics?

Arun Chandavarkar: They are on track. So we will initiate clinical trials for them in sometime, so they are on track in terms of our next wave of generic insulins. But at this stage, I think our focus is clearly on getting the Glargine approval**.**

Prakash Agarwal: Understood and lastly on if am seeing this fact sheet here, I am just trying to understand Biologics, Branded Formulations you have made us understood on the UAE piece. Biologics if I see the India GAAP numbers, there is a growth of 9% and if I remove this 12 crores on a base of last year, we see a growth of 26%, so what is really the change of this 12 crores Q2 fiscal 2016?

Siddharth Mittal: Reversal of revenue amounting to 12 crores in Q2 of last year because of difference in timing of revenue cut-off between I-GAAP versus Ind-AS. Thus is just a timing difference, so when you look at Q3 FY2016, that 12 crores would be added back.

Prakash Agarwal: So for the simplicity sake in terms of tracking, we should track I-GAAP in revenues or Ind-AS as per you?

Siddharth Mittal: Well Ind-AS should be the better one but if you want to compare performance on a like-to-like basis this year, you can track I-GAAP as well.

Prakash Agarwal: Yes, because that is what you said last quarter, that India GAAP is better like-to-like comparisons.

Kiran Mazumdar-Shaw: For this year but we want to transition to Ind-AS as soon as possible because it becomes very confusing afterwards.

Siddharth Mittal: And this year for all the quarters and for the full year these adjustments will be there. In some quarters, the impact might be positive while in some quarters it might be negative. To compare performance on a like-to-like to basis, I-GAAP is fine but as we move to next year, we will obviously be reporting only Ind-AS numbers and all our commentary will be linked to it.

Arun Chandavarkar: And just to add to what Siddharth mentioned, I think in a different context in response to an earlier query, I mentioned that typically our performance should be viewed more on an annualized basis not just because of the accounting issues but also because of the tenders, the lumpiness and all, the nature of our business is like that. So really if we look at our core performance, we prefer to look it as half year and then full year sort of a performance because there will always be variance not just because of the cut-off but also because of the nature of the business.

Prakash Agarwal: Understood, fair enough and lastly on the CAPEX when I asked it was about $150 million for the MAbs and somebody repeated saying $250 million, what is the right number for the MAbs?

Siddharth Mittal: $250 million was for CAPEX done in Malaysia and $150 million was for the MAbs.

Moderator: Thank you. That was the last question. I now hand the floor over to Mr. Saurabh Paliwal for his closing comments, over to you.

Saurabh Paliwal: Thank you everybody for joining us today. If you still have any unanswered queries, please feel free to get in touch. Wish you all a very Happy Diwali and we will now conclude this call. Have a good day.

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