Biocon Limited's Q1 FY15 Earnings Conference Call
July 25, 2014

Key Participants from Biocon Group's Senior Management Team

- Kiran Mazumdar Shaw: Chairperson and Managing Director
- John Shaw: Vice Chairman
- Arun Chandavarkar: Chief Executive Officer & Jt. Managing Director
- Siddharth Mittal: President, Finance
- Abhijit Barve: President, R&D
- Ravi Limaye: President, Marketing
- Peter Bains: Director, Syngene International
- M.B. Chinappa: President, Finance, Syngene International
- Manoj Nerurkar: Chief Operating Officer, Syngene International
- Saurabh Paliwal: Head, Investor Relations

Presentation Session

Moderator: Ladies and gentlemen, good day and welcome to Biocon Limited Q1FY15 Earnings Conference Call. As a reminder for the duration of this conference, all participants' lines will be in the listen-only mode. There will be an opportunity to ask questions at the end of today's presentation. Should you need assistance during this conference, please signal the operator by pressing '*' and then '0' on your touchtone phone. Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Saurabh Paliwal of Biocon Limited. Thank you.

Saurabh Paliwal: Thank you. Good afternoon everybody, and welcome to Biocon's earnings call for Q1 FY15. I am Saurabh Paliwal from the Investor Relations team. We had released our results last night and the same are available on our website. To discuss the business performance and the outlook for the Company, today we have with us Ms. Kiran Mazumdar-Shaw, Biocon's Chairperson and Managing Director and our colleagues from the senior management team.

Before we proceed with the call, I would like to remind everyone that this call is being recorded and a replay will be available for the next few days. The call transcript shall be available on our website soon. I would like to add that today's discussion may be forward-looking in nature and must be viewed in conjunction with the risks that our business faces. The safe-harbor contained in our press release also pertains to this conference call. After the end of this call, please feel free to get in touch with the investor relations team with any additional queries that you may have. Now I would like to turn the call over to Ms. Kiran Mazumdar.

Kiran Mazumdar-Shaw: Thank you, Saurabh. Good Afternoon Everyone. I welcome you to Biocon's Earnings Call for the First Quarter of Fiscal 2015 ended 30th June 2014. Let me begin with our key Financial Highlights for the Quarter.

- Group sales were at Rs.719 crore.

- The Biopharmaceutical sales were Rs.547 crore vs. Rs.540 crore last year. Within this segment, Biopharma sales were flat at Rs.436 crore and Branded Formulations sales grew 10% to Rs.111 crore.
- The Research Services segment registered a growth of 12%, delivering Rs.172 crore.
- At the group EBITDA level, we posted Rs.191 crore, which is a growth of 9%. EBITDA margins were very healthy at 26% for the quarter.
- We had a net FOREX gain of Rs.1 crore this quarter.
- Group net profit for the quarter was at Rs.103 crore, PAT margins stood at 14%, and PAT growth has been close to 10% this quarter on a year-on-year basis.
- Long-term borrowing for the group at the end of Q1 FY15 stood at Rs.704 crore, coming from drawdowns made for the construction of our Malaysia facility.

The subdued revenue growth in Biopharma this quarter is partly attributable to the political turbulence in the MENA region which has impacted some of our business. We believe this is a temporary phasing issue and the underlying demand continues to be strong. We hope that stability in the region will restore business momentum and the performance should improve in the second half of this fiscal. Regardless, we will also recalibrate our business in other geographic regions to compensate for any unpredictable variability coming from this region.

Moving on to discuss Individual Verticals: As communicated previously, we continue with our portfolio optimization initiative in the **Small Molecules** vertical with a clear bottom line focus. Our Statins business has been stable while Immunosuppressant and Specialty API manufacturing continues to provide upsides to the business. We have begun our foray into the U.S. generic space, with the filing of our first set of ANDAs this quarter. On the specialized API front, we were impacted by reduced off take from one of our clients due to an ongoing re-launch and repositioning of the end product by the client. We expect the off take to normalize next fiscal, once the client's product regain sustained growth momentum.

Now coming to the **Biosimilars** vertical, our Malaysia project remains on track, and we expect the plant to be commissioned as per plan, in the second half of FY15. We will then commence filing for regulatory approvals for the Malaysia facility in various countries. The Insulins opportunity and demand continues to be robust, and we are continuously working to debottleneck our current operations in Bengaluru, to extract maximum efficiencies from our current capacities until Malaysia gets approved. On the development front in Monoclonal Antibodies and Recombinant Proteins, our partnered programs continue to progress, and we expect to have additional programs enter clinical trials this fiscal.

On to the **Branded Formulations** vertical– Biocon continues to be a focused, specialty product company in chronic therapy areas with a significant contribution from biologics and complex molecules. We believe we have overcome the market turbulence of last fiscal and expect the growth momentum to pick up in the remaining quarters of this year. I would like to mention here that although on a YoY basis we have demonstrated 10% growth in Branded Formulations, we have grown 19% sequentially this quarter as compared to Q4 FY14, which also signals the recovery and growth momentum that this segment is gaining. We effected a reorganization in the Branded Formulations

vertical over the past few months. The reorganization aims at driving synergies around key anchor brands and optimization of product portfolio, most notably in the Cardiology and Diabetes divisions. Brand building and market share will be our focus.

An update on **Novel Molecules** – Clinical studies for IN-105, our oral Insulin program, continue to progress well. As communicated earlier, we expect to get read-outs from the first set of studies towards the end of this fiscal. In terms of Itolizumab, our anti-CD6 asset, our licensing discussion with interested parties continue while we do the ground work towards initiating trials for expanded indication in India and overseas.

Finally, coming to the **Research Services** business, Syngene is a premier research services company in India which has gained a leadership position over time. It is also the fastest growing and the most successful in this segment. Contract Research business by nature is cyclical and goes through phases. As a result, we have seen slower growth in the business this quarter. Syngene has been investing in additional capacities to fuel the growth of its business. It is expected that the impact from these investments would come towards the second half of this fiscal. The highlight for this quarter was the extension of Syngene's research collaboration with BMS, which has been rolled over for another 5 years until 2020. The business fundamentals for this segment remains strong and there is good visibility for growth.

Before I conclude, I would like to leave you with some key messages:

- We recorded muted growth this quarter due to a variety of reasons that I discussed. However, in the context of our business model and strategy, we remain on track with our plans whether it is the ANDAs in the Small Molecules business, advancement of our Novel and Biosimilars pipeline or sharper focus on our Domestic Formulations business. We continue to take small steps towards diversifying our revenue base and adding growth in our areas of focus. Clearly, we have some positives that will help the business in the long run.
    - We initiated our ANDA filing which is a step towards generic formulation.
    - Syngene extended its collaboration with BMS, providing revenue visibility till 2020.
    - We successfully faced multiple USFDA audits this quarter, which we believe is an important value differentiator.
- We maintained our EBITDA margin despite the headwind and increase in certain costs, like mandatory CSR spends, salary increments, etc., kicking in this quarter.
- But challenges remain. The clinical trial environment in the country continues to be challenging and affects our plan for India-centric clinical trials in both Novel Molecules and Biosimilars.
- R&D spends on an annualized basis is expected to increase significantly, and as communicated previously we expect R&D spends to be in the range of 8-10% of Biopharmaceuticals segment revenue. There will be lumpiness in the R&D spends on a quarterly basis, but on an annualized basis we believe this will increase and reflect in our P&L statement. I might also add here we have capitalized Rs.16 crore of R&D spend this quarter, and hence the gross R&D spends for the relevant periods should be compared for a better understanding.
- Significant growth capacity in Insulin will only come post commercialization and regulatory approvals of the Malaysia plant.

With that I will conclude my remarks and open this up for question-and-answers. Thank you.

Q&A Session

Moderator: Participants, we will now begin with the Question-and-Answer session. We have the first question form the line of Harith Ahamed from Spark Capital. Please go ahead.

Harith Ahamed: I had a question on the Glargine Phase-III trials which you are about to commence this year. So, we released a PK-PD study data from the Phase-I Glargine trials in July 2012, and there has been a delay in the commencement of Phase-III trial. So just wanted to understand why there has been this delay and when exactly you are planning to commence this Phase-III study?

Abhijit Barve: I think if you look at the timing, the Phase I trial was done before our partnership with Mylan. So once we had the partnership with Mylan in place, we started speaking to the various regulatory authorities for feedback as part of our standard process before we commit to these kinds of investments. The trial is going to start as has been publicly announced.

Harith Ahamed: In this quarter we have had around Rs.19 crore of licensing income. So, from which partnership has this licensing income come and do we expect this kind of an amount for the remaining quarters of this year?

Siddharth Mittal: The licensing income has come from multiple molecules and as we have mentioned in the past, it is not predictable. We continuously look for partners to out-license molecules. In terms of whether this trend will continue, it is very difficult to say but there are certain novel molecules and biosimilars rights where we are looking for partners. Last year our licensing income for the full year was roughly 15 crore, while this year we have 19 crore in the first quarter. We have good partners and some molecules have been licensed to multiple partners.

Harith Ahamed: On Syngene, do we still book losses on account of hedges there and if yes, what is the amount for this quarter?

M.B. Chinappa: As indicated previously, the hedge rates for FY15 and FY16 are very close to the market level, so we have had minimal losses in hedges.

Siddharth Mittal: This quarter, our overall FOREX gain has been Rs.1 crore, which includes the forwards, hedge costs and the cost of amortization.

M.B. Chinappa: I have one more point to add… what really hits our books today is the premium cost for the hedges that we have taken to give us a floor rate protection.

Harith Ahamed: I just missed the amount of R&D that is capitalized this quarter – is it Rs.14 crore? Is it entirely from Trastuzumab?

Siddharth Mittal: Rs.16 crore. We cannot give the breakup.

Moderator: Our next question is from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: I am trying to understand what really happened in the MENA region – how influential is this region for Biocon, because for the first time we have highlighted this issue, so could you clarify on this?

Ravi Limaye: We have some important products across the portfolio that we sell in MENA and you know the various problems that this region is going through. That has to an extent affected our progress in that region. I must add that this impact should get corrected in the subsequent quarters.

Surya Patra: Whether the same issue was there even in the previous quarter or how is it?

Ravi Limaye: This is more recent, I would say. And I would like to repeat, it is the phasing issue and should get corrected.

Surya Patra: Regarding Syngene, we are observing that the growth has definitely moderated over last couple of quarters. On the other hand you are saying that the capacity is now coming which will drive growth. So, does that mean you had seen some sort of capacity constraint for your manufacturing activities, some clarity on that front like whether it is a manufacturing opportunity that you are seeing in the near future or it is like you are seeing more CRO activities in Syngene, which will drive growth?

Peter Bains: To address that question, what we are seeing this quarter is in fact a similar pattern to that that we have seen over the last few years. The Q1 revenue growth being relatively soft and this is following a very strong Q4 performance. But, we do have good line of sight and see good incremental growth quarter-on-quarter throughout the rest of this fiscal particularly with new capacities coming on stream. We see that picking up in the second half of the year. I think it is important to also state we are very much in line to achieve the full year guidance that we have given.

Surya Patra: Whether you have given any full year guidance for Syngene with regards to growth?

Peter Bains: The reference was towards the mid-term guidance that we have given earlier for the period of 2018. We are looking at an average growth rate of 18-20% and we are very much in line with that.

Surya Patra: With this capacity expansion, we should be expecting some sort of manufacturing-related growth in the current fiscal, is that correct?

Peter Bains: Yes, we would expect to see that picking up in the second half of the year.

Surya Patra: Just an update on this Glargine again. Whether you have initiated the Phase-III global clinical trial for Glargine and whether the money that what you have capitalized R&D spend it is relating to that?

Abhijit Barve: As Siddharth mentioned, we have not given a breakup of where the capitalization is coming from. Having said that, I think the Glargine trial is on track to be started very soon.

Surya Patra: Can you please give us some update on the progress of the clinical development of your rh Insulin for US and Europe?

Abhijit Barve: As we have mentioned in the last call, we are on track with our harmonized filing strategy so that we can combine the Malaysian capacity with the U.S. and EU filing.

Surya Patra: With the commissioning of the Malaysia plant you will file even in US?

Abhijit Barve: We would not be sharing the details, but it kind of fits with our overall strategy that we have committed in the past.

Surya Patra: Can you give some sense, whether it is a couple of years away so far as Insulin launch in US is concerned or it is in line with the European timeline?

Arun Chandavarkar: I think the timelines you have in mind sort of are okay, because we are not talking about something happening within the year or two.

Moderator: Our next question is from the line of Girish Bakhru from HSBC Securities. Please go ahead.

Girish Bakhru: First question was on the Biopharma. If I understood clearly, statins you said was stable. Can you give a more color on whether it was more decline in Immunosuppressants or API or Orlistat kind of molecules, where did the decline happen largely?

Arun Chandavarkar: I think we have explained in Kiran's opening comments that the Biopharma sector as a whole was impacted by two things: One was the regional instability in MENA which we indicated was a temporary phasing issue. We hope that as the region stabilizes, our business would improve and we are proactively taking measures to rebalance growth initiatives in other regions. The second thing was specific supply related issue that we were doing to a client. That client is repositioning its product and is in the early stages of re-launch. This repositioning by the client has resulted in significantly decreased off take this year compared to last fiscal, and we see that off take being muted in the remaining part of this fiscal for now.

Girish Bakhru: Can you quantify the amount or the percentage contribution that specific supply was say…?

Arun Chandavarkar: We do not give product-wise or region-wise breakup. However these two events would account for the delta that you see between what would have been our growth, otherwise in terms of your expectations.

Girish Bakhru: You expect this Specialty API surprise to bounce back, right?

Arun Chandavarkar: Not in the short-term but we hope things will recover in the next fiscal as it is completely dependent on our client.

Girish Bakhru: Second question was on the Insulin filings. Specifically in US, I know it is still time to that, but any color that you can give on whether it will be NDA filing or a BLA filing?

Arun Chandavarkar: Recently, another company had filed their Basal Insulin in U.S. through 505(b)(2). I think we had mentioned clearly that we are looking at that as a positive because it clarifies the path to be followed. I think we are likely to follow down that path as well.

Girish Bakhru: So you will do 505(b) (2) on all the Insulin, right, not just…?

Arun Chandavarkar: Right now, we are talking about the Recombinant Human Insulin and the Basal Insulin, but I presume it would apply to the portfolio. Although I must say we have not taken any decision on that.

Girish Bakhru: Just following that, when you suppose say, file rh Insulin in US. Do you anticipate any challenge from innovators on patent; are there any patents that are waiting to expire?

Arun Chandavarkar: We would not like to comment specifically on any challenges on IP, because that always becomes a part of our strategy, but clearly from a molecule patent perspective they do not exist, because Insulin is an old molecule.

Girish Bakhru: So you are saying process patent might affect this, right?

Arun Chandavarkar: It is not be prudent for me to comment on IP matters.

Moderator: We have the next question from the line Ranjit Kapadia from Centrum Broking. Please go ahead.

Ranjit Kapadia: This is regarding Syngene listing. We had said in the last conference call that we will list Syngene after the elections. So, any update on that? Second thing on Clinigene, what is the current status of the clinical trials in India? Whether we expect the growth to be maintained in that space?

Kiran Mazumdar-Shaw: Let me answer your first question by saying that we are committed to listing Syngene. Right now I cannot give you clear optics on the timing, because we are evaluating a number of options. As soon as we are ready to disclose this, you will know when the listing will happen. But right now I am unable to give you a firm commitment on when the listing will happen. Now as far as the question on Clinigene is concerned, of course, clinical trials continue to be a challenge for us in terms of getting approvals in time. Having said that, we are beginning to see some signs of improvement and recovery on this front and we only hope that things will get better.

Ranjit Kapadia: Do you feel that you will be able to achieve the full year target this year for Clinigene?

Kiran Mazumdar-Shaw: Clinigene is currently doing a pretty decent business and is not as dependent on clinical trials as it used to be earlier. It will meet its numbers in terms of what it is planning to do. However, Clinigene is still a very small part of our overall Research Services business. So while we are

very confident of delivering our current targets, the true growth prospects that Clinigene has, it will only happen once there is more clarity and predictability in terms of clinical trial approval.

Moderator: Our next question is form the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal My question is on the India business. How do you see this business going forward? We used to have fairly high above market growth rate, and I guess we have had disturbances in the market over the last few quarters, but that seems to be stabilizing for most of the other players in the industry.

Ravi Limaye: As was mentioned in the opening remarks, the focus is on creating a specialty organization with a focus on creating high-end specialty products. Towards this end, we have reorganized the business to drive some of the products which we believe would be our key growth drivers. We are also focusing on driving a profitable growth. So with all these initiatives in place, we expect the India business to deliver a decent double-digit growth.

Nitin Agarwal: Secondly, on this Biopharma business, although you talked about some of the phasing issues and all happening in MENA, but this business has been kind of flat for the last five quarters now. We have been saying that Insulin and some of these other businesses have been growing very well. So which is the part of the business which has been dragging this growth?

Ravi Limaye: As we have said before, our focus in Small Molecules is to move the portfolio to a more profitable product mix which will include Immunosuppressants etc. So that strategy continues and we believe that that would continue to drive a profitable growth for the company.

Siddharth Mittal : If you look at the FY18 guidance that we have given, last year revenues were around $250 million and the FY18 projections is like $300 million for the small molecules vertical, which implies a single-digit growth. So as Ravi mentioned, the outlook is to have a profitable growth for which we optimize the product portfolio and move up the value chain from APIs to Formulations. In terms of an overall outlook, we are not going to see more than single-digit growth for small molecules business.

Nitin Agarwal: That would be the entire Biopharma piece as we classify that?

Siddharth Mittal: Biopharma also includes the biosimilars vertical.

Nitin Agarwal: How many ANDAs have we filed, any comments for the US?

Kiran Mazumdar-Shaw: Several. We cannot give you exact numbers for confidentiality reasons.

Arun Chandavarkar: When it comes in the public domain, you will know anyway.

Moderator: We have the next question from the line of Chirag Dagli from HDFC Asset Management. Please go ahead.

Chirag Dagli: A couple of things; first in rh Insulin, assuming that you follow the 505(b)(2) route. Do you think you will get full substitutability?

Abhijit Barve: That is a tough question. I think the regulatory policies are evolving in the U.S., so we cannot really comment on substitutability. Under the 505(b)(2) there is a clause for substitutability but we do not know how it will be evaluated by the agency. Even within FDA, there is a lot of discussion going on this particular issue.

Chirag Dagli: Secondly, I was looking at the balance sheet. Fixed assets have increased quarter-on-quarter by about 100 crore. Part of this is explained by this capitalized R&D of Rs.16 crore. What is the balance Rs.84-85 crore addition?

Siddharth Mittal: There are two things – one is Malaysia capitalization, so we still continue to build the Malaysia plant, and w.r.t. that we have added close to Rs.100 crore. Then there is regular CAPEX for Syngene and Biocon which has been offset by Rs.51 crore of depreciation. The number you see is on net basis.

Chirag Dagli: Sir, given that you have already launched Glargine in the Indian markets, you will also capitalize the Glargine spend for the developed market filings, right?

Siddharth Mittal: As we have explained, the Capitalization policy is the same and we cannot follow different capitalization policy for different molecules. However, we have some deferred revenue setting off the developmental spends for Glargine. This was the amount that Mylan had paid us when this deal was signed. So right now Glargine expenses are being offset against deferred revenue.

Chirag Dagli: Your guidance of 8-10% of sales on R&D is after adjusting for all of these. So basically this is the net impact on the P&L that you will show? The gross spend would be much higher obviously?

Siddharth Mittal: Yes.

Chirag Dagli: On the BMS contract, how should we think about the longevity of this opportunity, as in what kind of work we are doing, how relevant it is for BMS and what happens post five-years when this agreement comes for renewal?

Peter Bains: First of all, we are obviously delighted to be able to announce this extension, which puts another 5 years on the existing agreement, taking the partnership to 2020. This is by far the largest collaboration of its type in India, and the number of scientists that Syngene employees in BBRC is in excess of 400. This extension obviously provides a strong underpinning foundation for our Research Services business, and is also a very strong reinforcement and validation of our integrated discovery and development model. As BMS announced in the press release, it is a significant part of their global R&D platform; it is the largest R&D site that they have outside of the United States; and it is contributing to their small molecule portfolio across the board. Specifically they have developed 6 clinical candidates from the collaboration, and one candidate is now in a global clinical trial. I think

that gives a flavor that it is a broad integrated capability platform that can have an impact across the discovery-development continuum and plays an important role in Bristol's global R&D efforts.

Chirag Dagli: So this is across several therapy areas that you are working with?

Peter Bains: Yes, it is multi-therapeutic.

Moderator: Thank you. Our next question is from the line of Nitin Gosar from Religare Invesco. Please go ahead.

Nitin Gosar: Just a clarification, you mentioned that Custom Research is going to face kind of growth issue because of the Specialty API which is not going to be there for remaining part of the year?

Arun Chandavarkar: I think you mixed up the two group companies. The Specialty API that we were referring to was in Biocon, not in Syngene.

Nitin Gosar: Second question is if you can help us understand what is the ex-MENA region growth that we have reported for the year?

Arun Chandavarkar: We do not give region wise growth rate, but I have publicly stated that our MENA region was challenged, clearly, the ex-MENA region has grown much faster.

Moderator: Thank you. Our next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: Just wanted to check on the ANDA filings. Is there an overlap between these products and what we are supplying to customers which is the API? Will this bring about any conflict with the customers?

Arun Chandavarkar: We have a mix up of both situations, and I think we are not unique in this space and many companies have addressed this. Having said that, I would not say necessarily that all products are in the category you described. There could be a couple in that category as well.

Sameer Baisiwala: Where there is an overlap once you get an approval and get into the market, would your business with the customers continue or is it something that would force it to cease?

Arun Chandavarkar: We will never let down a customer, because after all the customer would have developed their own dossier using our API, and we would lose credibility if we then did not support a customer. So we would be judicious in how we go about this of course, and we will avoid conflict of interest situation to the extent possible.

Sameer Baisiwala: The second question, is it possible to update the progress of Phase-III Global Clinical Trials that is going for Trastuzumab and what are the timelines that you are looking at?

Abhijit Barve: The clinical trial remains on course in terms of what guidance we have been giving for the recruitment rate. Having said that, breast cancer trials are tricky in terms of recruitment, but we are fairly confident of meeting the timeline that we have given as well as our partner Mylan has committed to.

Sameer Baisiwala: Is it possible to refresh us with the timelines that has been mentioned?

Abhijit Barve: I would not be able to do that, Sameer.

Sameer Baisiwala: On the research spend, I think Kiran, you mentioned in the commentary that Rs.47 crore has been spent and around Rs.16 crore has been capitalized. The fact sheet actually says about gross spend of Rs.37 crore.

Siddharth Mittal: Sameer, so let me take that question. As far as R&D spends are concerned 31 crore has gone to P&L, 7 crore has been offset against deferred revenue which are mainly for Insulins and 16 crore has been capitalized. So, the absolute gross is Rs.54 crore

Sameer Baisiwala: But then why do you not mention this Rs.16 crore in the fact sheet?

Siddharth Mittal: We will start mentioning it from the next quarter because we have recently started capitalizing.

Moderator: We have the next question form the line of Sachin Kasera from Lucky Investments. Please go ahead.

Sachin Kasera: Just two questions; one was regarding the domestic business; you mentioned that for the full year you expect the growth to be high double-digits. This quarter we have just been at a double-digit, which means that over the next three quarters you expect the growth rate to be faster than what you have delivered in Q1?

Ravi Limaye: I mentioned that the growth rate would be double-digit. I did not mention high double-digit and I think we will continue to grow ahead of the market. We have put a restructuring effort in place, we are concentrating on specialty products and profitable growth and I think all these initiatives will certainly result in double-digit growth which will be ahead of the market.

Arun Chandavarkar: I think you have seen also from the fact sheet that the sequential growth in Branded Formulations has been Rs.18 crore.

Sachin Kasera: Just a follow up on this…you mentioned that you are focusing more on Specialty business. Would this mean that the profitability of the domestic operations would improve compared to last year?

Ravi Limaye: Yes, that is our aim.

Sachin Kasera: Any update on the launch of Trastuzumab in the domestic market? How this quarter been? Is it going as per schedule? Or if you can tell us, what is the number of patients they are at currently benefitting from the drug - some color on that?

Arun Chandavarkar: We have co-exclusive rights to commercialize Trastuzumab in emerging markets. We cannot give much granularity on that, not only for competitive reasons, but also because the matter is sub judice in the Delhi High Court.

Sachin Kasera: Second question on the Malaysia facility. You mentioned that you are looking at starting it in H2. Are we looking in terms of commercial operations? Is it going to be a Phase-I? Or are we just looking in terms of starting to go for the validation, if you can give us some perspective?

Arun Chandavarkar: It will be starting the facility to go in for validation, because if you look at any pharmaceutical product, especially Biologics, you would need to complete the IQ/OQ/PQ first and then apply for regulatory approval. So that is the standard sequence we would have to follow as well.

Sachin Kasera Are there also stages in this Phase-I or this Phase-I entirely will start at one-go?

Arun Chandavarkar: There are no stages, except that we have distinct drug substance and drug product facilities.

Moderator: We have the next question from the line of Vipul Chandani from CD Equisearch. Please go ahead.

Vipul Chandani: When you talked of Biopharma business, you suggested that the cause of impact was on account of some specific supplies to client. Can you give us some more clarity on that?

Arun Chandavarkar: This was a reference to our Fidaxomicin supplies to Cubist. As Cubist has announced, they are looking to reposition and relaunch Dificid in the U.S. market. They have also publicly stated in their call that they are in early stages of the re-launch of the product. So whilst the Cubist is going through that phase, certainly there are limitations to the offtake from our side.

Vipul Chandani: You talked that first and the foremost reason that Biopharma was flat was because of impact in MENA region. Can you give me the chunk of revenue which is coming from that region?

Arun Chandavarkar: Unfortunately we do not give product wise or region wise breakup.

Moderator: We will take the next follow-up question from the line of Chirag Dagli from HDFC Asset Management. Please go ahead.

Chirag Dagli: I had a question on the Research Services profitability. If you compare against FY14, there has seen a very sharp improvement in the profitability of this business. Going forward, what is the sustainability of these margins – can they improve from here on?

Peter Bains: I think even in the past, we have said that the EBITDA margin would be in the range of the low-30s and the profit margin after tax would be in the range of high-teens and low-20s, and we see that as sustainable.

Moderator: Thank you. Participants that was the last question. On behalf of Biocon Limited, that concludes this conference call. Thank you for joining us. You may now disconnect your lines.

Note: This document has been edited to improve readability