Transcript

Biocon Limited Q2 FY19 Earnings Conference Call
October 26, 2018

Participants from Biocon's Senior Management Team

- Kiran Mazumdar-Shaw: Chairperson & Managing Director, Biocon
- Arun Chandavarkar: Chief Executive Officer & Jt. Managing Director, Biocon
- Siddharth Mittal: Chief Financial Officer, Biocon
- Prasad BSV: President & Chief Operating Officer (Small Molecules), Biocon
- Shreehas Tambe: Chief Operating Officer, Biocon Biologics
- Paul Thomas: Chief Commercial, Biocon Biologics
- Suresh Subramanian: Head - Branded Formulations India, Biocon
- Saurabh Paliwal: Head, Investor Relations, Biocon

Prepared Remarks session:

Moderator: Ladies and gentlemen, good day and welcome to Biocon Limited's Q2 FY19 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode, and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone telephone. Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Saurabh Paliwal from Biocon Investor Relations. Thank you and over to you, Mr Paliwal.

Saurabh Paliwal: Thank you, Janice, and good morning, ladies and gentlemen. I welcome you to the earnings call for the second quarter fiscal 2018-19. Before we proceed, I would like to remind everyone that a replay of today's discussion will be available for the next few days about an hour post the conclusion of the call. We shall be putting out the transcript on our website in the coming days as well.

To discuss this quarter's performance and outlook for the rest of the year, we have the company management comprising Dr. Kiran Mazumdar-Shaw - our Chairperson and 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 conclusion of this call, if you need any further information or have questions, please do get in touch with me. With that, I would like to turn the call over to Dr. Kiran Mazumdar. Over to you, ma'am.

Kiran Mazumdar-Shaw: Thanks, Saurabh and thanks Janice. Good morning, everyone. I wish all of you and your families a very festive and Happy Diwali season ahead.

I would like to start with the key highlights for the quarter.

- As you are aware, our partner Mylan commenced commercial sales of Fulphila which is our biosimilar Pegfilgrastim in the US market. I should like to remind you that this is the first biosimilar Pegfilgrastim to be approved and commercialized in the US and the first product from our joint portfolio to be launched in the US market.

- Our partner Equillium filed an Investigative New Drug or IND application and received go ahead from the US FDA to progress Itolizumab, our novel anti-CD6 molecule into clinical development in the US in certain orphan indications.

- In September, the European Medicine Agency's Committee for Medicinal Products for Human Use or CHMP issued a positive opinion recommending approval of Fulphila™, our partnered biosimilar Pegfilgrastim. The CHMP positive opinion will now be considered by the European Commission with a likely approval expected by November 2018.

- In October, the same committee also issued a positive opinion recommending approval of Ogivri®, our partnered biosimilar Trastuzumab and the decision of this approval by the European Commission is expected by December 2018.

- Our partner Mylan initiated the commercial launch of biosimilar Adalimumab across major markets in Europe post October 16, 2018 and Biocon will receive economic benefit for this product in line with our global collaboration with Mylan.

Now moving on, I would like to present some key financials for this quarter:

- Total consolidated revenue for the quarter was at Rs.1375 crores, up 35% over last year.

- Revenue from operations were Rs.1321 crores, which grew 36% over last year. This includes licensing income of Rs.5 crores for this quarter compared to Rs.8 crores in Q2 of last year.

In terms of segmental performance,

  - Small Molecules revenue was at Rs.432 crores for Q2, up 23% over last year;

  - The Biologics segment was the strongest performer, reporting 136% growth to Rs.367 crores;

  - Branded Formulations was down 7% at Rs.164 crores; and

  - Research Services or our Syngene business grew 25% to Rs.419 crores this quarter.

- We booked a forex gain of Rs.24 crores this quarter as compared to Rs.18 crores in Q2 of last year and this gain is reflected in the other income line of the profit & loss statement.

- We incurred gross R&D spend of Rs.120 crores this quarter corresponding to 13% of revenue excluding Syngene. Of this amount, Rs.77 crores is reported in the P&L. We capitalized an amount of Rs.43 crores related to biosmilars and insulin analog development expenses. The gross spends are higher than last year primarily on account of increased spend in Biosimilars and Insulin Analogs in terms of their development programs.

- Based on the strong operational performance, EBITDA grew 69% to Rs.394 crores. EBITDA margin for this quarter was 29% as compared to 23% in the corresponding quarter last year.

- Core margins, i.e. EBITDA margins net of licensing, forex and R&D improved from 26% in Q2 last year to 33% this quarter.

- Net Profit for the quarter increased from Rs.69 crores in Q2 of last year to Rs.355 crores this quarter. This includes one-time gain arising out of an exceptional item reported in a quarter as the company fair valued its investment in US based Equillium. Adjusting for the exceptional gain and associated tax, Net Profit for the quarter was Rs.184 crores representing a net profit margin of 13%.

I would now like to delve a little deeper into our segments:

Small molecules as I mentioned earlier grew 23% over last year. This was on account of a better product mix accompanied by volume growth in statins, immunosuppressant and other key APIs. Our Rosuvastatin Calcium and Simvastatin tablets continue to gain market share in the US which added to the growth.

The **Biologics segment** revenue more than doubled as compared to last year, growing 136% year-on-year. Sales and profit share from commercial launch of biosimilar Pegfilgrastim in the US led to the strong performance during the quarter. Trastuzumab sales continue to do well in the emerging markets with launches in newer geographies and increased prescription share in markets where it has already been commercialized. Recently, our local partner launched the product in Turkey where our Trastuzumab was the first biosimilar Trastuzumab to be approved in that country. In Algeria, our product continues to enjoy a wide acceptance amongst patients and prescribers while there has been a strong uptake of Trastuzumab in Brazil.

The Insulins business recorded a strong growth led by sales in several emerging markets. Biocon holds dominant market share in human insulin in Mexico, Malaysia, Thailand and many markets in Latin America, directly or through its local partners.

When it comes to **Branded Formulations**, the revenues in this segment which include sales in India and UAE, decreased 7% compared to last year. Performance in India was impacted due to a higher base in Q2 last year, which benefited from restocking by trade post GST implementation. Decrease in sales, seen in major divisions was partly offset by growth in Comprehensive Care and Nephrology. In UAE the in-licensed metabolics product portfolio and Glaricon, our brand of Insulin Glargine continue to gain market share, while in the Branded Generics market, we faced challenges with repricing of products by the Ministry of Health.

Research Services, which is our Syngene business reported a growth of 25% over last year, driven by small molecule discovery services and increased traction in the dedicated R&D centers. During the quarter, Syngene has commissioned a new dedicated facility for Bristol-Myers Squibb and renewed its collaboration Baxter which involved a widened scope of engagement and setting up of additional infrastructure.

Let me now turn to **Product Development Updates**:

As a part of our novels molecule portfolio - Phase-2/3 study of our oral insulin candidate, I**nsulin Tregopil** is progressing well.

Equillium, our partner for **Itolizumab** for US and Canada, received approval for an IND for the molecule from US FDA. It plans to conduct clinical trials for orphan indications, including treatment of acute and chronic Graft Versus Host Disease or GVHD and asthma, and expects to initiate clinical trials in the first half of 2019. To fund the clinical trials, Equillium raised $65 million in its maiden public offerings and listed on NASDAQ on October 12. Basis the IPO pricing, Biocon's ~13.5% stake in Equillium is now valued at $32 million.

Before I conclude, I would like to summarize our performance and our expectations for the rest of the financial year.

We have finished the first half of this fiscal delivering a strong performance across Small Molecules, Biologics and Research Services segments. Increase in sales growth helped by a better product mix in small molecules and growth in the Biologics segment led by Pegfilgrastim have resulted in better margins and consequently doubling of earnings over the first half of last year. We look forward to a strong performance across business segments in the second half of this fiscal. We expect momentum in the Biologics segment to continue with new market launches expected later in the year and increased penetrations in markets where our products have already been commercialized.

With that I would like to open it up for question-and-answers. Thank you.

Q&A session:

Prakash Agarwal, Axis Capital: Ma'am, first question is trying to understand this Biologics sales that you've done. Is there a thought of revising your guidance of $200 million given the momentum has really picked up, so just wanted your thoughts there as you just mentioned that you see incremental penetration across products and also new launches in newer markets that would really help?

Siddharth Mittal: Prakash, there is no revision to the guidance. As you know the numbers for the first half have been strong and that gives us the added comfort that we will meet our $200 million guidance. We are not revising numbers for the year.

Prakash Agarwal, Axis Capital: And the guidance was largely for emerging markets, did not include regulated markets, so it would be over and above, right?

Siddharth Mittal: The guidance was primarily from emerging markets, but it did include launch quantities for developed markets as we had expected launches in developed markets in this fiscal.

Prakash Agarwal, Axis Capital: Just trying to understand this better, would it be fair to say that the launch quantities you mentioned about Peg it is like is going to increase from here and hopefully there is no channel filling as such because it is a huge molecule in the US, would that understanding be correct?

Paul Thomas: This is Paul. I think it is early days in the launch and so we will have to see how this evolves and I think really Mylan would be best place to comment on the trajectories going forward.

Prakash Agarwal, Axis Capital: Last question is on margins. Despite higher R&D, margins have really come on well. So this is the new base is what we should consider going forward given the business momentum is picking up?

Siddharth Mittal: I will not really look at one quarter and say it is the new base. As the sales grow in our Biologics segment, which is more profitable as compared to other segments, we would continue to report higher margins. Further, if you look at the segment wise results this quarter, even the Small Molecule segment delivered a strong earnings at the profit line. Biologics segment, which was actually loss-making last year because of Malaysia capitalization, has turned profitable. So combination of everything will hopefully continue to help improve our margins on a go forward basis.

Dheeresh Pathak, Goldman Sachs Asset Management: I wanted your thoughts on the biosimilar Glargine with Merck and Samsung withdrawing from that, just wanted to understand if you can give us some thoughts on why they would have done it?

Dr. Arun Chandavarkar: We will not be able to speculate on why they would do it. Our information is what we have read and is in the public domain. However, from our perspective of course we have strongly invested in our entire insulins portfolio comprising not just Glargine, but the basket of Insulin Analogs as well as Recombinant Human Insulin and we have always guided saying that we wish to be a dominant player in this space. I think in Kiran's opening remarks, we have already mentioned how we have established dominant position in many of the key emerging markets, and as and when we are able to get approvals and penetrate markets globally, try to continue to believe and invest in this space going forward. We clearly of course are awaiting the opening of the US market which we have said can happen for Glargine sometime in early 2020 and that would further bolster our presence.

Dheeresh Pathak, Goldman Sachs Asset Management: On the numbers, so ex of Syngene the other expenses in Biocon's business - the overheads which is the employee cost and other expenses, so they have increased quarter-over-quarter adjusted for R&D also, they are up like some Rs.40 crores, so is there some investments in employee, some hiring or something of that sort or it is there some one-off if you can talk about that, is there a currency one-off in your other expense ex of Syngene, I know they had called out, so is there anything if you can explain that will give more color on this?

Siddharth Mittal: The currency impact is reflected in the “other income” line. In terms of “staff costs”, we continue to add more people every year to cater to growth of our various businesses. The “other expenses” have gone up in line with the revenue increase, like the marketing expenses which are directly linked to the sales, they have gone up. There has been no abnormal increase that has happened in this quarter.

Dheeresh Pathak, Goldman Sachs Asset Management: As you will have this large dollar denominated earning stream that will come from developed markets biosimilars, are you going to hedge that or you will not hedge?

Siddharth Mittal: We do hedge our net exports through range forwards, and most of our hedges are within the range and so we continue to benefit from the rupee depreciation.

Surya Patra, Phillip Capital: A positive development on the Itolizumab front. Sir, just wanted to have some clarity on the Itolizumab front. This is the out-license molecule to Equillium?

Dr. Arun Chandavarkar: That is correct.

Surya Patra, Phillip Capital: So what incremental benefit Biocon can have out of this development if it progresses well, so whether the manufacturing right or marketing or profit share right or what that can come for Biocon out of that?

Dr. Arun Chandavarkar: Let me just give some color to this transaction. This is as you said licensing deal for Itolizumab for the US and Canadian market for a set of indications. The licensing deal involves as Kiran mentioned in her opening remarks an equity stake in Equillium which post the IPO stands at about 13.5%. Additionally, Biocon retains the manufacturing and supply rights for the product to Equillium, both clinical as well as commercial. On top of that Biocon is entitled to royalties and sales milestones upon commercialization.

Surya Patra, Phillip Capital: Is there any funding requirement for the clinical development from the Biocon side?

Dr. Arun Chandavarkar: As mentioned in the opening remarks, the funding of this has been raised through an IPO by Equillium and as disclosed Equillium raised about $65 million in the IPO which is adequate for the funding requirements for this molecule for the indications outlined.

Surya Patra, Phillip Capital: Secondly on the Pegfilgrastim, what was swing on the Biologics revenue that we are sequentially seeing, what portion of that would be coming from the Peg and what from the progress in the emerging markets? Also if you can indicate whether any profit share of the Peg is there in this Biologics sales number?

Dr. Arun Chandavarkar: Yes, this quarter because of the launch of Pegfilgrastim in the US market, the revenue includes both the supply of product as well as our share of profit from Mylan sales and as we have already mentioned good chunk of the increase, the delta over previous quarter has come due to Pegfilgrastim. However, our base business is strong and continues to grow in other geographies and with other biosimilars.

Surya Patra, Phillip Capital: So that means there is no lag between the profit share and the revenue share in the Peg business, that is what the fair understanding because the launch itself happened in July right?

Siddharth Mittal: We book the profit share when Mylan sells the drug to their customers. On the inventory that they hold, we do not book profits. So there will be some lag in booking profit share, because, if you recall our first quarter call, we have supplied the launch quantities actually in Q1, which would have been liquidated by Mylan in Q2. They will have inventory with them currently, the profits from which will come in the next quarter.

Surya Patra, Phillip Capital: So that means this quarter also there was supply?

Siddharth Mittal: There will be continued supplies, we will supply every month.

Surya Patra, Phillip Capital: Third on the Adalimumab front, is there any one-off benefit that is there because of Adalimumab launch in Europe?

Siddharth Mittal: There is no one-off benefit as there are no licensing payments from Mylan. It is an in-licensed product from Fuji Kirin Japan and the launch has been done with that product.

Surya Patra, Phillip Capital: Can you provide some clarity about what kind of milestone that Biocon can get?

Siddharth Mittal: There is no milestone, we will get our profit share.

Surya Patra, Phillip Capital: On the CAPEX front since you are seeing the successful launch of Pegfilgrastim in US and there is a likelihood of the launch of the Peg and Trastu in Europe and there is ramp-up also visible in the emerging markets, is there any clear thought process about the MAb plant what we have been talking about since sometime and when that should be ready?

Dr. Arun Chandavarkar: The investments in the manufacturing facility are already on. I think we have mentioned it for the last few quarters that we had triggered an expansion of our monoclonal antibody facility with an outlay of about $200 million spread over three fiscals and that is very much on track.

Surya Patra, Phillip Capital: That would be available in two year time, is that fair?

Dr. Arun Chandavarkar: Approvals would be market by market, but from a commissioning standpoint, yes.

Shyam Srinivasan, Goldman Sachs Securities: My first one is on Pegfilgrastim in the US again. What is the current market share that we are tracking as of the quarter close and how is it tracking in line with your expectations? How has the innovator kind of responded to the entry of the biosimilar?

Dr. Arun Chandavarkar: In terms of what is available in the public domain is what I can allude to. If any detailed specific questions on launch strategies and launch update, I would defer to Mylan. What we know from publicly available sources is that there has been a 3% market share of the syringe market based on the initial data.

Shyam Srinivasan, Goldman Sachs Securities: Looking at that market share, is it tracking in line or do you have to do certain other things like take pricing down, any of that needs to be done?

Dr. Arun Chandavarkar: I would defer all these questions to Mylan, but what I can say is right now as far as Biocon is concerned, everything is going as per plan.

Shyam Srinivasan, Goldman Sachs Securities: My second question is on the Small Molecule business. We have seen actually a sequential uptick and margins have also improved. So can you just give us some outlook on how the pricing environment is specifically in the US and in the rest of the world and what has led to this kind of uptick sequentially?

Dr. Arun Chandavarkar: One reason for the uptick has been the better product mix that we have had and of course increased demand. We have seen both the uptick in volumes as well as uptick in terms of steadiness in terms of the pricing. Bit of the revenue gain is of course also come from the currency benefit that we had. So clearly I think in the past we have mentioned that at least in terms of some of our base products like the statins, we believe we have seen the bottom of that and there has been no further significant erosion in terms of prices. We guided for like a low single digit erosion of prices. Some of that erosion has been offset by the currency. Secondly, of course, you know that our business in terms of generic formulations through our ANDA business has also started to make meaningful contributions to the Small Molecules segment through Rosuvastatin and Simvastatin and we would have couple of other molecules in that basket going forward. So that also has been a decent contributor to the revenue.

Shyam Srinivasan, Goldman Sachs Securities: My third question on Adalimumab. Do you know what the price discount that you had to launch it in Europe?

Dr. Arun Chandavarkar: No, that is not something that we could talk about.

Shyam Srinivasan, Goldman Sachs Securities: My last question is on the tax rate. In 1Q I think we had guided that tax rates will go up. If I strip out that exceptional gain it seem to have come down at 21% at least that is what we could calculate. Is there something changing there or we will stick to our earlier guidance?

Siddharth Mittal: I think for Biocon excluding Syngene we should be looking at 24-25% for the year.

Abhishek Nama, Prescient India Health: I just wanted to understand launch of Ogivri in the European market. So what will be your strategy to launch because market is already occupied by various key companies, so how will you launch your product what will be your strategy to capture the market share?

Dr. Arun Chandavarkar: All the commercial decisions in the developed market for our partnered portfolio with Mylan would be determined by Mylan. So all these questions regarding commercial strategies, launch timings, pricing, competitive responses are best addressed to Mylan.

Abhishek Nama, Prescient India Health: One more question about emerging markets, so apart from Turkey, Algeria and Brazil, what are your next countries targeting to launch Trastuzumab biosimilar?

Dr. Arun Chandavarkar: We continue to file in emerging markets and as and when we get approvals we will launch. Basically, the launch cycle will be determined by the cycle of approvals and it is hard to predict which country would approve first because we do multiple filings simultaneously across many markets.

Sameer Baisiwala, Morgan Stanley Research: Just on Glargine for the US market, what are the next few steps for you to do the site switch to Malaysia?

Dr. Arun Chandavarkar: I think our bridging trial is progressing well and that was basically the data that US FDA requested for. So once we have the data, we expect to respond to the CRL**.** As you know we have always guided that there would be no impact on the launch timing which is largely determined by the 30-month stay and that position continues to hold.

Sameer Baisiwala, Morgan Stanley Research: After once you finish the bridging study, then what are the next couple of steps -- would you require FDA to come down to do re-inspection?

Dr. Arun Chandavarkar: This is about the dossier, this is not about GMP. The data is largely a clinical bridge, so it is more a dossier evaluation.

Sameer Baisiwala, Morgan Stanley Research:The second question is from a launch timing perspective, the underlying Para IV court case, do you not think that can potentially delay you?

Dr. Arun Chandavarkar: The 30-month stay I am referring to will end sometime in March 2020.

Sameer Baisiwala, Morgan Stanley Research: That 30-month stay is for the approval of 505(b)(2) file. It is not a timeline for the judge to give the judgment, that case would still be undergoing, so?

Dr. Arun Chandavarkar: That is Mylan's call in terms of launch strategies post the 30-month stay subject to us getting the approval.

Sameer Baisiwala, Morgan Stanley Research: The next question is on the Pegfil in the US, I know you cannot talk too much on the commercial side, but it is a general question which is coming from Remicade Inflectra launch where as you know the innovator signed exclusionary contracts through bundling of its portfolio, it is a very general trend, but what it resulted in was complete blocking out of the biosimilars more or less. Now the question here is for your Pegfil, is it something that you have so far seen in the market or not? I am not looking for any data or any such thing.

Paul Thomas: Hi Sameer, this is Paul. Thanks for your question. I think we have seen that dynamic and a lot of press about that dynamic with Inflectra. I think the product is present in a different part of the market. So I think we can bridge over directly necessarily. Obviously, I think specifics on this will have to come from Mylan, but I think I would just suffice it to say that we are in a different part of the market and I think the other thing to remember is that Pfizer is still recognizing significant meaningful sales that are growing 20% or something like that quarter-on-quarter in the US even with the challenges that are faced.

Sameer Baisiwala, Morgan Stanley Research: First, if I have understood you correctly, you are in a different part of the market, so the part of the market that you are in cannot be blocked so much through these exclusionary contracts?

Paul Thomas: There are lots of ins and outs to how each company will apply their contracting and their pricing strategy. So my limited comment would be that even within the same molecule you will not be able to necessarily apply the same thinking across all of them, but I think certainly with a different molecule and a differently structured market, I would not make that assumption, but I think it is better to be addressed to Mylan.

Sameer Baisiwala, Morgan Stanley Research: My favorite question Arun to you on Copaxone. How is the refiling in progress… are you on track for fiscal '19 refiling?

Dr. Arun Chandavarkar: I told you that once I gave you a guidance and then having not kept that, I refrain from giving you a guidance, but believe me we are actively working on that and we would file as soon as we can.

Sameer Baisiwala, Morgan Stanley Research: Last one from my side is on Aspart, how is the regulatory progress, you commenced the Phase-3 clinical trial for that?

Shreehas Tambe: Sameer, this is Shreehas. As we said before we are expecting to start the Phase-III clinical trial in the second half of this year and we are trending well to those dates that we have guided before.

Sameer Baisiwala, Morgan Stanley Research: And you would take 24-months to complete this, would that be the understanding?

Shreehas Tambe: Trial timelines would be around that time and then it follows with the phase of finalizing of the database and then putting the documentation together for the CSR.

Vipul Shah, Sumangal Investments: Can you comment on the capacity utilization of Malaysia sir?

Siddharth Mittal: We do not provide comment on our capacity utilization for our plants. We had guided that Malaysia operations would break even this year and we are on track to achieving that.

Vipul Shah, Sumangal Investments: So to interpret that we break even in this quarter or are we expecting it by this year end March 2019?

Siddharth Mittal: This quarter has seen a very minimal impact of Malaysia, but it will be breakeven for the full fiscal year.

Ranjit Kapadia, Centrum Broking: I have two questions: My first question is how many scientists are there in BMS project and Baxter project? My second question is related to number of MRs in the Branded Formulations segment, and when this Branded Formulation is likely to reach critical mass because currently it is just 12% after so many years?

Kiran Mazumdar-Shaw: I do not have the exact numbers, but I think the BMS numbers are little over 500 in the dedicated center and Baxter I think it is over 100. As far as our Branded Formulations business is concerned, I will turn it over to Suresh.

Suresh Subramanian: Hi, thanks for your question. On the Branded Formulations business in India we have around 850 field force. On your second question on how will we ramp up, I think currently it will be two ways -- one is driving therapeutic leadership in Oncology and Metabolics. We have come some distance in the last two years and through our new launches from our own internal stable in the coming years and through in-licensing activity that is going on, that will form the basis of driving a critical mass for BFI in the coming years. Hope that answers your question.

Charulata Gaidhani, Dalal & Broacha: My question pertains to Pegfil and Trastu, which are the other markets where you have received approvals but not yet launched?

Dr. Arun Chandavarkar: For Trastuzumab, the big market from a developed market perspective is clearly the US where we have received approval and not yet launched. In emerging markets for reasons of competitive dynamics, I am not at liberty to disclose publicly because that would basically alert competition in terms of where we are ready to launch.

Charulata Gaidhani, Dalal & Broacha: And what would be your R&D guidance for '19 and '20?

Dr. Arun Chandavarkar: I think we would continue to maintain our previously stated guidance of around 13% to 15% gross R&D spends ex-Syngene.

Charulata Gaidhani, Dalal & Broacha: And CAPEX?

Siddharth Mittal: For capex**,** we have guided that it will roughly Rs.750 crores per year. So we continue to maintain those estimates for the next one or two years.

Prakash Agarwal, Axis Capital: Just a clarification on what sir said is on the market share, was it 3% of the total market or is it excluding the On-Pro kit, i.e. the syringe market?

Dr. Arun Chandavarkar: I think it is excluding that. I do not have the direct information on that, this is just third party information, so you can corroborate this.

Prakash Agarwal, Axis Capital: Secondly, one more clarification on the Equillium revaluation that we have gained. So this is largely on account of losing control and we have to revalue. So does this happen annually, quarterly, what is the base of the current valuation?

Siddharth Mittal: It is one-time valuation and it is because of loss of significant influence that we had. The fair valuation was done as of September when we had actually lost the significant influence. This is a valuation that was conducted by Equillium and was not the IPO valuation.

Prakash Agarwal, Axis Capital: IPO valuation would be much higher.

Siddharth Mittal: No, slightly higher. We indicated that $32 million is the current value of our holding which is equivalent to little over Rs.200 crores. The fair valuation gain recorded during the quarter was Rs.189 crores.

Prakash Agarwal, Axis Capital: And would this be annually accounted?

Siddharth Mittal: This investment will be quarterly fair valued and the differential will be carried through OCI and not through P&L.

Prakash Agarwal, Axis Capital: This is clearly one-time?

Siddharth Mittal: One-time non-cash exceptional gain.

Prakash Agarwal, Axis Capital: Lastly, on the capitalized piece, which are the current assets which are getting capitalized and how do we see the R&D for next year?

Siddharth Mittal: I think Arun just answered on the R&D that we continue to maintain at around 13% to 15% of ex Syngene revenues. As far as the capitalization is concerned, we continue to capitalize Bevacizumab which is the biggest spend right now and a very small portion of Trastuzumab and Glargine given the additional trials that we are doing in the US.

Prakash Agarwal, Axis Capital: Are we breaking it down the capitalized value for the asset?

Siddharth Mittal: No.

Prashant Nair, Citi Research: Just one question, can you give any sense on the timeline for launch of Semglee in Europe?

Dr. Arun Chandavarkar: I think Mylan in their previous calls guided for launch by the end of 2018 and I think they are on track for that.

Surya Patra, Phillip Capital: One more clarification, with the approvals for the biosimilars like Peg, Trastu and the Glargine coming in Europe, is it fair to believe that the revenue traction in the emerging market will really surprise positively and much better and that would be better than the European contribution in the immediate visible future?

Dr. Arun Chandavarkar: I am not quite sure whether there is a link between the two markets because clearly each market acts to its own dynamics. The volatility in some emerging markets comes from markets which are tender driven where sometimes you may win some or lose some, but as far as retail markets and other markets are concerned, you will see a steady growth.

Surya Patra, Phillip Capital: I was coming from the point that since Herceptin or Trastuzumab itself if you consider, it is almost equally distributed across US, Europe, and ROW and the way the market has expanded in India post launch of the product at a discounted price point, possibly the similar scenario is possible in the emerging market as well, so from that standpoint I was…?

Dr. Arun Chandavarkar: I agree with you that there will be an expansion of the market. I am not talking about Trastuzumab, but if you see the European market for other biosimilars which companies have launched, there has been significant increase in access because of the lower pricing. Now this distribution that you are talking about one-third, one-third, one-third in Trastuzumab is based on innovator pricing and innovator sales. Clearly that dynamic may look different on a biosimilar base because the pricing in different markets and the value in different markets may be different.

Surya Patra, Phillip Capital: And second on the Sandoz association front, any progress so far that is worth discussing?

Dr. Arun Chandavarkar: They are early stage assets and as we have said before they are yet to enter the clinic. They continue to make progress on the R&D front.

Surya Patra, Phillip Capital: From our side, we are also contributing equally in the similar manner?

Dr. Arun Chandavarkar: That is correct; it is a 50:50 sharing.

Damyanti Kerai, HSBC Research: My question will be regarding the broad market for biosimilars in the US. So like we have now launched Fulphila and we have not heard anything like major change coming on the market development as such regarding acceptance by the channel and all, so what would be your comment like -- are

you seeing any changes which will be ultimately favorable for biosimilar acceptance in the US in long run or situation is more or less similar like we are not seeing much changes there?

Paul Thomas: This is Paul. Thanks for your question. I think as you mentioned there are various different dynamics going on in the US and it is still evolving. I think we earlier in the call there was discussion on the contracting kinds of challenges that some players have seen in those therapeutic areas, at the same time there has been a lot of commentary from FDA about trying to reduce the role of middlemen in the supply chain and rebating, changing things like that and some further commentary yesterday from or today I guess from the Trump administration on working on drug pricing. I think overall there is a lot factors in play, but clearly the biosimilars are part of the market that is trying to reduce the burden on the healthcare system, the government and payer cost burden overall and I think these changes in general should be supportive of biosimilars overall. I think biosimilars are clearly part of the solution in the long run.

Damyanti Kerai, HSBC Research: This we have been hearing for some time now, but thing is as such we have not seen any tangible announcements coming in the market or tangible changes in the market. So any expectation around that line, when we can see something positive coming from the government which they can implement to increase adoption of biosimilars? I know it is difficult to predict, but any thought over there would be helpful.

Kiran Mazumdar-Shaw: As Paul mentioned, I think there is an intention of the Trump administration to support biosimilars and there have been statements made to that effect without a clearly articulated policy. But having said that you also heard him saying that even in the biosimilars that have been launched there is now indication that there is improvement in acceptance, you just heard that Pfizer themselves have seen 20% steady growth of uptake. So it tells you that things are going in the right direction and I think these are early days in terms of biosimilars in the US market and you will likely to see a much greater acceptance going forward.

Nitin Agarwal, IDFC Securities: Arun, we have done a phenomenal job with our first wave of biosimilars. How should we look at life beyond that in terms of which would be our sort of second wave of new launches and what should be the typical timelines for commercialization of second wave of biosimilar?

Dr. Arun Chandavarkar: Clearly, if you look at it, Biocon has been consistent in its belief in the biosimilar story and that consistency is shown by the large portfolio of products that we have partnered with Mylan where we have now got 11 products partnered with Mylan, which include two products added earlier this year to the collaboration. We also have a partnership with Sandoz as you know. We have not disclosed the number of products, but clearly there are products there which add to the pipeline and beyond this we would be looking at developing products on our own as well. So from a long term perspective we would have a very healthy portfolio of biosimilars which will be developed in a prudent way and based on what we believe are the likely market formation dates from a LOE perspective. We see a very healthy pipeline of products coming into the market. If you look at the Mylan portfolio itself in addition to the three products where we have already received approvals in some major market or the other, either Europe or US or Canada or Australia or Japan, clearly, we have made significant progress in the clinic with Bevacizumab. So that is the next thing to look forward to. Glargine approval in the US is coming on. Aspart will be entering Phase-III trials shortly. So clearly we are making advancements there and although the Sandoz programs are at an early stage, I think when we announced the Sandoz partnership we clearly said that from a timing perspective they would address opportunities which open up towards the middle of the next decade, whereas Mylan sort of addresses opportunities in the earlier part of next decade. So clearly there is a wave and our sort of judicious approach to expanding capacity reflects that belief where as we get approvals, as we expand portfolio, and as we gain market share, we will be a dominant player in biosimilars.

Kiran Mazumdar-Shaw: In fact I would also add by saying that as a company I think we have one of the largest portfolios of biosimilars under development and I think that should basically tell you about how committed we are to be a dominant player in biosimilars. So this is clearly a very-very differentiated strategy, no doubt it is a high risk capital intensive strategy, but it is actually beginning to play out for us positively.

Dr. Arun Chandavarkar: And just to add what Kiran said the other differentiating factor, it is not just the size of our portfolio, but the differentiated portfolio that we have in terms of different technology platforms. We have a large portfolio of antibodies which of course many other companies also are pursuing, but we also have a large portfolio of insulins and insulin analogs. So looking at both baskets together and other recombinant proteins, we would have breadth as well as depth in our portfolio.

Kiran Mazumdar-Shaw: And a fully integrated model because another very big challenge in this whole biosimilars area is having the kind of global scale capacity, manufacturing capacity to address these kind of market opportunities which not everyone has.

Nitin Agarwal, IDFC Securities: Just add on to that, in your assessment, how important is it in biosimilars to be in the first wave of launches?

Dr. Arun Chandavarkar: It is obviously nice to be in the first wave of launches, but it is not so precipitous as in small molecules, where there is significant value erosion between the 180-day exclusivity and post that. We have not seen that kind of a difference yet, but it is early days. We do not know how the dynamics will change if there are for example 10-15 players per molecule.

Nitin Agarwal, IDFC Securities: The point I was making is in your assessment when you sort of project, you were doing your internal assessment on the future opportunities, hypothetically what stage the product does not start to become attractive for you, I mean, when you believe that even third or fourth or fifth player or up to number five, it does not really bother you, if you say probably fifth player in the line to get an approval it does not bother you or after number three it is not such exciting proposition, is there a framework that you guys use?

Kiran Mazumdar-Shaw: Right now I think you should understand that these are very early days of biosimilars. I think there are not too many players. So I think these are questions we will address at a later stage. Right now you can see that there is also a shakeout even at this early stage. You also heard certain company say that they would like to sort of drop out of the biosimilar strategy. So it is not an easy area to be in, so these are early days yet, it is an evolving space, obviously we will look at our strategy as and when dynamics change, but at this point in time we do not see this becoming an overcrowded space.

Harith Ahamed, Spark Capital: Just one question from the balance sheet. This is on the other current liabilities which I believe is the deferred revenues and this number has increased by close to Rs.300 crores versus March. Just wanted to understand which products are these related to and over what time period this revenue will get booked? Lastly, whether this will be booked as licensing income or as part of product sales?

Siddharth Mittal: You are right, it is relating to the deferred revenue adjustment that we had done once we had to adopt the new accounting standard at the beginning of the year. The amount I think in the balance sheet is roughly Rs.200 crores and this will be recognized over a period of five to seven years, it is booked in licensing income. As mentioned in Kiran's opening remarks, that number for the quarter was roughly Rs.5 crores and it was a similar number in the first quarter as well. So you will see roughly 20 crores a year unwind every year from this line.

Sameer Baisiwala, Morgan Stanley Research: Just a broader industry question, I think there have been some studies in Europe which was brand to biosimilar switch and which have been very successful and I think that

has accelerated the utilization adoption in markets like UK and I think now biosimilar to biosimilar studies are also underway and experience has been good that nothing happens if we switch the even the existing patients overnight into biosimilars. This situation is quite contrasting to what we are seeing in US at the moment and I recognize it is two or three or four years behind Europe, but any such studies are they underway in US or do you think anything that can be done from a manufacturer's side to accelerate biosimilar take up?

Dr. Arun Chandavarkar: I think the Europe studies that you are talking about were not sponsored by the companies involved, they were government or institutional sponsored studies. If I remember correctly, I think one of them was done by the Norwegian government for this switching. As you know the European healthcare model is very different from the US healthcare model, there is a significant role of institutions like NHS and government funding of healthcare, so it was in their interest to do these kind of studies early on. In the US, I am not sure the role of government in doing such studies. So to get private companies to do the studies would probably be linked to some sort of return on investment from these studies. So having said that our assessment is that the importance of switchability depends on the therapy and the use. So what applies for one kind of a therapy, say the diabetes or autoimmune may not necessarily apply to oncology or some other. So it is a largely therapy and practice specific and clearly switching can also defacto happen if for example, there is a sudden change in formulary or coverage which mandates coverage. So there can be a switch driven by payers which is also sort of an indirect switch that can happen either in US or in Europe. It is very early as you rightly said to predict which way. All of these options are open and all of us are keeping our eyes wide open to see what is happening everywhere because being first movers, there is an advantage, but there is also a first mover uncertainty around which way it will go but we are prepared for either way.

- End of Transcript -

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