

Transcript

Biocon Limited Q2 FY20 Earnings Conference Call October 24, 2019

Participants from Biocon's Senior Management Team

- ✿ Dr. Kiran Mazumdar-Shaw – Chairperson & Managing Director, Biocon Limited
- ✿ Mr. Siddharth Mittal – President – Finance & Chief Financial Officer, Biocon Limited
- ✿ Dr. Christiane Hamacher – CEO, Biocon Biologics
- ✿ Mr. Shreehas Tambe – Chief Operating Officer, Biocon Biologics
- ✿ Mr. Paul Thomas – Chief Commercial Officer, Biocon Biologics
- ✿ Mr. Alexander Zach – Head of Policy, Government Affairs & Market Access, Biocon Biologics
- ✿ Mr. Saurabh Paliwal, Investor Relations, Biocon Limited

Prepared Remarks Session:

Saurabh Paliwal: Thanks, Janis. Good morning, everyone. I welcome you to Biocon's Q2 FY'20 Earnings Conference Call.

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

To discuss this quarter's business performance and future outlook for Biocon, we have today with us the leadership team at Biocon 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 end of this call if you need any further information or clarifications, 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: Thank you, Saurabh, and good morning, and I wish everyone a very happy Diwali in advance. I welcome you to Biocon's Earnings Call for the Second Quarter and the First Half of FY '20.

Let me start with some "Key Management Updates."

Dr. Arun Chandavarkar - CEO and Joint Managing Director of Biocon will retire from the company on November 30th 2019 as per the policy that we have enunciated. Arun as you know has played a very critical role in the evolution of Biocon over nearly three decades. He has made invaluable contribution to enable the company to deliver on its long-term commitment to its stakeholders. Arun's vision and drive has strengthened the foundations of Biocon and he leaves behind a very rich legacy of excellence. We wish him all the very best in his retirement. However, we will continue to engage him with various company activities including on a board role at Biocon Biologics.

I am also pleased to share that Mr. Siddharth Mittal - Current CFO and President - Finance will take over as Chief Executive Officer and Joint Managing Director of the company for a period of five years commencing December 1st 2019. Siddharth has been a core member of the leadership team at Biocon since May 2013 and I am confident that in his new role he will build immense value for Biocon and its stakeholders and will be a worthy successor to Arun.

Now coming to “Key Business Highlights for this Quarter.”

- ❖ Biocon expanded its geographic reach to China through a license and supply agreement with a subsidiary of China Medical System Holdings Limited for the three generic formulations products. This agreement will allow Biocon to take its US approved generic formulations to patients in China, allowing an early entry into the world’s second largest pharmaceuticals market. Biocon will be responsible for the development, manufacturing and supply of the products while CMS will be responsible for registration and commercialization. The total addressable market size for these three products in Mainland China is a little under \$1 billion as per IQVIA data.
- ❖ Biocon Biologics expanded its R&D footprint in the quarter by acquiring Pfizer Healthcare India Limited’s R&D capital assets to set up a 60,000 square feet world-class integrated R&D facility at TICEL Bio Park in Chennai. The high end facility will enable Biocon Biologics to expand its R&D capability and fast forward the development of its biosimilars from lab to pilot scale. The facility is expected to be operational in a few months post qualification and will house over 250 scientists.
- ❖ Biocon and Mylan received US FDA approval for the supplemental Biologics License Application for an additional production line to manufacture Ogivri 150 mg per vial drug product. Now, this new manufacturing line is also certified by the EMA and significantly enhances our drug product capacity for supplying Trastuzumab to the US, EU and other markets. The approval follows a pre-approval inspection of Biocon’s new drug product facility as what we refer to as the B2 biologics facility that was conducted between September 10th and September 19th of this year.
- ❖ On the sidelines of the recently concluded 74th Session of the United Nations General Assembly, I had a great privilege of making an announcement that Biocon Biologics will enable universal access to recombinant human insulin at prices of \$0.10 per day for low and middle income countries. This announcement is something that we believe is extremely important. It was very well received and we are working now with various governments to see how we deliver on this commitment.
- ❖ The Malaysian insulin glargine manufacturing facility received the certificate of GMP compliance from the European Medicines Agency. This approval expand Biocon Biologics capacities multifold with the new large-scale devices facility coming up to serve the needs of people with diabetes in the EU.
- ❖ Biocon Biologics also in-licensed an early stage preclinical biosimilar asset from Just - Evotec Biologics, a subsidiary of Evotec SE and will develop, manufacture and commercialize the biosimilar under the Biocon Biologics label in global markets. Just - Evotec, the company has received an undisclosed license fee and will receive milestone payments.
- ❖ During the quarter, our API manufacturing facility in Bengaluru successfully underwent an inspection by COFEPRIS, the Mexican health regulatory agency and reported zero observations.
- ❖ Syngene operationalized the first phase of a new 50,000 square feet research facility in Hyderabad which will house a team of nearly 150 discovery research scientists once it is fully operational.
- ❖ Syngene also successfully completed yet another US FDA inspection without any 483s or major observations. The audit was conducted to inspect its facilities as an analytical laboratory for general GMP coverage.

Now, I will discuss “Financial Highlights for this Quarter:”

- ❖ Total revenue was up 17% at Rs.1611 crores.
- ❖ Revenue from operations stood at Rs.1572 crores in Q2, up 19% from last year.
- ❖ From a segment perspective,
 - ❖ Small molecules reported revenues of Rs.530 crores, up 23% from last year.
 - ❖ Biologics grew 40% to Rs.516 crores.

- ❖ Branded Formulations were at Rs.128 crores; while
- ❖ Syngene was up 11% at Rs.465 crores.
- ❖ We booked a FOREX gain of Rs.16 crores this quarter as compared to Rs.24 crores in Q2 of last year, and this gain is reflected in the other income line of the profit & loss statement.
- ❖ Gross R&D spends were Rs.123 crores for this quarter, which corresponds to 11% of revenue ex-Syngene. Of this, Rs.104 crores is reported in the P&L and the balance has been capitalized. The capitalized amount as previously disclosed relates to various biosimilar development programs. The increase in R&D expenses as compared to last year is largely on account of higher spends across small molecules, biosimilars and novel development programs.
- ❖ EBITDA for Q2 FY'20 stood at Rs.441 crores, which is an increase of 12% over last year. EBITDA margin for this quarter was 27% as against 29% last year. EBITDA margins have shown a slight decline in gross margins largely on account of higher R&D expenses, increase in employee and other costs including higher marketing and profit share expenses.

I must emphasize here that we are building a global talent pool in terms of our leadership and other critical functions across the organization which obviously is adding to people cost. I must further add that the increase in employee cost is also reflective of the new organizational structure where we will have independent management team for each one of our separate businesses that is small molecules, biologics and novels. We will continue to invest in building this global talent pool as required in order to support our expansion in global markets.

- ❖ Core margins, i.e. EBITDA margin net of licensing, impact of FOREX, and R&D stood at a healthy 33% which is very similar to last year.
- ❖ Net profit for the quarter stood at Rs.216 crores. This includes certain exceptional item, and adjusted for the exceptional item and associated tax, net profit stood at Rs.189 crores, which is up 3% from last year on a comparable net profit margin at 12%.
- ❖ Return on Capital Employed, (ROCE), at the consolidated level which was 15% in FY'19 has improved to 17% on an annualized basis in the first half of this year. We expect the ROCE to continue to improve with continued momentum in growth in our Biologics business.

Let me now discuss "Business Performance This Quarter on a Segmental Basis."

Small Molecules reported strong revenue growth of 23% over last year with revenues growing from Rs.432 crores to Rs.530 crores in Q2 FY20. Revenue growth was led by robust performance of our Generic Formulations portfolio, along with higher sales of Immunosuppressants and Specialty API. The Generic Formulations business grew with the expansion of our client base for Rosuvastatin, Simvastatin and Atorvastatin Formulations which have been commercialized under our own label in the US.

On a half yearly basis, revenues grew 21% over H1 to Rs.1009 crores. PBIT margins for the Small Molecules segment were 22% for the quarter as compared to 20% last year. And this was reflective of a better product mix, which included a higher sale of Immunosuppressant and Specialty API products. For the first half, PBIT margins improved from 19% in H1 of FY19 to 22% this year.

Now coming to "**Biologics**." The Biologics segment maintained its strong growth momentum in Q2 of FY'20, with segment revenues growing 40% to Rs.516 crores from Rs.368 crores last year. Growth was led by the sales of Pegfilgrastim in the US, Adalimumab in EU and Trastuzumab in several emerging markets like Brazil, Turkey and Algeria. Furthermore, two of our co-developed biosimilars were commercialized in Australia. Semglee and Ogivri are the first biosimilar insulin glargine and Biosimilar Trastuzumab respectively to be made available in Australia through the Pharmaceutical Benefits Scheme.

On a half year basis, revenues grew 63% to Rs.1006 crores. PBIT margins for the Biologics segment were 25% for the quarter and 31% for the half year. Products mix, higher spends on R&D and increased costs related to global talent acquisition impacted the segments margins this quarter.

Launch of Trastuzumab in the US and availability of additional capacities of Pegfilgrastim will help revenue growth and improve segment margins in the second half of this fiscal.

ROCE for Biologics, which was at 11% in FY19, has improved to 16% on an annualized basis in the first half of FY20, and we expect the significant bolus in ROCE in the coming years as we monetize the investments made in our biosimilar pipeline.

Some “Biosimilar Pipeline Updates.”

- Biocon Biologics has a comprehensive product pipeline of 28 molecules under development including 11 with Mylan, several with Sandoz and is independently developing many. The company’s therapeutic basket includes molecules for diabetes, oncology, and immunology as well as other specialty areas.
- In terms of specific updates on Mylan-partnered programs, Bevacizumab, our biosimilar Avastin, the global Phase-III clinical trial for this molecule is on track with filings planned with EMA and US FDA in the second half of FY20.
- We have initiated a global Phase-III clinical trial for Biosimilar Insulin Aspart, and we expect a filing with EMA in the second half of FY20, whilst the US FDA submission is expected by mid-calendar year 2020.
- Work on the Sandoz programs is underway with spends being expensed in the P&L. All programs are currently under early stages of development and are a couple of years away from entering the clinic.
- Update on Biocon Biologics Independent Programs - Recombinant human insulin that we are developing for the US market has made good progress in our Phase-I PK/PD clinical trials and we expect the study reports to be available in the next few months, post which we expect to start Phase-III trials, for which advice is being sought from US FDA.

In terms of our “**Novel Portfolio Update**”, our partner, Equillum, which has licensed Itolizumab for development in the US and Canada have initiated a Phase Ib clinical trial in patients with lupus nephritis. Another trial for acute asthma has already been initiated in Australia.

Branded Formulations: The performance of the Branded Formulations segment remains subdued with modest growth in India and continued challenges in the UAE. The business reported revenue of Rs.128 crores this quarter and on half yearly basis revenues were at Rs.262 crores.

Research Services segment which is largely the Syngene business reported revenues of Rs.465 crores, growth of 11% over last year. On a half year basis, revenues grew 7% to Rs.886 crores.

Growth during the quarter was driven by continued growth in the Discovery Services business and consistent performances in the dedicated R&D center and development service business. With growing demand for its services as well as its continued investments in leadership, quality compliance, safety and business development activities, Syngene remains very well positioned in improving revenue and operational efficiency over the long-term.

In summary, I would like to say that we have delivered a strong performance in the first half of the year. We expect the growth momentum to accelerate in the second half of FY20 driven by biosimilar launches in the US and Generic Formulations business, and additional capacities coming online.

With this, I would like to open the session up for question-and-answer. Thank you.

Q&A Session:

Prakash Agarwal, Axis Capital: *Congratulations to Siddharth. Ma’am, first question on the guidance or the aspirational guidance that we are seeking for Biocon Biologics of \$1 billion by fiscal ‘22. We have done about \$140-odd million in the first half. So, just trying to understand the building blocks, is it all organic because given the 4 products which are at advanced stages, if we build that up, we are still not getting the numbers. If you could help us which direction we should think about?*

Kiran Mazumdar-Shaw: Well, I will get our CEO of the Biologics business to respond, but yes, it is going to be organic based on all our products. Let her explain to you.

Christiane Hamacher: Yes. As we have said before, we have a platform of 28 molecules across different disease areas which are under development. And together with our partner where we are covering all the markets globally, we are building the business sequentially and are reaching the \$1 billion by fiscal year 2022 as an aspirational target. The market in the United States, we are seeing that the biosimilar penetration is actually enhancing. The launch of biosimilar Pegfilgrastim was one of the most successful ones and we are part of it. As you are also aware, major molecule, Trastuzumab will be launched in the United States end of this calendar year. More molecules are coming, and building this ambition means that at least one molecule will be launched in the United States year-by-year.

Prakash Agarwal, Axis Capital: Yes, but we are talking about fiscal '22 and what we are aware as ma'am also said that we are expecting Trastuzumab by December and then you have insulin glargine. I mean, are there more products before we head onto fiscal '22?

Kiran Mazumdar-Shaw: There are many other, I think you did not listen to my comments. There is Bevacizumab, there is Aspart. There are several products that will be added to this basket before fiscal '22

Prakash Agarwal, Axis Capital: I just wanted to reiterate the guidance of 15% gross R&D. Would that still hold for fiscal '22?

Siddharth Mittal: Well, for fiscal '20, it would be between 13% and 15%.

Kiran Mazumdar-Shaw: But you can roughly look at this guidance going forward because we are going to be developing a large number of pipeline products across our businesses. So, obviously, yes, you can take that as a rough indicator of R&D spend.

Prakash Agarwal, Axis Capital: And this year was 15%?

Siddharth Mittal: Yes, this year's H1 was around 11%, but we are expecting R&D expenses to go up in the second half. So, on a full year basis, it should be around 13%.

Neha Manpuria, JP Morgan: Just to go back to the \$1 billion by FY '22, would it be fair to assume that a large part of the delta from where we are today that the \$1 billion would essentially come from developed markets, i.e., the US and EU?

Christiane Hamacher: Talking about the US\$1 billion opportunity, a significant part is coming from the United States, we also see the market in Europe as a great opportunity as well as as most of the world markets. We are a global player and together with our partners are making products available across the globe.

Neha Manpuria, JP Morgan: For the EU market, have we started seeing any contribution at all from the three products that we have got approval there or would that be reflected more...Peg I understand probably will be reflected in the second half? What about Ogivri and Insulin?

Paul Thomas: This is Paul Thomas. Europe is a very competitive market for biosimilars. It is a place where we have not had the benefit of first mover advantage for our products and building share will be a gradual process. Mylan is choosing appropriate places to focus, both tender and non-tender markets. There is a variety of different markets there. But we are in the process of building share and we are seeing some meaningful contributions there. I think it was mentioned about Adalimumab in Europe contributing already, and as you know, that goes straight to the bottom line for us. So, the market is sizable, it is growing in Europe and we are well placed together with Mylan, we are there for the long run, we are well placed for long term success with our in-house manufacturing, our broad portfolio, our commercialization presence. So, we are committed to addressing the unmet needs there, and we are confident of our growth there.

Neha Manpuria, JP Morgan: In the September inspection, the Bangalore facility also had a drug substance inspection. So, has that not been cleared as yet by the FDA? We mentioned in the press release that we have got the drug product additional capacity for Ogivri. There was another drug substance inspection also which had happened at the same time, right as per the press release mentioned?

Shreehas Tambe: Yes, we have actually had multiple inspections at our India manufacturing location, and we have been sharing those with the investors.

Kiran Mazumdar-Shaw: We are awaiting that approval. The time given to us is in November. It has not yet been communicated to us, but we are confident.

Shyam Srinivasan, Goldman Sachs: *Just one on Fulphila. So, your press release talks about ramp-up in capacity post this November event let us assume. So are you still confident that if we see secondary data market shares have been falling off from the peak that we saw in say maybe May-June. So what gives us the confidence that we can start getting back into the market and start taking share upwards again?*

Paul Thomas: Sure, thanks for that question. I mean, you are right, there has been a market share data reported with some month-to-month ups and downs. But we look at that as some month-to-month variations. Overall Fulphila still been one of the strongest launches that we have seen of a biosimilar in the US market, right. So, we are still very happy about Mylan's ability to drive demand for Fulphila in this market. Customers have been convinced about biosimilars overall. The question about whether US customers will adopt biosimilars, I think it is really not there now, and we are proud of being able to have brought this product to the market, a difficult product before anyone else and remains a difficult product for people to bring to the market. We are happy about the uptake that has been above our expectations and the choice of customers that have been maximizing the opportunity, really with choosing appropriate customers that can maximize the pricing, the profitability, things like that. So, I think now as you said, we are scaling up to address additional customer segments as we go forward, address global markets. So, we are definitely confident about substantial additional growth opportunity going forward because there is still substantial untapped market. So I think we still feel very good about this product.

Shyam Srinivasan, Goldman Sachs: *Paul, just to follow-up here. So, are we also assuming at some point of time the Onpro market which has shifted slightly towards vials, will the trend continue because Coherus secondary data is 40% share almost, Sandoz could come anytime, is there some comfort level still that market share is set to gain both from vials as well as from perhaps Onpro?*

Paul Thomas: Yes, certainly, I think that is right. That shift of Onpro to PFS that is happening over time, there is market expansion happening over time. So, I think there is multiple favorable dynamics there. There is not an underlying medical need for Onpro and the kind of market share that it has. So, some of that will shift.

Shyam Srinivasan, Goldman Sachs: *My second question is on Ogivri in the US. Is there a more specific timeline you are sharing on when the launch is? I know it is this quarter, but anything there would be helpful. And the second point is just on Amgen's launches of both Avastin and Herceptin. We see the shares are very different; so, Herceptin share is like 1.5%, whereas Avastin share is 6%. I know Avastin is a slightly further out opportunity for us, but for Herceptin, have you picked up anything from the market on how the biosimilar has been accepted by the players?*

Paul Thomas: We are very much looking forward to that launch. It plays very well to the base that we have built here. I think with our Trastuzumab, this has been a three to four-year story. So we are very much looking forward to that launch. Amgen, the difference between the two products in the launch, I think that is too early to comment on differences there, it is just very early in that launch stage. So, I do not think those are really meaningful things to comment about, but I think customers we have, we built relationships with the same customers with our Pegfilgrastim launch for the past year and a half. They know that we are the only player with biosimilars of both Pegfilgrastim and Trastuzumab coming to the market, and doctors have been looking forward to this from the time that they have seen our HERITAGE data at ASCO. So, I think there is pent-up demand here. We are operationally ready. We have both the 150 mg and the 440 mg available here for this market. So, I think lots of positives we are looking forward to unfolding once we launch.

Shyam Srinivasan, Goldman Sachs: *My last question is on Semglee in the US again. Are we still confident that we will get the facility clearance in time and also launch before the 22nd March 2020 deadline where the pathway changes, would that be something that we are confident of reaching because there are certain news that we may need to refile to a new pathway in case we miss that deadline? I know there is a lot of ambiguity there, but just your thoughts around the whole Semglee opportunity in the US.*

Christiane Hamacher: Yes, Semglee opportunity is an exciting opportunity for us. We are very confident that we will be clearing the facility as planned. We have put the CAPA plans in place. We are working closely with the regulator and we do not expect any impact on our commercialization plans for Semglee in the US.

Prashant Nair, Citi: *So just one follow-up question on Semglee. I know we are confident that we will get approval before the transition date, but is there any view on what would be required if for any reason approval does not come through by that date, would a refiling be needed in any form and how long would the delay be if any such eventuality occurs?*

Christiane Hamacher: Look, these are all speculations and we are not thinking along that line. As I mentioned, we are very, very confident that we are getting the approval and that there is no impact on the commercialization plans.

Prashant Nair, Citi: *One additional question on Fulphila. So, we expect additional capacity soon. Do you have any thoughts on potential competition in this space from new players? I know Sandoz has been talked about. So do you have any sense on when competitive intensity could pick up from... it could move from a two player market to three or four player market?*

Paul Thomas: No, I mean, we really cannot speculate on what the others are doing. I think there has been talk about expectations for others to come in by now which we have not seen any entries. So, we cannot comment further.

Sameer Baisiwala, Morgan Stanley: *Best wishes to you Arun and congrats to Sid. Kiran, a quick question on your very good effort of promising \$0.10 per day insulin. Can you share some more details, how sizable can this be over time? How much capacity would this take up as we go forward? Would this be a profitable proposition for Biocon or would it be at no-profit basis?*

Kiran Mazumdar-Shaw: Obviously, it is not at a low profit basis. I will ask my colleague Alexander Zach to give you some more optics on this, because this is about our very-very pragmatic and innovative access program that we want for the world.

Alexander Zach: Let me quickly introduce myself. Alexander Zach, I am heading Policy and Governmental Affairs and Access for Biocon Biologics. So, we made this offer in the context of the UNAIDS. It is a side event at the UN General Assembly. It has actually offered to the world actually to low and middle income countries for access to affordable insulin. And this is an offer that actually is directed towards governmental purchases, which also circumvents all the middlemen and all let us say supply chains in between. So that is one thing. And I think the other thing I would like to point it out, it is an offer made from an organization that is based on a very profitable and a very good cost structure, vertically integrated from end-to-end production. We have our production in Malaysia and in India as you know which makes us also to be a good cost player on this side. And let me also point out, as we are making this offer to governments, this is also about volume and economies of scale which in the end makes it profitable.

Sameer Baisiwala, Morgan Stanley: *Christiane, again going back on Semglee for US, getting the approval in time is one thing. Second part is on the patent side. I think recently the Delaware court had ruled that it would not invalidate the two patents simply because review board had done so. So, could IP be a challenge to your launch in time?*

Christiane Hamacher: Thank you for your question. I hope you understand I am not making any comment on this topic at this moment.

Sameer Baisiwala, Morgan Stanley: *Okay, but you remain confident of launch towards the end of March?*

Christiane Hamacher: Absolutely, we remain confident.

Sameer Baisiwala, Morgan Stanley: *A quick question on the capacity expansion both for Pegfil and Trastu. Earlier, the company mentioned that the capacities that you had earlier designed was targeting 15% to 20% of US market. So, with these two expansions, what is the sort of market that you can cater to?*

Shreehas Tambe: Sameer, I do not recollect having disclosed the percentage market share, but suffice to say that we have all the targeted taking a substantial market share all along to be a dominant player in this space. So, I think the expansions that you have seen us make has always been to make sure that there is no idle capacity cost that we are carrying and we have always been a dominant player in whichever investments and products that we made. So, you will see that in the products that we are launching and the products that we will bring to the market going forward.

Sameer Baisiwala, Morgan Stanley: *This is on your aspirational target of \$1 billion biosims by fiscal 2022. I remember, Kiran that a few years back when you had given your overall sales five year target of \$1 billion, the company had taken it very seriously and had updated us every now and then. Can we expect the same from this biosim target or is it a little bit more loose aspiration in that nature? Second, a quick clarification on this. Does this include your partner share, or this is all the revenue going to your books?*

Christiane Hamacher: Thank you for the question. The US\$1 billion aspirational target is by no means a loose target. We have a strategic growth plan based on several key initiatives and we are managing this business holistically. We are aiming to become a multinational company, a major global leader in this space. This US\$1 billion only includes our share.

Surya Patra, Phillip Capital: *Just wanted to have a clarification on the kind of R&D outfit that you have acquired from Pfizer, and you have indicated something like 250-odd scientists would be working for that. So, whether this is a kind of a cost center and it would be just working for developing a product for our own portfolio or what financial implication one should really think since it would be operational soon?*

Kiran Mazumdar-Shaw: As you know, we have been very aggressive about developing 28 molecules as biosimilars and this will call for a very large capacity expansion which obviously would have slowed down the progression of these kind of assets, and therefore, as a means of accelerating the pace of development, this was an opportunity that saves us time, and therefore we believe that this was a very critical and strategic investment that would help us to shave off two years of development timelines of many of our early-stage assets. And because of that, we decided this is a great opportunity and we made this very attractive acquisition. Secondly, this obviously offers us an opportunity to hit the ground running so to speak, because it is a very sophisticated R&D facility which Pfizer itself was using to develop biosimilars. So, I think we are very well placed to actually ramp up capacity very, very fast. And this as we said will become operational very soon and we expect that these 250 scientists that we are also talking about will happen sooner than later and therefore it positions us very strongly to accelerate the development programs of all these molecules that we have just talked about. So, in terms of the cost, yes, it is a cost center, it is not a research services business. And roughly the kind of R&D costs that you can think about is the same, around 15% of revenues which is what we have stated all along. So it does not increase that amount. It basically is roughly in that same line and it is very much an integral part of our business.

Surya Patra, Phillip Capital: *Though there is a sequential improvement in the Biologics revenue, but there is kind of a decline in the margin profile of that segment this quarter. You have validated some of the reasons. I just missed that. Can you repeat it?*

Kiran Mazumdar-Shaw: Yes, so if you look at some of the factors that have contributed muted PBIT margins, it is largely on account of greater R&D spend and greater people cost. As I just mentioned to you that in our ambition to become a global player, we are increasing our hiring of global talent which is also adding to some of that cost, but most significantly is the increase in the R&D cost. If you compare it from last year to this year, you can see the difference. So it is almost the entire amount. If you can add the R&D cost and as I said, if you look at core margins, they are the same. But it is because we have increased R&D cost and some people cost that there is a difference.

Christiane Hamacher: May I encourage you again to look at half year results. If you look at the half year one basis segment revenue, they grew 63% from Rs.617 crores to Rs.1006 crores and we are very excited that we have passed the milestone of Rs.1000 crores, and we have a strong PBIT margin of 31% for the half year, and we expect a significant performance and growth momentum, even stronger in the second half of this year on the back of new launches and additional capacity that we will make available.

Surya Patra, Phillip Capital: *Just one last clarification that on the Pegfilgrastim market share decline what we have seen on month-on-month basis or quarter-on-quarter basis this time. Is it by any chance linked to capacity or supply issues because of the inspections that were happening or the line extension that you were building or any reason and hence after all this event now you should see kind of a sequential pick up again, how should really one look at this number?*

Kiran Mazumdar-Shaw: So the first thing I want to categorically emphasize it has got nothing to do with inspections. This has got to do with the maximization of whatever available capacity we have to-date. So, there has been no impact on decline of market share because of anything to do with inspections or capacity as such. But basically we are enhancing capacity which hopefully we will now start seeing much greater market share for us in the second half.

Surya Patra, Phillip Capital: *On the core tax number after adjusting for the exceptional income and the tax on that, so that also looks bit higher for this quarter, near about 26% against normal 22%, 23% like that. So any comment on that, Siddharth, sir?*

Siddharth Mittal: So Surya, look at it on H1 basis, effective tax rate is at 23%. Obviously, when you accrue for all the taxes, you look at on a full year basis and we expect the full year to be at 23% ETR.

Hari Belawat, Techfin: *This is regarding this US FDA inspection for the new biological manufacturing unit. There were eight observations, appears to be a large number. What type of these observations are there and when do we think that these will be resolved?*

Shreehas Tambe: I assume you are referring to the facilities based in India. For the eight observations that we have received, we just also announced that we have received the approval from the US FDA for our additional capacity for the drug product line just recently. So, yes, we do receive observations whenever there is an inspection and it is put on the Form 483, but we have been able to successfully respond to the agency with corrective actions and preventive action plans which the agency has accepted and awarded us the approval for our new drug product facility as we have seen.

Hari Belawat, Techfin: *One more related to this. Is it the same unit for which you got CGMP from EMA in March 2019?*

Shreehas Tambe: Yes.

Hari Belawat, Techfin: *Does it mean that you can start exporting from this unit to the European countries and export to US only after getting US FDA clarifies this matter?*

Shreehas Tambe: Yes.

Kiran Mazumdar-Shaw: Just to tell you when you get different regulatory approvals, those pertain to those markets. So, when you get EU approvals, you can market to EU, but it does not mean that you can just automatically export to the US. The US also when it gives its approval, does not mean that you can export to EU either because of that. Each regulator has its own approval for their individual markets. So we have to get distinct permission from EU and US for their respective markets.

Girish Bakhru, Bank of America: *Would it be possible to share Semglee performance so far in EMEA and what kind of bump up can we expect with the capacity now available from Malaysia?*

Paul Thomas: As I said before about the Europe market, I think we are taking step-by-step approach in building up our presence in this market and that will evolve over time.

Girish Bakhru, Bank of America: *On the US side, when we are aiming for approval by March for Glargine, do you also expect FDA to give some color on interchangeability or would that be a later outcome?*

Shreehas Tambe: The interchangeability outcome as you said is non-applicable under 505(b)2 directly and we believe that should not affect any plans that we made at this point in time to realize this opportunity in the United States.

Girish Bakhru, Bank of America: *Right, but do you think in overall CY'20, would there be a focus on getting insulin interchangeable given there is a lot of discussion within FDA to get insulin interchangeable approved, so, is there like a realistic opportunity for you guys to get interchangeability on glargine?*

Paul Thomas: So I think the transition certainly FDA has said that opens up because it is in a 351k context. It opens up the regulatory possibility for interchangeability. So that is there for insulins as a possibility. It is not a must for gaining market share in the US. I think we have seen very clearly with the insulins market in the US that payers, PBMs are driving switches without the need for any interchangeability designation. We have clinical data supporting use in our patients who are already on glargine also, but I think this is really not a hurdle in the insulins market in the US.

Girish Bakhru, Bank of America: *Just on the similar side, I was reading on some of the comments from the FDA that they are probably willing to even approve rh insulin biosimilar. I am not sure if you discussed that opportunity in your initial remarks. Do you see this as a sizable opportunity still and possible launch in CY '21-22?*

Kiran Mazumdar-Shaw: I think I did mention in my comments that we are developing rh insulin for the US market, and that we expect the read-out of our Phase I PK/PD very soon, and we are certainly trying to develop this product for the US market especially in context of the recent insulin crisis that the US has been discussing both in the Congress and in the Senate. So, I think this is something we perceive as a big opportunity for Biocon and we certainly hope that we can expeditiously enter the US market depending on how the regulatory process pans out. Right now of course we are in discussion with the regulators and seeing how quickly we can get into the market, but that is as far as I can share with you.

Girish Bakhru, Bank of America: *Just on the \$1 billion guidance, I know it is a very significant number to even look from a modeling perspective, but if you could give color, would there be significant emerging markets growth in lieu of US approvals or how should we actually look from the emerging market perspective side from the biosimilar growth?*

Kiran Mazumdar-Shaw: I think you have to look at how many molecules are there in developed markets. Right now you can see that we already have color on four molecules in terms of developed markets, for instance, we already have color on Pegfilgrastim, we have color on Trastuzumab, we have color on Insulin Glargine and on Adalimumab. Add to this of course the Bevacizumab which we believe we will get approval before FY'22. And then if you look at the other products that are also on the anvil, we are not factoring for that in the billion dollar. That would be an upside like recombinant human insulin and aspart. But if you look at these products holistically in terms of the global markets, we believe that emerging markets also are growing very-very rapidly. If you look at today's numbers, yes, I think you are seeing that the contribution from US is clearly a very important contribution, but we have significant contribution of our Biologics business from emerging markets at this point in time which will only grow. So that is why we are very confident that globally the Biologics business is going to be a very strong robust business, both balanced between developed markets and the emerging markets. So, I really think that we are not just talking in a very speculative way. We are talking about a very strong play in these markets. China is something that we also believe is a very-very important market for us by FY'22. Remember, Mylan will be merging with Pfizer's Upjohn Division. Upjohn itself has a very large presence in China, and you know that biosimilars are going to be very important in this equation. Upjohn itself has made a statement saying that they are focusing a lot on biosimilars for their differentiated growth potential. So, I think everything augurs very well for the Biologics business and that is why we are very confident of reaching the \$1 billion target by FY'22. And maybe Christiane would like to add.

Christiane Hamacher: Looking at published data, the biosimilar opportunity globally by 2025 is US\$260 billion globally. As mentioned several times, we have a platform of 28 molecules, we have marquee partners and we are serving patients across the world in all major developed markets. China opening up as an opportunity with biosimilars for the first time this year being listed on the national drug reimbursement listing, and we are also covering all most of the world markets. Why else are we confident? Because of our cost structure, our overhead, we are very-very well positioned to come in with price, volume, agreements that are very-very competitive, and on the other hand, we have the muscle to also go for value maximization. That means we can serve the market in very specific ways.

Aditya Khemka, DSP Investment Managers: *Most of my questions have been answered. Just the one left on the Fulphila market share loss that we have seen recently. So, we have been saying in the past that there is some capacity constraints we have for Fulphila and we have also been saying that one biosimilar ideally is not substitutable with another biosimilar and there are no studies between two biosimilars claiming to be similar or interchangeable. In that light, could you explain how the new capacity coming online will actually help us gain ground in Fulphila because given the decline in market share, we are probably not even utilizing our existing capacity to the fullest?*

Paul Thomas: I do not think we have talked about data about switching being an issue. I do not think that is a factor in a market like this. It is a short acting product, it is not used for a long period of time. So turnover of patients is quick and also in an institutional market, it is less important. So it is not really a factor holding things back, and overall, there is still plenty of untapped market here to work with. I think we have opportunity to expand into different customer segments and the market share in the existing segments also there is plenty of upside we have, I think a lot that has not been taken by biosimilars yet.

Kiran Mazumdar-Shaw: I think we would be very pleased to explain to you if you are interested offline about some of your concerns because I think you have not quite understood some of the factors in the market, and offline, I think we can explain it to you.

Aditya Khemka, DSP Investment Managers: *Sure, ma'am, I will take this offline.*

Charulata Gaidhani, Dalal & Broacha: *My question pertains to China. By when do you see China contributing to revenues?*

Christiane Hamacher: China is very, very exciting opportunity because we just actually alluded to that with the merger of Upjohn and Mylan and Upjohn having headquarter in Shanghai, this is a unique positioning in the market. Our molecules are under development for China and we expect market entry in the near to mid-term future with our monoclonal antibodies as well as with our insulins.

Charulata Gaidhani, Dalal & Broacha: *So, would it be somewhere around FY'22 or FY'23?*

Christiane Hamacher: This is at the moment difficult to specify and the reason is that there are a lot of changes in the regulatory environment in China, but our aim is that we are commercializing our products in the near to mid-term future in China and we are observing China closely, not only the regulatory environment, but also the reimbursement and funding environment in China is becoming more and more favorable for biosimilars. As I have mentioned before, for the first time this year, biosimilars are being made available in the national drug reimbursement listing, what usually means that patients across the nation are getting reimbursement of 70% to 80%. So, for us, China is a tremendous opportunity together with our partner for the near to mid-term future.

Charulata Gaidhani, Dalal & Broacha: *And my second question is by when would we expect US FDA approval to Malaysia?*

Shreehas Tambe: We are saying that we expect to have the approval in place by March 2020 for our Malaysia site insulin glargine.

Charulata Gaidhani, Dalal & Broacha: *Have we filed our responses?*

Shreehas Tambe: Yes, we have responded to the agency with a comprehensive CAPA plan and we are working with them with periodic follow-up updates.

Raj Mohan, Individual Investor: *This is a query to Dr. Christiane Hamacher. You are an industry veteran who has held superior responsible positions in global innovator companies. After spending six months with Biocon, could you share your impressions with respect to its capabilities in addressing the humongous opportunities in biosimilars? In the context of its integrated and lower cost capabilities that have been so painstakingly developed so far, how would you perceive its rarity and not so easier replicability which could create a moat of sorts over the medium-term? What also are the shortfalls or gaps that Biocon needs to fill?*

Christiane Hamacher: Thank you very much for your question. I am certainly extremely excited to work at Biocon. I tell you why. I believe that Biocon Biologics is absolutely uniquely positioned worldwide as a biosimilar company. Why? We see ourselves as the only company that is solely focusing on biosimilars and that is fully vertically integrated and that is a fantastic foundation to build on with the 28-molecules. I am absolutely impressed by the dynamic and learning agility of the organization. What we currently doing? We are blending the best out of both world here at Biocon Biologics India and complementing that with talent from all parts of the world coming from the top pharma and biotech companies. This entrepreneurial environment allows us to be truly disruptive and innovative and we have just spoken today about the announcement that Kiran made at the United Nations General Assembly side event where we are really well positioned to reach patients in the middle of the income pyramid and that allows us to open tremendous opportunities. We are also in such an entrepreneurial environment so that we are thinking beyond products using technology and digital in the future to a big scale as well as data to deliver healthcare to patients and healthcare professionals and other stakeholders in a very different way. I am extremely excited that many talents from different pharma companies are joining us and are complementing the enormous strength that Biocon Biologics have.

Chirag Dagli, HDFC Asset Management: *Through the call the sense I get is that the EM contribution in your Biologics business versus where it is currently and, in your guidance, or your aspiration of \$1 billion is going to increase dramatically led by China. Is this understanding correct?*

Kiran Mazumdar-Shaw: I must correct you. China is not factored in the \$1 billion target. That can be an upside if it happens earlier.

Chirag Dagli, HDFC Asset Management: *But the emerging market contribution?*

Kiran Mazumdar-Shaw: The EM is based on our existing presence in many of these emerging markets, which we understand very well, and therefore we know what the traction can be in this market, and of course we have also factored in the developed markets where we expect to see tremendous growth because we have not entered many of these markets. As you know, we are just about entering the US market with our Trastuzumab and we obviously have other opportunities with Semglee, but before FY '22, we will also be hopefully in the US and European markets and other markets with Bevacizumab. Adalimumab is already in Europe. So, I think we have very granular optics on how we are going to get to the billion dollars. I can assure you that this is not a speculative number, this is a very well worked out number where we have strategic initiatives to get there.

Chirag Dagli, HDFC Asset Management: *If you sort of broadly split it into EMs and developed world versus where we are today in the billion dollar target number, how different will the EM and developed world contribution be?*

Paul Thomas: We said that we are present in the emerging markets and those markets will grow as we add products, as we continue to build our share there. But certainly, the transformation ahead of us is we are just embarking on this journey of bringing these products to the developed markets, to the US in particular. It is still very early in that journey and we have multiple products coming forward. So, I think those developed markets beyond the US, Europe, Australia, New Zealand things like that are there. So we expect new products and developed markets to increase in importance over time.

Saurabh Paliwal: Thanks, Janis. Thank you, everyone for joining us today. If there are any further questions or clarifications, please do get in touch with me. Have a good day.

- Ends -

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