



Transcript

Biocon Limited Q3 FY20 Earnings Conference Call January 24, 2020

Participants from Biocon's Senior Management Team

- # Dr. Kiran Mazumdar-Shaw – Chairperson & Managing Director, Biocon Limited
- # Mr. Siddharth Mittal – Chief Executive Officer & Jt. Managing Director, Biocon Limited
- # Dr. Christiane Hamacher – CEO, Biocon Biologics
- # Mr. M.B. Chinappa – Chief Financial Officer, 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
- # Ms. Fionnuala Doyle – Head of Regions - Commercial, Biocon Biologics
- # Mr. Sundaresan Ramanan – Regulatory Affairs, Biocon Biologics
- # Mr. Saurabh Paliwal - Investor Relations, Biocon Limited

External Participants during Q&A session

- # Surya Patra – Phillip Capital
- # Damayanti Kerai – HSBC
- # Vikram Agrawal - Valuegen Investment Managers
- # Shyam Srinivasan – Goldman Sachs
- # Prakash Agarwal – Axis Capital
- # Sameer Baisiwala – Morgan Stanley
- # Raj Mohan – Professional Investor
- # Charulatha Gaidhani – Dalal & Broacha
- # Hari Belawat – Techfin Consultants
- # Pratik Shah – Apex Capital
- # Cyndrella Carvalho – Centrum Broking
- # Harith Ahamed – Spark Capital
- # Nitin Agarwal – IDFC Securities

Prepared Remarks Session:

Saurabh Paliwal: Good morning, ladies and gentlemen. I welcome you to Biocon's earnings conference call for the third quarter and nine months of fiscal FY2019-20. Before we get started, I would like to remind everyone that replay of today's discussion will be available for the next few days, about 60 minutes post the conclusion of this call. The call transcript shall be made available on the website in the coming days.

As part of today's presentation and to discuss the company's business performance and outlook, we have 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 conference call. Today's discussion maybe forward-looking in nature, based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements. After the end of this call, if you need any further information or clarification, please do get in touch with me.

With this, I would hand over the call to Dr. Kiran Mazumdar. Over to you, ma'am.

Kiran Mazumdar-Shaw: Thank you, Saurabh. Good morning, everyone. And since we are still in January, I would like to wish everyone a very Happy New Year.

Let me start with **Key Board and Management Updates**.

- ✿ The Board has approved my appointment as Executive Chairperson of the Company for a period of five years subject to shareholders' approval effective April 1, 2020.
- ✿ Further, the Board has approved the change in designation of Mr. Siddharth Mittal from Joint Managing Director to Managing Director of the Company effective from April 1, 2020, and accordingly, Mr. Siddharth Mittal will be the Managing Director and Chief Executive Officer of the company effective April 1, 2020.
- ✿ Mr. M.B. Chinappa has been appointed Chief Financial Officer of Biocon Biologics effective January 6th 2020. He was earlier the CFO at Syngene.

Now, coming to **Key Business Highlights for the Quarter** –

- ✿ Ogivri, which is the brand name of our Biosimilar Trastuzumab, co-developed with Mylan, was launched in the United States. It is the second biosimilar from our partnered portfolio commercialized in the U.S. after Fulphila, biosimilar Pegfilgrastim which was done in 2018. Ogivri was also commercialized in Canada and additional EU markets by Mylan.
- ✿ In November, Biocon and Mylan's supplemental Biologics License Application (sBLA) for Pegfilgrastim drug substance to be manufactured at Biocon's new Biologics manufacturing facility was approved by the U.S. FDA. This approval will enable Mylan and Biocon to scale up capacity multi-fold and address the growing market opportunities in the U.S. and other global markets for the product.
- ✿ Biocon and Equillum expanded their collaborational license agreement for Itolizumab, to grant Equillum exclusive rights for developing and commercializing Itolizumab in Australia and New Zealand.

Another important development earlier this month was that Activ Pine LLP, an affiliate of True North Fund has infused \$75 million in Biocon Biologics. This is a primary equity infusion for a 2.44% stake at an equity valuation of \$3 billion and an enterprise valuation of \$3.5 billion on a pre-money basis. Biocon Biologics will deploy this money towards CAPEX investments as well as on R&D.

Moving on, I will now discuss **Financial Highlights for this Quarter**.

- ✿ Total revenue was up 14% at Rs.1784 crores.
- ✿ Revenue from operations stood at Rs.1748 crores, up 13% from last year.

From a segment perspective,

- ✿ Small Molecules reported revenues of Rs.544 crores which is up 16% from last year.

- ✦ Biologics continued its stellar growth with 31% YoY growth this quarter with revenues at Rs.588 crores.
- ✦ Branded Formulations revenues were at Rs.157 crores and
- ✦ Research Services (Syngene) revenues were up 11% at Rs.519 crores.

- ✦ We recorded a FOREX gain of Rs.15 crores this quarter as compared to a loss of Rs.28 crores in Q3 of last year.
- ✦ Gross R&D spends however rose sharply. They were at Rs.155 crores for this quarter ex-Syngene, and of this Rs.131 crores was reported in the statement of profit & loss and the balance has been capitalized. The capitalized amount relates to various biosimilar development programs.

The increase in R&D expenses as compared to last year is on account of higher spend across Small Molecules, Biosimilars and Novel development programs.

- ✦ EBITDA for this quarter stood at Rs.480 crores which is an increase of 18% over last year, and EBITDA margins were at 27% compared to 26% last year.

Core EBITDA margins, which is EBITDA margins net of licensing, impact of FOREX and R&D stood at 33% which is up from 32% reported last year.

- ✦ Net Profit for the quarter stood at Rs.203 crores. But this includes a tax impact of certain exceptional items primarily pertaining to transfer of development and commercialization rights of fusion proteins to our wholly-owned subsidiary, Bicara.

Adjusted for this impact Net Profit for this quarter stood at Rs.225 crores, which is 6% up from last year, and adjusted net profit margin stood at 13%.

Let me now discuss our **Business Performance this Quarter**.

The **Small Molecules segment** reported strong revenue growth of 16% over last year with revenues growing from Rs.469 crores to Rs.544 crores. Revenue growth was led by strong performance of Generic Formulations, supported by growth in immunosuppressants and specialty API sales.

I'm pleased to report that the Generic Formulations business crossed the Rs.100 crores mark in revenues for the first time this quarter. Increased market share across our portfolio of Generic Formulations led to strong YoY growth.

For the first nine months of this fiscal, segment revenues grew 19% over a similar period last year to Rs.1553 crores.

PBIT margins for the Small Molecules segment were 19% for the quarter as compared to 21% last year, the decrease largely on account of higher R&D expenses during the quarter.

For the nine months period, PBIT margins were at 21% against 20% reported in the previous year.

Now coming to **Biologics** - The Biologics segment maintained its strong growth momentum in Q3 FY'20 led primarily by Trastuzumab and Pegfilgrastim. Revenues increased 31% from Rs.449 crores to Rs.588 crores.



On a nine months basis, segment revenue grew 50% from Rs.1066 crores to Rs.1594 crores. Growth again was led by these two leading biosimilars - Pegfilgrastim and Trastuzumab, in the United States. Adalimumab in EU also contributed to this as well as Trastuzumab in several emerging markets.

PBIT margins for the Biologics' segment were 25% for the quarter and 29% for the nine months.

For the quarter, the benefit from the recent launch of Trastuzumab in the U.S. was negated by increased cost of operations with respect to remediation of the Malaysia facility, higher R&D spend and deferment of sales.

We expect enhanced performance from the Biologics segment in the fourth quarter with continued sales of Trastuzumab and the full higher impact of Pegfilgrastim both in the US and other regions driving revenue growth and improved profitability.

I would now like to provide **Specific Update on the US Insulin Glargine Program** –

We have recently responded to the CRL received from the U.S. FDA and are working closely with the agency to address all questions related to the Malaysia facility clearance. If you recall the CRL largely pertains to this.

Post our submission, the FDA has notified us that it plans to inspect our Malaysia insulin's facility in February this year.

In parallel there has been a recent legislation in the US mandating the continued review of pending insulin marketing authorization applications under Sec.505 of the Federal Food, Drug and Cosmetics Act after transition of insulin to be regulated as biologics that is happening in March.

And with the recent legislation in place, the NDA to BLA transition for certain Biologics which is scheduled post March 23rd 2020 will not affect our application review by the FDA.

FDA has set a target action date for our application in June and we remain on track for mid-2020 launch in the US as stated previously by Mylan.

Coming to the **Novel Portfolio Update** - Our first-in-class oral prandial insulin molecule, Tregopil has commenced multiple ascending dose studies in people with Type-1 diabetes in Germany. This study is being done in partnership with the US-based JDRF or the Juvenile Diabetes Research Foundation, a leading global organization that funds Type-1 diabetes research and advocacy worldwide.

We have expanded the scope of our licensing agreement with our partner Equillum for Itolizumab, to include Australia and New Zealand. Equillum had originally secured exclusive rights to develop and commercialize Itolizumab for the U.S. and Canadian markets in May 2017. Equillum is developing the asset for the treatment of acute graft versus host disease (aGVHD), severe asthma and lupus nephritis.

Coming to **Branded Formulations** - The performance of this segment remain subdued. The business reported revenues of Rs.157 crores in the quarter and Rs.419 crores for the nine months.

The performance of India has remained flat while we continue to face challenges in the UAE; however, there are some green shoots in the UAE with respect to some of the biosimilars.

Coming to **Research Services** - Syngene reported revenues of Rs.519 crores, a growth of 11% over last year. Performance for the quarter was mainly driven by strong performances from Discovery Services and Development Services.

Revenue for the nine months grew 9% to Rs.1405 crores.

Continuing its commitment to offer leading-edge science capabilities, Syngene has extended its Biologics discovery and pre-clinical research capabilities in cell therapy and innovative cell-based approaches to treating cancer, including CAR-T therapy.

Syngene gains two significant regulatory approvals this quarter demonstrating ongoing commitment to operate at global standards.

In summary, Biocon has delivered a strong all-round operational performance in Q3 and the first nine months of fiscal 2020. The Biologics business will continue to be the growth driver for Biocon for the rest of the year.

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

Q&A Session

Surya Patra: *Just wanted to clarify, whether we have started getting the benefit of the capacity addition this quarter and the launch of Trastuzumab in US in this quarter already?*

Christiane Hamacher: When comes to Pegfilgrastim we got our expanded capacity approved in November. And it is a bit early to comment on the market share gains within this short period of time because we started supplying from our expanded capacity in December. We are actually now targeting to broaden patient access across the United States including segments like the 340B and that is one-third of the market in the United States. So, we are very much looking forward to our significant growth in the coming quarters in this segment in the United States. Biosimilars, overall in this segment for Pegfilgrastim only controls about 29% of the market. So there is a huge opportunity still remaining for biosimilars to grow, and we are very well positioned to capitalize on that.

Surya Patra: *Could you please provide some clarity, what are the kind of a trajectory that we should be seeing for the Pegfilgrastim which the recent period has seen some kind of a dip in terms of market share and all that? Hopefully the new facility would be benefiting that way.*

Paul Thomas: Thanks, Surya. This is Paul Thomas. So, yes, we have seen the supplies from that. They have started to go into the market I think as Christiane has said, we are definitely taking advantage of that, and it is very early now for the market data to come in, but we have seen increases in both prescriptions and volume share, and we expect this to continue. We definitely look for a new trajectory going forward as we take advantage of the continued market opportunity and the good relationships that are there for the product.

Christiane Hamacher: Let me also address Trastuzumab. We are very pleased with initial reception this product has received in the US market. When we are coming into the market, Mylan have actually built relationship with the spectrum of customers that are essential -

oncologists, the clinics, the GPOs over the last year and a half, and we have already demonstrated with Pegfilgrastim our successful launch there. Customers know that we are the only company that has two biosimilars, Pegfilgrastim and Trastuzumab. And with Trastuzumab, we have no associated legal risks as we are operationally very well prepared because we are approved for both, the 150 mg and 420 mg. While we expect that market share shifts will be more gradual because of the length of treatment duration for patients, with our marquee partner we are very well prepared to compete in this market place and to be a major player when it comes to Trastuzumab in the United States.

Surya Patra: *Just one more question on the gross margin, ma'am. So, we have seen, obviously sequential improvement on the Biologics sales with the new launches. Congratulations for that. But simultaneously since last couple of quarters, the gross margin scenario has to some extent marginally slipped. So whether the margin profiles within the Biologics product-to-product differs or anything else to infer from this?*

M.B. Chinappa: Hi, Surya. Chini here. Yes, the profit margin will vary based on products and will vary based on the markets. In Q3 we did supply Peg and Tras to the US markets. This will translate to higher secondary sales in subsequent quarters, and with that, we will start to see the margin improvement. We expect enhanced performance in Q4.

Surya Patra: *And also the element of the profit share possibly could benefit subsequently, is that right, sir?*

M.B. Chinappa: So, generally, the larger part of our profits get booked on secondary sales. And along with that, we will start to see the margin improvement.

Damayanti Kerai: *Obviously, we have seen good start to the product. But can you share like how we are progressing there in terms of formulary coverage or like other marketing initiative given that we are expecting two more competitors to join in this market in first quarter of this calendar year?*

Paul Thomas: I think early days. Mylan can comment further. While there are other competitors coming, we are also in a very unique position, being the only ones with Pegfilgrastim and Trastuzumab biosimilar working with a starting point. It is the same customer base and we will be able to expand to other segments with both products together. So, at this point, there are contracts in place with key stakeholders, distributors, group purchase organizations, providers, payers. And there is broad payer coverage, national, regional and local level. So we have that base in place. There is the patient support and reimbursement systems that are already in place in oncology for these products. So well placed to grow this product.

Damayanti Kerai: *Also, ma'am, during her opening commentary mentioned about some deferred sales in the Biologics. So, can you elaborate on that please?*

Paul Thomas: It is not a single item that stands out there. But there are always some moving parts as we supply to partners in various markets. So, as that grows, then the top and bottom lines will grow in the next quarter.

- Kiran Mazumdar-Shaw:** And you can understand that at the year-end this often happens.
- Damayanti Kerai:** *Have we filed for Bevacizumab in the US? I think earlier we indicated for calendar '19 filing.*
- Sundar Ramanan:** This is Sundar Ramanan. Our practice has been to inform you of our filing once the document or the dossier has been accepted by the agency. We will inform you in the due course once you cross that stage.
- Vikram Agrawal:** *I have a couple of questions. The first one is that Biocon recently set up a subsidiary called Biocon Biosphere. Can you briefly explain what this company is about and how does it strategically fit with the Biocon group?*
- Siddharth Mittal:** So we have set up this subsidiary to set up our API manufacturing plant in Vizag. We have mentioned in the past that we are investing \$100 million to expand our immunosuppressant capacity multi-fold as we see a very strong traction for immunosuppressants. And all our new manufacturing facilities would be under this legal entity for the Small Molecules business which will also enable us to avail the tax benefit of 15% which the Government of India had announced earlier this year that any new manufacturing entity set up after Oct'19 will be eligible for a reduced rate of 15%. So to also avail that lower tax rate, all the new manufacturing units would be set up under this entity.
- Vikram Agrawal:** *Second is any major milestones to look out for in the calendar year 2020?*
- Kiran Mazumdar-Shaw:** I think there are several milestones to look forward to and I think as we hit those milestones, we always announce it and share it with all of you. But as you can understand, we have actually hit some major milestones, for instance, the Trastuzumab launch in December was a very important milestone, and the approval of our expanded Pegfilgrastim facility was also a very important milestone because that now enables us to go beyond the U.S. We had not been able to even address the European and emerging market opportunity. But I think this now enables us to actually do all of that. And I think you are likely to see a big upside from that effort. The third thing is as you know we have also recently commissioned our large Biologics facility and we hope that that will be approved in the near future. That should be an important milestone because that also sets up an expanded facility for our biosimilars. And then we have many other things to look forward to, the Glargine approval, we have other biosimilar insulins also which we expect to be approved during this coming fiscal, and we expect many-many launches to take place, not just in biosimilars, but even Small Molecules has certain milestones to look forward to. And we also expect our Research Services also to have many milestones in the way they are augmenting their business. So, I think there are a number of very exciting milestones ahead. And I hope that everyone of this is successfully reached, and we will be very happy to share it with you as and when we reach it.
- Christiane Hamacher:** Let me share a bit on Glargine because we at Biocon uniquely positioned when it comes to biosimilars in insulin. We are very much looking forward to the launch of Glargine in the second half of calendar year 2020 as already also stated by Mylan. We have a unique portfolio of biosimilars in the insulin space, and here we only expect less number

of players than in other segments, and we will be the first one in the United States to launch a Biosimilar Glargine. So, we are extremely well positioned. We are looking forward to it.

Shyam Srinivasan: *My first one is on Pegfilgrastim. In the opening remarks, I believe I heard that going forward we will look at the 340B hospitals as well as a segment. If I recollect right, I think Mylan Biocon have targeted the small clinics in the past. So, just want to understand the dynamics here. This is kind of assumed to be a more competitive space. Would we look at some kind of a pricing action given that this could be competitive? The last one on this particular question is on Sandoz. How have they approached after their launch?*

Paul Thomas: I think on the second piece of it first, with the new competitor quite recent really have not seen any change in the market dynamic based on that at this point. So nothing really to comment there. In terms of the additional segments we are going into, I think we are broadening overall which we are looking forward to. And certainly, government segment, 340B has a government controlled aspect to it, and it does have a different pricing dynamic, it also has different incentives for biosimilar use and it has a group purchasing set up there. So, there are various aspects that make it quite attractive. It does work in a different sort of a pricing segment than the commercial customers.

Shyam Srinivasan: *Would that be lower or higher? I am just trying to get that sense.*

Paul Thomas: There are mandated government discounts for 340B. I would not get into specifics on the level of it, but there are some certain mandated discounts there.

Shyam Srinivasan: *My second question is on the Small Molecules. I think I noticed the press release talk about Rs.100 crores formulations number. About 20% of looks like Small Molecules now. Is there a commensurate improvement in margins that comes with this or our API business is more profitable? So I am just trying to understand from a margin dynamics how this would play out.*

Siddharth Mittal: Shyam, I cannot get into details of which business is more profitable. Obviously, the generic formulations, crossing Rs.100 crores milestone is an important achievement for us because as you know this business we started few years back; we started commercializing these products 2 years back, and we are obviously looking at a long-term impact, and also an integrated play where we are going to forward integrate some APIs to formulations. In long-term, we obviously expect the business to be accretive to our margins as we have specialty products and differentiated products in our portfolio.

Shyam Srinivasan: *Last question is on the True North investment. \$75 million if I recollect, right. Press articles suggested we need more than \$75 million. So, are there more rounds that we need to look at from a private equity infusion perspective going forward?*

M.B. Chinappa: Yes, we had indicated that we are looking at some additional funding. We will update you over the next few quarters.

Shyam Srinivasan: *Chini, is it like another \$200 million, \$300 million because just to get a sense of where the funding would come and what is the size of that? I think that is what I am trying to look at.*

M.B. Chinappa: We had indicated that we are looking to raise \$200 million to \$300 million. No further updates on that at the moment.

Prakash Agarwal: *This is Prakash. First question on EBIT margins especially Biocon Biologics. So margins have been flat despite Trastu and Peg coming in. Did I hear correct from Chini sir about the profit is yet to pickup or the sales would come in the subsequent quarters, if you could just clarify or reconfirm that?*

M.B. Chinappa: Prakash, a couple of points here; one is, Peg has not translated to secondary sales. So that will come through in the subsequent quarters. As far as the Trastu, I think we have supplied launch quantities, and the benefit of that is kind of negated as we stated today in the opening comments by the remediation of the Malaysia facility, some sales having been deferred and the increased R&D cost. So, that is why you are not seeing the spike in margins.

Kiran Mazumdar-Shaw: R&D cost have jumped 71% YoY, if you can see there, we have added Rs.54 crores in terms of R&D expenses compared to the previous quarter last year. So, I think that should give you some optics on why you have seen a muted EBIT in that sense compared to last year.

Prakash Agarwal: *Secondly, on reiteration of the guidance of a billion dollar by fiscal 22, we would probably end this year by about 300 plus/minus?*

Kiran Mazumdar-Shaw: Yes.

Prakash Agarwal: *So you are talking about a big step-up. If you could just give broad colors that we all know that Peg is ramping up, Trastu will ramp up, we will have Insulin Glargine, are there bigger assets apart from these three? And the second part is how do you divide this into developed markets like US, Europe and emerging markets?*

Christiane Hamacher: First of all, thank you for the question. We have well marked out all of these opportunities. I like to set the scene by saying six molecules from our portfolio of 28 have already been commercialized. When it comes to the \$1 billion, let me structure it in three chunks; one is U.S., U.S. will be the biggest driver to achieve the \$1 billion. We expect faster penetration for Pegfilgrastim, the effect of the Trastuzumab launch, we will definitely see Glargine and we have also mentioned Bevacizumab and Aspart will also be launched in the United States. The U.S. will be the biggest driver, followed by Most of the World Markets and Europe and other Developed Markets. What actually is very encouraging that we are seeing in the United States that double-digit market share for biosimilar molecules in the U.S. are achievable. We also expect looking at the dynamics in the U.S., few players in the biosimilar space compared to generics and much more disciplined play when it comes to price and price erosion. I just want to point out again that we are also an early mover in the Glargine space in the United States. We are also uniquely positioned. The growth in Most of the World Markets where we are launching additional products and seeing also additional penetration, will also help us to get to the

\$1 billion aspiration. What we currently have not factored in this guidance is any additional opportunity in China. That is all about the \$1 billion guidance so far.

Prakash Agarwal: *Would you like to give a broad color like US 70% and Europe, EM, some broad color there?*

Christiane Hamacher: We will do that later. U.S. will definitely be the dominant segment.

Prakash Agarwal: *On the margin front, again, would you like to give some color, how would the margin look given these are better margin businesses, how would the margin look in fiscal '22?*

M.B. Chinappa: We will guide on margins at a subsequent date. It is too early to guide on margins now.

Sameer Baisiwala: *Can you please remind us on your BLA filing timeline for Beva and Aspart?*

Sundar Ramanan: Bevacizumab, we have filed. Our policy has been to update you on our filing once it has been accepted by the agency. So, we will update you in the due course. On Aspart, that is what I mean to say, we expect to file in calendar year 2020.

Sameer Baisiwala: *The second question is Chini for Trastu. You had a one month of sales and then my guess is some sort of a channel filling. So, was this a typical quarter already or do you think the typical quarter is to follow as we go forward?*

M.B. Chinappa: Trastu will really play out over a full year. It is in the year two you will see the full benefit of Trastuzumab. It is a steady build up.

Sameer Baisiwala: *One final question on the private equity raise. So first of all is \$200 million to \$300 million is sufficient for the sort of pipeline that we are looking at? I would imagine that each product would take \$200 million plus/minus? And second why are we doing it in tranches and not in one-go?*

Kiran Mazumdar-Shaw: Sameer, we have been talking to a few interested private equity investors, and obviously, True North has been first of the block and we expect the others to follow. If there is no real sort of plan to do it in tranches. But this is really what has evolved over time in terms of the opportunity for people to invest. Secondly, this amount is adequate to see us through up to the IPO quite comfortably. So, I think that is the plan that we wanted to basically set a baseline kind of valuation, and we expect then to be approaching the IPO with certain events that would obviously position us well for the IPO. So I think that is really the kind of plan to then raise extra capital because by that time obviously we will need to raise more capital to further invest in our R&D pipeline. I think right now what we really wanted the money for was to really make sure that our CAPEX spend that have been very-very high in expanding our capacity as well as looking at some of the development programs that need more injections as they get into the clinic, are actually supported without further debt.

Raj Mohan: *On Pegfilgrastim, Fulphila you have talked about it a lot. According to IQVIA data, Udenyca from Coherus is shown to have over 3x the unit market share as Fulphila in the last quarter of calendar 2019? With the new Bangalore facility getting FDA*

approval which you have unmuted will aid scaling up capacity multi-fold. How do you think volume market share would play out especially with Sandoz too starting? Basically, as indicated the Coherus has 3x your market share? Would you be heading up the 2x gap that you have with Coherus at the cost of the originator Amgen and we have any timeline in terms of the ramp up in market share?

Paul Thomas: Certainly, we expect we have significant growth ahead of us based on using this new capacity, it will be in the U.S., and it will help us grow in other markets as well going forward. And as you have pointed out, there is plenty of room for biosimilars overall to grow here. So we have momentum to build on with our existing customer base and our expansion. I think I mentioned earlier, we have seen good increases, really several percentage points in some of the data for prescription share already, and we expect that these are early numbers in weekly kinds of things, but we definitely see the signs of strong momentum to grow in this market and we expect that to happen.

Raj Mohan: ***Objective data points like currently, from a 6% market share and operate at 20%, you could head towards the 20% mark within this calendar, and would it be at the cost of Amgen?***

Paul Thomas: Yes, at the cost of the originator certainly we do expect to be pulling market share from the originator. This is less than one-third of the market there, I mentioned before, about 29% overall in the latest data for biosimilars. So, we would definitely expect to take share from the originator. And when some of these segments can move relatively quickly, the government segments that we talked about. So, while I do not think we would talk about a specific market share target, we definitely do not see that gap as something that cannot be bridged.

Raj Mohan: ***Does this sort of alter your strategy of modular capacity enhancement especially with the success of Fulphila where you encountered capacity constraint down the line, do you feel obviously would you alter this with more aggressive non-modular large capacity initiation?***

Shreehas Tambe: I think that is a very nice question. This is Shreehas Tambe here. I think the important thing to remember in the Fulphila launch is that it has been one of the most successful launch of any biosimilar in the United States. So I think it does come with a certain upside that the demand has taken us with the positive surprise that it has come. And I think our approach of being cautious about how we have invested, has stood us well over a period of time. And I think these kind of sometimes positive surprises on capacity are helpful. And we remain optimistic as we go ahead in terms of our capacity build up is. Looking at the investments we have made, on Trastuzumab, you can already see, Kiran just talked about it that we are having a new drug substance facility come up and you have seen the additional capacities for Pegfilgrastim as well as our drug product facilities come on line. We have built substantial capacity for insulins as well. So I think we are well positioned, at the same time careful about the kind of investments that we make rather than having a huge idle capacity on our books.

Raj Mohan: ***And then coming into this market share estimates of about 29% of the Neulasta market has been taken by the biosimilars, and one-third of the same has been***

broadly taken from Onpro. Are we seeing an accentuation of the loss of the Onpro market, and are we able to break into the Onpro market in a very material fashion? Do you expect similar patterns to emerge in Trastuzumab and the biosimilar competes with a subcutaneous version of Roche?

Paul Thomas: Definitely, we expect those market shares to shift for biosimilars to take share from both of those. I think we have talked about in the past for the Onpro product. There is a small minority of that, that is for really a practical need there and the rest is based on what is being offered there. So that market share can move. When talking about Europe, the subcutaneous really has not come into a lot of discussions about how biosimilar market shares are playing out. I think we have heard the originator talk in the past as well that this is not expected to be a long-term barrier to biosimilars, it is more of a short-term hurdle, think it is largely out of the conversation, not a significant factor. So, definitely expect the shares but those are not ceilings for biosimilars.

Raj Mohan: ***Mylan had indicated to a slower ramp up of obviously compared to Fulphila in their investor interaction. So in this case, you have a settlement with Roche. Could you give any color as a percentage of Fulphila share gain that Roche witnessed initially? What would Ogivri be especially with more competition?***

Christiane Hamacher: I do not think you can exactly compare these segments, because the treatments of patients follow a very different schedule. I like to point out that the duration of treatment for Trastuzumab is a much-much longer one compared to Pegfilgrastim where it is a more an acute treatment. So, treatment algorithms, treatment durations are different. Therefore, ramp up here in the Trastuzumab biosimilar segment is expected to be more gradual and will play out over the first one to two years.

Raj Mohan: ***As you also target substantial volume growth in more developed markets with disruptive pricing and government assistance, would the endeavor be to maintain margins with the multiple volume stores, and is it practically possible?***

Paul Thomas: You are talking about across in developed markets you are saying?

Raj Mohan: ***What I am saying is comparing non-developed market thrust which will have multitudinal volumes when compared to developed markets, but then at a lower price point, but then would the volumes be compensating for the price discounts or the price shortfall that you have in non-developed markets, would that be the endeavor of the company to sort of maintain margins at the gross and operating levels as the same as developed markets in non-developed markets, is it practically possible?***

Christiane Hamacher: Our strategy right from the beginning was that our cost structure overall will allow us to play the price volume game as well as value maximization, and we are serving patients together with our partners across the world. So you have to see the overall picture. We will be able to serve markets at different price points to go for price volume as well as for value maximization and overall run a very profitable business.

Charulata Gaidhani: ***My question pertains to the R&D and the remediation cost for Malaysia. How do you expect these costs to go up over the next two years?***

- M.B. Chinappa:** The remediation cost will start to taper off. There will be some additional costs in this quarter and it is really taper off over the next fiscal year. So that is not something that will play out over two, three years. R&D spend as we have guided in the past is on an upward trajectory. We have started to see increased spend in this fiscal. As regards to future years, we will guide you in the subsequent quarters.
- Kiran Mazumdar-Shaw:** I just want to add to that, Biologics itself has indicated a very large and growing pipeline, and in addition to the Small Molecules also has a growing pipeline of ANDA generics. So all this requires a lot of investment. Apart from that we have also seen increased investment in our novels. Therefore, you are seeing an increase R&D spend, but the important thing to factor is that the return on this R&D spend is going to be enormous. So I think once again I keep sort of harping on this point that whilst from an accounting point of view, R&D is an expense, we personally believe there is an investment for growth. And that is how you should be viewing R&D expenditure, which of course we have also demonstrated in our initial launches of our biosimilars, which in the past if you remember was always a concern. But that R&D spend has meant a huge-huge growth for Biologics in the last two fiscals.
- Charulata Gaidhani:** **My second question pertains to the sBLA for Pegfil that is for drug substance. So the drug product would also get expanded in due course?**
- Kiran Mazumdar-Shaw:** I think the challenge we had was really drug substance because the capacity constraints that we had actually emanated from drug substance. And from a drug product capacity point of view, that had been addressed because we had a large capacity for drug product. But I think with the approval of the drug substance facility, this actually now caters to the market needs that this product demands. And as I said, the drug substance capacity expansion has been multi-fold and this now allows us to go beyond the US markets to other markets like Europe and other global markets.
- Hari Belawat:** ***This is regarding this Biocon Biologics IPO. When do we plan this IPO to come and what will be the size of the IPO?***
- Kiran Mazumdar-Shaw:** So, as you know, we have taken a private equity round at this point in time and according to the understanding we have with the private equity investors, they would like to see an IPO within three years. So, you can understand that we are positioning ourselves to do the IPO sooner than that date. So as and when we ready to approach the capital markets for an IPO, we will certainly let you know.
- Hari Belawat:** ***Size also will be decided later? What will be the size of the IPO?***
- Kiran Mazumdar-Shaw:** Yes, we will definitely share all this information with you closer to the date.
- Hari Belawat:** ***One more clarification; there are two companies, Biocon Biologics Limited and Biocon Biologics India Limited. As per my understanding this is Biocon Biologics Limited IPO will come?***
- M.B. Chinappa:** Yes, that Biocon Biologics Limited is the UK entity and Biocon Biologics India Limited is the parent company for the biosimilars business which is based in India. At the moment, we are really looking at listing of Biocon Biologics India Limited.

- Hari Belawat:** *So all the funds which we are raising through private placement and all this is in Biocon Biologics India Limited?*
- M.B. Chinappa:** That is right, yes.
- Pratik Shah:** *My question is, you spoke about the research and development cost of Rs.155 crores this year. Can we just know that where are these research and development costs attributed to for this quarter?*
- Kiran Mazumdar-Shaw:** I just mentioned that these costs are attributed largely to some of the biosimilar program, some of the ANDAs that we are developing and some novel programs.
- Cyndrella Carvalho:** *Just wanted to understand on the Small Molecules margin, we are seeing some sequential dip on the segmental PBIT margin. Is there any one-off over there or how should we look at it?*
- Siddharth Mittal:** Cyndrella, it is due to increase in R&D expenses. Operating margins have remained constant, but R&D expenses which has gone up on an overall basis obviously has impacted Small Molecules margin as well.
- Cyndrella Carvalho:** *In terms of Bevacizumab commercialization, we are looking at it in FY'22 only, right, is that the correct one?*
- Kiran Mazumdar-Shaw:** Yes, I think it will happen before FY'22. So that is what the hope is.
- Cyndrella Carvalho:** *So we are looking forward for approval by end of FY'21, somewhere there?*
- Kiran Mazumdar-Shaw:** That is the hope.
- Harith Ahamed:** *On this new antibody facility in Bengaluru, can you give a sense on the timelines for when the operating cost from the facility will come in to the P&L, and when you will start depreciating the facility? And if you can also quantify these approximately when these kick in from FY'21 or will they be pushed to FY'22?*
- M.B. Chinappa:** The cost will start to hit the books from FY'22 onwards. And of course this will also come through the increased supplies. So we do not see that as impacting margins.
- Harith Ahamed:** *Can you quantify roughly how much pre-operating expenses are kind of being capitalized and potentiality can come into the P&L to whenever that extent?*
- M.B. Chinappa:** Pre-operating expenses have not yet started. The capacity tests are being completed this quarter. And then next year we would have the pre-operative expenses which would all be capitalized because it's still in the validation stage. Once the plant is ready for commercial use, we will start expensing it and that would be FY'22. And as I indicated, with this will also be increased supply from the facility. So we do not see this as impacting margins.
- Harith Ahamed:** *On the Bevacizumab and Aspart, I think you mentioned the guidelines for your US filing. Can you provide the guidelines for Europe?*

Sundar Ramanan: We will inform you once the agency accepts our packages. That has been our practice and that is what we will do. As far as Aspart is concerned, we have filed already and the file has been accepted and is currently under review.

Harith Ahamed: ***And then last one on the Small Molecules segment. You mentioned that you crossed over Rs.100 crores of revenues from the generic business there. Can you give some color on the R&D spend there, how much of our R&D is going into that segment? A number of ANDA filings you are targeting each year. Some color on the areas of filings if you can?***

Siddharth Mittal: I think we indicated that our overall R&D expenses will be in the range of 12% to 15% of our top line excluding Syngene. The percentage will be higher for biosimilars it is more expensive to develop biosimilars compared to the generic drugs. So without splitting up the R&D spends for Small Molecules business, obviously the percentages are much lower compared to biosimilars and novel biologics. As far as the number of filings are concerned, we cannot guide on the number. We will be looking at a specialty play, so we are not going to look at a me-too kind of business where we will focus on a forward integration, looking at all our specialized APIs and specialized formulations. So, I think in the past also we had mentioned that we would look at a single-digit filing, and obviously, we are building a portfolio you would have seen recently the approvals we have got, we have also received a tentative approval for another molecule recently. So again, lot of these drugs are playing into our focused therapeutic areas of oncology, of diabetes, of cardiology with our statins portfolio, immunosuppressants and immunology.

Nitin Agarwal: ***Siddharth, on the Small Molecules, what are number of active products that we have in the market right now?***

Siddharth Mittal: In the US, we have three commercialized products and we have other products where we have the approvals but we cannot launch because of the IP situation, and we do expect to launch additional products in the coming years.

Nitin Agarwal: ***Secondly, since you have discussed a lot about the EBIT margin for different segments now, there is a large component of unallocated expenses which are there, if the segments have profitable breakup. Would you help us understand what is this Rs.50 crores amount for quarter, what really amount to, that is a fairly reasonable amount of cost on an annualized basis?***

Siddharth Mittal: Before the whole reorganization, as you know, Biocon was split into various verticals, which are Small Molecules, Biologics and Branded Formulations. And all those the common costs were unallocated. We will now with the whole restructuring getting to an end by this fiscal year, next year we would be able to identify most of these expenses either to the Small Molecules business or to the Biologics business, and the corporate cost would then be a very small number which would purely be relating to the corporate cost relating to the board and the common team which will be there. So, we will see a much low number starting next year.

Nitin Agarwal: ***Lastly, on the formulations businesses across India and Middle East, how should we look at the business over the next couple of years?***

- Siddharth Mittal:** I will comment on Middle East first and I'll hand over to my colleague to comment on India business. But Middle East has been a challenging market for us, we have seen lot of headwinds because of the new regulations where in lot of companies were forced to take a price reduction. So, our entire portfolio of generics have seen significant price reduction. So Middle East what used to be a very lucrative market is looking challenging. We are in the process of discussing with our joint venture partner, Neopharma on the way forward, and I think over the next one or two quarters, we will have a better sense in terms of where this business is headed. I will hand over to my colleague, Finn, who will comment on the India business.
- Fionnuala Doyle:** This is Finn, thank you for your question. So India is very important to us, India is our home country, and we continue to be inspired and committed to providing high quality medicines and biosimilars to Indian patients. And yes we are aware of the issues that we have been having within India and we are working through them. For example, some of the very specific issues in India are around very significant pricing pressure, increasing competition, and the opportunity to address how we can look at efficiencies and productivity and how we develop our medicines and run our business. To that end, we are exploring new and disruptive business models that will enable us to both drive efficiencies but also to reach more patients more efficiently. And we will come back to you with a plan in early next year.
- Nitin Agarwal:** ***For diabetes, insulin supplies to WHO and other multilateral agency we talk about, the low cost diabetes, how important is that segment from a revenue projection and from a potentially profitability contribution to the Biologics business?***
- Alexander Zach:** So, this is Alexander Zach. I am heading Access in Biocon Biologics. You were referring probably also to the \$0.10 initiative and what are we going to do with low and middle income countries. And that we will want to provide affordable access to insulin to these countries which is addressing actually a public health issue. We are currently already engaging with countries on that. So this is on one hand about access. But we are also cognizant about the profitability, which is also given if we can play with these countries, let us say the volume game and we are perfectly also positioned to play that volume game.
- Prakash Agarwal:** ***One question on the China access. I think in the opening remarks in the emerging market segment you spoke about that. So, what are the initiatives we are taking or where is the development happening especially on the backdrop of Mylan-Upjohn merger also?***
- Christiane Hamacher:** Mylan and Upjohn together are very well positioned for the China market. As you are aware, Upjohn has its headquarters in Shanghai. That means the knowledge about the markets, the market segment, how to enter this market which is actually a province-by-province market, all this is there. We will inform about the specific strategies about the molecules in the future. It is the second biggest market and what was very encouraging that last year for the first time the biosimilars were listed on the National Reimbursement Drug List which actually ensures nationwide reimbursement for the biosimilar with an extremely high reimbursement coverage for all patients. So China is certainly one of the next big opportunities when it comes to Most of the World markets. And we are very

well positioned because of Mylan and Upjohn and their strength in this market, in particular Upjohn.

Prakash Agarwal: ***Secondly on the CAPEX, if you could just help us understand this year's CAPEX and next year CAPEX for Biocon Biologics and the group as a whole.***

Siddharth Mittal: Prakash, I think at the group level we have had nine months CAPEX of Rs.1500 crores and we expect a similar kind of run rate to continue with this in the fourth quarter and also in the next year. So, we are building capacities across all our three businesses.

Prakash Agarwal: ***One was the API plant that you are building...***

Siddharth Mittal: That is right. We are having a pipeline and we have for our biosimilars business so additional anti-bodies capacities is being built.

Prakash Agarwal: ***This does not include the Malaysia phase-2?***

Siddharth Mittal: No.

Prakash Agarwal: ***So, Rs.2000 crores this year and Rs.2000 crores next year?***

Siddharth Mittal: Yes.

- Ends -

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