

Transcript

Biocon Limited Q1 FY20 Earnings Conference Call July 26, 2019

Participants from Biocon's Senior Management Team

- # Kiran Mazumdar-Shaw: Chairperson & Managing Director
- # Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon
- # Siddharth Mittal: Chief Financial Officer - Biocon
- # Christiane Hamacher: Chief Executive Officer – Biocon Biologics
- # Shreehas Tambe: Chief Operating Officer - Biocon Biologics
- # Paul Thomas, Chief Commercial - Biocon Biologics
- # Suresh Subramanian, Head – Branded Formulations India, Biocon
- # Saurabh Paliwal: Head, Investor Relations - Biocon

Prepared Remarks Session:

Saurabh Paliwal: Thank you, Inba, and good morning, ladies and gentlemen. I am Saurabh Paliwal from Biocon Investor Relations, and I welcome you to this call to discuss the financial performance for the first quarter of fiscal 2019-20. 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. As part of the management team today, we have our Chairperson, Dr. Kiran Mazumdar-Shaw, 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 have forward-looking statements based on management's current beliefs and expectations. They 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 these forward looking statements. After conclusion of this call, if you need any further information or clarifications, please do get in touch with us.

Now I would like to turn the call over to Dr. Kiran Mazumdar. Over to you, ma'am.

Kiran Mazumdar-Shaw: Thanks, Saurabh. Good morning, everyone. I welcome you to Biocon's earnings call for the first quarter of FY20.

Let me start with **key financial highlights for this quarter.**

- # Total Revenue for the quarter was up 25% at Rs.1490 Cr
- # Revenue from Operations stood at Rs.1466 Crores in Q1 FY20, which is up 30% from last year.

From a segment perspective,

- # Small Molecules reported revenues of Rs.480 Crores, up 20% from last year

- ❖ Biologics segment revenue grew 96% to Rs.490 Crores.
- ❖ Branded Formulations were at Rs.133 Crores, down 9%, while
- ❖ Syngene was up 4% at Rs.421 Crores.
- ❖ Gross R&D spends were Rs.110 crores for this quarter, which corresponds to 11% of revenue ex-Syngene. Of this Rs.79 Crores is reported in the P&L and the balance has been capitalized. The capitalized amount relates to various biosimilar development programs, including oncology antibodies as well as insulins.

The increase in these spends as compared to last year is largely on account of higher spends across small molecules, biosimilars and novel development programs.

- ❖ EBITDA for Q1 FY20 stood at Rs.462 Crores, an increase of 51% over last year. Consequently, EBITDA margins have improved from 26% last year to 31% this quarter, reflecting a very positive impact from growth in our higher margin biosimilars business across global markets.
- ❖ Core margins that are EBITDA margin net of licensing, impact of Forex and R&D, stood at 36%, up from 27% last year.
- ❖ Net Profit for the quarter stands at Rs.223 Crores, representing a very robust growth of 86% over last year. This was driven by significant improvement in the quality of our earnings led by higher profitability in the Biologics segment. This number excludes an exceptional tax charge pursuant to the restructuring of group entities, which then brings the number to Rs.206 Crores.

I will now discuss our business performance this quarter.

Small Molecules: The strong revenue growth of 20% in this segment was led by higher sales of APIs as well as a robust performance of our generic formulations portfolio.

API growth was driven by immunosuppressants. In generic formulations, the business built on its strong performance in the previous quarters, with Rosuvastatin and Simvastatin formulations maintaining their market shares and recently introduced Atorvastatin registering good growth through the acquisition of key accounts in the U.S. market. Sequentially, this segment saw revenues increase 2% over Q4 FY19, aided by the growth in generic formulations.

On *segment margins*, a better product mix, which included higher sale of immunosuppressant products in Q1 FY20, resulted in improvement of segment margins when compared to the same period last year as well as the previous quarter.

Investments in our new fermentation-based API capacity expansion: We recently started work on a new Greenfield fermentation-based manufacturing facility in Visakhapatnam, Andhra Pradesh to cater to the anticipated strong volume growth in the small molecules APIs business. This expansion will enable us to deliver on our vertically integrated strategy of developing and commercializing our own ANDAs and also service the needs of our global API customers. Expected investment in this capacity is roughly Rs.600 Crores and the facility is expected to be operational over the next three years, followed by commercialization based on regulatory approvals in major markets.

Now coming to our **Biologics segment**, which has seen an outstanding growth this quarter. This business has continued to maintain its strong momentum that you saw in the last quarter of FY19 and this quarter we have seen revenues almost double from Rs.250 Crores last year to Rs.490 Crores this quarter.

Strong sales of Fulphila, biosimilar Pegfilgrastim in the U.S. coupled with higher revenues from insulin products in the emerging markets resulted in the strong growth seen this quarter. Biosimilar product sales in the EU also contributed to sales, which includes our biosimilar Trastuzumab.

On a sequential basis, revenues grew 9% over Q4 FY19 on the back of biosimilars.

Biosimilar business highlights -

Ogivri, which is our biosimilar Trastuzumab co-developed by Mylan and Biocon became the first Trastuzumab biosimilar to be approved in Canada and the second biosimilar from Biocon and Mylan's joint portfolio to be approved in the country.

Our Malaysian insulins facility underwent a pre-approval inspection by U.S. FDA for Glargine drug substance, drug product and device assembly facilities. We received 12 observations across the three units. We are confident of addressing these expeditiously, and we do not expect any change to our partner Mylan's commercialization plants for Insulin Glargine in the U.S.

Our partner Mylan has extended the commercialization rights for in-license Hulio, biosimilar Adalimumab from Europe to global markets. Biocon under the terms of its global partnership with Mylan for monoclonal antibodies, retains its economic interest in this expanded in-licensing arrangement, and will gain a share of profits from global markets.

We continue to extend our geographic footprint in the developed markets with our partner, Mylan, launching Ogivri, (biosimilar Trastuzumab); Semglee, (biosimilar Insulin Glargine); and Hulio (biosimilar Adalimumab) in more markets in Europe during the quarter. In the emerging markets, our biosimilar portfolio continues to do well with approvals for biosimilar Trastuzumab and Insulin Glargine in more markets during the quarter.

Update on clinical trial progress:

For Bevacizumab, the global phase III clinical trial for this molecule is on track with submissions expected in the EU and U.S. by the end of this fiscal.

For Insulin Aspart, global phase III clinical trials for biosimilar Insulin Aspart remain on track. EMA submission is planned in the second half of FY20 while the U.S. FDA submission is expected in mid-calendar year 2020.

We have initiated a Phase I PK-PD clinical trial of our recombinant human insulin for the U.S. market in Q1.

In terms of *margins*, the Biologics segment reported PBIT margins of 38% this quarter as compared to 11% reported last year and 33% last quarter. The improvement of segment PBIT margins is on account of strong growth in biosimilar sales globally, and on a sequential basis, PBIT margins improved due to a higher contribution from Fulphila sales in Q1 FY20.

Coming to capacity planning. Our investment strategy for manufacturing has been to build capacity in a modular manner inline with our projections of the market opportunity. This has allowed us to scale up capacity in response to higher-than-expected demand, even as we balance exposure to any underutilized capacity and costs in the

early phase. We will continue to invest in expanding our manufacturing capacities to address volume growth on account of increased penetration of our products in developed and emerging markets and also to support new biosimilar pipeline development and launches.

Last month, we announced that our new drug products manufacturing facility in Bengaluru received EU GMP certification. This facility further strengthens our ability to deliver products to meet increasing demand and launch our products in more markets, including the U.S. in due course.

The new monoclonal antibodies facility in Bengaluru is expected to be commissioned in FY20 followed by qualification and validation activities. Commercial operations from this new facility are expected to start late FY21 or early FY22.

Outlook for Biosimilars:

Pegfilgrastim continues to be a great growth opportunity for us with a favorable competitive and commercial landscape in the U.S. coupled with strong commercial efforts by our partner, Mylan. Our strategy has been to focus on the quality of earnings in the market share that we have got. We are confident of capitalizing on this opportunity going ahead.

We expect the growth momentum in biologics revenues to continue in FY20, driven by new product introductions, market entries and increased penetration of products already launched by our partners in various markets. We expect substantial full year growth in Biologics revenue with gradual sequential expansion. With a significant part of this growth expected in the second half, the positive impact on margins resulting from this growth should be visible in FY21 and beyond.

Given our current position and how the biosimilar industry is evolving, we believe we have both an opportunity and obligation to shape the biosimilar space. We have therefore set ourselves a vision of becoming a “Global Leader in Biologics” delivering affordable access to innovative and inclusive healthcare solutions, thereby transforming patient lives. This will require us to leverage a technology-driven operating model within healthcare achieved through strategic initiatives going ‘beyond the product’ in our aspiration to gain market share in key markets, unlock underserved patients and differentiate us from competition.

Novel portfolio update: Our partner Equillum has licensed Itolizumab for development in U.S. and Canada, initiated a Phase 1b/2 trial with Itolizumab in patients with acute graft versus host disease or GvHD and a Phase 1b trial in patients with uncontrolled moderate to severe asthma.

Coming to **Branded Formulations**. We have seen a decline of 9% compared to last year. While the India business registered small growth, revenues in the UAE declined as uncertainty in the local market continued to weigh down the overall performance of this segment.

Market Access and Oncology divisions were the key growth drivers for the India business with key brands, Basalog, CANMAb, BIOMAb EGFR, Renodapt and KRABEVA reporting strong double-digit growth.

The UAE business performance for the quarter continued to be impacted by expected re-pricing of branded generic products mandated by the Ministry of Health.

On a positive note though, we were encouraged by the uptake of two of our biosimilars, CANHERA, biosimilar Trastuzumab; and Glaricon, biosimilar Insulin Glargine in the local U.A.E. market. Both products have been well received and have started making inroads in their respective markets.

Now coming to **Syngene**. The performance during the quarter was driven by growth in Discovery Services and steady performance in the dedicated R&D Centre business. Growth in Development Services and Manufacturing Services were impacted by project phasing and is expected to pickup through the remainder of the year.

In order to meet the growing demand for its services, Syngene has announced opening up of a second R&D location in Hyderabad for the next phase of R&D expansion. The facility is in the final stages of commissioning and is scheduled to be operational during Q2 of FY20.

So in *conclusion*, I would like to say that we are at an inflection point of our growth story as we pursue our ambition across various business segments with innovative science at the heart of what we do to develop high-quality products - be it a complex generic, a high-quality biosimilar or a cutting-edge novel therapeutic.

We have started the year on a solid footing, delivering a strong performance this quarter. We believe we can build on this start in the coming quarters and deliver a strong overall growth in FY20. Biosimilar revenue growth is expected to be the biggest growth driver with a larger portion of the growth expected in the second half of this fiscal.

With this, I would like to open it up to questions.

Q&A Session:

Neha Manpuria, JP Morgan: *Thank you for taking my question. My first question is on the margins, after the strong performance that we have seen in the core margins in this quarter, and given Madam's commentary that second half would be even stronger for Biologics, is it fair to assume that core margins for FY20 could be significantly higher than the 32% that we guided or in the level of the 32% that we guided in the last call?*

Siddharth Mittal: Neha, we are already at 36% this quarter. I think what we said in the last call is that on a full year basis, we do not expect the core margins to go down. The launches are going to happen in the US later this year and we will capture sales for only a few months. While we will aim to capture an upside on the margins, but at this stage, we are very confident that we will be able to sustain the margins of last year and probably this quarter.

Neha Manpuria, JP Morgan: *Okay, so it is fair to assume that margins for this quarter can be maintained?*

Siddharth Mittal: That is what we will aim for.

Neha Manpuria, JP Morgan: *My second question is on Fulphila. We have seen Mylan's market share sort of plateau as per Symphony data, I understand it might not be fully accurate. But when we look at capacity and given, again, in the opening comments that we will add capacity on a modular basis depending on penetration of our existing products, should we see more capacity coming onboard for Fulphila, let us say, in the later half of this year or next year.*

Siddharth Mittal: That is correct.

Prakash Agarwal, Axis Capital: *Thanks for the opportunity and congratulations on good numbers. Just trying to understand the Q-and-Q run rate better, especially Fulphila. So I am just trying to understand is it the function of better market share versus last quarter or is it a function of what Madam said, better commercialization by Mylan? If you could throw some light there?*

Paul Thomas: Sure. I think there is a few different things as we continue to progress in the launch in this market. There are a few different dynamics. I think there is customer selection, which is an important part of what Mylan is doing, is choosing the right customer to work with where they and we are both getting the maximum value from this product. So I think part of it is the customer mix, you can say, and then certainly wholesaler buying patterns will impact some of this also there.

Prakash Agarwal, Axis Capital: *Okay and if I can ask one more, on Trastuzumab we saw Amgen launching at risk, if you could explain us better in terms of is there an early mover advantage for the strength they have launched or they could create a market with that strength? Better understanding would help.*

Christiane Hamacher: Mylan and Biocon were the first ones who got approval of the Trastuzumab biosimilar in the United States, and you know that Mylan had the first settlement. So we expect that we will be the first to launch without a legal risk. We are very well positioned because we have approval for both the 420-milligram multiuse vials as well as the 150-milligram single use vials that will allows us to best meet the needs of various customers. As you are aware, the settlement agreement between Mylan and Roche is confidential.

Prakash Agarwal, Axis Capital: *Okay and would the understanding be correct that the market currently is sitting at 150 mg versus what Amgen has launches the 400 plus mg, would that understanding be correct?*

Christiane Hamacher: Yes. That is correct.

Prakash Agarwal, Axis Capital: *Okay understood and one more if I can squeeze in on the Adalimumab opportunity, just if you could rehash the timelines for the U.S.?*

Siddharth Mittal: I think Mylan's settlement with AbbVie is for launch in July 2023.

Tushar Manudhane, Motilal Oswal: *So just on the material cost, which has been actually flat year-on-year and even down sequentially. So can you just explain that part?*

Siddharth Mittal: Material cost is flat year-on-year, which is good news because the revenues have gone up by 30% and the material cost has remained flat, which has resulted in the gross margin increase of 10% on a year-on-year basis and the reason it is flat because we have a component of profit share booked in our topline, which does not come with any associated material cost. Second reason is the better product mix. Biosimilar margins are much higher compared to other businesses, and as the product mix gets better, the gross margins get better.

Tushar Manudhane, Motilal Oswal: *Profit share component if you can quantify?*

Siddharth Mittal: We cannot quantify the profit share.

Tushar Manudhane, Motilal Oswal: *And secondly if you can for the overall R&D gross, R&D spend for FY20?*

Siddharth Mittal: We maintain a guidance of 15% gross R&D spend ex-Syngene revenues.

Shyam Srinivasan, Goldman Sachs: *Thank you for taking my question. Just going back to the question on the capacity constraint for Neulasta at this point of time. Siddharth, if you can just tell us what is the signpost we need to keep in mind? Is there an inspection that is involved? What could be the likely timeline of that? When do you think the additional line for more Neulasta supplies, Fulphila supplies could come through, I think that is the first question?*

Shreehas Tambe: Shyam, it will be all of the above. As we have said before, we have always invested in capacity in a modular way. So as we have seen capacity, the demand come up, we have always planned for capacity and any capacity that does come up, it will go through these requirements of inspections, filings prior to that and then supplies. But we have actually been doing this quite a bit, so we are quite confident about being able to add more capacity towards the end of the year.

Shyam Srinivasan, Goldman Sachs: *So second half this fiscal is potentially when you could have, okay the best way to see it would be increase in market share on Fulphila again in the market and that could be likely second half?*

Shreehas Tambe: We aim to bring in more capacity towards the end of the second half of this year. We also believe that we will make a further impact because as you know, we have already had a very, very successful launch of Fulphila, and we continue to create a strong demand for our product. So yes, we will create more capacity to meet up with that increased demand.

Shyam Srinivasan, Goldman Sachs: *Okay last additional question on this. I think just going back to Ms. Kiran's earlier comments that we still think this opportunity remains. So is it possible that we can get higher share from here despite, say, a Sandoz coming or maybe an Intas coming next year, you still think Fulphila could be bigger opportunity than today?*

Paul Thomas: Sure. IAs we commented, Mylan with Biocon were the first ones to come in, make a difference for our customers in oncology and this was the largest oncology product out there in the US and I think the trajectory has been strong, we have been able to choose the right customers there for the launch trajectory, and we definitely think there is a lot of further upside there.

Shyam Srinivasan, Goldman Sachs: *Got it. Thank you and my second question is on biosimilar Herceptin in the U.S. Given that Amgen has done an at-risk launch, is there an acceleration clause in any of your settlement agreements, let us assume Amgen is there for the next two weeks, the Appeals Court does not kind of stop it. Can you accelerate your launch?*

Christiane Hamacher: As you are aware, there is a confidential agreement between Roche and Mylan in place, and we cannot further comment.

Shyam Srinivasan, Goldman Sachs: *Okay and my last question is on insulin. We got 12 observations across three units, what are the severity of these observations. I know Ms. Kiran said actually that the timelines are not getting shifted, but what gives us the confidence that, say next year, whenever the kind of timelines kind of clear up for insulin, will be in the market in the U.S.? Thank you.*

Shreehas Tambe: We take each inspection very seriously, and we work towards improving our quality systems whenever we have these inspections. Each of these observations make our system stronger and we believe that the part of this pre-approval inspection that we underwent at Malaysia for Insulin Glargine has been a part of making our systems stronger further than they have been in the past. As you know already from a commercialization standpoint, we will be under the provisions of the Hatch-Waxman Act, which prevent us from getting into the US market until March of 2020. So clearly at this point, we do not see any change to our commercialization plans in the United States between Mylan and us.

Surya Patra, Phillip Capital: *Thanks for this opportunity and congrats on the great set of numbers. Just on the Biologics capacity that we are on that front. So is it fair to believe now we have already hit 100% utilization?*

Shreehas Tambe: Surya, it would be difficult to comment on percentage utilization of capacity, but needless to say, we have always planned for capacity to meet up with the projections that we see coming up for the demand for our products, and we proactively always track towards making capacity available. So I would not specifically comment on percentage utilization, but needless to say we have made substantial investments to add to our infrastructure and capability.

Siddharth Mittal: Kiran had mentioned in her commentary that the new antibody plant would be commissioned later this year. We will have significantly enhanced capacity which will subsequently go through regulatory approval process. We are addressing increasing our capacities, in line with our growth and the demand of the market.

Surya Patra, Phillip Capital: *And is it possible to say, Sir, the new capacity would be like 2x, 3x of the current capacity that you are having and knowing the fact that the opportunities in the Biologic and different regions and the kind of progress that you are making in the various regions?*

Kiran Mazumdar-Shaw: I actually did mention to you that we see ourselves as being a global leader in biosimilars. So obviously, the capacity expansion is going to be along those kinds of aspirational lines. So we are putting in very significant expansion in our capacities.

Surya Patra, Phillip Capital: *Okay and on the progress on the European market front, anything that you can add like, currently how big is that in the overall biologic base or business, Europe has achieved what percentage or anything on that European penetration front or the progress front if you can add?*

Christiane Hamacher: I mean, the European biosimilar market, it is a very sizable market and where we have seen very good share trajectory of the biosimilar monoclonal antibodies, for example. We are very much looking forward to a very meaningful growth contribution in Europe over the coming years and addressing together with our partners the different market archetype in very specific ways.

Surya Patra, Phillip Capital: *Next question would be on the R&D spend front. So if you can just see, though sequentially there is a bit decline in the kind of a quarterly R&D spend and obviously R&D spend cannot be very linear or it could be lumpy. But for the full year, what is the kind of ramp up that one can expect here in the R&D spend front and to the revenue guidance what we had given that it would be around 10% near about of the biopharma revenue, ex-Syngene. So whether that will be the trend that you are guiding?*

Siddharth Mittal: Surya, I have mentioned some time back that the R&D guidance for the year is maintained at 15% of revenues ex-Syngene at a gross level. So there is no change to it and as you know that there is lumpiness in the R&D expense. So this quarter was 11% but previous quarter was 17%. But on a full year basis, it will be around 15% of the top line ex-Syngene.

Surya Patra, Phillip Capital: *And the quantum of a capitalization would be any sense on that, sir? Since we are taking up new projects, and which are progressing also.*

Siddharth Mittal: It will not be significantly different from what you have seen now. I mean, this quarter we capitalized roughly Rs.30 Crores of R&D. So on a full year basis, you can assume between Rs.120 crores to Rs.150 crores.

Surya Patra, Phillip Capital: *Just on the forex front, sir, anything that is there in the numbers, since in the press release that you have mentioned, there is a*

Siddharth Mittal: Yes. So this quarter was complete forex neutral at a group level. We have zero forex gain or loss.

Surya Patra, Phillip Capital: *On the branded formulation business, how should one really look at in one event that we have rationalized our portfolio domestically to focus more on the critical care business and in the UAE side we are seeing our critical care product, again, like the biosimilars are getting good progress there and simultaneously there is a kind of a price correction pressure. So how should one really look at? And this quarter is also kind of negative trend that we are witnessing in terms of growth.*

Siddharth Mittal: UAE headwinds will continue for another quarter or so. The headwinds are more on the generic drugs there, while our biosimilars - both Glaricon and Canhera are doing very well and growing in line with our expectations. I will hand over to my colleague Suresh who can comment on Branded Formulations India business.

Suresh Subramanian: The Branded Formulations business did have a small blip because of some streamlining of discounts and a change in internal structure in the Metabolics team. While the impact was because of these two reasons, it is very gladdening to note that some of our key brands in oncology, BIOMab, KRABEVA and CANMAb have really gone up to big growths that we have not seen in the last couple of quarters and also Basalog in Metabolics has grown by 34%. So that is much above market and much above the previous quarter's growth. So we expect to see high double-digit growths in the coming quarters through the restructuring that we have done in the Metabolics, which is basically going to bring in more focus on key markets and key targeted customers. So therefore, it is going to be a change in the coming quarters for Branded Formulations India.

Charulata Gaidhani, Dalal & Broacha: *Congrats on the good set of numbers. My question pertains to the recent insulin prevention price control that has been accepted. While I know that it could create havoc amongst the U.S. players, how do you anticipate this to impact the market going forward?*

Paul Thomas: Thanks for the question. I think there are a few different proposals being circulated now. Some focused on insulin, some focused on the broader market. I think overall, we are just very happy to be in a position that we are in, offering a solution for that and will really help impact health care costs in the right direction. As we discussed last quarter, we are definitely part of the solution for all of this. In some of the broader proposals, there have been explicit recognitions of this with increased incentives for biosimilars on the reimbursement side, which is great to see. On the insulin side, in general, I think overall, changes in rebates and control of list prices is generally I think a positive thing for biosimilars and maybe for pharmaceuticals in general, because we know it causes a lot of distortions in behavior. So it is generally positive, we will see how these things play out; they are all early stage in the evolution. But overall, it is definitely recognizing the impact that biosimilars have to play in this market.

Christiane Hamacher: As we are positioning us as a major global player in the biosimilar space, policy shaping is very high on our agenda and a focus area of Mylan and Biocon.

Aditya Khemka, DSP Mutual Fund: *Yes, thanks for the opportunity. I have two questions. Firstly, you mentioned the profit share this quarter helped improve your gross margins. But if you could and I appreciate that you cannot quantify it, but if you could give us a directional sense as to how much has the profit share changed from your fourth quarter of FY19 to first quarter of FY20? Has it like materially gone up 100%, 200%? Or has the profit share been, like, largely the same between the fourth quarter and the first quarter?*

Siddharth Mittal: Well, it is one of the reasons for the sequential increase, but we cannot break up the sales from supplies and the profit share, but it has gone up compared to Q4.

Aditya Khemka, DSP Mutual Fund: *And that has been a material increase?*

Siddharth Mittal: Yes.

Aditya Khemka, DSP Mutual Fund: *And secondly, on the EBITDA margin, a previous participant asked this question, I find your commentary quite confusing to be honest, so last quarter was the fourth quarter of FY2019 was 32% and first quarter of FY20 you did 36%. And in the same breadth you aspire to maintain EBITDA margins of both the quarters. So is it 32% or 36% or somewhere in between? I mean what exactly is your guidance there?*

Siddharth Mittal: It was 34% in Q4 and it was 36% in Q1. So even the increase that has been there, it is 32% to 36%, it is 34% to 36%. And it is thereabouts, right? So I cannot get that specific whether it will be 34% or 36%, directionally what we said is our core margins will be in line with what we have seen and Q1 has been a good quarter. We expect to maintain these margins for rest of the year.

Aditya Khemka, DSP Mutual Fund: *Perfect. And just some color on the Herceptin markets, so I appreciate that a competitor has launched and it is a strength, which is not a big part of the market, but if you could just help us understand the market a little better. Herceptin is an acute therapy, right? So every year does the entire patient pool completely change in terms of is the NRx like 100% of the TRx in a given year? Or is the NRx or the new prescription 30%, 40% of the total prescriptions in a given year? How is that split?*

Paul Thomas: I would not call it an acute therapy, of course, the therapy can be over the course of multiple years. So the nature of this market is even compared to Pegfilgrastim, it is much longer duration therapy. Market will evolve differently. And so that nature of the market, we know it is not a generic market to begin with, we have the nature of the market here that you are talking about, logistics involved with a different SKU. So we are very excited about the opportunity that is ahead of us.

Aditya Khemka, DSP Mutual Fund: *Sorry, if I pick up that? So you are saying that it is a more chronic therapy compared to Pegfilgrastim, which was a more acute therapy. So in that sense, could you give us some sense of how many patients are incrementally coming on the Herceptin therapy? And then you have Perjeta, which is a combination, so I am talking of the plain Herceptin product. How many patients incrementally come to the market as fresh patients? And correct me if I am wrong, but your expectations internal should be do target the new patients or would you also expect to get a meaningful amount of market share in the older patients on the plain Herceptin therapy, the monotherapy?*

Paul Thomas: Sure. I think on a customer-by-customer basis, they will take different approaches, certainly we have seen plenty of examples where the uptake is not limited to new patients. So I do not think our planning is based certainly that there is a smaller percentage of new patients in this market compared to Pegfilgrastim. I do not think it is black and white, it is a different market than Pegfilgrastim, but I do not think it is only a new patient opportunity there.

Aditya Khemka, DSP Mutual Fund: *Okay. Just as a follow up, excuse me for that. But how are the payers sort of in discussion with you? What is the color that the payers are giving you? I mean do you feel that the payers in the tiering of the reimbursements, they would place you higher to any of the older patients come to the newer therapy and your biosimilar therapy?*

Christiane Hamacher: Mylan will be in the position to answer this question. Let me share with you how we see the Trastuzumab opportunity. We, together with our partner, are a global player. And we are very excited to have the opportunity to serve patients across the globe. We are very well positioned when it comes to the quality of our product, our cost of goods as well as our overhead structure with our competitiveness to serve also the middle of

the income pyramid, in particular when we talk about what we call most of the world countries and not any more rest of the world countries. Therefore we are extremely excited about the global opportunity of Trastuzumab.

Neha Manpuria, JP Morgan: *Yes. Thank you so much. On Insulin Glargine while we maintain the time line for March 2020 for Mylan's launch, in case we are not able to meet that time line due to approval or litigation, how much rework would be required or what time would be required to sort of meet the revised standard of the FDA for insulin filings?*

Shreehas Tambe: So just a couple of comments on that first. See what we have always clarified is you have not discussed specifically any launch timing, you have said that under the provisions of the Hatch-Waxman Act where Insulin Glargine will fall under, we would not be able to launch prior to March 2020. Our commercialization plans remain unchanged. So that is the first clarification. The second point that you have asked is what amount of rework would that mean were the agency to ask us to do that? At this point, as we said before, we remain confident that we will be able to work with the agency because we are working with them closely and we should be able to respond to that and have no change in the plans that we have made for commercialization of Insulin Glargine in the US.

Neha Manpuria, JP Morgan: *But in case even if the litigation does not allow us to launch, but we get a tentative approval, in that case no rework would be required, is that correct? Even if the launch is delayed for some reason?*

Shreehas Tambe: At this point, we wouldn't want to comment on any litigation or any outstanding procedures on that.

Nitin Agarwal, IDFC Securities: *Siddharth, on the other expenses there has been a lot of variation through the quarter, and this quarter is sharply down on a quarter-to-quarter basis. Any specific reasons for that?*

Siddharth Mittal: The main dip is because of the profit share expense that we shared with Mylan in certain territories.

Nitin Agarwal, IDFC Securities: *But how should we sort of look at this number? Is there a way to modeling perspective, or this line? Any sense on how should one look at it?*

Siddharth Mittal: It is difficult to model because there are a lot of moving parts in this line item.

Nitin Agarwal, IDFC Securities: *When you say that the gap on the Biocon part is largely because on some professional arrangements you have with Mylan.*

Siddharth Mittal: That's correct. And the other half is the difference in Syngene.

Nitin Agarwal, IDFC Securities: *And on this Pegfilgrastim capacity constraint that we talked about, is it fair that sort of emerging out of the demand sort of outstripping our initial assessments on the product or has there been any other factor, which has played out on that?*

Shreehas Tambe: I do not think we refer to any constraint at this point. I think we have always said that we have been building capacity and making investments in a modular fashion to address any potential upside. We said that we have had a very, very strong and successful launch of Fulphila in the US market, probably one of the best that a biosimilar has seen in that market, and we see the strong demand which is coming up and we have been making investments proactively to bring in more capacity to the market towards the later part of the year.

Nitin Agarwal, IDFC Securities: *So just too sort of correct myself, there has been no capacity constraint on our ability to meet Fulphila marke?. It is essentially the way the market is developing, and we see more pickup in the markets that is how and our capacity increase will be in line with that?*

Paul Thomas: I think we are happy with the trajectory that we have had in this market, the success of this launch, and we expect further growth over time as we go forward in this market.

Nitin Agarwal, IDFC Securities: *And lastly on a broader basis on a biosimilar market, what we have seen essentially at least a small molecule market, when there are 3 to 4 players the market gets extremely competitive from a pricing perspective. Now when we see incrementally the U.S. market is still evolving on the biosimilar side, when we have potential situations like maybe Trastuzumab or Avastin. For example, Trastuzumab already has got 5 approvals. When a point in time, say in a year or so, when, say, all 4 or 5 or 6 guys are in the market, do you see the dynamics in the market being any different than they are in a small molecule market situation with 5 or 6 players? And why should that be in terms of it is going to be any different?*

Paul Thomas: I think many small molecule markets nowadays will have much more than that also, right, I think the typical model that we see is it would be more than that. The investments involved and their time commitment involved in bringing these products to market are very different than in the generic space. And I think that has a relevant impact on how market dynamics play out. So I think lots of that will evolve over the coming years.

Sameer Baisiwala, Morgan Stanley: *Sid, can you give some color on the emerging market of Biologics this quarter that is Q1? And you have talked earlier about volatility in tenders. So how was it during this quarter?*

Siddharth Mittal: Sameer, the emerging markets business also contributed to the growth for Biologics segment and in terms of the tender that is something that we are watching closely. I think as we have alluded to in the past, we have a huge opportunity in the US and Europe. And we want to make sure that we have capacities to address those markets and the tender business, which tends to be opportunistic. We will address these tender markets as and when we have excess capacity.

Sameer Baisiwala, Morgan Stanley: *Christiane to your comment on the European market and you said that you are very excited about the growth that lies ahead, why you referring to the 3 in-market products? 3 products which are already in market? Or is it about the new approvals as you go forward?*

Christiane Hamacher: I was referencing the penetration of molecules that are already in the market, where in the European market we have seen significant trajectory when it comes to market share capturing for biosimilars across various areas.

Sameer Baisiwala, Morgan Stanley: *Fair enough. The penetration does go much higher and much faster, but we have not seen that so far for your products.*

Christiane Hamacher: So our own products in Europe, it is very, very early days, and we remain very confident, because there is a high unmet need for biosimilars in Europe.

Sameer Baisiwala, Morgan Stanley: *Just on Pegfil in the U.S., so you said that Mylan is very choosy about the customer, having a very good customer selection, who are these customers? They are hospitals, nursing homes and clinics, is that what you have in mind?*

Paul Thomas: Sure. I think it would be inappropriate to get into details like that, I think, on this call. It is a competitive market and these are important choices made by each player.

Sameer Baisiwala, Morgan Stanley: *Okay. No worries. One final from my side. Kiran, how are you thinking about the next wave of products, beyond the three which are already there in clinicals right now?*

Kiran Mazumdar-Shaw: As you know, Sameer, we have another partnership with Sandoz, so that is another wave of products. But also Biocon has initiated its own portfolio of biosimilars, which we are very excited about because we need to go into this segment on our own, and as we have gained confidence of developing biosimilars, and now have the confidence of taking on many of these developments on our own. So you are seeing a very interesting evolution of Biocon as a very aspirational and committed player in biosimilars.

Abhishek Sharma, IIFL: *Yes thanks for taking my questions. Just one on the expense side. You set up this new subsidiary in Boston, the R&D center, Bicara. So is it now running at full expenses or do you expect that expenses on account of that will continue to go up through the year, number one? Secondly, similarly on API given the fact that you are now setting up new CapEx, so does the R&D number or the R&D mix change more towards API?*

Siddharth Mittal: So the first is we do have some expenses for Bicara, our Boston-based subsidiary in the P&L. It will keep going up during the year as we hire more people, but the R&D expenses already include the expenses incurred on those Novel Molecules. So it will all fit within the overall guidance of 15%. In terms of API, again the R&D expenses for API and Generic Formulations is already included in the P&L under R&D expenses. The new facility commissioning will take two years. So operating overheads will start going up only after the facilities commission, which is probably in FY22. So till then from a P&L perspective, there will be no additional impact.

Abhishek Sharma, IIFL: *Yes. And lastly, on Biologics, is the entity as you envisage running it as truly independent at some point in future, on that account is it fully staffed now or do you anticipate expenses going up there as well?*

Siddharth Mittal: Well, most of the expenses are already in and though we are hiring certain additional employees to complete the structure, we do not expect a significant increase from the numbers which you have probably seen in Q1.

Raj Mohan, Individual Investor: *Thanks for taking my call and congratulations on a great set of numbers. Though you talked about the next wave in biosimilars being driven by the Sandoz collab and your own indigenous development, objectively on a longer-term basis, do you have any revenue targets to share? As you had targets of this \$200 million by FY18? To a rounding figure though large like \$1 billion target, do you have any time lines? And is there a possibility that a larger portion of this would be driven by your end-to-end strategy of your own biosimilars?*

Kiran Mazumdar-Shaw: So I think we are in a very strong trajectory to reach many of these targets that you talked about. We would like to share the numbers as we move along, but suffice to say that we are going to see some very strong growth ahead. And by the time, our own portfolio kind of kicks in, it will be in the next wave of biosimilars, which will be beyond a five-year time horizon. So I would not like to comment of a time horizon beyond five years at a time. We are very confident that we will, of course, cross \$1 billion target in five years time and beyond, because we are quite optimistic about those kinds of numbers. But we would like to shape this market and then share with you a much more well-understood market dynamics and then give you better projections as we move along. But we are very, very focused on strong inroads, market penetration and aggressive growth. We are very confident that we will attain these very strong numbers in the years ahead. But at this point in time, we really do not want to give you exact numbers because I think we will be in a better position to do that once the market basically starts being much more accepting of biosimilars, which we expect to happen in a year's time or year-and-a-half time. So then would be the time when we should actually tell you what our future prospects in terms of targets are.

Raj Mohan, Individual Investor: *Fair enough. One final question. After a robust start to the small molecules business this fiscal and a positive commentary to back it, would the growth estimate for the entire year resemble this 20% range?*

Siddharth Mittal: Well, it is difficult to give guidance for the full year. I think we are confident to have a good growth but on a full year basis, I would not necessarily confirm that we will be able to maintain the 20% growth level.

Cyndrella Carvalho, Centrum Broking: *Thank for the opportunity and my question was on the smaller molecules that would we be able to sustain the kind of margins for that segment that we have reflected or any comment on that?*

Siddharth Mittal: So this quarter we have had good margins for Small Molecules compared to Q4, in which the R&D expenses were high. Again, R&D expenses would have an impact on the margins. So it is difficult to give optics on the segment margins because the R&D expenses would impact these margins. But from a pure operating performance perspective, yes, we have had a very good quarter on account of strong sales in our immunosuppressants business and a very decent growth in our generic formulations business and a good product mix. So we definitely expect to continue this momentum, but the margin just to reconfirm, can get impacted because of variability in R&D expenses.

Cyndrella Carvalho, Centrum Broking: *Okay. That is helpful. And coming to the immunosuppressant, Madam highlighted that it is one of the drivers, so any trends that we are observing there? Any comments on that side?*

Siddharth Mittal: Well, it has been a very, very important portfolio for us. We have some key molecules, which are amongst the top five or six products within the portfolio beyond statins. So that has been a good growth driver, high-margin business, some of these molecules have a lion's share of the global API market, and we continue to build on that momentum, and the plant that we are now going to build in Vizag is going to address increased demand that is coming in for immunosuppressants.

Cyndrella Carvalho, Centrum Broking: *Okay. And just a clarification, the contribution, the profit share would include the adalimumab contribution also in it?*

Siddharth Mittal: That is correct.

Cyndrella Carvalho, Centrum Broking: *And is there any meaningful change over these sequential quarters in it, if you could specify?*

Siddharth Mittal: Well, from adalimumab there is not a meaningful change I think, as Christiane alluded to that it is early days in Europe and Mylan did launch the product late calendar quarter of 2018 and they are doing quite well.

Cyndrella Carvalho, Centrum Broking: *Okay. And so Madam, I mean we had highlighted that we have some plans in terms of unlocking value for the Biologics Biosimilars segment. Any time lines have we booked on it or anything?*

Siddharth Mittal: We are in the process of completing the restructuring. We expect the restructuring of the legal entities to complete within this calendar year, after which we will consider the unlocking of value at the right time and at an opportune moment.

Cyndrella Carvalho, Centrum Broking: *Anything on the Malaysia plant in terms of the OpEx and the utilization?*

Siddharth Mittal: Well, we continue to supply to various emerging markets and Europe from that facility and later this year once our partner, Mylan, launches the product in the U.S., we would supply it from Malaysia. In terms of the operating expenses, the operating fixed operating expenses are to the tune of \$55 million for this facility.

Rohit Shah, Individual Investor: *I just had one quick question. Is there any time line on when we are going to update capital by spinning off the Biologics division?*

Siddharth Mittal: No. There is no specific time line that we can comment on.

Moderator: Thank you, ladies and gentlemen, that was the last question. I would now like to hand the floor back to Mr. Saurabh Paliwal for closing comments. Over to you, Sir!

Saurabh Paliwal: Thank you, everyone, for joining us today. If there are any further questions that need to be addressed, 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.*