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Ladies and gentlemen, good day, and welcome to the Q4 FY '20 earnings conference call of Biocon Limited. (Operator Instructions) Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Saurabh Paliwal from Biocon Investor Relations. Thank you, and over to you, sir.

Thank you, Janus, and good evening, ladies and gentlemen. I welcome you to Biocon's Fourth Quarter and Full Year of Fiscal '19/'20 Earnings Conference Call. Before we proceed with this call, I would like to remind everyone that a replay of today's discussion will be available for the next few days about an hour following the conclusion of this call. The call transcript will be made available on the website in the coming days.

To get started, we have the company's management led by our Chairperson Dr. Kiran Mazumdar-Shaw, and other colleagues from the senior management team are available here.

I would like to take this opportunity to remind everyone about the safe harbor related to today's conference call. The discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements.

At the end of the call, if you need any further information or have any questions, please do get in touch with me.

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

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [3]

Thank you, Saurabh, and good evening, everyone. I welcome you to Biocon's earnings call for the fourth quarter and full year for the fiscal 2019/'20.

As you can see, we are living through unprecedented times. And of course, I must say that this is a format which hasn't changed, whereas other formats of communication have. So I would like to make a couple of points upfront on the broad impact of COVID-19 on Biocon operations and how we have responded in terms of our preparation to sustain our operational performance amidst all this turmoil.

First and foremost, in line with our commitment to provide a safe working environment to our employees, we significantly reduced the number of people in our facilities to only those who were required to carry out manufacturing and quality operations based on planned production schedules. All other employees either stayed back or were working remotely from home. And I would like to add that the work from home that

was put into effect was done so very rapidly with all the sophistication that is required to operate from home on Internet in a secure manner. I'm very proud of our employees and want to thank them for their efforts in rising to the challenge and responding positively to the situation. It has helped us maintain our critical manufacturing operations with reduced manpower, while we continue to address the needs of medicines and services for patients, partners and customers across the globe. In recent weeks, we have also added to this fleet of people operating at the workplace by getting many of our research workers back to the labs.

Earlier this month, there was some easing prescribed by the central and state governments, and we have started to gradually scale up our operations with more employees reporting at site for work with required safety precautions to made in a safe and infection-free environment. A substantial number of employees still continue to work remotely from home. And we are continually assessing the situation and look to normalize our operations to pre-lockdown levels by the end of this month. This is, of course, subject to the evolving COVID situation in the cities and areas we operate in as per government-mandated guidelines.

I'm also very pleased to report that Biocon has played a very important role in coming out with workplace protocols along with various industry bodies. Secondly, the turmoil caused by the COVID-19 pandemic, obviously, has disrupted supply chains and impaired mobility due to the nationwide lockdown, and it did have a bearing on our manufacturing operations. We put into place business continuity plans to minimize this impact. We did experience delays in receiving and sending shipments, but that did not have a very big impact, though it did impact our Biologics business, whilst the other businesses did not get this impact of this disruption. The logistics situation has now begun to rapidly improve after the relaxation provided by the government in early May, which allows for unhindered movement of goods vehicles across the country. We have also seen imports for raw materials gradually normalized, and outbound logistics have also now significantly improved.

Having adequate inventory of key raw materials to sustain operations during the period of the lockdown has helped us tide over this challenging period, both for Small Molecules as well as Biologics. We are adequately stocked with few months of inventory to carry out our critical manufacturing operations and are continuously evaluating our requirements to overcome another lockdown kind of situation. In Small Molecules, therefore, we have decided to discontinue manufacturing of certain products, which were sourced from China and were not strategic. The impact of this discontinuation will be made up by repurposing the facilities towards manufacturing strategic products over the long run.

Now coming to our performance. After 3 strong quarters, Biocon has reported a weak fourth quarter. Two of our businesses, the Small Molecules and the Research Services segment, delivered actually very strong revenue growth amidst these unprecedented times. It was only the Biologics segment that was extremely challenged during the quarter and reported a weak performance. Dr. Christiane Hamacher, CEO of Biocon Biologics, will elaborate further on the Q4 performance for the Biologics segment later in the session.

Thirdly, spending on medicines across the globe for non-COVID diseases has seen reprioritization with health care systems strained due to dealing with the pandemic. In that backdrop, there will be tremendous opportunity for volumes of generics and biosimilars to ramp up as the situation improves and spending returns. At Biocon, we are very well placed in both these areas and expect to come out stronger once things normalize.

In the next quarter, that is Q1 FY '21, we expect our financial performance to improve over Q4 with uptick expected from Q2 onwards. The U.S. FDA approval for Semglee or Insulin Glargine is expected shortly. This will add to our current portfolio of biosimilars, which includes Fulphila, the pegfilgrastim and Ogivri, trastuzumab and create a growing portfolio of biosimilars for the Mylan partnership.

On the regulatory front, our biologics facilities, both in India and Malaysia, have received positive EIRs from U.S. FDA as well as EMA. These approvals will significantly expand our capability to address U.S., European and global market opportunities with a competitive advantage.

Now moving on, I will present key financial highlights. I will first discuss the highlights for the quarter followed by the highlights for the full year. The fourth quarter delivered year-on-year revenue growth wherein revenues increased by 6% to INR 1,644 crores compared to INR 1,557 crores in the same period last year. Revenues from operations stood at INR 1,581 crores, up 3%, driven by healthy growth in Small Molecules, which was up 15% as well as Research Services, which was up 14% as compared to Q4 last fiscal. The Biologics segment performance was impacted by COVID-19 related to logistics and other challenges, while branded formulations also declined 12% as compared to last year.

We recorded gross R&D spends of INR 139 crores this quarter, which corresponds to 14% of revenue ex Syngene. Of this amount, INR 125 crores is expended in the P&L, while the balance amount has been capitalized. The increase in R&D spends reported in the P&L statements are primarily on account of higher spends across biosimilars and insulins. Given the depreciation of the rupee against the dollar, we booked a ForEx gain of INR 35 crores this quarter as compared to a loss of INR 7 crores last year. This gain is reflected in the other income line of P&L statement.

EBITDA for the quarter is down 11% to INR 382 crores. EBITDA margin for the quarter stood at 23%. Reduction in gross margins due to lower sales in the Biologics segment, higher R&D spend, higher staff costs, plus increase in operating costs in Malaysia have led to the reduction in both EBITDA and EBITDA margin. Core margins, that is EBITDA margins net of licensing impact of ForEx and R&D, stood at 29%. Net profit for the quarter was at INR 123 crores, down from INR 214 crores last year.

Now coming to FY '20. During FY '20, total consolidated revenues for the year grew to INR, 6,529 crores, which is a 15% increase as compared to INR 5,659 crores the previous fiscal. Revenues from operations were up 15% at INR 6,367 crores. Small Molecules reported revenues of INR 2,094 crores, which is the first milestone of crossing INR 2,000 crores, which is up 18%, a very strong performance by the Small Molecules segment. And as far as Biologics was concerned, they actually had a very strong annual growth of 29%, delivering INR 1,951 crores as against INR 1,517 crores the previous fiscal.

Branded Formulations recorded a revenue decline of 18% at INR 536 crores, while Syngene also reported a 10% revenue growth at INR 2,012 crores, which is also another milestone for Syngene, having crossed INR 2,000 crores. We incurred gross R&D spend of INR 527 crores on R&D this year, corresponding to 12% of revenues, excluding Syngene. Of this amount, INR 439 crores is reported in the P&L, while the balance has been capitalized. The capitalized amount relates to biosimilars and insulins development expenses. For the full year, we spent higher amounts across biosimilars and insulins as well as ANDA and novel development programs.

For the full year, we booked a ForEx gain of INR 65 crores compared to a gain of INR 28 crores the previous fiscal. EBITDA for the full year was INR 1,765 crores, which was up 15%. And EBITDA margins were at 27%, which is very similar to the previous fiscal. Core margins, that is net of licensing, impact of ForEx and R&D, stood at 33% which was up 1%. That was 32% the previous fiscal. Reported net profit for the year stood at INR 748 crores, which includes certain exceptional items. Adjusted for exceptional items and associated tax, net profit for the year was INR 760 crores with net profit margins at 12%.

Coming to reviewing business segment's performance for the fourth quarter and the full year, let me start with Small Molecules. The strong performance of the Small Molecules segment during the fourth quarter was led by a further ramp up of our generics business in the U.S. market. For FY '20, the improvement over the previous fiscal was led by a strong performance of generic formulations in the U.S. on the back of consistent client acquisitions and increased market share for all our products. This was also aided by the API business performance, which has been driven by a better product mix and realization over the previous fiscal.

Branded Formulations business has underperformed yet again. And we believe that this business is going to be a strong focus for us to see how to turn it around for a better performance. The business has been challenged with pricing pressure, which has led to a decline in revenues. And there have been logistics and distribution disruptions in the month of March, which has also contributed to a further decline. I would also mention that our Branded Formulations business in the UAE through our JV entity NeoBiocon has not only faced significant business challenges in the last fiscal, resulting from mandated price rebates from the Ministry of Health UAE but is now facing other challenges wherein our JV partner has come under investigation for governance issues, which is likely to have a reputational impact on the JV. As a company committed to the highest standards of governance, we have decided to wind up the JV entity. Going forward, we will plan to market our Biologics products under our own brand name.

Research Services delivered a steady year-on-year growth in the fourth quarter, led by a continued strong performance in discovery services and a very healthy Q4 performance in development services. For the full year, the performance was driven by a broad-based growth across all business verticals and an improved traction in discovery services.

Now moving to Biologics. I will hand it over to Dr. Christiane Hamacher to discuss the performance of the Biologics segment.

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [4]

Good evening, everyone. For Biocon Biologics, let me dive straight into the factors that have impacted our Q4 performance. After 7 straight quarters of strong revenue and profit growth, we saw a sharp dip in Q4 performance with segment revenues coming down by 21% and segment profits coming down by 84%. The COVID impact was significant. About INR 103 crores of products that were scheduled to be shipped at the end of the quarter was held up due to logistics issues related to COVID. In addition, we were impacted by lower profit share contribution from our partners. We take comfort from the fact that market share of our products in the U.S. are maintained at the same level, and as such, we believe this sharp dip is a onetime effect, and we will see a recovery from Q1 onwards. We expect pegfilgrastim and trastuzumab pace to pick up with new contracting in the U.S. and gain traction in many markets across Europe and rest of the world.

Other recent launches by our partner, Mylan, include pegfilgrastim in Canada and Australia, which adds to our oncology portfolio with trastuzumab in both countries. Mylan has reiterated that they have strong confidence in their long-term capabilities from physician payer hospital standpoint to fully execute commercially on the growing biosimilar portfolio throughout this fiscal and in the coming years. We are, therefore, confident to reach our target of USD 1 billion by fiscal year 2022.

Moving on to regulatory matters. We received FDA pre-approval for our Malaysia manufacturing facility for Insulin Glargine. We also received a favorable district court decision with respect to our ongoing patent litigation for Insulin Glargine and further API decisions remain pending. Through Mylan, we also continued to be engage in active discussion with the FDA on a viable path to obtain an interchangeable designation. As such, we remain on track for launch midyear 2020. Glargine is a USD 2.2 billion market, and we believe this product will be an important contributor to our growth in fiscal year '21 and beyond. In addition, we expect Mylan to launch etanercept in Europe in the second half of this calendar year. Biocon has shared economics in this program.

Other updates on our Biosimilar programs include the review of our BLA for biosimilar bevacizumab, both by U.S. FDA and EMA. On the insulin front, we are on track with the development of Aspart. Our recombinant human insulin program is also progressing well and has the new 351(K) pathway. Overall, we are targeting to have at least 8 biosimilars being sold in developed markets by the end of fiscal year 2022, addressing a market opportunity of approximately up to USD 35 billion. Our pipeline is expected to continue to deliver at least 3 additional molecules between fiscal year '23 and fiscal year '25. Thereafter, we expect to launch 2 molecules per year.

COVID has given us an even larger opportunity to shape with our similar landscape. Global health care will be compared to leverage both generics and biosimilars to contain health care costs, and we would like to position ourselves in a leadership league that drives our vision of delivering affordable access to innovative and inclusive health care solutions. We continue to seize the biosimilar market as a significant opportunity to be played out over many years and across markets globally. All regions show strong promise with high single to strong double-digit growth underlining the tremendous potential that biosimilars offer.

The total global market of all biosimilar monoclonal antibodies and therapeutic proteins is anticipated to grow from approximately USD 25 billion to date to USD 55 billion in 2025 based on consensus estimates. Whilst we are currently focused on developed markets such as U.S., Europe and Japan through strong partners, we also believe that the demand for biosimilars in rest of the world markets is rapidly increasing. We already have a presence in the majority of the top 20 markets, and we plan to expand our geographic footprint even further. With 28 molecules in our portfolio covering oncology, diabetes, immunology and other therapeutic areas, we offer one of the industry's largest and most diverse global biosimilar portfolios. We are one of the few fully integrated players with [scientists], speed and manufacturing scale that provides competitive advantage and uniquely positioned us as a fully integrated pure-play global biosimilar company. We see fiscal year '21 as a step-up year with strong revenue growth and steady EBITDA margins. We will be able to provide more color on this guidance in the next earnings call after some of the COVID-related uncertainties recede.

With this, I will hand back to Kiran.

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [5]

Thank you, Christiane. So let me conclude by giving -- making some comments on the outlook. The new financial year comes with a new set of challenges in the midst of the ongoing COVID pandemic. However,

we are confident of emerging from the current situation stronger and more determined than ever to deliver on our commitments to our patients, partners and stakeholders. While uncertainties may persist during FY '21, we expect the Biologics segment to continue to lead overall revenue growth for Biocon and steady growth expected in both Small Molecules as well as Research Services.

With that, I will now open it out for questions and answers.

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Questions and Answers

Operator [1]

(Operator Instructions) We take the first question from the line of Prakash Agarwal from Axis Capital.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [2]

My first question is on, again, the statement, which Christiane made on the biosimilar business, that there is INR 103 crore delay in shipment. So how do we think about it? Like if we add that, it is flat Y-o-Y, but still there's a decline of 20% Q-on-Q. In the past, we have said that Biosimilar business would continue to ramp up pace. So what are we missing there? Why the Q-on-Q big large dip, a? And b is on lower contribution from the partner. What is leading to that? Are the primary sales and secondary sales too different?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [3]

So let me answer that by saying that, as you know, Christiane talked about 2 factors that basically gave us this sharp decline in performance this quarter. One, as you rightly said, was the INR 103 crores, which, as you say, it is not good enough to show why we didn't grow. The second one really was about the COVID impact in the U.S. where I think the movement of inventory to distributor channels was certainly very badly impacted in the month of May -- in the month of March, which also then directly impacted us as well. So I think this is what has really led to this very sharp decline. We have seen a pickup of the business, both in the U.S. and many other markets, and that is why we feel confident that we will see a good recovery in Q1.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [4]

Okay. And the second part, ma'am, on the lower contribution from the partner, I mean, the EBIT margins are down to 7% versus an average of 25% to 30%.

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [5]

Prakash, it's Chinni here. Yes, Prakash, as you kind of picked up the secondary sales and the primary sales play, and secondary sales, of course, is the sales from the wholesalers to the hospital and clinics and primary sales defined as the sales by us to a partner and a partner to the [joint venture]. The real measure of performance is, of course, the secondary sales. And as you've seen from the data, generally, our market share is steady at the prior quarter levels with a slight uptick in trastuzumab. However, during this quarter, this not -- this did not lead to a matching increase in primary sales, thereby impacting both our revenues and profits. Again, as Christiane already mentioned, we see this as a one quarter effect, and we are confident that when you look at the overall business, we will see recovery in Q1 and normalization in Q2.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [6]

Okay. If I may just add one follow-up, like Kiran ma'am said that it's more so due to the impact in the U.S. So given these are hospital-led products, so we are seeing some improvement. So the patients have to necessarily come to the clinics or hospitals to get the treatment done? Or there are some campaigns being done by Mylan or to just to -- what are the initiatives which are taken in terms of closing the gap?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [7]

So let me answer this question. As you know, with the growing COVID pandemic in the U.S., I think there was a lot of challenges in many of the hospitals to offer the treatments to patients -- non-COVID patients, as you know. And therefore, there was a lot of focus on COVID treatments and many of these patients have basically had to defer a lot of their treatment. Now it's all coming back. So we believe that with these improvements, you are going to see business recovering very rapidly.

Operator [8]

We'll take the next question from the line of Dhaval Shah from Girik Capital.

Dhaval Shah, Girik Capital - Equity Research Analyst [9]

Ma'am 2 questions on the Biologics. First is on our $1 billion revenue guidance for FY '23, how would our Biologics balance sheet be like? What would be our capital employed, expected return on capital? Just want to get some flavor on that. Then secondly, if you want to understand the entire business economics of the Biologics business, which balance sheet should we look at the -- which company's balance sheet should we look at, Biologics India Limited or the limited? Can you just also give some clarification on that?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [10]

So let me first correct you, it is FY '22 that is our $1 billion target. And we remain committed to that target because you cannot be questioning that target based on one quarter's performance. This is a one-off, as we've said before, and we are on the path to recovery, and therefore, we are not at all concerned about not meeting any of those targets. We are very confident that we will meet the $1 billion target by FY '22. Coming to the balance sheet, I will request Chinappa to comment.

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [11]

The balance sheet part of it is, see, it's actually difficult to create the Biologics' balance sheet currently because it's a combo of Biocon Biologics India Limited. There's a U.K. entity. There's a Malaysia entity. And we have another Malaysia entity also just set up. Now we will, in the subsequent quarters, actually present to you independent to fully detailed P&L for the Biologics segment and the Small Molecules segment. So thereby, you will start to see from next quarter onwards a full report of separate businesses. But for now, it's difficult, and there's a lot of common costs that are getting apportioned, and you can't read the full.

Dhaval Shah, Girik Capital - Equity Research Analyst [12]

Okay. So see, we have...

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [13]

But there was a second part of your $1 billion question where you asked what the margins will be. It's difficult to really split margins down into FY '22 because it's also dependent on the R&D cost and the mix of -- and really how much the R&D spends are. But for now, if we look into FY '21, as Christiane already mentioned, we're looking at steady margins despite higher R&D cost.

Dhaval Shah, Girik Capital - Equity Research Analyst [14]

So broadly, we have currently INR 4,500 crores invested as capital employed as per the FY '20 press release. Now so to achieve a INR 7,000 crore top line, $1 billion. So this would -- so how would our capital employed move? So what are the economics of this business? I understand R&D is a big component of capital employed. But broadly, given it's a 2-year period, we would have some sense and what would be the ROC look like because we are currently at some 10% for FY '20. And also given a lot of our new products are getting launched in U.S., which are higher margin, so this will broadly give us some idea to us in terms of how should we approach this INR 7,000 crores profitability.

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [15]

[Perhaps behind it], but I'll just give you a directional sense. See, today, our capital assets, the total investment is just under $500 million. If we look at -- if we look at the gross fixed assets, I'm not looking at net fixed assets and not at the working capital, it's INR 3,300-odd crores. Now from there, we have additional CapEx that's underway some work -- investment in -- capital work in progress plus some additional CapEx coming up next year. And that total investment can support $1 billion guidance. So you will...

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [16]

So I think from an ROC point of view, we are guiding in the range of around 20% to 23% ROC in the next 2 years.

Dhaval Shah, Girik Capital - Equity Research Analyst [17]

Okay. Okay. Great. So your current gross lock at INR 3,300 crores and which will see addition for the -- in manufacturing facility for the new product?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [18]

Yes.

Dhaval Shah, Girik Capital - Equity Research Analyst [19]

Okay. And in terms of the CapEx guidance, it will be INR 1,000 crores ex of Syngene for the next -- over next 2 years?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [20]

It will be roughly $200 million per year for next 2 years. That's half for Biologics, another half for Small Molecules.

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [21]

Okay. This is at a group level. This is at a group level, ex Syngene.

Dhaval Shah, Girik Capital - Equity Research Analyst [22]

Ex Syngene, correct. And from this, $100 million would be, you said it will be for Biologics and $100 million will be for...

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [23]

Yes, exactly.

Dhaval Shah, Girik Capital - Equity Research Analyst [24]

Okay. Okay.

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [25]

So we are giving you an ROC for the Biologics business.

Siddharth Mittal, Biocon Limited - MD, CEO & Director [26]

I think in the past I've mentioned that if you look at the segment ROC, Biologics, which has obviously inched up over the last couple of years, is at 11%, as you rightly said, in FY '19 and FY '20 when you compare with Small Molecules and Research, which is already at 2022. The scope for improvement in Biologics is huge because from a profitability perspective, Biologics is the most profitable segment. And what we definitely expect, when we are out of the capital investment cycle, the ROC with a higher EBITDA margin would start going up significantly and will catch up definitely at a group -- other segment's level.

Dhaval Shah, Girik Capital - Equity Research Analyst [27]

Correct. Correct. Correct. And sir, and this on -- in terms of the balance sheet to understand the entire business, you said over the next 2, 3 quarters you will be grouping everything under one entity, the entire Biologics business. Do I understand correctly?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [28]

So I think what Chinni meant was that we will be reporting segment sales. We'll be redoing our segments next year. So there will be Small Molecules. There will be Biosimilars, no longer Biologics because Biologics also has novel biologics as a part of this. There are only expenses. And there is a Branded Formulation India component, which is currently reflected in the segment revenue, but they are going to be reclassified under Biosimilars. And Research Services will continue as is. So from a segment reporting, you will see segment revenue and segment results in 4 segments: Small Molecule, Biosimilars, Research Services and Novel Biologics. The detailed P&L for all the entities was uploaded once a year on a website, in line with the requirements of Companies Act. So it will be visible once a year. Now the statutory requirement obviously is to present a consolidated balance sheet and P&L along with segment revenues and segment capital employed.

Dhaval Shah, Girik Capital - Equity Research Analyst [29]

Yes. Yes. And sir, the money, what we raised is under Biologics India Limited. Am I correct?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [30]

Yes. Yes. Right.

Dhaval Shah, Girik Capital - Equity Research Analyst [31]

Okay. And the IPO, whenever in the future it comes, it will be for Biologics India Limited?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [32]

Yes.

Operator [33]

We take the next question from the line of Dheeresh Pathak from Goldman Sachs.

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [34]

Just a follow-up to the earlier participant's question. Just Biocon ex Syngene CWIP, I'm seeing about INR 1,340 crores. So can you just explain the underlying assets (inaudible) CWIP ex Syngene?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [35]

So Biocon ex Syngene is up INR 330 crores compared to March '19, of which significant portion is pertaining to our new Biologics facility, which is under commissioning. And our new Research Services facility, which was acquired in Chennai from Pfizer and certain other capacity enhancements that are underway. But the new antibody facility and the Chennai R&D facility would be the largest component of that increase.

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [36]

Okay. And this $200 million CapEx over 2 years for biologics, this would be sufficient to...?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [37]

Not -- Dheeresh, it's $200 million per year over 2 years -- for 2 years.

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [38]

It's split 50-50, right? So in 2 years, you will spend $200 million for Biologics, right?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [39]

Yes.

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [40]

And that -- so that $200 million over 2 years for Biologics, that is sufficient to give you enough manufacturing capacity for $1 billion of sales, right?

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [41]

Right, yes. So the turnover growth will be higher than the asset growth, and we'll see improved asset turnover and an improved return on capital.

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [42]

Okay. And then Chinni, you also just mentioned that there is a gross block of INR 1,300 crores in Biologics. And the asset side is about some INR 6,000-odd crores mentioned in the published numbers. That leaves...

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [43]

No. No. (inaudible). I think I said gross block, not net block.

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [44]

Yes. But the assets are showing as INR 6,300 crores. So even if net block is lower than this, then there is a lot of working capital sitting in Biologics. Am I looking something?

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [45]

Yes. There is -- the (inaudible), obviously, there's working capital, which represents the rest of the investment.

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [46]

But Chinni, compared to the scale of the business, it looks like a lot of working capital. It's like more than INR 3,000 crores working capital for a business which is making INR 2,000 crore?

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [47]

[The growth number], sir, INR 3,000 crores.

Siddharth Mittal, Biocon Limited - MD, CEO & Director [48]

No. No. No. It's INR 3,000 crores for sure. See, you look at the capital employed of Biologics is at INR 4,500 crores. The net block is how much?

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [49]

And asset size, we'll have to look at? Because the capital employed is just shareholder equity. I'm looking at the assets, assets are INR 6,382 crores. Maybe I can take it off-line?

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [50]

Yes, take it off-line. There is a big CWIP also sitting in there.

Dheeresh Pathak, Goldman Sachs Asset Management (India) Private Limited - Executive Director [51]

Okay. Okay. So that INR 3,300 crores did not include the CWIP.

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [52]

Yes. What I meant is what was deployed as assets, and there's a CWIP component. I'll walk you through that.

Operator [53]

Next question is from the line of the Damayanti Kerai from HSBC.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [54]

So recently, your partner, Mylan in their March quarter call mentioned that they are shifting to execution and strategic performance for the biosimilar franchise. So if you can update us on how your commercialization and marketing strategy has changed since you launched your first product in the U.S. So that will be helpful. And how this is in line with your target for $1 billion sales from Biosimilar by fiscal year 2022?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [55]

So thank you for your question. Question's regarding marketing strategies and operations. Mylan is in a best position to state that. But as I've already said, Mylan has expressed. And so we have a strong confidence in their capabilities. Because of what we expect in an expansion of the pegfilgrastim business, and you are aware that trastuzumab was just launched end of last year in December, we expect the market trajectory. We are looking forward to the upcoming launch of Glargine in the U.S. And certainly, the U.S. is the biggest component for reaching the USD 1 billion mark. So we remain very, very confident. Mylan has clearly expressed, focusing on commercial execution. And with that we also predicted that new contracting in the U.S. for all our products will come through.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [56]

Sure. So you just mentioned expansion of pegfilgrastim opportunity will be critical towards our $1 billion goal. So how much progress we have made in new segments, say, 340B hospitals? And how as the new ramp-up capacity has helped in reaching out to newer markets or newer segments?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [57]

I think this is a question better pose to Mylan because they will be able to give you some visibility on these kind of questions. I don't think it is right for us to comment on their behalf.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [58]

Sure, ma'am. Last question from my side. How much of your operating cost is flexible in nature? And if the COVID situation goes on for a bit long, how much headroom you have to manage cost in near to medium term?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [59]

So if you look at the fact sheet the expenditure section, so power cost, staff cost, and I would say more than 50% of other expenses would be fixed in nature. What is variable is obviously the material cost -- part of R&D cost and other part of the other expenses.

Damayanti Kerai, HSBC, Research Division - Analyst, Healthcare and Hospitals [60]

So Saurabh, most of our costs are fixed in nature. And as you mentioned, some are flexible, which we can manage if situation persist longer.

Siddharth Mittal, Biocon Limited - MD, CEO & Director [61]

Yes. Yes. That's right. So you look at the gross margin. I think gross margin is the best indicator. 61% is the gross margin for the quarter. And gross margin is at the material and the power level. And if you look at the net margin at 8%, which would mean that you will have around 20% to 30% as the fixed cost.

Operator [62]

We take the next question from the line of Neha Mantri (sic) [Neha Manpuria] from JPMorgan.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [63]

My first question is on the Biologics business. You mentioned that FY '21 should see a stable margin, stable EBITDA margin in Biologics. Could you give us some color on what could be the R&D spend? Could it be significantly higher, which will lead to this stable margin? And also just related to that question, how are you looking at pricing? What have you seen in pricing for Ogivri, given we've seen multiple players come through in the quarter?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [64]

So let me answer that by saying that, obviously, competition is factored in when they look at projecting what their outlook is going to be, and I think Mylan has already projected that they are very confident of good performance in FY '21 and beyond. So I think if you look at that aspect, then I think it is not that competition is something that was not factored. Secondly, I think as far as we are concerned, when you look at stable margins, obviously, we do realize that there's going to be increased R&D spend. There will be a factoring of some of the investments, capital investments that have been made. So considering all that, we still expect to sustain these kind of margins that we are seeing in FY '20. So I think that's the way it has to be looked at, saying that despite large increases in R&D spends and depreciation, we are likely to still maintain stable margins.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [65]

Siddharth, in that case, can I ask you what is the guidance for R&D for FY '21? Is it still 15% ex Syngene, 15% of sales ex Syngene?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [66]

No, I think the range will be 12% to 14% at a gross level. The absolute number, well, it will go up, but the revenue growth in Biologics will also increase the base.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [67]

Yes. So in which case, given we'll have 3 products contributing in FY '21, even with the higher R&D, a large part of our cost increase had come in through in FY '20. Shouldn't we be seeing some margin improvement in FY '21? What am I missing here?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [68]

Yes. So there is -- obviously, the 3 products are more from a commercial perspective, but there are many other products which will be in development stage and will be advancing to the next stage of development. So the expenses would be required to continue to fund the pipeline in both our businesses.

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [69]

And remember, this is at a consolidated level. So you're going to see even the ANDAs and the biosimilar pipeline being developed, plus the novel programs that we are developing. I think you are missing the

point that it is not just the Biologics business on a stand-alone basis.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [70]

Fair enough. My second question was on the fundraising in Biologics. After the first tranche, given the current COVID environment, a, do you see a delay in the subsequent round? And b, in case there is a delay, could this, for whatever reason, impact our ability to fund our growth plans for the next year in Biologics?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [71]

So Neha, let me take the second question first. We do have enough leverage on our balance sheet to take money. So even if there is some delay, we do not anticipate an issue because all the investments which are being planned, we already have a plan to fund those CapEx. And obviously, the business, as it grows into next year and generates the kind of margin that we indicated will also generate operating cash.

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [72]

And I think, Neha, I would like to add that just 1 quarter dip doesn't mean anything. So I think you have to read it in view in the perspective of saying that this was a one-off temporary blip. But we are very confident that the business is recovering, and this is a very strong business. And this is a business that is on a growth trajectory. So I don't think you have to panic at 1 dip in 1 quarter.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [73]

No, no, ma'am. Fair enough. I was just wondering from a CapEx and R&D funding in case the fundraising -- subsequent rounds of fundraising is delayed.

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [74]

Yes. I mean, as Siddharth just explained, we are well covered and well leveraged in that sense. I don't think we are really in a situation where we are desperate for raising the next level, but it's something that we are looking at in terms of raising this funding because it's important for us to create the value that we have talked about.

Siddharth Mittal, Biocon Limited - MD, CEO & Director [75]

But also in general, I mean, yesterday also there was an article in one of the newspapers that there has been a slowdown in the overall private equity transactions because the investors are taking a cautious approach and wait-and-watch approach. So naturally, there could be some impact as a result of COVID on the timing.

Operator [76]

Next question is from the line of Nithya Balasubramanian from Sanford Bernstein.

Nithya Balasubramanian, [77]

I just wanted to start by saying a simple thank you for, obviously, providing us with essential medicines, stand the world with essential medicines during these difficult times. So thank you. I had couple of questions on Insulin Glargine. So you did mention interchangeability. So one question is, do you have any visibility into what the FDA is expecting and any visibility on time lines as to when that might materialize? And the second one is basal insulin, obviously, rebates are very, very high, 70%, 75% rebate is what we see in this space. And given that your intent has been to improve affordability in this space, I would expect meaningful discount in this product. And interchangeability, obviously, determines how much of a discount can Mylan actually give in this market. So question about how you're thinking about when this interchangeability might happen and how your discounting and pricing strategy might actually change depending on that?

Sundar Ramanan, Biocon Limited - VP & Head of Global Regulatory Affairs [78]

Okay. I'll take the question. This is Sundar Ramanan. I'll take the question with regards to the FDA and interchangeability. As you know that the agency issued a guidance for insulins that specifically talked about a pathway that will lead us to a faster requirements for interchangeability of insulins. And we are actively working with the agency in bringing that faster. And once we get to know the path, we'll be happy to share the details with you for now. We are actively working with the agency.

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [79]

Regarding the pricing and discounts, this strategy is specific, and we are not commenting on the details. But Mylan is very versed and test all the capabilities to position our molecule in the U.S. market in a successful way.

Nithya Balasubramanian, [80]

Sure. But if I might just follow it up, I understand that you don't want to comment on Mylan's commercial strategy. But the point I'm making here is there's a huge swing between the kind of revenues that Mylan and subsequently Biocon can make depending on [whether there's] interchangeable status or not. So is the plan then to go ahead and commercialize the product irrespective of whether you have interchangeability or not in June or whenever you have the approval and then tweak the strategy if and when you get interchangeability? And does that mean we might see significant changes in the market status as well?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [81]

Paul, can you please take that question?

Paul Vazhayil Thomas, Biocon Limited - Chief Commercial Officer of Biocon Biologics [82]

Sure. Thanks. Yes. So I think a couple of things. I think it's a sizable market, right? We talked about $2.2 billion market. This is with discount factored in there already. With that, those existing rebate structure factored in there already and we know that there's still a need on insulin affordability for patients. And so this can be -- so there's a need that is waiting for Mylan to address. So we think there's an opportunity there. In terms of the criticality of interchangeability, I think we've talked before that this is certainly something that we are pursuing. And Mylan has talked about that as well. But we've also seen that this market is very centrally driven by payers, by PBMs, and they are able to move market share. They've shown ability to switch between products without the requirement for interchangeability. So it's really not a -- it can be a factor, but I wouldn't characterize it as the critical must have for moving share in this market.

Nithya Balasubramanian, [83]

Can I read that as interchangeability is not really critical for your $1 billion aspiration?

Paul Vazhayil Thomas, Biocon Limited - Chief Commercial Officer of Biocon Biologics [84]

Yes. I think that's fair.

Operator [85]

Next question is from the line of Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan, Goldman Sachs Group Inc., Research Division - Equity Analyst [86]

Just the first one on the Small Molecules. Can you just talk us about the pricing environment right now in the U.S.? Secondary data seems to show that it's kind of easing now. But are you seeing it in your portfolio as well? And do you think it's sustainable? Maybe there is some March effect with stocking up and stuff. But do you think you're now moving to a trajectory where inflation or deflation is kind of easing U.S. generics?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [87]

Shyam, the pricing pressure has normalized, which means there's still a price erosion, which is an annualized price erosion in the range of 5% to 10%. The good part is that with a strong currency, we make up an impact of what -- otherwise, we end up giving us a discount, we partially make it up. Now we do not see the situation changing where a serious disruption in terms of competition or significant number of new approvals coming in from FDA, which will increase the pricing pressure to the levels what we have seen in 2019.

Shyam Srinivasan, Goldman Sachs Group Inc., Research Division - Equity Analyst [88]

Okay. That's helpful. Just carrying forward because of the COVID impact, we have seen a lot of noise around API and API shifting out of China and to potentially India and other countries even your conversations with your customers in the U.S. and Europe. Are you getting a sense of that, that you could actually play a larger role in API supply to these countries?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [89]

I think there's definitely discussions happening, but I don't think that there has been anything concrete on this. I feel there's a lot of panic created because once the COVID started in China, everybody's eyes were towards China. And when the COVID spread to other parts of the world and China resumed normal operations, I think the focus has changed to -- shifted to India because India is still dependent on China. So I think the risk on China has been lesser of a focus. And the fact that the regulatory time lines to qualify an alternative source ends up being few years, right now, in absolute short term, the customers don't have a choice to switch over. But once the dust settles down and if things get to somewhat level of normalcy, that's when we'll know really if there is a structural change of move from China to other parts of the world in terms of the API sourcing.

Operator [90]

Next question is from the line of Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [91]

Christiane, when you mentioned that you expect 8 approvals for developed markets by fiscal 2022, are you including Aspart and human insulin in this?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [92]

Yes, both molecules are included, Aspart and recombinant human insulin.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [93]

Okay. Great. And if you can update us on the progress of the clinical trials and if the current COVID situation is impacting these 2 drugs? And what are the filing time lines for the U.S. market?

Sundar Ramanan, Biocon Limited - VP & Head of Global Regulatory Affairs [94]

The COVID will not affect our clinical development. We will keep you posted in the future calls with regards to our filing.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [95]

Okay. Great. And just on the biosim sales this quarter, if I were to read your expectation going forward, when do you expect the Q3 sales, Q3 fiscal '20 sales to return back? Is it in Q1 current year, Q2, any color would be very helpful.

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [96]

And so what we have clearly said is that we will recover from Q1 onwards, and we will normalize back to growth from Q2 onwards.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [97]

Okay. When you say normalized, you're referring to Q3 level where we left, I guess?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [98]

Yes, back to growth, back to growth trajectory.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [99]

Okay. And as things stand today, what's the status on the manufacturing and outbound logistics? I mean is it more or less normalized its business as usual?

Shreehas P. Tambe, Biocon Limited - COO of Biocon Biologics [100]

Sameer, this is Shreehas here. So things are not perfectly normal here, but we are trying -- we are seeing that things are returning to a better position than it was a couple of months ago.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [101]

Okay. One final question from my side, if I may. The employee cost has been going up every quarter for the last several quarters. So is there any specific areas where we are hiring? Are these high-value talent that you're hiring? Any color would be very useful.

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [102]

So with the high-value talents we are hiring, we are very, very specific and very, very strategic on hiring talent for a few key positions in our organization to deliver on the strategy and also the commercial execution, in particular. We are very strategic, very, very focused on a few talents for our business.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [103]

Christiane, is it for developed markets? Is it for emerging markets? If you can help with that?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [104]

It's actually for global functions where we cover all the markets.

Operator [105]

(technical difficulty) Mr. Surya Patra.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [106]

Okay. Just one clarification I just wanted to have before asking any question. Madam, in the opening remarks, you talked about (inaudible) backward integrated activities like undoing some of the manufacturing in-house instead of procuring the raw materials from outside. Can you just -- is it about the Small Molecule business that you are referring? Or it is for the Biologics business?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [107]

No. This is about small molecules. As you know, there was a lot of dependence on certain imports from China. And I think that's what we were referring to saying that we actually had stocked up. We have a large inventory. And because of that, we don't see any disruption.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [108]

Okay. Fine. My first question would be, ma'am, see, in fact, this Malaysia venture, since we have completed the year, what was the kind of -- can you just give some sense about the kind of breakeven situation there? What is the cost impact that we are still seeing for the consolidated business from that? And you also mentioned about the higher operational cost right now for that setup. Along with that, what is the time line for the next phase of expansion there in the Malaysia?

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [109]

So Surya, Malaysia facility is still operating at a loss in -- actually in FY '20 the loss increased, but we'll see FY '21 Malaysia moving back to profitability with the launch of the Glargine in the U.S.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [110]

Okay. Okay. So in fact, to having a kind of impression that the losses at the Malaysia level should be decreasing compared to FY '19 with the supply starting from the current base was -- whether we have not seen that kind of trend?

Shreehas P. Tambe, Biocon Limited - COO of Biocon Biologics [111]

So Surya, this is Shreehas here. You're right, actually. As we -- we've said before, once we have approvals in the U.S. and other markets start coming in, we will see Malaysia return to profitability in the coming year. Additionally, I think you had asked a question, which is related to a subsequent phase of investment. I think in the opening remarks, Kiran and then Christiane also talked about the pre-approval that we are looking at for Glargine and a subsequent approval to get that into the U.S. At this point, we have adequate capacity to meet our current market projections, and we are confident about that. And we are geared up to take up the subsequent phase of investment shortly which we will keep you posted in due time.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [112]

Okay. And just on the Branded Formulation business, which is transitioning to move towards or moving towards part of the Biocon Biologic business and we have also winding of the JV there in the UAE, so what is the fate of that business? How should we be looking at? What about the licensing path that the JV is currently having where it will come to -- whether it will be there with them or will have that license impact? Some color on that business possibly will be helpful.

Siddharth Mittal, Biocon Limited - MD, CEO & Director [113]

So let me talk about the JV business first. The JV revenues in the last whole fiscal was roughly INR 70-odd crores. So it was a very small base. We had a loss. If you look at the fact sheet, Biocon's share of JV loss was INR 29 crores. So on a sale of INR 70 crores, there was a significant loss, which is at 49%, we had INR 29 crores of loss. So that's the reason why we are shutting down the operations. Now there were 2 parts of the business in UAE. One was this -- the JV business, which was purely the Small Molecules generics -- branded generics business, which is what we are shutting down. So there are 2 products -- 2 biosimilars in the market, one is glargine and second is trastuzumab, which was included in Branded Formulations. But going forward, it will be part of Biosimilars segment, and that would continue.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [114]

Okay. So -- okay. So what portion of the revenue line would be really be moving out because of this restructuring, sir?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [115]

As I said, INR 70 crores, out of INR 536 crores of Branded Formulation sales, roughly INR 70 crores is the JV revenues.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [116]

Okay. Fine. Just last, one more question on this. See, this -- on the margin profile and the business progression that we have been talking, by 2020, we are expecting about $1 billion kind of Biologic sale, which is more than 3x of the current Biologic revenue that we are generating. So given that ramp up for the jump that we are expecting to achieve, and we are not also seeing that the R&D spend, which is the biggest cost component there, it's not likely to move in the similar tandem, so then should not be -- we'll be seeing a kind of significant improvement in the overall profitability of Biologic as well as the overall Biocon business by 2020?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [117]

2022, you mean, FY'22?

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [118]

Sorry, 2022.

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [119]

Surya, a couple of points. I'll just answer the Biologics business. So when I meant steady margins, and I said for FY '21 at the EBITDA level really included the benefits flowing below that. It's too early to guide for FY '22. Obviously, there is -- because I mean it's still -- I mean, it's dependent on R&D spend, of course, and the sales mix, which is product mix and region mix. So have not yet given guidance around FY '22 numbers. We will do that at the appropriate time.

Siddharth Mittal, Biocon Limited - MD, CEO & Director [120]

But what we've also said is that biosimilars business is the highest margin business as that business is the highest growth driver over the next 2 years. The consol margins would go up. And obviously, from a research expenses perspective, the absolute number would go up. But over the -- I mean, the 12% number is more for next year as we go forward and we reach the $1 billion number on an absolute -- the percentage would start coming down even if the absolute number was up. So the margin accretion would happen.

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [121]

And as you said, since you're going to triple the top line of Biologics, and it's a high-margin business, so you can proportionately see that the R&D spend would obviously come down.

Operator [122]

Next question is from the line of Aimee Truesdale from Jupiter Asset Management.

Aimee Truesdale, Jupiter Asset Management Limited - Analyst [123]

This is Aimee Truesdale. First question is actually on China. Given the Mylan-Upjohn merger, when do you start expecting to see Biologic sales in China? And is that -- is any of that included in the $1 billion target?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [124]

Number is not included. The China number is not included in the $1 billion target.

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [125]

But there's absolutely no doubt that the merger of Mylan and Upjohn will absolutely strengthen the position and the opportunity to see for our Biosimilars in China. It's very, very encouraging to see in the last 2 years that Biosimilars have entered the national drug reimbursement listing, which in one go allows that whole nation has access to biosimilars. And we believe that Mylan and Upjohn together as the address will play a strong role in China.

Aimee Truesdale, Jupiter Asset Management Limited - Analyst [126]

Great. That's really great to hear. Any sense of time line on when -- is it a matter of months or is it kind of years?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [127]

No, we are currently not commenting on the time lines.

Aimee Truesdale, Jupiter Asset Management Limited - Analyst [128]

Okay. Great. And just my second question is, you speak about expecting a recovery in the next few quarters. Just wondering what your base case is for COVID. When are you sort of building in for a vaccine or treatment to be available and -- you building in a second place?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [129]

Well, this is being speculated across the world. But as far as we are concerned, we are really focusing on safety in the workplace. And I think we will try and aim to keep our operations going, and we will look at seeing how we can keep the logistics and the supply chain efficiently running. So I think that's where we will focus. It's very difficult for us to predict whether there's going to be a second wave or not. But we will be in a state of preparedness because we should plan for a second wave, and that's the way we look at the future.

Operator [130]

We take the next question from the line of Nitin Agarwal from IDFC Securities.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [131]

Ma'am, will it be possible for you to give us a flavor of the geographical split between U.S. and the non-U. S. market for the Biologics business as it is now? And when you -- as it could be under the $1 billion FY '22, we're talking about $1 billion of revenues. Any sense on what kind of geographical data we're looking at in the business then?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [132]

So what I can tell you, there are 3 components that are important, and I mentioned in the order of magnitude to reach the $1 billion component. Number one is the United States. Component number two, most of those markets; and component number three is Europe and other developed markets.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [133]

Okay. That's helpful. And Siddharth, what could be consolidate net debt as of [year-end]?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [134]

Just a minute. So the consol net debt as of March '20 is INR 760 crores, give or take, $100 million.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [135]

Okay. And lastly, second, what proportion -- you mentioned about the Biologics business partly being shifted from Branded Formulations to Biologics from next year. On an aggregate annual level, what would be the amount of the business that we are shifting into Biologics now?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [136]

So I just mentioned it some time back, INR 536 crores was the full year revenue for branded formulations. INR 70 crores was UAE. So remaining INR 460 crore, INR 470 crore is branded India.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [137]

But that won't be all Biologics, right?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [138]

Well, the branded formulations business has been completely under Biocon Biologics. So the 70% plus of that revenue is Biosimilars, but the remaining is pertaining to Small Molecule drugs, but the operations is being managed by Biosimilars business.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [139]

Okay. These are all will be reported under Biologics revenues going forward?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [140]

Biosimilars revenue. So as I had mentioned earlier also that we will split Biologics into 2: Biosimilars and Novel Biologics.

Operator [141]

We take the next question from the [Raj Mohan], private investor.

Unidentified Participant, [142]

And I wish to take this opportunity to deeply appreciate the various efforts taken by Biocon and Mr. Kiran ma'am in the fight against COVID for the benefit of the society at large and then spearheading a lot of the Indian pharma industry initiatives. You indicated -- on the Biologics front, you indicated to the post-COVID scenario. Well, structurally, one should expect a much stronger environment for biosimilars what -- with the global economies coming under a severe financial stream. How about the structural impact on the regulatory environment, like FDA due to COVID-19? Do you anticipate the engagements and approvals to be swifter? How do you see the movement towards approval of, say, Semglee in this context?

Sundar Ramanan, Biocon Limited - VP & Head of Global Regulatory Affairs [143]

At this point, we don't see any impact of COVID on the regulatory interactions with the agency, and we remain confident about the Semglee approval along with our partner, Mylan, as we have previously indicated.

Unidentified Participant, [144]

Well, in fact, on the contrary, I was wondering whether things could be moving a bit more faster post-COVID than the global economic scenario when an approvals come in faster.

Sundar Ramanan, Biocon Limited - VP & Head of Global Regulatory Affairs [145]

See, as you know, in the U.S., these are statutory time lines, and FDA has to go through certain -- under PDUFA and BsUFA acts, they have certain mandate and standard time lines, and that's what they're going to go through.

Unidentified Participant, [146]

Okay. Next, coming to market share gains in Fulphila post your capacity expansion, where are we now currently in terms of market share? And what is the internal estimate on reaching closer to 20% as the (inaudible) seems to have gained a couple of more points in market share this quarter from 20% to 22%.

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [147]

Paul, can you, please, take that question?

Paul Vazhayil Thomas, Biocon Limited - Chief Commercial Officer of Biocon Biologics [148]

Sure. I think we've been consistent. We're around this [6%] market share level. And we see this growing over time. I think as Mylan has talked about, the foundation is built, the capabilities are there from physician, payer and hospital standpoint. And there are green sprouts, as they've talked about, that they're seeing. So we expect steady progress upward on our share here.

Unidentified Participant, [149]

Okay. Mylan has, in their call, indicated to garnering about 3% market share in Ogivri. Has Biocon been impacted by lower profit share this quarter? And do the larger recognition flow through the next quarter?

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [150]

Yes, we have been impacted by lower profit share this quarter. And as we said, there has been a lot of impact on account of COVID. Because we have seen a huge drop in hospital treatments, which, of course, have also impacted the uptake of many of these products. So we do expect to see a good recovery this quarter. And as Paul just mentioned, there are green fronts that we are seeing, and we expect this to now pick up, and we will recover during this quarter.

Unidentified Participant, [151]

Okay. One final question on etanercept, which is, I believe, launched by Mylan in Europe. What is the market size? And when could the U.S. launch be planned?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [152]

Peter, can you take that question?

Peter James Bains, [153]

Yes. Thank you for the question. So the current estimated value in Europe based on 2019 sales of the originators about $2 billion. As you know, the CHMP has just given a positive recommendation end of March. The U.S. launch is anticipated more towards the end of this decade. So I hope that, that addresses your question.

Operator [154]

Next question is from the line of Charulata Gaidhani from Dalal & Broacha. As there is no response from the current participant, we take the next question on the line of Bharat Sheth from Quest Investment.

Charulata Gaidhani, Dalal & Broacha Stock Broking Pvt Ltd., Research Division - Analyst [155]

Hello?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [156]

Go ahead.

Charulata Gaidhani, Dalal & Broacha Stock Broking Pvt Ltd., Research Division - Analyst [157]

Yes. Can you quantify the loss from Malaysia in FY '20?

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [158]

Excluding R&D cost, it is INR 160 crores.

Charulata Gaidhani, Dalal & Broacha Stock Broking Pvt Ltd., Research Division - Analyst [159]

INR 160 crores?

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [160]

INR 160 crores.

Charulata Gaidhani, Dalal & Broacha Stock Broking Pvt Ltd., Research Division - Analyst [161]

Okay. Yes. My second question pertains to just like you quantified INR 103 crores as impacted by shipment delays, is there any -- what would be the number in the current quarter?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [162]

Current quarter is not over. So...

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [163]

What do mean by that question? We didn't understand.

Charulata Gaidhani, Dalal & Broacha Stock Broking Pvt Ltd., Research Division - Analyst [164]

No. In the sense, this number is up to March. So...

Siddharth Mittal, Biocon Limited - MD, CEO & Director [165]

The current quarter has to complete.

Kiran Mazumdar-Shaw, Biocon Limited - Founder & Executive Chairperson [166]

But the current question is yet to be completed in June, right?

Charulata Gaidhani, Dalal & Broacha Stock Broking Pvt Ltd., Research Division - Analyst [167]

Yes.

Siddharth Mittal, Biocon Limited - MD, CEO & Director [168]

Ends on July 2.

Charulata Gaidhani, Dalal & Broacha Stock Broking Pvt Ltd., Research Division - Analyst [169]

Okay. Okay. And my question is, what is the kind of growth we expect in small molecules going forward?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [170]

Well, the growth on a full year basis should be a high single digit to low teens for Small Molecules business. And this is for the next 1 or 2 years, in fact.

Operator [171]

Next question is from the line of Bharat Sheth from Quest Investment.

Bharat Sheth, Quest Investment Advisors Pvt Ltd. - Head of Equities [172]

Siddharth, you said that we are spending, I mean, $200 million on the Small Molecule. So that -- when do we see the impact of that in translating in the top line? And how much out of that will be for this backward integration? If you can give some sense and color. So over the next couple of 3 years, I mean, how do we see the Small Molecule business?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [173]

Yes. I think the impact would -- given the gestation time lines to -- from ground 0 to commercial, it takes anywhere between 4 to 5 years. And this $200 million will be going in new manufacturing capacity. We already started the Vizag immunosuppressant greenfield plant, and we will be adding more drug substance and drug product facilities, which is part of this $200 million outlay. And we expect the revenues to start in 3 to 4 years' time line. But the full impact of the $200 million investment would be definitely beyond that 3, 4 years' time frame.

Bharat Sheth, Quest Investment Advisors Pvt Ltd. - Head of Equities [174]

What kind of asset turnover do we really expect at the peak level?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [175]

See, we -- in Biocon Small Molecules, we don't talk asset turnover because it's a combination of API and generic formulation. Being a large component, when you compare it with the other industry players, their asset turnover tends to be high because they capture the generic formulation sales. So you have an apple to orange kind of comparison. But you look at the ROC, last few years, it's been stable at 22%, 23%, and that number should be able to realize once we complete the investment phase.

Bharat Sheth, Quest Investment Advisors Pvt Ltd. - Head of Equities [176]

Okay. And would you like to give some kind of guidance on the tax rate from FY '21 onward?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [177]

Yes. I think at a group level, it should be somewhere around 25%. If I have to pick a number, if I have to pick a range, it can be -- it can fluctuate between 23% to 27%.

Bharat Sheth, Quest Investment Advisors Pvt Ltd. - Head of Equities [178]

I believe this -- once the Biologic, which has been moving to this U.K. side. So we have the losses sitting in the Malaysia and U.K. also, there is no, I mean, taxation, correct?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [179]

No, U.K. has taxation.

Bharat Sheth, Quest Investment Advisors Pvt Ltd. - Head of Equities [180]

We have some tax exemption, I believe.

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [181]

Tax rates are lower. And there are some under Patent Box some more concessions under Patent Box. But -- and that's the thing. Malaysia has a tax payment. It's currently operating at a loss, and the additional profits will not have a tax.

Bharat Sheth, Quest Investment Advisors Pvt Ltd. - Head of Equities [182]

That's why I just want to understand from the whole consolidated basis. So would it be a little lower, I mean, than what you are looking, Siddharth?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [183]

No. No. I think I would rather give a guidance which is more midway and something which there are a lot of moving parts on tax with so many subsidiaries and R&D expenses setting in subsidiaries where there is no profit and the profitable commercial business setting in entities where there are -- there's also moving

parts in terms of the tax, SEZ benefits. And also, I would definitely expect that 25% is something you should factor in, in your model.

Operator [184]

Next question is from the line of Prakash Agarwal from Axis Capital.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [185]

Just a couple of clarifications. So one of the participants did ask about recovery from Q1 and normalization from Q2, which is a statement by Christiane. So just making it clear what you mean by normalization is growth on a Q3 fiscal '20 number? Or do you expect to reach that level by Q2? Or my understanding was in Q1 itself, you will be at the Q3 number level. If you can clarify that, that will be helpful.

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [186]

So what we mean is recovery in Q1, and normalization is meaning going back to growth what we have seen in Q3.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [187]

Yes. Similar level...

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [188]

Recovery is going back closer to where we were at Q3.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [189]

Okay. And build a growth in...

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [190]

Normalization is back on the growth trajectory that we have been showing over the last several quarters.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [191]

Yes. So we will exceed the number in Q2, for sure, is what I'm trying to understand, most probably?

M. B. Chinappa, Biocon Limited - CFO of Biocon Biologics India Ltd. [192]

Exceed what?

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [193]

The Q3 number, so we are heading towards the Q3 number in Q1, and we are most probably in all likelihood, we are all set to exceed the number, what we have already achieved in Q3. Is that the way to understand?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [194]

Look, we have -- at present, we are looking forward to a strong revenue growth in fiscal year '21 on the back of the molecules in the United States and also on the back of increased market penetration of our molecules in EU and rest of the world. We clearly expect that we will go back to the growth trajectory that we have seen before.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [195]

Yes. Okay. And just to tie that up with your 2022 guidance of $1 billion, so as one of the participants also said that you need to double every year, so what I understand is it would be more '22 heavy in terms of -- so we would unlikely double this year. Would that be correct understanding or closer to doubling?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [196]

So we actually expect that for both year fiscal year '21 as well as fiscal year '22, we see a strong growth trajectory. We have several molecules already on the market. We expect largely to be in the United States, additional molecules to launch with bevacizumab and Aspart and all of this gives us a strong revenue growth potential for both year, fiscal year '21 as well as fiscal year '22.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [197]

Okay. And just one last one, if I may. So you mentioned from '23 to '25, you have visibility of 3 launches and '25 onwards, you have visibility of 1 or 2, I missed that point. If you could just help me repeat that, please?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [198]

So what I have said is that our pipeline is expected to deliver at least 3 additional molecules between fiscal year '23 and fiscal year '25. And also then for the coming years, we expect to launch 2 molecules per year.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [199]

Okay. Lovely. And is there any update on the Sandoz deal, like anything we can share, how are we progressed since we have crossed fiscal '20 as a year as a milestone. So anything you want to share?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [200]

And when it comes to Sandoz, the development of our molecules are in very early stages. And what we have is according to plan.

Operator [201]

We take the next question from the line of (inaudible) from [Dawn Capital].

Unidentified Analyst, [202]

Firstly, I'd like to commend you on the $0.10 mission initiative. I have 2 questions. The first one pertaining to the biosimilar insulin. Would you be able to provide a rough estimate of total insulin sales in FY '20 and a sort of approximation of the geographic distribution?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [203]

For recombinant human insulin, our insulin franchise, I'm not sharing the details on a product basis or across regions.

Unidentified Analyst, [204]

What about insulin analog?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [205]

It's the same for the insulin analog that we are not providing specific data on a product basis.

Unidentified Analyst, [206]

Right. Okay. And then next question, could you provide some sort of comment on the uptake you're seeing in trastuzumab and pegfilgrastim when it comes to the outpatient formularies in the U.S.?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [207]

Paul, can you please take that question?

Paul Vazhayil Thomas, Biocon Limited - Chief Commercial Officer of Biocon Biologics [208]

Sure. So when you talk about formularies, I think it's a little bit for -- oncology is a little bit different than a retail pharmacy product where the PBMs drive it. It's much more the insurance company coverage levels and -- rather than PBM formularies, and they're less of a factor. But coverage levels are quite high, really the vast majority of payers are covering the product. And so coverage is good.

Operator [209]

Next question is from the line of Yatin Mohane from Iroha Investment.

Yatin Mohane, [210]

My question is on the Biosimilar business. I think over the last couple of years, the market in U.S. and Europe has evolved into a more competitive landscape with the innovators and other biosimilars adopting quite aggressive strategies, including exclusivity contracts. So just wanted to get your view on what gives us confidence to sort of achieve the $1 billion revenue target?

Christiane Hamacher, Biocon Limited - CEO & MD of Biocon Biologics India Ltd. [211]

And we are actually very confident to achieve the $1 billion revenue target. It has 3 important components. Our molecules in the United States most of the world's market, where our Biosimilar business also continue to do really, really well. We have also got many more registrations in the last year, for example, when it comes to trastuzumab. And we are now starting to commercialize this more and more. And also, Europe is the third component. What's not factored in this $1 billion guideline given is China. Also with our increased portfolio, as I've mentioned, also bevacizumab and Aspart, the fact that trastuzumab was just recently launched and that Glargine is an upcoming launch in the United States, we remain very, very confident to cross the USD 1 billion line by end of fiscal year 2022.

Operator [212]

Next question is from the line of Vishal from Nirmal Bang.

Vishal Manchanda, Nirmal Bang Securities Pvt. Ltd., Research Division - Research Analyst [213]

I have a question on the interchangeability status of Lantus. Can you guide whether this interchangeability status would only be for the vial or it would also be for the pen version?

Sundar Ramanan, Biocon Limited - VP & Head of Global Regulatory Affairs [214]

The question is for both vials and the pen, right?

Vishal Manchanda, Nirmal Bang Securities Pvt. Ltd., Research Division - Research Analyst [215]

Yes.

Sundar Ramanan, Biocon Limited - VP & Head of Global Regulatory Affairs [216]

Okay. So like I mentioned before, we are pursuing and discussing with the agency and -- on the interchangeability actively, and we will come back to you with -- once we have clarity.

Vishal Manchanda, Nirmal Bang Securities Pvt. Ltd., Research Division - Research Analyst [217]

Would any clinical trials be required? Or you have done some basic trials and that -- and on the basis of the same, you are pursuing this interchangeability status?

Sundar Ramanan, Biocon Limited - VP & Head of Global Regulatory Affairs [218]

So late last year, the agency issued a guidance that talked about if the data package is analytical, similarity package is strong enough, there may be provisions to entertain the discussions with agency on interchangeability and biosimilarity. So that's exactly what we are doing.

Vishal Manchanda, Nirmal Bang Securities Pvt. Ltd., Research Division - Research Analyst [219]

And is there any chance that interchangeability status can come along with the Lantus approval that you are expecting anytime now? Or it's going to be a separate dialogue and it will take some time?

Sundar Ramanan, Biocon Limited - VP & Head of Global Regulatory Affairs [220]

When we get clarity on that, we'll provide you the same as well.

Saurabh Paliwal, Biocon Limited - Head of IR [221]

Do we have any more questions, Janus? Well, if there are no more questions, I thank everybody for being...

Operator [222]

I'm so sorry, sir. I just lost my connection for a minute. We have one last question from the line of Nithya Balasubramanian from Sanford Bernstein.

Nithya Balasubramanian, [223]

So very quick one. I just wanted to check on your Copaxone filing in the U.S. Have you responded to the queries from the FDA? What is the current status? And do you have any visibility on the launch time?

Siddharth Mittal, Biocon Limited - MD, CEO & Director [224]

Yes, we have responded to the CRL on Copaxone to the FDA. The file is under review. We have -- we are going back and forth in terms of the information that the FDA is asking as they review this -- our response. We have been assigned a new target action date. But at this stage, it's pretty early to comment when we'll launch the product, the approval is on track because FDA still has to review certain critical sections. And given the complexity of this drug, we rather cross that bridge across the milestone where we know that the approval is imminent. And at that point of time, we'll let you know.

Operator [225]

Thank you. Well, ladies and gentlemen, that was the last question for today. I would now like to hand the conference back to Mr. Saurabh Paliwal for his closing comments.

Over to you, sir.

Saurabh Paliwal, Biocon Limited - Head of IR [226]

Thank you, Janus, and thank you, ladies and gentlemen, for joining us on today's call. If any further questions, do feel free to reach out to me. Have a lovely evening.

Operator [227]

Thank you. Ladies and gentlemen, on behalf of Biocon Limited, we conclude today's conference. Thank you for joining. You may now disconnect your lines.