

## Biocon Limited Q1 FY18 Earnings Conference Call July 28, 2017

### *Participants from Biocon's Senior Management Team*

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- ❖ Kiran Mazumdar-Shaw: Chairperson & Managing Director
- ❖ Arun Chandavarkar: CEO & Jt. Managing Director
- ❖ Siddharth Mittal: President (Finance) & CFO
- ❖ Ravi Limaye: President – Marketing
- ❖ Suresh Subramanian – Sr. Vice President & Head – Branded Formulations India
- ❖ Prasad B.S.V: Sr. Vice President & Head - Small Molecules
- ❖ Shreehas Tambe: Sr. Vice President & Head - Insulins
- ❖ Paul Thomas: Vice President & Head - Biosimilars
- ❖ Saurabh Paliwal: Head, Investor Relations

### *Conference Call Participants during Q&A*

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- ❖ Prakash Agarwal, Axis Capital
- ❖ Sameer Baisiwala, Morgan Stanley
- ❖ Nitin Agarwal, IDFC Securities
- ❖ Dheeresh Pathak, Goldman Sachs Asset Management
- ❖ Abhishek Sharma, IIFL
- ❖ Charulata Gaidhani, Dalal & Broacha
- ❖ Aishwarya Agarwal, Reliance Mutual Fund
- ❖ Surajit Pal, Prabhudas Lilladher
- ❖ Alok Dalal, CLSA

### *Presentation Session*

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**Saurabh Paliwal:** Good morning everybody. I welcome you to Biocon's first quarter fiscal'18 earnings conference call. Last night, we had sent out our results. Hope you got a chance to view them.

Before we proceed to this call, I would like to remind you that a replay of today's discussion will be available for the next few days immediately following the conclusion of this call. We will be posting a call transcript on our website in the coming days as well. To discuss this quarter's financial performance for Biocon, we have today with us, Dr. Kiran Mazumdar Shaw, Biocon's Chairperson and Managing Director along with other colleagues from the senior management team.

I would also like to take this opportunity to remind everybody about the safe harbor statement that is contained in our press release. Today's discussion maybe forward looking in nature based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces that may cause our future results performance or achievements differ significantly from what is expressed or implied by such forward looking statements. After the conclusion of the call, if you have any further questions or need any further information; please feel free to get in touch with me. Now, I would like to hand over the call to Dr. Kiran Mazumdar. Over to you, ma'am.

**Kiran Mazumdar-Shaw:** Thank you, Saurabh and good morning everyone. I welcome you to Biocon's earnings call for the first quarter of fiscal'18 which has ended on June 30<sup>th</sup> this year.

Let me start by giving you some key highlights for the quarter.

- ❖ The long awaited US FDA Oncologic Drugs Advisory Committee (ODAC) meeting was held on the 13<sup>th</sup> of July and I am very pleased to say that we received an unanimous vote of 16-0 from this committee who recommended for approval, Mylan and Biocon's biosimilar Trastuzumab in support of eligible indications of the reference product and includes HER2-positive breast cancer in the metastatic and adjuvant settings.
- ❖ Biocon also received an approval from the Drugs Controller General of India for its biosimilar Bevacizumab for launch in India.

Now before I go on to the numbers I would like to give you a background on our financial performance for the quarter.

We had a very strong start to the biologic's business led by Insulins in emerging markets. However, the first quarter has been soft for Biocon on a consolidated basis, both at the topline as well as the bottom-line as compared to the same period last fiscal.

Let me explain the few underlying factors that have resulted in this performance. These include

- ❖ Sluggish sales of few APIs this quarter which impacted our small molecules segment,
- ❖ Lower licensing income which is a lumpy part of our business,
- ❖ Channel destocking due to GST, that impacted the Indian Branded Formulations business,
- ❖ Weak dollar which impacted our exports numbers,
- ❖ Continued impact on Syngene performance due to the fire in December last year, and
- ❖ There was also a one-time positive impact in Q1 FY17 on account of migration to the IndAS, the new Indian Accounting Standards which were adopted from April 1, 2016.

All the mentioned factors have had a combined effect on the revenue line.

Further –

- ❖ The capitalization of the Malaysia facility has added significant fixed and operating cost to the expenses line.
- ❖ Annual increments given in Q1 have increased our employee cost this quarter.

These two factors combined have impacted our performance at the bottom-line for Q1.

I will now represent **the key financial highlights** for this quarter.

- ❖ Total consolidated revenues were 988 crores which are down 4% as compared to last year.
- ❖ Revenue from operations was 934 crores which showed a decline of 6% as compared to Q1 last quarter. This includes licensing income of 8 crores this quarter as compared to 17 crores in Q1 of last year.
- ❖ From a segment perspective –
  - ❖ The Small Molecules segment revenue was 363 crores, down 17% from Q1 of last year. However, when adjusted for IndAS, it will show a decline of 5%.
  - ❖ Similarly, the Biologics segment revenue was up 15%, but when adjusted for IndAS, this actually shows a growth of 27%.

- ❖ Branded Formulations revenue was down 17% to 130 crores as against 158 crores last year.
- ❖ Syngene, our Research Services Segment's revenues came in at 291 crores in Q1, up 6% compared to Q1 FY17 and on a standalone basis, Syngene reported 6% growth in total revenues at 308 crores, with EBITDA of 113 crores and PAT of 62 crores.
- ❖ We incurred a total spend of 96 crores on R&D this quarter. Of this amount, 58 crores is reported in the P&L corresponding to 9% of revenues excluding Syngene. We capitalized an amount of Rs. 38 crores related to our biosimilar development expenses.
- ❖ We booked a Forex gain of 17 crores this quarter coming almost entirely in Syngene. The gains appear under other income and are on account of hedging gains for the USD contracts and that matured during the period.
- ❖ Group EBITDA was 246 crores for Q1 reflecting a decline of 19% with EBITDA margins at 25%. However, core margins that is EBITDA margins net of licensing impact of Forex and R&D stood at 29%. EBITDA has been impacted by fixed and operating cost related to Malaysia that was booked starting this quarter. Further, there were increased staff costs as we rolled out annual implements in Q1. If we were to adjust for the one-time IndAS impact from Q1 of last year, the decline in EBITDA would be 9%.
- ❖ Interest and depreciation cost increased 60% to 115 crores for the quarter, largely again attributable to the start of Malaysia cost hitting our P&L statement.
- ❖ Reported net profit for the quarter was 81 crores which represents a net profit margin of 8%.

Now coming to individual business segments –

**Small Molecules** - After adjusting for one-time positive impact to transition to IndAS in Q1 of last year, this segment was down 5% YoY due to a shortfall in API sales. While there continues to be pricing pressure, we are also impacted by the weaker dollar. The business equilibrium in the segment remains balanced.

**Biologics** was the strongest performing division for us this quarter. Adjusting for IndAS impact in Q1 of last year, this segment grew 27% YoY, driven by strong sales of insulin products, both Human Insulin and Insulin Glargine, in emerging markets. Licensing income was lower as compared to last year signifying its inherently lumpy nature.

We expect the Biologics segment to continue its strong growth during the year. I must add that it is very dependent upon regulatory approvals, tender outcomes and purchase timelines and unfortunately, these timelines are difficult to accurately predict.

As we have stopped capitalization of further expenses of the Malaysia plant, depreciation and fixed expenses amounting to \$48 million annually are now being charged to the profit and loss account and the impact of the same is evident in our financial results. We have started earlier than we hope to offset a large portion of the cost through product sales and other emerging markets which are dependent upon local regulatory approvals and emerging markets and the cost share arrangement that we have with our partner. The impact is expected to be uneven varying in different quarters due to ramp-up periods and different activities every quarter. Since the exact timing is hard to predict, any shift in expected timeline will have an impact that could impact the profitability for Malaysia and consequently our consolidated P&L.

The performance of our **Branded Formulations** showed a decline of 17% as compared to last year. This performance was along expected lines. Channel disruption in India due to the GST roll out and discontinuation of Oncology product Abraxane, both in India and UAE markets were the key reasons for the underperformance. However, our UAE business, although small performed well. This quarter,



we launched Biocon's biosimilar Glargine under our brand name Glaricon and also in-licensed cardiovascular drugs Imprida and Imprida HCT in collaboration with Novartis.

We expect the GST impact seen in Q1 to start normalizing in Q2 with gradual recovery in inventory levels with distributors and stockists. From a full year perspective, we do not expect any major impact of GST to our India business performance.

We secured our second biosimilar oncology antibody approval in India with DCGI approving our biosimilar Bevacizumab, a biologic prescribed for various cancer including metastatic colorectal cancer and lung cancer.

Our focus remains to continuously strengthen our anchor brands as we work towards getting the Branded Formulations business back on the growth path.

Now coming to **Research Services (Syngene)** - Post the fire incident in December'16, Syngene is now showing signs of recovery. While Syngene has not yet fully recovered from the impact, there is positive movement and it seems to be headed in the right direction.

Two notable highlights for Syngene this quarter were the expansion of its agreement with Amgen and a manufacturing agreement that it has entered into with a Japanese pharma company to manufacture and supply, a novel chemical entity for commercial launch in Japan.

The revised agreement with Amgen involves expansion of both the scale and scope of the work done by Syngene for Amgen. It entails increased headcount, doubling of infrastructure allocation and a wider range of R&D activities. As you will recall, the Syngene Amgen Research Center is a dedicated R&D center that was inaugurated in September 2016.

Further, Syngene has also signed a multiyear manufacturing agreement with a Japanese specialty pharma company, to manufacture a novel chemical entity for commercial launch in Japan. As you know the Japanese market is amongst the most stringently regulated markets globally and this contract is a strong validation of Syngene's ability to meet these high standards. Syngene has been involved with this project since the proof of concept stage and we are happy to see it progress towards commercialization.

Now coming to **R&D highlights** - Our proposed biosimilar Trastuzumab gained unanimous endorsement at the FDA's Oncologic Drug Advisory Committee meeting held earlier this month. This is the first biosimilar Trastuzumab recommended for approval by ODAC and it certainly is a very proud milestone for all of us at Mylan and Biocon. Along with Mylan, we now look forward to engaging with the US FDA to seek final approval which has enabled our collaboration to expand access to this high quality affordable Trastuzumab for treating HER2-positive breast cancer in the US.

In terms of other progress report on other biosimilars - We received market authorization in India for our biosimilar Bevacizumab indicated for the treatment of various cancers including metastatic colorectal cancer and lung cancer. The global Phase 3 study for the molecule continues to recruit patients.

With respect to our pending EMA Marketing Authorization Applications for proposed biosimilars of Trastuzumab and Pegfilgrastim, we have received the GMP compliance certificate from the French medicines regulator ANSM for our biologic drug substance facilities that produce Trastuzumab and Pegfilgrastim. However, the biologic drug product facility will require a re-inspection post implementation of the Corrective and Preventive Action or CAPA plan submitted to the regulator. We are working expeditiously to address the concerns of the regulator and will request for a re-inspection at the earliest.

Now coming to **Novel Biologics**, we continue to make good clinical and regulatory progress in our portfolio of molecules. The clinical trial application for a Phase 3 study with our Novel Insulin Tregopil in Type 2 diabetes filed with the Indian regulator DCGI in Q4 FY17 is under review. Plans for a clinical trial for patients with Type 1 diabetes are also underway.

We initiated stage 2 of the Phase 1 study for a subcutaneous form of our anti-CD6 mAb, Itolizumab, in Australia during the quarter.

In Immuno-Oncology, our lead molecule FmAb2, a fusion antibody progressed in preclinical development during Q1 of this fiscal.

So in closing, I would like to end by saying that after a soft performance in Q1, we maintain our cautious outlook for FY18. While the Small Molecule portfolio faces its regular pricing challenges, the performance of the Biologics segment is expected to be strong but dependent upon tender outcomes and regulatory approvals in the emerging markets. We expect Branded Formulations to be steady this year while Syngene is expected to return to its high teen growth trajectory with an expected strong second half performance.

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

### *Q&A Session*

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**Prakash Agarwal:** **Just one question on Trastuzumab, your comments on ANSM where the drug product review and the inspection would happen, what is your take on the US FDA front, I mean since the TAD is near but with the background of the 483 that we have, what is our understanding here on US FDA front?**

**Arun Chandavarkar:** As far as the US FDA observations go, we had earlier commented that similar to ANSM we have responded in terms of a CAPA plan to the US FDA and we are on track to complete all the CAPAs over there. Subsequent to our response, we have not heard from the FDA in terms of any further clarifications that may be required.

**Prakash Agarwal:** **So what I understand is we have already settled with the innovator and with Europe not having the patent, so this could be just awaiting ANSM, is that the right understanding?**

**Arun Chandavarkar:** No, that is not the correct understanding. The global settlement has specified timelines in terms of market formation dates in different jurisdictions and specified dates include global markets including Europe.

**Prakash Agarwal:** **And it is not one date, it could be different markets, different dates?**

**Arun Chandavarkar:** Yes. That is correct.

**Prakash Agarwal:** **Understood. And sir second question is trying to understand our Pegfilgrastim opportunity where we see the guys who were ahead of us have seen CRLs and our TAD date is due later this year. Just trying to understand would all these molecules go through the similar FDA panel in the advisory committee or it is just the first one that goes through, any understanding would help?**

**Arun Chandavarkar:** At this moment, we do not have definitive clarity on that. I know a few other companies have talked about that the advisory committees are normally constituted for the first filer. But we are not sure at this stage whether that is necessarily true because there is not enough precedent to say that.

There was some talk about whether since Filgrastim was approved, Pegfilgrastim would need a committee or not, but we do not have much clarity on that. All we can say is at the moment we are not aware of an advisory committee constituted for our review.

**Prakash Agarwal:** **Understood. And lastly on the Biologics, the guidance that we have given, \$200 million at the current fiscal 17 exit rate we need to grow this business by 50%-60% year-on-year for the next 2 years. So is emerging market opportunity enough or you dependent on some Europe to start kicking in in second half of fiscal 19?**

**Arun Chandavarkar:** We have guided that substantial part of that \$200 million will be driven by emerging market approvals in various jurisdictions including approvals in emerging markets from our Malaysia facility. Therefore, substantial part of that \$200 million or even more than that would come from emerging markets.

**Prakash Agarwal:** **But Europe would also start this what you are saying?**

**Arun Chandavarkar:** In a small way.

**Prakash Agarwal:** **By fiscal 19?**

**Arun Chandavarkar:** Yes.

**Sameer Baisiwala:** **Sid, the first question is on the \$48 million charge that we expect from Malaysia, how did we do in Q1? I know it could be uneven, but does not look like you did a substantial booking out there?**

**Siddharth Mittal:** We did book \$12 million in interest, depreciation and other expenses during the quarter. Since these expenses are fixed in nature, there will not be much of a fluctuation every quarter.

**Sameer Baisiwala:** **Okay. The second question is on 483s in Bangalore for US FDA. Another quick question here is was it related to the API site for Trastu or was it for the formulation site?**

**Arun Chandavarkar:** The observations that were discussed earlier were for our Biocon Park site in Bangalore which has both the drug substance and the drug product facilities located on the site under the same FEI number.

**Sameer Baisiwala:** **And just taking a step back, what would you think would be, in a way to say the global size of the emerging market tender business? You can take a year, two-year out. Is it a \$100 million, \$500 million business for your portfolio of drugs?**

**Arun Chandavarkar:** See, we have already said that the substantial part of our long-term guidance of \$200 million out of the \$1 billion target will come from emerging markets. So clearly that is going to be much larger than the \$100 million you talked about. You are asking how much of that is tender.

**Sameer Baisiwala:** Yes, I am saying, how much is the addressable tender market, in emerging markets in general?

**Arun Chandavarkar:** Tenders are a substantial part of that \$200 million.

**Ravi Limaye:** It is a mix of both tender and trade. I will give you an example. Let us take for example Trastuzumab. The emerging market opportunity as quoted in IMS is \$1.2 billion. There are markets which are only tenders and there are markets which are only prescriptions and there are markets which are both tenders and prescriptions. So it is very difficult to give an exact number but overall emerging market opportunity is \$1.2 billion for say Trastuzumab.

**Sameer Baisiwala:** Okay, thanks. Just one final question if I may. For Neulasta Pegfilgrastim, what I have seen is the 3 players ahead of us in the US and subsequent to their BLA filing, all three have been litigated. I have not seen Biocon filing being litigated. Is that understanding correct and if so why?

**Arun Chandavarkar:** See, I do not want to speak specifically on anything to do with litigation until it is disclosed and until we choose to disclose anything in consultation with Mylan. So at this stage I cannot talk anything about our litigation strategy on our biosimilars.

**Nitin Agarwal:** Siddharth, just coming to the previous question around the Malaysian expenses, I think Malaysia got expensed out from this quarter only, right, or we have some part of it even in the previous quarter?

**Siddharth Mittal:** There was a very small portion in the previous quarter which was related to administrative expenses. The booking of plant related expenses has started from this quarter.

**Nitin Agarwal:** Yes. So the surprising thing is your R&D expense, your other expenses and staff expenses have not shown that kind of impact you are talking about on a Q-o-Q basis. So it is a little surprising. So can you help us understand it better because a reasonable amount that should come through in this quarter.

**Siddharth Mittal:** The staff expenses have gone up by 18% YoY and it does reflect increase on account of inclusion of Malaysian staff cost. Also, a large part of the increase is in interest which has gone up by 10 crores. Further, depreciation has gone up by 33 crores, of which 26 crores was on account of Malaysia. Looking at the 'other expenses', they look quite similar when compared to Q1 of last year. However, if you look at the results as per the SEBI format, you will see there is a recovery of cost from co-development partners which is at ~37 crores compared to ~13 crores in the Q4 of FY17. Increase is on account of expenses for Malaysia being recovered from our partner and the offset is reflected under other expenses.

**Nitin Agarwal:** **So, it is just on a modeling perspective, the staff expenses and the other expenses that you have reported in this quarter, it should be budget them as around these base numbers to go ahead?**

**Siddharth Mittal:** Definitely staff cost. The other expenses could fluctuate a bit because a lot depends on how much you are able to recover from partners and that depends on the activities that happen during the quarter. For e.g. if we have higher commercial manufacturing operations, the amount recovered from the partners will go down which would end up being reflected in increase in other expenses.

**Nitin Agarwal:** **And how much will be the recovery for this quarter?**

**Siddharth Mittal:** I will refer you again to the SEBI format reporting. The total amount recovered from co-development partners is 37 crores. Now that does not include only Malaysia, but also includes R&D cost that is paid by our partners, including Mylan.

**Nitin Agarwal:** **Okay, thanks. That is helpful. Secondly, on the Malaysian plant regulatory inspections, have we had both EU and US inspecting those plants and what is the status of these inspections?**

**Arun Chandavarkar:** Yes. We have had the inspection from the European authorities in Malaysia. We are awaiting the report.

**Nitin Agarwal:** **And the US haven't inspected them as of yet?**

**Arun Chandavarkar:** No.

**Nitin Agarwal:** **And likewise on the Glargine filing, by when that should be done in the US?**

**Arun Chandavarkar:** I think at this stage we have not given any specific date. We are engaged with the regulator in terms of deciding in how to enable our filing.

**Nitin Agarwal:** **And if I may squeeze in a last one, just on the recent experience with Remicade biosimilar launch in US, we have seen a year of launch and like 5% market share by the biosimilar and we have seen recently the second biosimilar coming in with a 35% price discounting. Is this sort of in line with your expectations around how the biosimilar markets will evolve in the US given the fact that this is probably the first relevant biosimilar which is being commercialized in the US?**

**Paul Thomas:** I think there are not enough data points in the US to really be able to make any generalization there. It is still early days. Each Company has a particular strategy and products are different. So, I would say it is too early to generalize based on that.

**Dheeresh Pathak:** **The Malaysian tender, how much of that I think earlier you had guided it is about 150 crores per year. So if you can give any color in terms of how much of that was there in this quarter?**



- Siddharth Mittal:** It is roughly \$20 million (net) a year and is spread out evenly during each quarter.
- Dheeresh Pathak:** **It was there to that extent this quarter as well, does it fair understanding?**
- Siddharth Mittal:** Yes.
- Dheeresh Pathak:** **Okay and did you mention the TAD date for Pegfilgrastim can you give that again?**
- Arun Chandavarkar:** 9th October.
- Abhishek Sharma:** **Just two questions. You filed for Glargine in Europe in November 2016 and now we are in July 2017, so what is the quantum of additional work that you were required to do for the US filing given the fact that your Phase 3 would essentially be the same?**
- Arun Chandavarkar:** I think we mentioned this earlier that the different regulatory agencies have different requirements as far as accepting the dossier is concerned, and clearly, there are differences between what the FDA expects, EMA or Japan or Canada or any of the other agencies expect. We had also indicated earlier that it is not also necessary that it is going to be the same Phase 3 trial because for the European application, we had talked about a trial in Type 1 and we had talked about the FDA requiring Type 1 and Type 2. So there are differences in requirements in different regulatory agencies.
- Abhishek Sharma:** **Even if I were to sort of take that, but from what I understand your Phase 3 regulatory trials even for US were over at around time when you were submitting for EU if I recall it correctly. So just wanted to understand what is the delay, is it more on the administrative side or is there any bigger large additional study required or is it something that around FDA's willingness to accept the file?**
- Arun Chandavarkar:** Right now the only color I can give to this is that we are in discussions with the FDA in terms of how to enable our filing. I have already mentioned that there are differences in regulatory expectations across different regulators within the developed markets itself. So the specifics about what each regulator demands, I would not like to discuss for competitive reasons, but clearly there are differences and we are engaged with the regulators in all jurisdictions to discuss how to enable the filing.
- Abhishek Sharma:** **Right. And just the other question. So, your EU inspection I presume was triggered by your Glargine filing in November, is that right?**
- Arun Chandavarkar:** Yes.
- Abhishek Sharma:** **And when was the inspection done sir?**
- Arun Chandavarkar:** Which one?

**Abhishek Sharma:** **The EU Malaysia?**

**Arun Chandavarkar:** Done in April.

**Charulatha Gaidhani:** **My question relates to small molecules. There has been a pricing pressure over the last few quarters. When do you see this reversing?**

**Kiran Mazumdar-Shaw:** Very difficult to make any prediction on that Charu, because it is all about market dynamics. We have also been affected by the weak dollar. So we cannot have any kind of clear predictable statement to make until we see some stability in the market and some strengthening of the dollar. Then maybe we could provide you some optics.

**Charulatha Gaidhani:** **And in APIs, are we focusing on only few therapies?**

**Kiran Mazumdar-Shaw:** Well, you know we have a portfolio of APIs which is our strong hold, largely immunosuppressants and statins. Those are the anchor APIs that we have and then of course we have also got range of other smaller APIs, but these are the two growth drivers.

**Charulatha Gaidhani:** **So is it because there are too many players in the business?**

**Kiran Mazumdar-Shaw:** No, I do not believe that is the reason because we clearly know that in some of these areas, we are very strong. In fact, we have a very large market share in all these APIs. I think it is just to do with periodic phasing kind of issues.

**Charulatha Gaidhani:** **My second question pertains to branded formulations. It has seen a 17% decline due to the GST. Now how much of this would you while insulin, I believe is a necessity. So did you see any volume impact in insulin also?**

**Suresh Subramanian:** The stocking at the wholesalers' level and therefore the purchase with us has been impacted due to GST. But the market had carried inventory which was sufficient enough to push the insulin to the patient. So we will have to wait and see as to how much will be the impact in the subsequent months and how we recover from the GST impact. So to answer your question, the volume should not be impacted when we look at it from a 2-3 month perspective. I should also tell you that our market share of insulins have gone up and both Insugen and Basalog have actually performed over the market growth. So, that is an indication that the overall volumes have not been impacted, but what is optically seen by way of our performance is impact because of stockist uptake from us.

**Kiran Mazumdar-Shaw:** And I must also tell you that there has been pricing pressure as well because there is drug price control effect, there are also other competitor pricing. So I think if you were to look at this sector purely in terms of volume growth, we have done well overall. But when you look at the pricing pressure that the whole Branded Formulation industry in India is undergoing, I think you will see this impact.

**Aishwarya Agarwal:** Can you please help me with Glargine substitutability study and when are we filing the product?

**Arun Chandavarkar:** As I mentioned in response to a previous question, different regulators have different requirements and in terms of the substitutability study, Glargine filing is not through the biosimilar pathway, it is through the 505 pathway. So the regulatory requirements in the 505 pathway are not same as through the biosimilar pathway. So that is why we mentioned there are different requirements and we are engaged with the regulators as to when we can enable this filing.

**Aishwarya Agarwal:** Thank you and the next is what is the market size of Trastuzumab because I understand there are two indications, one is MBC and EBC the size in US is \$2.7 billion and \$4.1 billion. So if you can correct me that will be very helpful sir.

**Arun Chandavarkar:** See in terms of, if you look at our ODAC approval, our ODAC approval was for all eligible indications which mean they actually recommended for approval to the FDA extrapolation to all the breast cancer indications.

**Aishwarya Agarwal:** So what is the market size in US of all the indications together?

**Arun Chandavarkar:** It is around \$2.5 billion.

**Aishwarya Agarwal:** Sure. And sir one last thing is about this Pegfilgrastim, so there are other players who have got CRLs, just want to understand how prepared we are in terms of our filing or what are the different features we have? Any light will be helpful on this?

**Arun Chandavarkar:** See, the companies that have received responses, I mean CRLs in the past have probably received it for very different reasons. So it would be hard to extrapolate that to anything to do with our filing. As far as we are concerned we are so far on track to proceed towards the target action date in October.

**Aishwarya Agarwal:** Sure. And sir just one more to squeeze in, about Glargine you said that you are in touch with the regulatory authority and you are looking for what to do for this substitutability study. So why I am asking this is, if you have a 505(b)(2) and then you need to have a sales force and then you market the product and then gradually gain the market share, it is a time taking thing. Whereas once you do this substitution study it will work for you as a generic. So is there any more information which can be shared on this aspect for our improved understanding?

**Arun Chandavarkar:** We are confident that the clinical trials that we have done including whether it is required for interchangeability or not would support our commercial strategy. The commercial strategy is driven completely by Mylan in the US and they have obviously looked through our development strategy and made sure it is aligned with the commercial strategy that they have.

**Aishwarya Agarwal:** **And sir, once your filing goes to FDA, I guess that is the time when the FDA inspection for Malaysia will be triggered?**

**Arun Chandavarkar:** Yeah. Normally pre-approval inspections get triggered after the file is under review.

**Surajit Pal:** **Could you please tell me, I mean the before question, you say it is March when ANSM has visited your Malaysian plants?**

**Arun Chandavarkar:** We said that European authorities designate different countries. So without discussion specifics all we are saying is that we were inspected by the European authorities.

**Surajit Pal:** **So any observation post visit?**

**Arun Chandavarkar:** We cannot provide any specifics. All we can say is, all CAPAs have been addressed and responded to.

**Surajit Pal:** **So, the thing is that whenever there is any visit, any observation if there is any are given then and there only. So I was just thinking that any observation over there...?**

**Arun Chandavarkar:** Yes. That is what I have said. We have responded to the CAPAs pertaining to Malaysia.

**Alok Dalal:** **Has the US FDA given a classification for the Bangalore plant as in terms of NAI, VAI or OAI?**

**Arun Chandavarkar:** See, we are awaiting an EIR. The classification comes only when somebody tells you that it does not meet something and all that. So right now the CAPAs are all proactively done. We have addressed the CAPAs and responded already.

**Alok Dalal:** **Okay. So in your view US FDA may not re-inspect the plant and like say the European regulator?**

**Arun Chandavarkar:** Yes. As I mentioned to a previous question we have responded with CAPAs and have not received any further feedback or communication from the FDA in terms of seeking further clarifications. So at this stage all we can say is that we have responded to all the observations. Of course, when we say responded, we have of course responded in our view in a satisfactory manner. We can say we have put in our best. We have clarified earlier that the issues raised were not classified as critical.

**Prakash Agarwal:** **Just referring to your annual report you did give some guidance on Insulin Glargine filing by 1st half of fiscal 18. I mean given the past comments you made during the call, are you not certain of the same?**

**Arun Chandavarkar:** See, we will engage with the regulators. At this stage we do not want to give a specific time until we have clarity.

- Prakash Agarwal:** So it could be a couple of quarter here and there, I mean broadly...
- Arun Chandavarkar:** We cannot allude to a specific timeline at this point in time.
- Prakash Agarwal:** Okay. And similarly for Adalimumab, you have given fiscal 18 is your filing, because you have mentioned in the annual report just reconfirming.
- Arun Chandavarkar:** The same applies to Adalimumab. We would be engaged with the regulators to see how to enable the filing.
- Prakash Agarwal:** And secondly on the Malaysia cost of \$12 million, so which is more or less ascertained at \$48 million annual and 12, so the other operating expense it is fair to assume will increase with the activities ramping up probably in the second half with more revenues coming in. Is that right understanding?
- Siddharth Mittal:** That is correct. The variable costs which are primarily material and power costs will depend on what commercial activities happen during that period.
- Sameer Baisiwala:** Arun, can you update us on the Copaxone file and is there any TAD that is around the corner?
- Arun Chandavarkar:** I think in the last quarter call I had mentioned that in response to a request for additional information from the FDA, it would take us until the end of the year to submit a response. So until we do that we do not expect any further progress from the FDA.
- Sameer Baisiwala:** Okay. So end of fiscal 18 is when you would submit your data?
- Arun Chandavarkar:** I mean give or take a month, yes, that is our expectation.
- Sameer Baisiwala:** Okay. And then another 9 months or whatever time it takes for the TAD, it is about...?
- Arun Chandavarkar:** That I do not want to hazard a guess at this stage, but I can say that from our side we are targeting to, submit our responses roughly by end of the fiscal.
- Sameer Baisiwala:** Okay, wonderful. And the second question is on Trastuzumab. I have gone through the ODAC final outcome, it very clearly states MBC as the indication but does not very categorically write early stage EBC in the indication, and even it does talk about all eligible indications. So is there a fine print there or the moment you get into the market you can market for both the indications?
- Arun Chandavarkar:** The ODAC committee on a specific question of extrapolation to all eligible indications which means of course beyond the indication that was done in the clinical study, voted 16-0 in favor of that. This clearly means that

extrapolation to all the indications and eligible means the indications that are approved for the reference product.

**Sameer Baisiwala:** Okay. And just one final question on Trastuzumab again. I do not know how much you can talk about the global settlement, but it is quite out of place. So philosophically if you can explain us that why would Europe be included as part of that settlement when there is no breathing patent, so to say. Patent has expired. That is one. And second is, hypothetically speaking if you do not get your approval in the first cycle review by US FDA and by French authority, would any delay mean that there is a loss of business based on your settlement launch timing?

**Arun Chandavarkar:** So, to answer your first question as you rightly concluded there is not much disclosure I can make on the global settlement. Those questions are best directed at Mylan because they are the ones who have exclusive commercial rights in the developed markets and they would be the people who would decide whether anything can be disclosed beyond what has already been disclosed. In terms of the commercial impact, I think we have already mentioned in the past, probably that we do not see a major impact in terms of commercial launch timings.

**Charulatha Gaidhani:** My question pertains to Trastuzumab. How much time will it take after once the FDA clears the settlement? How much time will it take to start supplies and get the share of profit?

**Arun Chandavarkar:** I think we had already mentioned in response to the previous question that I cannot discuss specific guidelines in terms of the global settlement. So I cannot talk of specific launch date. Clearly wherever the market is open we would commence supply. I mean, if you are talking about the target action date that is specific only to the US.

**Saurabh Paliwal:** Ladies and gentlemen, thank you for joining us today. Hope we have addressed all your questions. If there are any further questions or you need any clarifications, please do reach out to me. Have a good day.

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