Transcript

Biocon Limited Q1 FY19 Earnings Conference Call
July 27, 2018

Participants from Biocon's Senior Management Team

- Kiran Mazumdar: Chairperson & Managing Director
- Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon
- Siddharth Mittal: Chief Financial Officer - Biocon
- Prasad BSV: President & Chief Operating Officer - Small Molecules
- Shreehas Tambe: Chief Operating Officer – Biocon Biologics
- Paul Thomas, Chief Commercial Officer - Chief Commercial Officer - Biocon Biologics
- Suresh Subramanian: Head - Branded Formulations India - Biocon
- Naren Chirmule: Head - R&D - Biocon
- Saurabh Paliwal: Head, Investor Relations - Biocon

Moderator:

Ladies and gentlemen, good day and welcome to Biocon Limited's Q1 FY19 Earnings Conference Call. As a reminder, all participants will be in the listen-only mode, and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Saurabh Paliwal from Biocon Investor Relations. Thank you and over to you, sir.

Saurabh Paliwal, Investor Relations

Thank you, Aman, and good morning, ladies and gentlemen. I welcome you to Biocon's earnings call for the first quarter of fiscal '19. We declared results yesterday. I hope you had a chance to look at them. Before we proceed, I would like to remind everybody that replay of today's discussion will be available over the next few days about 60 minutes post the conclusion of this call. We will post the transcript of the call on our website in the coming days.

Moving on, to discuss this quarter's performance and outlook, we have today with us Biocon management led by Dr. Kiran Mazumdar-Shaw, our Chairperson cum Managing Director, and other colleagues from the senior management team.

I would like to remind everybody that today's discussion may have forward-looking statements based on management's current beliefs and expectations. They must be viewed in conjunction with the risks that our business faces that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements.

After the end of this call, if you need any further information or clarifications, please do get in touch with us. With this, I would like to turn the call over to Dr. Kiran Mazumdar. Over to you, ma'am.

Kiran Mazumdar-Shaw, Chairperson cum Managing Director - Biocon

Thank you, Saurabh. Good morning, everyone. I welcome you to Biocon's earnings call for the first quarter of fiscal year 2018-19.

Let me start with key highlights for the quarter.

- I am pleased to share that our partnered biosimilar Pegfilgrastim Fulphila received approval from the US FDA last month. Our partner Mylan has launched the product in the US as the more affordable therapy option for cancer patients undergoing chemotherapy. It is indeed a significant milestone for Biocon and sets the tone for the future success of our Biologics business. Very few companies have received two biosimilar approvals from the US FDA and we are very proud of this achievement. It makes us as I said the first company from India to get this biosimilar commercialized in the US and we are the only company from India to have two of its biosimilars approved by the US FDA.

- Biocon's Sterile Drug product manufacturing facility for Biologics in Bengaluru received EIR from US FDA and the EU GMP certification during the quarter.

- We presented PK/PD data on our novel Insulin Tregopil at the American Diabetes Association Scientific Sessions in the US and Syngene extended and expanded their agreement with the Baxter Global R&D Center until 2024.

Moving on, I will present the key financial highlights for this quarter.

- Total consolidated revenues for the quarter were Rs.1193 crores, up 21% compared to last year.

- Revenue from operations were Rs.1124 crores which were up 20% as compared to last year. This includes licensing income of Rs.5 crores this quarter as compared to Rs.8 crores in Q1 of last year.

- From a segment perspective,

  - Small Molecules segment revenue was up 10% to Rs.400 crores.

  - Biologics grew 36% to Rs.250 crores

  - Branded Formulations grew 13% to Rs.147 crores; and

  - Syngene's revenues were up 39% at Rs.406 crores in Q1.

- We incurred gross spend of Rs.88 crores on R&D this quarter corresponding to 12% of revenues excluding Syngene. Of this amount, Rs.44 crores is reported in the P&L. We capitalized an amount of approximately Rs.44 crores related to our Biosimilars and insulin analogs development expenses. The gross spends are lower than last year due to timing of some of the activities on a quarterly basis. The amount in the P&L has reduced on account of capitalization of Bevacizumab-related expenses which were reflected in the P&L in Q1 of last year.

- We booked a forex gain of Rs.39 crores this quarter as compared to Rs.17 crores in Q1 of last year. This gain is reflected in the other income line of the P&L. Of the total amount, Rs.28 crores is coming from Biocon while the rest is attributable to Syngene.

- Group EBITDA grew 25% to Rs.307 crores with EBITDA margins at 26%. Core margins that is EBITDA margins net of licensing impact of forex and R&D stood at 27%.

- Reported Net Profit for this quarter was Rs.120 crores, up 47% from last year, representing a Net Profit margin of 10%.

- The Effective Tax Rate at 27% for the quarter is slightly lower than last year of 28% due to lower losses and overseas subsidiaries during the period under review.

Coming to discussing individual business segments –

Small Molecules: The revenue growth in this segment was led by key APIs and increased generic formulations sales. Higher sales of immunosuppressants and increased market share of Rosuvastatin formulation in the US were key contributors. We also launched Simvastatin tablets in the US market during the quarter. Several Drug Master Files were filed and developed and key emerging markets during the quarter strengthening our Small Molecules API pipeline.

Coming to **Biologics**: This segment was led by higher sales of biosimilar monoclonal antibodies in emerging markets, supported by the insulins business. The primary driver for growth this quarter was Trastuzumab with strong retail market uptake witnessed in Brazil and robust market share in certain markets in the AFMET region. Our Insulin's portfolio continued to improve its market share in several emerging markets.

Clearly, we are seeing a strong offtake of our biosimilars portfolio products in emerging markets, which enjoy wide acceptance from patients and prescribers. With a strong start in the year and several regulatory submissions made in emerging markets recently, we expect a further pick up in the Biologics business growth in the coming quarters. The recent launch of Pegfilgrastim by our partner Mylan in the US and Insulin Glargine sales in EU and Australia, which are planned for later this fiscal, are expected to provide a further tailwind to this segment performance. We remain confident of achieving the $200 million target revenue for this segment in FY19.

In Q1, the growth in **Branded Formulations** segment which comprises product sales in India and UAE, was led by growth in the India Branded Formulations business. The India business growth this quarter benefited from the lower base in the same quarter last year due to GST implementation. Metabolics, Nephrology, Immunotherapy and Comprehensive Care divisions aided the business performance with strong growth reported for some of our key brands.

In the UAE, the business continues to garner market share in the Metabolics segment through increased sale of in-license products and our Insulin Glargine which was introduced recently.

In terms of **Research Services**, Syngene recorded a strong growth this quarter. The growth was driven by good performances within Biologics Manufacturing, Discovery Services and Chemial Development Services.

Syngene also announced the extension and expansion of their agreement with the Baxter Global R&D Center until 2024. They also announced the re-commissioning of Phase-1 of the upgraded S2 facility which was damaged due to a fire incident in December 2016. The progress made provides good visibility on underlying growth expectations for Syngene for this year and the long-term.

Now for some product development updates:

In Europe, the regulatory review of our **marketing authorization applications or MAA for Biosimilar Trastuzumab and Pegfilgrastim** are progressing well, and we expect a decision by CHMP by the end of calendar year 2018.

For the **US market**, Biocon and Mylan are generating additional clinical data for **Insulin Glargine** in support of the manufacturing site changed from Bengaluru to Malaysia. All activities as agreed with the US FDA in this regard are progressing as planned. We will expeditiously provide the requested data to the regulator in response to the Complete Response Letter (CRL) we received for this product. We do not anticipate any impact on the approval and launch timing of Insulin Glargine in the U.S.

As part of our Novel Molecules development programs, our oral insulin candidate, Insulin Tregopil advanced in pivotal Phase-2/ Phase-3 study in type-2 diabetes with more patients in India being randomized during the quarter.

Before I conclude, I would like to summarize our performance in Q1 FY19 and the expectations for the rest of the financial year.

We have had a positive start to the year with a good performance in the first quarter. We were able to increase sales in the Small Molecule segment despite challenges persisting in the generics industry. Branded Formulations also grew in double-digits and we expect a better performance from this segment this year. The growth segments, namely Biologics and Syngene have made a strong start, building upon the traction from last quarter. Recent and upcoming launches of biosimilars coupled with traction in Research Services provides us a good launch pad to accelerate growth in the subsequent quarters during this financial year. We have positive expectations on our overall performance this fiscal.

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

Prakash Agarwal, Axis Capital

Just trying to understand this R&D line better. We had earlier talked about Rs.4.5 to Rs.5 billion kind of run rate. We are tad lower as per the quarterly run rate is concerned. So, how should we think about for the full year, is there any change?

Siddharth Mittal, Chief Financial Officer - Biocon

No change in the R&D guidance, it would be in the range of Rs.4.5-5 billion for the full year. As we said, R&D expenses cannot be evenly spread throughout the quarters, this quarter at a gross level it was Rs.88 crores and we definitely expect the expenses to go up in the coming quarters.

Prakash Agarwal, Axis Capital

Secondly on Fulphila, again congrats on launching it as well. Just trying to understand this in terms of ramp-up how should we think about the acceptance and the ramping up of the product, what are the initial feelers if you could share?

Paul Thomas, Chief Commercial Officer - Biocon Biologics

I think certainly we are looking forward to this launch, we are excited about this product going forward, and we look forward to seeing how it develops. I think it is too early to speculate at this time and about specific market shares that we are targeting.

Prakash Agarwal, Axis Capital

Would the sales of Fulphila be recorded in the current quarter, Q1 there is some impact, I understand profit share would obviously come later, but would the manufacturing sales would have gone?

Siddharth Mittal, Chief Financial Officer - Biocon

The launch quantities were included in this quarter's number. It is a very small number.

Prakash Agarwal, Axis Capital

From here obviously it would ramp up more?

Siddharth Mittal, Chief Financial Officer - Biocon

Yes and more importantly, the profit share would start coming as Mylan starts liquidating the inventory in the markets.

Prakash Agarwal, Axis Capital

With a quarter lag, sir, would that be right to understand?

Siddharth Mittal, Chief Financial Officer - Biocon

Yes, that would be fair. For the inventory they maintain, obviously, there will be no profits on that, but for the initial launch quantity, I do not think there will be a big lag. So, we expect whatever initial sales they do, the profits will be captured in Q2.

Prakash Agarwal, Axis Capital

Secondly on Glargine, just looking at Clinical Trials website, so talks about completion of additional clinical data by December '18. So, post which in terms of timelines we would be looking to submit the data, and should we expect calendar '19 as the approval?

Siddharth Mittal, Chief Financial Officer - Biocon

This product was filed under the 505b2 route and given that we have litigation on this product, there is a 30-month stay on FDA approval. The stay gets over in March 2020. What we have said earlier is that we expect to get the tentative approval before March 2020. The final approval will not come till the 30-month stay concludes or the litigation is settled, whichever is earlier.

Prakash Agarwal, Axis Capital

That I understand. I am just understanding with the clinical trial data being completed, would it be fair to see an approval by '19 is what I am trying to understand?

Arun Chandavarkar, Chief Executive Officer - Biocon

As Siddharth mentioned, the approvals are linked to the whole 505b2 patent litigation, the 30-months stay. So, that is what drives some on the clock. But from our side clearly you can see that the trials are going on track, and also in Kiran's opening remarks, we have guided saying that we are on track in terms of approval and launch in the U.S.

Prakash Agarwal, Axis Capital

Lastly on the cash pile, given we had some stake sale in Syngene what will be the cash position and the capex for the quarter sir?

Siddharth Mittal, Chief Financial Officer - Biocon

We have cash of ~Rs.2,150 crores with the debt of ~Rs.2,500 crores, so the net position is roughly Rs.300+ crores. The cash what we collected from sale of Syngene stake sale was ~Rs.340 crores and we had capex at the group level of almost a similar amount. So, compared to March, our cash position remains largely unchanged.

Damyanti Kerai, HSBC Research

Can you broadly indicate at what price discount compared to the reference product we have launched that in the US market?

Paul Thomas, Chief Commercial Officer - Biocon Biologics

I think it has been indicated in the press and Mylan has confirmed also about the 33% discount in the list price, the WAC price in the market. So, that is the information available at this time.

Damyanti Kerai, HSBC Research

Coming to Insulin Glargine, you have indicated that we have done really well in Brazil. But can you also indicate how we have done so far in Japan in terms of like what kind of market share or sales we have garnered so far?

Paul Thomas, Chief Commercial Officer - Biocon Biologics

In Japan our launch there was after a prior launch of the biosimilar there. So, this has not been a big market for us so far. But we continue to watch and work with the partner to see how this evolves.

Damyanti Kerai, HSBC Research

Can you indicate how much R&D we have cumulatively capitalized so far?

Siddharth Mittal, Chief Financial Officer - Biocon

The total amount is ~Rs 590 crores. That includes the amount for internal capitalization as well as any intangible assets that we acquire.

Surya Patra, Phillip Capital

Just on the ramp up side for Fulphila, it would be very, very staggered or how it would be actually that one could really see and what is the likelihood of the competition there for Fulphila, what sense that you can provide?

Paul Thomas, Chief Commercial Officer - Biocon Biologics

We have seen different trajectories for different products in the US market and generally there is a gradual ramp up in the US market with the biosimilar launches there. So, that is the kind of the backdrop with other products that we will be looking at in comparison to our launch. In terms of competitors, we know Coherus has their target action date on November 3rd. So, that one is on the horizon, others are beyond that time and I do not think there is as much specifics available on their entry timing.

Surya Patra, Phillip Capital

Initially it would be one to two player kind of scenario and with the similar kind of the initial price trend what we have witnessed could be sustaining for relatively longer time, is that assessment fair?

Paul Thomas, Chief Commercial Officer - Biocon Biologics

Yes, I think that initial WAC price discount has been announced, and that is what it is at this point. I think would not be appropriate to talk about the competitive strategy or speculate about how that evolves.

Surya Patra, Phillip Capital

The two products which has already been though it is our partner product but in the meanwhile to accelerate the launch of the products in European markets for Etanercept and Adalimumab, Mylan has partnered with a third-party. So, how the economic interests are getting protected, can you just provide some idea about it? Also what is the kind of progress that we are seeing for the balance pipeline?

Siddharth Mittal, Chief Financial Officer - Biocon

Let me take the first question and then handover to my colleagues to answer the pipeline question. What we have said is that the profits from these in-licensed products Mylan will get will be shared with us in line with our original agreement with Mylan. For the developed markets, as you know, we have a profit share which is different from the emerging markets, and the same ratios would be applied to profits in the developed markets as well as emerging markets, respectively.

Surya Patra, Phillip Capital

This would be exclusive to Europe as of now and US plans will be with our own product only? That is how one should really believe sir?

Siddharth Mittal, Chief Financial Officer - Biocon

Right now, Mylan has announced for Europe, I cannot comment anything more than that. For Etanercept, there are certain emerging markets also included.

Shreehas Tambe, Chief Operating Officer – Biocon Biologics

On the pipeline, we have already guided I n terms of how our products are progressing, particularly on the clinical development of the Bevacizumab where we have progressed the molecule into Phase-3 global clinical trial. We also have our insulin analog, Aspart which has progressed through Phase-1 clinical studies. That is where we are at with that, and then there are series of products which we have listed even in our annual report which we believe will be moving through the clinical developments as per our plan.

Surya Patra, Phillip Capital

In regards to our Sandoz association, whether we have started our initiatives on that front and whether the R&D spend numbers relating to that has already been started flowing into the P&L so far?

Siddharth Mittal, Chief Financial Officer - Biocon

Yes, R&D expense numbers do include a very small component of Sandoz collaboration products.

Surya Patra, Phillip Capital

OnSimvastatin, though we have launched a product recently and after possibly seeing all possible kind of price competition scenario in US, now at this juncture still this product seems to be kind of a profitable one and possibly because of our integrated status, so can you give some sense what is the kind of profitability that one can really see or visualize for a late-entry product?

Siddharth Mittal, Chief Financial Officer - Biocon

We cannot give details of profits at the product level, but just to say that it is our second ANDA launch in the US after Rosuvastatin. I think more than the profit, it is more about us making inroads into the US generics market. It is also helping us set up base for our future ANDA launches. It is a profitable product, both as an API and as a generic formulation product.

Sameer Baisiwala, Morgan Stanley Research

Just on this you mentioned 33% list price WAC, but how did we gross to net -- would the rebates be out of ordinary or much what we see in the industry?

Paul Thomas, Chief Commercial Officer - Biocon Biologics

Sure, thanks for the question, Sameer. I think that level of detail about rebates is not something that we will be able to get into here.

Sameer Baisiwala, Morgan Stanley Research

You mentioned that there were quite a few DMF filed in Q1. Would this be for your API business or would you be the formulator for these products, how should we think about your new DMFs?

Siddharth Mittal, Chief Financial Officer - Biocon

The DMFs are for the API business.

Sameer Baisiwala, Morgan Stanley Research

Any thoughts on the launch timelines for Glargine for Europe?

Siddharth Mittal, Chief Financial Officer - Biocon

I think Mylan has communicated in their earnings call that they plan to launch the product by end of this calendar year.

Sameer Baisiwala, Morgan Stanley Research

Just from Aspart, I thought it is in Phase-3 right now, at least Mylan site says that, you mentioned Aspart is in Phase-1?

Shreehas Tambe, Chief Operating Officer – Biocon Biologics

Sameer, we just completed our Phase-1 study and we will be initiating the Phase-3 study shortly.

Sameer Baisiwala, Morgan Stanley Research

How much time do you think would this study take?

Shreehas Tambe, Chief Operating Officer – Biocon Biologics

We are discussing with the agency to see if we could work through an abbreviated study path. Otherwise, we would probably see a typical study take anywhere close to 24-months.

Sameer Baisiwala, Morgan Stanley Research

That is on your fiscal '19 Biologics guidance of $200 million. Sid, if I remember correctly, you had earlier in occasions mentioned that most of this would be coming from emerging markets. So, all these launches that we are now seeing in the regulated markets and I think there would be at least two, three of them would be over and about that?

Siddharth Mittal, Chief Financial Officer - Biocon

All that we can say is we are maintaining a guidance of $200 million, it would definitely include revenues from developed markets. We do not expect the numbers to increase significantly given that the penetration in the developed markets would take time.

Sameer Baisiwala, Morgan Stanley Research

And that view still remains, is it?

Kiran Mazumdar-Shaw, Chairperson cum Managing Director - Biocon

Let us put it this way, Sameer, I think we are confident now of delivering on the $200 million and any upside is obviously welcome.

Prashant Nair, Citi Research

My first question is just to reconfirm, so this $200 million sales guidance, does it include the biosimilars you are selling in India or does that get captured separately?

Siddharth Mittal, Chief Financial Officer - Biocon

$200 million is excluding India. India revenues are captured under Branded Formulations.

Prashant Nair, Citi Research

Secondly, on the Glargine launch planned in Europe, would this be across markets upfront or would it be a staggered launch? If so, then which countries do you plan to launch in first?

Shreehas Tambe, Chief Operating Officer – Biocon Biologics

This is probably best directed to Mylan as they would lead this piece in the collaboration. Having said that I think clearly there would be an approach in how we would commercialize in the European markets and we will probably reveal that through Mylan as we go along.

Prashant Nair, Citi Research

Does the US launch of Fulphila trigger some amortization of the capitalized R&D?

Siddharth Mittal, Chief Financial Officer - Biocon

We have not capitalized anything for Pegfilgrastim, all spends were expensed through the P&L.

Charulata Gaidhani, Dalal & Broacha

I wanted your view on the Small Molecules ramp up. Is this sustainable or is it one-off?

Siddharth Mittal, Chief Financial Officer - Biocon

We have had a good quarter and we think that on go-forward basis, our revenues are sustainable.

Charulata Gaidhani, Dalal & Broacha

Even the profitability?

Siddharth Mittal, Chief Financial Officer - Biocon

Largely, I would say, yes. We have had lower R&D expenses for our ANDA programs this quarter and as we ramp up and have more ANDA development expenses on go-forward basis, profitability for the segment will have an impact of that.

Charulata Gaidhani, Dalal & Broacha

My second question pertains to Branded Formulations - that also has seen healthy ramp up, you think that will be sustainable?

Suresh Subramanian: Head - Branded Formulations, India - Biocon

Yes, that will be sustainable because we have seen consolidation in the top-10 products and an improvement in the product mix as well. This has come with some increase in market share in these products as well, so we see it is sustaining in the months ahead.

Vrijesh Kasera, Mirae Asset Management

Just a couple of questions; one on Pegfilgrastim just correct me if I am wrong. There was a patent litigation that was filed by Amgen. Is that litigation still on and what is the status, so are we launching this at risk?

Siddharth Mittal, Chief Financial Officer - Biocon

The litigation is on.

Vrijesh Kasera, Mirae Asset Management

Secondly on your guidance of this $200 million which you said you are on track on achieving that. Just one question on this, if I assume that we are at around $200 million by FY19, going forward what is the kind of revenue which we would be happy achieving say next four-five years from the Biosimilars pipeline that we have including the Mylan and if at all Sandoz also get commercialized over the period of time?

Siddharth Mittal, Chief Financial Officer - Biocon

At this moment, we have not given revenue guidance beyond FY19.

Harith Ahamed, Spark Capital

The EIR for your drug product facility in Bangalore and the clearance from the EU regulator as well for the facility, does it cover the drug substance facility as well, if not what is the status of the drug substance facility in Bangalore?

Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon

All our Biologics facilities, both drug substance and drug products in Bangalore have the approval from the FDA and EU.

Harith Ahamed, Spark Capital

Going through the segmental break up of your revenues for the quarter, there is an increase in the inter segment sales, that is around Rs.80 crores and the highest value we have seen in recent quarters. So, what exactly is this and between which segments is the sales?

Siddharth Mittal, Chief Financial Officer - Biocon

So, it would be sale mainly from Research Services to Biologics, offset of this would be reflected in Syngene numbers.

Harith Ahamed, Spark Capital

In your notes to account, a note on incremental deferred revenue that you have recognized in the balance sheet, what is the offsetting entry for this, can you give more color on this?

Siddharth Mittal, Chief Financial Officer - Biocon

The offsetting entry is in 'Other equity'

You might be aware that IFRS has changed the revenue standards globally and in line with the change India is also mandatorily required to adopt to the new accounting standard and revenue recognition that is IND AS 115 and pursuant to that all our revenue contracts had to be reassessed. Traditionally all our licensing income was recognized as and when we had earned the revenues. However, under the new accounting standards, we are required to recognize the licensing income only once the product is launched and hence that resulted in a de-recognition of Rs.185 crores of revenue which was put in deferred revenue line which will be recognized over a period of time as we our partners get the product approvals. That will also change the way we recognize licensing revenues in the future because as I mentioned till March '18, the licensing revenues were accrued in the books as and when we invoice it to our customers. On a go-forward basis whenever we earn the licensing upfront, we will have to defer it over a period of time.

Harith Ahamed, Spark Capital

So, this increase in deferred revenue is by how much, what is the incremental change?

Siddharth Mittal, Chief Financial Officer - Biocon

Rs.185 crores is the amount that has been put in the balance sheet.

Harith Ahamed, Spark Capital

On the other income, there is a higher other income for the quarter at Rs.58 crores. So, can you provide a breakup of this?

Siddharth Mittal, Chief Financial Officer - Biocon

Forex gain is the main reason for the increase; out of Rs 69 crores, Rs 39 crores is forex gain.

Surajit Pal, Prabhudas Lilladher

My question is that the result of launch of Biosim vis-à-vis the market share has some mixed result, say for example your Remicade is a big product and what we found out is that despite having three Biosim, the original market share of the Biologics has not reduced much because of some strategy marketing taken by the originator and something that volume discount kind of scenarios. So, if those scenario could come to even to your product which you have launched or which you are planning to launch, what could be marketing strategy?

Paul Thomas, Chief Commercial Officer - Biocon Biologics

Thanks for that question. Definitely, the dynamics here are complicated. I think FDA commissioner has spoken out about some of these dynamics recently as well, they seem to be wanting to take action there. One thing I would add for perspective is that while some of these ramp-ups are gradual, the sales numbers reported by Pfizer so far are pretty meaningful, they are not negligible numbers so far, I think that has been >$50 million for a quarter, so they are not negligible even with these market shares. So,

I think there is a trade-off that is going on there and there are product specific dynamics. In terms of the way that Mylan approaches this and what particular strategies they take, I think they will be best placed to comment on it and certainly it is sensitive information at this stage.

Surajit Pal, Prabhudas Lilladher

My point was actually is that if Biosimilar guys got frustrated in terms of slow progression of market share, is there any possibility like sharp correction what Mylan did in Copaxone? Similar kind of erosion like say 40, 50 or 60% straight away so that we could grab the better market share, and that could be replicated by the other competitors also. So, ultimately the kind of big investment made by the Biosim guys might be falling short in terms of recovering?

Paul Thomas, Chief Commercial Officer - Biocon Biologics

Obviously, we are confident in our ability to monetize our investments, and for that this is a worthwhile market, but I think we would not comment further on the pricing dynamics.

Surajit Pal, Prabhudas Lilladher

Second question is that where does Biocon stands in terms of their filing in Copaxone because last time there were some queries, we had an update, after that what happened, is there any progress to that?

Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon

Yes, we made substantial progress in terms of preparing our response to the FDA. While we cannot be specific in terms of the timing, we are well advanced in terms of gathering the necessary information for our response.

Surajit Pal, Prabhudas Lilladher

So, do you expect further queries to come after that or you believe that this is the last, because since you have done it and others also have done it, so do you think that there is a possibility that is my point?

Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon

We have tried to prepare as comprehensive a response as we can. That is why it has taken us a time.

Hem Agrawal, Individual Investor

I have a couple of questions. One on the annual report on page #8, it says about Trastuzumab that 25% of the nearly 2 million women diagnosed there have that HER2 positive tumors. What percentage of these women use the Trastu treatment or use the Biosimilar treatment?

Kiran Mazumdar-Shaw, Chairperson cum Managing Director - Biocon

As you know, we are yet to launch our biosimilar Trastuzumab in the developed markets and our biosimilar Trastuzumab is certainly expanding the patient access in the developing world markets, so we are present in many emerging markets, and in India itself, we have more than doubled the access to this drug because of cost. So, we expect that this is something that will play a very strong role in

providing affordable access to this life saving drug. You are very right in asking that question as to how many of these patients actually can afford this drug. In most of the emerging markets up until Biocon and a few other biosimilars companies were able to offer this drug, I can tell you the access was very limited. In India itself, we are seeing a very rapid expansion of this particular drug to many patients who need it. So, we are sure that like we have done in many other segments like for instance insulin therapy we have more than expanded this market in terms of volume, almost ten-old -- thanks to all the access that diabetics have got to this drug. Similarly, we think that even for these cancer drugs which were only available to a few patients, we believe that we can actually have a multi-fold expansion in terms of patient access. So, that is what we are committed to, as you know, that is what Biocon has been focused on, that is our purposeful mission that we are on, and that is what we will stay committed on.

Hem Agrawal, Individual Investor

What percentage of the women in the developed markets adopts this biosimilars treatment in Biologics?

Kiran Mazumdar-Shaw, Chairperson cum Managing Director - Biocon

So, this is a gold standard in any case. So, anyone who has HER2 plus treatment will be given this drug. So, it is a standard protocol that is adopted in the developed world. It is also something which is spiraling their healthcare cost and therefore they are all very keen on getting biosimilars to bring down those costs, and recently the FDA commissioner actually made a very strong case for why biosimilars should be adopted more expeditiously than that is being seen.

Sameer Baisiwala, Morgan Stanley Research

Any update on BBL, the business restructuring that was being planned?

Siddharth Mittal, Chief Financial Officer - Biocon

No update, Sameer. We have applied for the government approval; we await the approval. The merger process has started for BRL and BBIL.

Sameer Baisiwala, Morgan Stanley Research

At some point in time in future, say over 12-months you plan to list biosimilars as a separate business - that thought process continues?

Siddharth Mittal, Chief Financial Officer - Biocon

There is no fixed thought process. On that we said is we keep the entities restructured in a way that if we have to unlock the value and monetize any of our assets, we can do it at an opportune time and listing is one of the options.

Sameer Baisiwala, Morgan Stanley Research

Arun, just specifically on Copaxone, so when do you plan to refile?

Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon

Sameer, I am not giving a specific timeline this time, because last time we did commit to a timeline and took us longer than that. So, in response to a previous question, I just said that we are trying to prepare a comprehensive response to the queries we received, and we are well advanced in terms of compiling all the necessary data that was requested.

Sameer Baisiwala, Morgan Stanley Research

It would be this calendar year. Would that be fair?

Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon

Do not want to comment, but yes, we are looking at this fiscal for sure.

Sameer Baisiwala, Morgan Stanley Research

On Fulphila, you mentioned Coherus TAD being in November, but any thoughts on Apotex because it is a private company, we have not seen much on that, so do you expect them to launch in the foreseeable future?

Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon

I would not want to comment on where our competitors stand because if you look at Pegfilgrastim say two years ago, we were behind in the queue and now we are actually the first to get approval and launch the product. So, I think what Paul was alluding to was not the specific competitors but more to the fact that we have our eyes wide open that competition will follow.

Sameer Baisiwala, Morgan Stanley Research

On Malaysian side, what could be the OPEX this year, do you think that it would be EBITDA breakeven this year, right?

Siddharth Mittal, Chief Financial Officer - Biocon

Yes, I think that is what we guided in April and we actually expect breakeven this year, when excluding R&D expenses. I did not mention EBITDA. The operating expenses are expected to be roughly $50 million.

-Ends-

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