Biocon Limited: Q1 FY17 Earnings Call Transcript
July 22, 2016

Participants from Biocon's Senior Management Team

- Kiran Mazumdar Shaw: Chairperson and Managing Director
- Arun Chandravarkar: CEO & Jt. Managing Director
- Siddharth Mittal: President, Finance
- Ravi Limaye: President, Marketing
- Narendra Chirmule: Sr. Vice President, R&D
- Shreehas Tambe: Sr. Vice President, Insulins
- Paul Thomas: Vice President, Biosimilars
- Bhavesh Patel: Vice President, Generic Formulations
- Saurabh Paliwal: Head, Investor Relations

Conference Call Participants during Q&A

- Surya Patra, Phillip Capital
- Prakash Agarwal, Axis Capital
- Sudhakar Prabhu, Span Capital
- Sameer Baisiwala, Morgan Stanley Research
- Dheeresh Pathak, Goldman Sachs Asset Management
- Nitin Agarwal, IDFC Securities
- Girish Bakhru, HSBC Securities
- Ujwal Shah, Quest Investment Advisors
- Harith Ahamed, Spark Capital Advisors
- Prashant Nair, Citi Research
- Chirag Dagli, HDFC Asset Management Company
- Ranjit Kapadia, Centrum Broking
- Surjeet Pal, Prabhudas Lilladher
- Andrey Purushottam, Cogito Advisors
- Shraddha Patil, Wealth Managers
- Charulata Gaidhani, Dalal & Broacha
- Manushi Shah, Research Advisors

Presentation Session

Saurabh Paliwal: Good morning, ladies and gentlemen. Thank you for joining us today for Biocon's Earnings Call for the first quarter of fiscal 2017. Last night we have released our results and the same have also been posted on our website. Before we proceed with this call, I would like to remind everybody that a replay of today's discussion will be available for the next few days immediately following the conclusion of this call. The call transcript shall be made available on the website in the coming days.

To discuss the Company's Business Performance and Outlook, we have the leadership team at Biocon comprising Ms. Kiran Mazumdar-Shaw – our Chairperson and Managing Director and other colleagues from the senior management team.

Before we proceed with this call, I would like to take this opportunity to remind everyone about the Safe Harbor. Today's discussion may contain forward-looking statements in regard to the future performance of the Company based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements.

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

Kiran Mazumdar-Shaw: Thank you, Saurabh. Good Morning, Everyone. I welcome you to Biocon's Earning Call for the First Quarter for fiscal FY'17.

Before I talk about the Business Performance for this quarter, I would like to highlight that starting this fiscal, we will be reporting numbers based on the new Ind-AS accounting rules. As a result of this, the segment's reporting has changed based on the new classification adopted by the company as per Ind-AS requirements. For the ease of investors and analysts however, I will be basing my discussion in terms of comparative numbers using IGAAP. We have provided the bridge to Ind-AS numbers through our 'Fact Sheet' that accompanied the 'Results' last night and I will touch upon the impact on Ind AS accounting in my closing remarks.

Now, let me start with **Key Business Highlights**:

As a part of our global Biosimilar foray, our partner, Mylan filed a Marketing Authorization Application or MAA for Biosimilar Pegfilgrastim for the EU markets in Q1 which has been accepted by the European Medicines Agency (EMA). The application will undergo the review process and this kicks off the process of filing of multiple biosimilar applications over the course of this fiscal for which we have already provided some guidance in previous quarters.

Another important highlight was that our partner, FUJIFILM Pharma (FFP) in Japan launched Insulin Glargine on 15th of July. Earlier in March this year as you know, FFP had received approval for this product from the Ministry of Health, Labor and Welfare of Japan and this we believe is a significant milestone for us as it marks the launch of our first biosimilar in developed market. Apart from monetization in the Japanese market, we aim to leverage the approval in taking Glargine to many other emerging markets, and of course, we are also readying ourselves to file in both EMA and USFDA for marketing authorization this fiscal.

Our partner Mylan presented the positive outcomes of the global Phase-III clinical study of our Trastuzumab at ASCO or the American Society of Clinical Oncology at their annual meeting in June in Chicago, which as you know is the largest global oncology meeting which attracts over 30,000 Oncologists. This we believe is a very significant milestone in our joint development program with Mylan, and this trial obviously enables regulatory filings of this product in EU and other regulated markets like US, Japan and others. Further, we remain on track to file Pegfilgrastim in the US and Glargine, Trastuzumab and Adalimumab as I mentioned earlier in US and EU this fiscal.

Another highlight was that our Malaysian site received regulatory approval from the Malaysian regulatory authority for recombinant human insulin (rh-Insulin) and this will allow us to participate in local tenders in Malaysia and it also paves the way for approval of the Malaysian site by other regulators.

We have also received regulatory approval for Insulin Glargine manufactured at the India site from the Malaysian Ministry for Health and we expect to launch our Glargine product in Malaysia later this year. As you know, our Insulin products have already been approved by the Malaysian authorities.

As a part of our Novel Molecules pipeline progress, our partner Quark Pharma also received regulatory approval to initiate the India arm of a global Phase II/ III study for a novel siRNA product,

QP1-1007. So these are the important highlights which we believe will deliver very important growth for us in the coming years.

Now, coming to **Key Financial Highlights for Q1 FY17**: I would like to again remind you that the numbers that I will be using for this discussion are based on the earlier IGAAP. The bridge to Ind-AS has been provided to you in the 'Fact Sheet', and therefore, let me start with my comparisons based on IGAAP.

- Consolidated sales grew 10% from Rs.825 crores last year to Rs.903 crores this year. Biocon sales excluding licensing income and capacity reservation fees grew 16% from Rs.537 crores to Rs.623 crores while Syngene grew 18% from Rs.224 crores to Rs.263 crores.
    - Now within Biocon, small molecule sales were Rs.357 crores, which reflects a growth of 9% and this was on account of higher sales of statins and immunosuppressants.
    - Biologics was a star performer, where sales were registered at Rs.107 crores, which reflects a growth of 53% and this is largely attributable to sales of our Biologic products in emerging markets, which really are the Insulins and antibodies/proteins, one of them being Trastuzumab.
    - Branded Formulations sales were Rs.159 crores, which reflects a growth of 15%, with strong performance in the Middle East and improved trends in the India business.
    - Licensing income in Biocon was Rs.17 crores as compared to Rs.64 crores last year. But, as you know, last year did include a capacity reservation fee of Rs.45 crores. Given licensing is a lumpy event, so I would not like to really get into details of the differences.
- We incurred a total R&D spend of Rs.92 crores this quarter, of which Rs.52 crores is reported in the P&L while Rs.40 crores has been capitalized on account of Trastuzumab and Glargine development-related expenses.
- Consolidated EBITDA was Rs.271 crores, reflecting a growth of 15% with EBITDA margins at 28%. Margin improvement this quarter was aided by a good product mix in Small Molecules, Biologics and contribution from Syngene.
- Core margins, i.e. EBITDA margins net of licensing income, impact of FOREX and R&D spends were at 32% compared to 27% last year, again reflecting a strong operational performance this quarter based on an enriched product mix.
- FOREX gain during this quarter was Rs.2 crores.
- Consolidated Net Profit grew 17% to Rs.147 crores with Net Profit margin of 15%. Within this Biocon's PAT grew from Rs.90 crores to Rs.103 crores this quarter while Biocon's share in Syngene's profit grew from Rs.36 crores to Rs.44 crores.

So in summary, I would like to say that we have had a very strong and confident start to FY'17 with robust operational performance. We initiated our developed market filings of our Biosimilars with Pegfilgrastim in the EU and other filings planned for our biosimilar candidates are on track as we had indicated. Overall trends of the businesses are in the right direction and we remain optimistic of our performance in the coming quarters and the years ahead.

We expect new product launches in Small Molecules, growth in Biologics, led by Insulins and Trastuzumab in emerging markets, steady improvement in the Branded Formulations business, and, of course, continued growth in Syngene, driving an overall positive performance of the company for the full year.

Now, before I close, I would like to briefly allude to the impact on financial reporting on the adoption of Ind-AS accounting standards.

- There is a change in segment reporting. As you would have seen, we have started reporting four segments -- **Small Molecules, Biologics, Branded Formulations and Research Services** instead of just two, as we used to report under IGAAP, which was just Biopharmaceuticals and Research Services. This change is a result of reporting requirements as defined by Ind-AS and is based on how the chief operating and decision-maker reviews businesses for resource allocation and performance assessment. Based on the above analysis and our internal reporting, we identified four segments and I would just like to briefly detail them as follows –

- **Small molecules** will reflect numbers that pertain to our APIs and Generic Formulations, including our ANDA business.

- **Biologics** will include Biosimilars, containing Insulins, Antibodies and Recombinant Proteins as well as Novel Biologics.

- **Branded Formulations** represent sales of finished dosages in India and overseas. Currently, overseas sales are in UAE while we are looking to expand in Sri Lanka and other neighbouring markets.

- **Research Services** segment represents numbers of Syngene.

As alluded earlier to in my remarks, Q1 FY'17 published numbers are based on Ind-AS accounting in accordance with the requirements. The previously reported numbers of FY16 have been adjusted based on Ind-AS reporting requirements and have been restated. The adjustments made are on account of the following:

- Change in revenue recognition policy due to different sale cut off rules;

- Impact due to employee stock option accounting; ESOP cost now taken at fair value instead of intrinsic value earlier;

- Change in hedge accounting; impact of FOREX fluctuation taken to Other Comprehensive Income and held in the Balance Sheet; and

- Our UAE business was represented through NeoBiocon in FY16, which was earlier consolidated on a line-by-line basis under IGAAP. It has been deconsolidated and only the share of profit has been recorded based on joint venture accounting under Ind-AS. This has been done for Q1 FY17, as well as for periods in FY'16. As part of our restructuring of legal entities to represent our various businesses, our UAE business is now accounted for through our wholly-owned subsidiary Biocon FZ LLC.

Now during the current fiscal year, every quarter, we will be providing numbers based on both Ind-AS as well as IGAAP. We will also provide the reconciliation between the two to explain the differences between the two accounting standards and the impact of the same on our financial reporting. This is really to help the investor community transition to the Ind-AS framework during the course of this

financial year and this practice will stop after the declaration of the Q4 and full year FY17 results next year. Next financial year, we will move completely to Ind-AS reporting, and will no longer report numbers based on previous IGAAP.

We are amongst the very early companies to actually adopt Ind-AS in this fiscal and we hope that this transition process is something that we can go through with our investors in a very smooth and seamless manner.

For any further details or clarification related to the Ind-AS accounting change, I would request you to kindly get in touch with our CFO -- Mr. Siddharth Mittal.

Now with this long-winded explanation, I would now like to open it up for Questions. Thanks.

Q&A Session

Surya Patra: A clarification; R&D expenses seems lower this quarter sequentially. So what is the kind of a capitalization that we have done and how much that we have charged to the third-party this quarter?

Siddharth Mittal: Total R&D expenses were Rs.92 crores, of which Rs.52 crores was in the P&L while Rs.40 crores has been capitalized. Comparing it with Q4, as we have said R&D expenses tend to be lumpy and there is no particular reason why it is up or down, but it is in line with what we incurred in Q1. Our overall guidance for the year in terms of R&D continues to be in line with what we have indicated earlier, which is 12% to 14% of Biopharma revenues in the P&L and 18% to 20% on a cash basis again of the Biopharma revenues.

Surya Patra: So since we are either completed or on the verge of completing Phase-III clinical trial for leading four molecules. So should we see some sequential decline in the R&D spend unless until we start Phase-III for the other molecules?

Siddharth Mittal: Even though we have reached end points or met the end points which will enable the filing, some of the trials will continue. So the R&D guidance that we have given assumes that some of these trials will continue for rest of the year.

Surya Patra: Second question on the Branded Formulations business. We see kind of meaningful growth sequentially as well as YoY. So, is there anything that in the top line the NeoBiocon revenues is added there or it is just a core organic growth what we are seeing?

Siddharth Mittal: As Kiran had mentioned in her opening comments that the Branded business has grown by 15% on a like-to-like basis. Last year, you will see in the Fact Sheet our Branded revenues were Rs.138 crores which comprised of India and NeoBiocon business, compared to that this year we have done Rs.159 crores. So on a like-to-like basis, there is a 15% growth, but when you look at the Ind-AS numbers it will show a higher growth since we have deconsolidated the revenues for last fiscal year relating to NeoBiocon.

Surya Patra: So that is why we are saying the share of profit in the JV of Rs.5 crores that is flowing from the NeoBiocon?

Siddharth Mittal: Yes.

Surya Patra: On the milestone income that we have received from the FUJI that we are sharing?

Siddharth Mittal: The milestone payment received from FUJIFILM is part of the Rs.17 crores of licensing income.

Surya Patra: So then the other income seems significantly higher than the trend, so Rs.50 crore kind of. So there it is not there that means?

Siddharth Mittal: No, it is not there. Main reason for the increase in other income is the interest income in Syngene of around Rs.12 crores. Till last year Syngene did not have significant interest income and in Q4 of last year they had taken a debt of $100 million and on which they have earned Rs.12 crores for the quarter.

Surya Patra: On the Malaysia plant since it has been approved now by the Malaysian government and possibly we will start commercializing that plant subsequently gradually. So how is the kind of a revenue ramp up that we should see from the plant and how the incremental cost would be added and whether the capitalization would be at one shot kind of a capitalization or it would be a gradual capitalization of various units, can you just give me some color on that?

Siddharth Mittal: Let me answer your question on revenues. As we mentioned that we have got the approval from local regulators for rh-Insulin which will enable us to participate in local tenders and these are all tenders which are for 2-to-3-years period. So we will give more details on the same in our coming quarters. This approval will also enable us to file for regulatory approval in other emerging markets. Again, we expect the revenues to commence in the second half of this fiscal year. As far as the expenses are concerned, we expect again the P&L charge to come in from the second half of this fiscal year. While we have received the regulatory approval for rh-Insulin, once we receive the regulatory approval for Glargine, which is expected in Q2/Q3, we would stop capitalizing the expenses. In terms of depreciation, as we have mentioned in the past, we are still working out the impact of depreciation as per the new GAAP and we hope to finalize the position with our auditors in Q2/Q3 and that is when we will let the market know what the accounting treatment would be.

Surya Patra: So currently may I know what is the operational cost run rate per quarter for the Malaysia plant?

Siddharth Mittal: There are multiple moving components and hence the run rate of expenses is difficult to quantify at this stage. The reason is that we are doing development of our products Lispro, Aspart, Glargine in that facility plus there is a reimbursement that we get from Mylan. So the net impact of all these things we will be in a better position to communicate in the latter half of this year.

Prakash Agarwal: Especially on the Biologics which have shown 53% growth Y-o-Y, however, they are flat Q-o-Q. So, we should see this business on a Y-o-Y growth trend and any outlook you can share especially for this business as your launches continues in for the Insulin and the Trastuzumab space in other emerging markets?

Kiran Mazumdar-Shaw: I do not think you should view it in that way, I think basically you should look at the opportunities that are coming our way in the Biologics space. As you have just heard, with this Malaysian approval also, I think there are new markets opening up for us. As you know, we were constrained in terms of Insulin capacity in the past, but I think this opens up new vistas for us. I think the very positive data that was announced at ASCO with our Trastuzumab also opens up new opportunities for Trastuzumab in many emerging markets. I think we are very positive that Biologics will show a good uptick this year and onwards and we also believe that because these are good margin products, I think it also contributes to the bottom line as well. Overall, I think we are very-very

pleased with the way the Biologics business is growing and I would not necessarily lead into this conclusion because of Q4 FY'16 and Q1 FY'17 showing not such a big growth. That is because we had a launch quantities supplied in Q4 FY'17 and these things tend to be lumpy. So, I think if I look at the base business it is showing good traction.

Prakash Agarwal: So net-net we should look at on a Y-o-Y basis, because as more and more products come in, we will continuously show this high growth.

Kiran Mazumdar-Shaw: Absolutely.

Prakash Agarwal: On the margins, as you said, with more higher margin products coming in, especially if I look at this quarter, so if I load the R&D as per last quarter, what are we actually missing, if we load the R&D, then our margins would have been largely flat on the gross margin side and the EBITDA margin side. So delta going forward would come from gross margin side only?

Siddharth Mittal: Prakash, the gross margins ex-licensing are up almost by 3% to 4% compared to last year. As far as the standalone performance, last year we had reported Rs.126 crores, of which Biopharma was Rs.90 crores, which included one-time capacity reservation net of tax amounting to Rs.35 crores. So on a normalized basis, Biopharma's PAT was Rs.55 crores at the total R&D expenses of Rs.50 crores in the P&L. When you compare it with this quarter, at the same R&D levels, our Biopharma earnings were Rs.103 crores. So we have almost doubled our profits at the same R&D levels in spite of increased operational expenses, like the salaries and other costs, which is coming on account of increase in revenues and much improved gross margins.

Kiran Mazumdar-Shaw: I think if you look at R&D costs last year and this year, they are almost the same. So I think you have to look at the huge improvement in the business.

Prakash Agarwal: If I look at the Malaysia, the products are expected to be approved and commercialized, so, second half we should expect these products to be commercialized, and any update on the EM commercialization from that facility?

Siddharth Mittal: As I just responded to the previous question from Surya, we expect revenues from emerging markets including Malaysian market in the second half for this facility.

Prakash Agarwal: So have we started filing for emerging markets from Malaysia, sir?

Siddharth Mittal: The first step is done which was receiving the local regulatory approvals and we will start the filing.

Prakash Agarwal: So can that be that fast in terms of six months' timeframe you will start getting approvals?

Siddharth Mittal: Certain regulators would be faster, some regulators would take longer. We cannot comment really on how soon, how late, which regulator will approve, but we definitely expect commercialization to start this fiscal year. One of the other things that we do expect is that India where we have had capacity constraints and we expect early approvals from the Indian regulators, which will enable us to at least import the material manufactured in Malaysia for the Indian market.

Prakash Agarwal: Lastly on Trastuzumab, just an observation here that we are working on metastatic breast cancer for which we have got favorable data on the studies that we have done, at ASCO also

that you have displayed. But, if I see the competitive landscape, most players are doing EBC and I understand they were earlier doing MBC and they moved to EBC. We do not know that. If you could help us understand this better?

Kiran Mazumdar-Shaw: I think each company has decided to pursue a certain strategy and I do not think we should be commenting on other companies' approach, all that we can say is that our data is of a very good quality and we believe that we will get the kind of regulatory review that will enable us to get approval. So, that is what we should be looking at. As you know, extrapolation of data is anyway being looked at very positively and in this particular case since the mechanism of action is the basis on which they will give you extrapolation; we do not see why EBC or MBC will make that decision. So, we are very confident that our data is of very high quality and that is what we will go with.

Prakash Agarwal: With extrapolation, we would be able to garner the EBC market as well?

Kiran Mazumdar-Shaw: Yes.

Prakash Agarwal: There is no constraint in terms of hiring patients or in that sense?

Kiran Mazumdar-Shaw: Please understand we have completed the clinical trial, and the patient recruitment, that is over. So, there is no question of now trying to recruit other patients.

Prakash Agarwal: The data that comes from metastatic breast cancer the patients are more volatile… we will take that offline.

Kiran Mazumdar-Shaw: I think you should understand. Please look at the ASCO data. That should answer all your questions

Prakash Agarwal: We have seen that it talks about better efficacy and safety data. So…?

Kiran Mazumdar-Shaw: So, basically we have passed all the requirements. Maybe Paul might want to comment.

Paul Thomas: Obviously, there is speculation that people can put into the discussion about biosimilars on many different fronts. There are different parties have reasons to insert doubt about the quality of biosimilars and things like that, but we feel confident about the approach that we have taken in that, again because the mechanism is the same across indications and the scientific basis for this we feel confident in our approach for extrapolation across all indications with the existing trial.

Sudhakar Prabhu: My first question is on the Branded Formulations domestic market. What has been the growth this year and how do you see the growth panning over the full year?

Ravi Limaye: So the Branded Formulations market overall growth has been 7%. It has been driven largely by our focus on the core brands, which have grown higher than 7%, strong double-digit for the core brands and we will continue with our strategy of focusing on these core brands to further drive growth in the coming quarters.

Sudhakar Prabhu: My second question is on the Malaysian market. You mentioned that you have got regulatory approvals for Insulin and Glargine. So if you could give us some sense on how big is the market and when do you plan to launch the products?

Ravi Limaye: So the market you can obviously refer in IMS, but I will give you the number; the Insulin market in Malaysia is about $18 million in tender, about $15 million in trade and Glargine market is about $1 million in tender and $4 million in trade.

Sudhakar Prabhu: On your guidance of $1 billion by 2019, are you on track for that or you see…?

Kiran Mazumdar-Shaw: I think we are more than confident of delivering on that.

Sudhakar Prabhu: The guidance which you had given for $1 billion, what was the currency which you had assumed?

Siddharth Mittal: Rs.50. So the only business which is impacted because of that is the Branded Formulations business.

Sudhakar Prabhu: This quarter we saw significant growth in your Biosimilar business of 53%. Do you think this growth number is sustainable?

Siddharth Mittal: Absolutely.

Sameer Baisiwala: Can you update us on the ANDA filings that you have done for Copaxone 20 mg and 40 mg, how are they making progress with FDA?

Bhavesh Patel: With GA 20 mg, we are working with FDA for the approval of the product and the 40 mg is also under review, but right now, we are concentrating on the approval of 20 mg, 40 mg approval will depend upon the litigation outcome.

Sameer Baisiwala: So for 20 mg, are there any pending queries from FDA and what are the possible timelines for your approval?

Bhavesh Patel: No comment on the FDA query, but we are targeting to get approval late this financial year.

Sameer Baisiwala: Just on the technical front, if you can share, what are the capabilities that you have for biosimilars that you are deploying into your ANDA business and targeting these complex injectables, so is it possible for you to share and how could the pipeline look over next 2-years?

Arun Chandavarkar: So we have mentioned in the past that some of the ANDA programs that we have selected do have synergies with our Biologics programs, because as you know in Biologics, we have built extensive capabilities in characterization, bioanalytical, design of clinical trials and all of that. So, there will be some small molecule initiatives, which will depend heavily on our ability to characterize, do bio assays, do bioanalytical work, or even if required, do equivalent studies in patients.

Sameer Baisiwala: Your press release mentioned that you were targeting to file a few ANDAs later this year. So some of them would be such complex injectables?

Arun Chandavarkar: We would not comment on what we are filing, but yes, our portfolio will be largely skewed towards complex generics, potent molecules. We have already announced we have initiated construction of a Solid Oral Potent facility. So that gives an indication of which way some of our molecules will go. Some would be also injectables.

Sameer Baisiwala: The second question I have is on Insulin portfolio. Is it possible for you to share what you see in market innovator reaction in the emerging markets? I remember that for the Indian markets the innovators had brought down the pricing quite competitive to the generic versions. So, is this something that you see or you think you will see in the other emerging market launches?

Arun Chandavarkar: Of course, we do expect to see competitive responses from innovators or other players, and we are prepared for that. With our Insulin and Glargine we have been in some of the emerging markets for quite some time now, and markets which are on the retail side, we make steady progress in terms of increasing our market share through local partners, markets which are tendered, we of course cannot predict that we will win a tender every time, but we have typically won some and on some occasions may not have won some, but we are never out of any market. If you see the growth of our Insulins over the last few years, all of this growth of course has largely come through emerging markets competing with the innovators.

Sameer Baisiwala: For the US and the European markets, when you take Glargine in these geographies, do you see the similar innovator reaction? I ask this question because for the other small molecules innovator does not ever drop its prices, it may have also a generic. So, for biosimilars do you think this is the way that they may compete?

Arun Chandavarkar: I think you have to draw your conclusions from the biosimilars that have already been launched in Europe or US or elsewhere. As you know that our commercial strategies in the developed markets would be driven largely by Mylan and I am sure Mylan would be well equipped to address any innovator response either way, whether they drop prices or whether they do not. But if you want precedence, the only data points we have is the few biosimilars that have been approved so far in Europe and US.

Sameer Baisiwala: Your P&L has several moving parts. But what is really striking to me this time is from last several quarters our earnings sort of were in the range of Rs.100 crores to Rs.110 crores give or take has now kind of decisively breaking out into Rs.140 crores, Rs.160 crores sort of a band. So do you think this is a sustainable level and this is a new base for you to work from?

Arun Chandavarkar: When we have given you the long-term sort of indication of $1 billion in FY19 or calendar 18, whichever way you look at it, we have indicated that -- this would be while improving our EBITDA margins. So, as our product portfolio changes to products which are towards the biologics side or products which are complex generics or differentiated APIs, clearly, we would see an improvement in margins and you are beginning to see that because of the traction we have got with our biosimilar launches in emerging markets.

Dheeresh Pathak: On this new segment reporting, would it be fair to assume that large part of the R&D which is expensed in the P&L is reflected in the Biologics segment as part of the segment reporting?

Siddharth Mittal: That is correct, but we also have R&D in Small Molecules. So when you look at the segment results or the profit before tax as a percentage of revenue, the fluctuations in Small Molecules especially in the fourth quarter of last year is on account of R&D expenses in Small Molecules pertaining to our ANDA development.

Dheeresh Pathak: You have started with this new segment reporting, so Biologics growth for the quarter has been (+50%). Can you just give a similar number for FY'16 last year, so that we will have a context in FY'16 you were growing at what rate and now first quarter you have grown at (+50%)?

Siddharth Mittal: We have not done this comparison for the FY'15 to compare FY'16 numbers. But needless to say that that the growth would be higher this year compared to the growth in FY'16, because Insulin we had capacity constraints, we did not have Trastuzumab sales, for the full year, we had the first emerging markets sales for Trastuzumab in the fourth quarter. So the growth in FY'16 compared to FY'15 would not reflect a similar trend.

Dheeresh Pathak: The Branded Formulations business, how much of it is India in the new segment reporting, how much is Middle East and other geographies?

Siddharth Mittal: Out of Rs.159 crores, Rs.120 crores is India.

Dheeresh Pathak: There also we have seen that first quarter margins are lower than FY16 full year margins. Can you just help us explain because expectation was that the growth will improve which we have seen and margins will also improve?

Siddharth Mittal: FY16 margins included share of profit from NeoBiocon without corresponding revenue due to deconsolidation under Ind-AS. Excluding this adjustment, the margin for the full year was 13%, in line with Q1 FY17. We expect the net margins to be closer to the company average, which is 15%. Our UAE business is more profitable, it is a tax-free business as there are no taxes in UAE and contributes higher percentage and our India business is now in the low single-digits.

Dheeresh Pathak: What were the ANDA filings this quarter and how many cumulatively now you have filed?

Siddharth Mittal: Cumulatively, we have 7 to 8 filings and this quarter I do not think we had any filings.

Dheeresh Pathak: For FY17 how many you expect to file?

Siddharth Mittal: Totally, we would have 20 to 25 filings over a period of 2 to 3-years.

Nitin Agarwal: On the Pegfilgrastim filing in the EU, how do you see the approval process or review process, how long will it take typically?

Paul Thomas: So the European timelines can vary from case-to-case, but I think in the 1-to-1.5-year basis is a general estimate.

Nitin Agarwal: Is there any particular reason why we went ahead with the European filing and we have not done the US so far, any incremental data points that you require for the US Peg filings?

Arun Chandavarkar: I think the regulatory requirements and timelines in different jurisdictions are different and this is just a reflection of that.

Nitin Agarwal: What I mean is do we need to add some additional work on that or it is just purely a function of the way you probably process the data?

Arun Chandavarkar: No, it is the same trial data, but it is just a time taken to comply with the regulatory requirements in different jurisdictions.

Nitin Agarwal: Siddharth, on the Malaysian facility, you talked about the emerging markets business really getting started from the second half of the year and you will start expensing the cost. But I guess is the facility designed to cater to the regulated market volume, will we have a period of mismatch between the cost and revenues for the facility?

Siddharth Mittal: Yes, obviously it is a very large facility and bulk of the revenues and the profits would come from Europe and US, and in both the markets we will be filing for regulatory approvals in this year and we will expect to launch in '18-'19 time period. So in the initial years, we would have emerging market revenues which might not be commensurate with the operating costs in that facility.

Nitin Agarwal: But earlier my understanding was that we were looking to capitalize cost so that when the regulated markets approvals came through, is there a rethink on that or…?

Siddharth Mittal: No, what we had communicated was that we will stop capitalizing the expenses once we have got the regulatory approvals from Malaysian regulators for both Insulin and Glargine. However, we will start depreciating once we get the regulated market approvals. The logic for that is that when you look at the accounting rules, it requires you to start depreciating when you put the plant for its intended use, and the intended use being the approvals in the developed markets.

Nitin Agarwal: So the above P&L costs will start reflecting in the second half of the year, depreciation costs will come in only when the regulated market approvals come through?

Siddharth Mittal: Yes.

Nitin Agarwal: When we report the Biological revenues, does the India part of the business also get included in that?

Siddharth Mittal: No, India part of the business is included in Branded Formulations in the Fact Sheet. However, in the segment reporting as per the SEBI format, the transfer is included as a part of Biologics and it has been taken out as a part of the inter-segment revenue. So, in the Fact Sheet we have shown revenues of Rs.107 crores. However, in the segment reporting of SEBI format, it shows Rs.160 crores. So, the delta you can assume as to be the amount transferred to the Branded Formulations.

Nitin Agarwal: That is sales on the Biologics that we make which are adjustments that you are making in that?

Siddharth Mittal: Let me again caution you on one thing, the difference of Rs.53 crores is not the sales of Branded Formulations that is at the transfer price. The Branded Formulation then marks it up and sells it to the end customers.

Nitin Agarwal: What kind of products do we classify in Biologics in categorization?

Siddharth Mittal: We have Insulin, we have Glargine, we have Trastuzumab, we have BIOMAb, we have Itolizumab, so all are biosimilars and as well as novels.

Girish Bakhru: Yes, just needed clarification; how many markets outside India are you selling Trastuzumab in right now?

Ravi Limaye: We are selling Trastuzumab in emerging markets, but I do not think we can give the number of markets.

Girish Bakhru: But the business of course will pick up more from second half. Are you expecting the larger markets to enter in this fiscal?

Ravi Limaye: Yes, that is right.

Girish Bakhru: If you could comment on what is the average price erosion you have seen in some of these markets - that will be helpful?

Ravi Limaye: I do not think we can get into that. It differs from market-to-market and also there is a competitive element to this.

Girish Bakhru: Just on the Glargine side, would filing wait for the interchangeability study to complete or would you file before that?

Arun Chandavarkar: So the Glargine filing, we will be proceeding as soon as the requirements for a specific jurisdiction have been completed. As I mentioned in response to an earlier question, the requirements could vary from jurisdiction-to-jurisdiction even amongst the developed markets. So, we will proceed with our filings as and when we meet the requirements for a certain jurisdiction. So, as you have seen with our Pegfilgrastim filing, not all markets filing will happen simultaneously. So, those markets that require maybe some additional data or which require a different way to compile data we will be waiting. But the trials that we do, as I mentioned in response to an earlier question, our global trials meant to support filings in all jurisdictions.

Girish Bakhru: I am just wanting to get more clearer sense on the US filing given that interchangeability will be large an issue there than the other markets. So, would you say that your filing would get more weight if you have completed that study or would you file it ahead of that?

Arun Chandavarkar: As I mentioned, again, without getting into the specifics due to competitive reasons, the requirements would be different in different jurisdictions. Because the reason I am saying that, I know you are asking about interchangeability, but the way interchangeability plays out in different jurisdictions is also very different, like for example in EU, EMA does not make a determination of interchangeability, it is left to individual countries, the US may have a different approach. So, we certainly have different strategies catering to different jurisdictions, for example, now we have got approval in Japan for Glargine already, and that is a developed market and it is interchangeable.

Girish Bakhru: So for that you did not need to do the study separately?

Arun Chandavarkar: I do not want to get into specifics, but all I can say is that do not draw conclusions from a filing in one jurisdiction based on what the requirements are for some other jurisdiction. Like Glargine, we have got approval in Japan. We have guided that we will file for approvals for Glargine through our collaboration with Mylan in the European and US jurisdictions later this fiscal. We are not saying that both will be filed at the same time.

Girish Bakhru: Just correct me, in Japan, you are the only biosimilar right now right for the Insulin Glargine?

Ravi Limaye: Lilly is also there.

Ujwal Shah: The question pertains to our Biologics business. If we look at the margin profile, in 4Q'16 the margin was close to 20%, 21%, PBIT margin that we have reported on segmental basis, whereas the margin has quite shot up to 28%, 29%. So, my question was what kind of sustainable margins does this business see going forward from the emerging markets?

Siddharth Mittal: The margin fluctuation is because of the R&D expenses and R&D expenses as we have said would be lumpy. The margin fluctuation will also be on account of licensing income included in each of the segment, again, which should be lumpy. But in the long-term what we have said is Biologics business, it is a very profitable business, very healthy gross margins and we do expect that this would be one of the healthiest businesses for us.

Ujwal Shah: A question also pertaining to Branded Formulations business, the Indian pie. I think you did mention that the margins for the Indian business were now low single digits.

Siddharth Mittal: It was an error on my side; it was low double-digits.

Harith Ahamed: Just on the Branded Formulations business, you mentioned around 80% of that is in India. Just wanted some color on where the rest of this Branded Formulation sales is coming from, any key markets that we should be looking at in the segment?

Kiran Mazumdar-Shaw: Rs.39 crores is UAE contribution, ex-India that is.

Harith Ahamed: In the Biologics business that is largely Glargine and Trastuzumab in emerging markets?

Kiran Mazumdar-Shaw: Insulin, Glargine, Trastuzumab and other biologics.

Harith Ahamed: Any color around the key markets for Trastuzumab?

Kiran Mazumdar-Shaw: Largely LATAM and Middle East.

Harith Ahamed: On Trastuzumab, can you talk a bit about the key steps from now to filing for these both in US and Europe and if you could indicate the timelines for the same?

Arun Chandavarkar: Based on that data that was presented at ASCO that one clear indication is of course that the trial is complete. Now that the trial is complete, it is a matter of going through the compilation of all the requirements and filing as soon as we are ready with the compilation.

Prashant Nair: For the full year, have you given any indication of where your R&D spend could be as a percentage of sales? The first quarter seems to be on the lower side, but I appreciate this is lumpy.

Siddharth Mittal: So, 12% to 14% in the P&L of our revenues ex-Syngene and 18% to 20% in cash again revenues ex-Syngene.

Prashant Nair: This would be the net spend on the P&L, right?

Siddharth Mittal: 12% to 14% is net, 18% to 20% is gross.

Chirag Dagli: So Pegfilgrastim that we filed, where have we filed this from -- are the facilities the same as where we service for the emerging markets?

Siddharth Mittal: Pegfilgrastim is not launched in emerging markets, it is a different facility compared to the monoclonal antibodies facility or an insulin facility. The manufacturing is done in Bangalore.

Chirag Dagli: Do we have enough capacities to say take double-digit kind of market share in this for the developed world?

Siddharth Mittal: Yes, we will be in a position to address the markets when it opens.

Chirag Dagli: From the same facility?

Siddharth Mittal: Yes, from the same site.

Chirag Dagli: Then similarly for MAbs, if you can comment whether we will be filing from the same facility that we have for the emerging markets.

Siddharth Mittal: Yes.

Chirag Dagli: We have enough capacity to address the developed world?

Siddharth Mittal: We will have enough capacity. I think what we have said in the past that we will be investing in another monoclonal antibodies facility, which will be based out of Bangalore, we are working out the details of that facility with our partner Mylan and would be announcing the details once we are in a position to give the size of the facility and the investment later this year.

Chirag Dagli: The filing that you were alluding to that you will do this fiscal, there will be two MAbs, right sir, those two MAbs will be filed from the Bangalore existing facility?

Siddharth Mittal: Yes.

Ranjit Kapadia: My question relates to the Domestic Formulations business. We say that we are restructuring the business and I would like to know whether benefits are as per our expectation? My second question is how much sales comes the products and the price control and the plan for introduction of new products in the domestic market?

Ravi Limaye: So, regarding restructuring, the objective of the restructuring was to focus on certain core brands in strategic therapy areas of interest, which is what we continue to do and it is showing results in the sense that our core brands are growing much faster than the overall Branded Formulations business. Regarding how much sale comes from price control…

Siddharth Mittal: The main two drugs that we have under price control -- one is Insulin, which is, I think last year we had mentioned has crossed Rs.100 crores in revenues. So, that has been under price control since years, even this year there has been some impact of the new pricing, the other product that we have is Atorvastatin which is under price control. I think those are the main, rest are minor.

Ranjit Kapadia: What is your plan for introduction of new products in the domestic market?

Ravi Limaye: We continue with our plans to introduce new products in, as I said, therapy areas of strategic interest. So that activity will go on. So we will look for products in Oncology, Diabetes, Virology and so on.

Siddharth Mittal: Which will be a combination of in-house molecules, we are undergoing Phase-III trial for Bevacizumab, and are also looking at in-licensing some of the molecules and some other ANDAs that we are developing for the other markets.

Surjeet Pal: I just have two questions: One is that given the Lilly's approval of biosimilar non-interchangeable, I would like to understand your observation of Lilly's launch for, say, last four to six months and your expectation considering that you might be launching with brand and certain marketing strategy. That is one. Second is that yesterday there was a late stage study of Amgen, Allergan, Trastuzumab data. That talks about that basically they missed the primary endpoint and still they are considering that they will be getting through in terms of approval. So, if I compare your data which you said that you have completed, could you throw some light on competitive landscape, how do you compare your data with their data?

Arun Chandavarkar: So, I think your first question was on Lilly's launch of Glargine and probably their strategy. I would not like to comment on their commercial strategies and the importance of interchangeability to Lilly's commercial strategies. #1, Lilly has not launched in US, which is of course the biggest value market for biosimilar Glargine, because I think they have announced that they would launch end of this year. So I would not like to really pass comments or judgment on competition. We remain focused on our strategy of filing for approval in each jurisdiction based on the requirements for that jurisdiction. These requirements straddle not just the clinical aspect, but also as you said the interchangeability aspect. In response to an earlier question, I think I clearly mentioned that the requirements in EMA, Japan and the US are different, both from an approval standpoint as well as interchangeability standpoint. Our strategy is designed to get us not just approval, but help us get market share in the jurisdictions that we launch. In reference to your second comment about the Trastuzumab data released by Amgen and Allergan last night, I would not like to comment on what they have said or what others have said about their endpoints and their confidence intervals. All I can say is that we have presented data through our partner Mylan at ASCO, and we are confident of submitting our data to the US and European authorities later this fiscal once we have completed compiling all the dossiers. I really would not want to comment on Amgen data. All I can say is we are confident of ours.

Surjeet Pal: I understood that you are confident of your data, in a sense definitely you guys have done is that how efficient or what is the efficacy data comparing between your data, because it is all public. So from that perspective, how do you rank your product, top-2, top-3, among the biosimilars who are competing for?

Arun Chandavarkar: That is for the outside world to rank, it is not for us to rank. We are now focused on getting approvals and then launching the product as and when we get approvals. I do not want to rank product quality or dossier quality, because certainly we do not have access to the totality of evidence from each company.

Andrey Purushottam: I just wanted to ask a few questions on the biosimilar space. My first question pertains to the launch in Japan. Can you shed some light on your pricing strategy vis-à-vis the price discount versus innovators etc., and kind of share that you might be targeting in let us say reasonable horizon?

Shreehas Tambe: So the pricing in Japan is decided by the Pricing Commission similar to the price controls we have there. It is a two-year price deck which is done. These prices are available in the public domain where our pricing is very similar to the pricing that has been awarded to Lilly. So this is awarded by the Pricing Commission at prices which are pre-set by the NHI as they would call it. With regards to the numbers, I think the pricing at current exchange rates would be around $14.5-$15.0 that the partner has been awarded, which is in the public domain already. I think the other question that you had was pertaining to the market share. I think, that is not something that we would like to say at this point, but as we have discussed earlier on the call, Japan is a market where we believe interchangeability of the product would be easier. Looking at the performance of other biosimilar products in the market, where these products have gained substantial traction in a short period of time, we believe with FFPs might and experience in that market, with the local clinical trial data, we should be able to garner good market share in Japan.

Andrey Purushottam: Second question is regards to the discussions with your US authorities on the Insulin space. Now, could you just shed some light as to how the discussion is forming with respect to two parameters? I think there was some debate on that the yeast being used is different from the other innovators and there were some discussion on biosimilars, etc. Can you just shed us some light as to how this discussion is progressing in the US and how are developments in Japan influencing them hopefully positively?

Arun Chandavarkar: I cannot comment on your question, because I think your question presupposes the content of our discussions with the USFDA as being revolving around host organism. I can tell you that the host organism that we use across our Insulins portfolio is the same and we have full confidence in filing for approval in the US and Europe, similar to the way we have already received approval for our Glargine in Japan.

Andrey Purushottam: A close relation of mine is undergoing treatment for breast cancer in Switzerland and she pays $3,000 a dose for Herceptin. In India, I was just looking at the prices and Roche apparently effectively after taking into account dealer discounts and selling it across Rs.55000 to Rs.56000 per vial. I believe that is also your pricing in India. Now, my question really was two-fold: #1, at that kind of pricing, if and when you were to establish yourself in the developed markets, what order of magnitude of change do you see in terms of your revenues or profits for your Biologics vis-à-vis right now? I am not talking for a number; I am just talking about order of magnitude. The second thing I am asking is that what is the scope for you in terms of price play? You decided to price it at Rs.56000 in India, could you price it at Rs.5, 000, could you price it at Rs.10, 000, and what does that do to the size of the market, and what is your thinking on this on a more long-term basis?

Arun Chandavarkar: At this point in time, we can only go by precedence that have been set and what the general consensus in terms of modeling price erosion for biosimilars in various markets could be. Right now I do not believe that the consensus feeling is that the biosimilar price erosion will be 90%, 95%. So clearly, the size of the market depends on the level of price erosion. What we have factored in is a reasonable rational commercial strategy and not something that is completely irrational.

Andrey Purushottam: What is this pricing flexibility that you have?

Arun Chandavarkar: The pricing flexibility is not something that we can comment on in the developed markets. That strategy will be driven by Mylan. But, if you are asking about cost of goods, our aim is to be competitive in any market.

Andrey Purushottam: I am just trying to get an understanding whether there is a possibility for 1000% gross margin, 3000% gross margin, 30% gross margin - what are we talking about in terms of the prices that we are talking about?

Arun Chandavarkar: I cannot comment on that, because that is talking about where does the price point and how low we can go. Clearly, you have seen in some of the molecules huge differences in prices in emerging markets and developed markets. Within the developed markets itself, huge differences between the US and some of the other developed markets. We are manufacturing product at a site at a certain COGS level to cater to all of these markets and try and be profitable in each of them.

Siddharth Mittal: One more thing I would like to add; currently, if you see our gross margins, we sell only in emerging markets and all the gross margins we have indicated in the past, Biologics gross margins are much higher than the company average. So, that will give you an estimate if we are making such a healthy gross margin in emerging markets, what would be the margins once we are in the developed markets.

Andrey Purushottam: Those are at comparatively low volume, because you are still at the early stages in emerging markets. Now, what is the strategy in terms of, let us say, emerging markets, are you planning to significantly drop prices in order to expand the market or are you playing the game of skimming the market, that is broadly what I wanted to ask?

Arun Chandavarkar: I know that is what you would like to know which I am not sure that any company would disclose its competitive commercial strategies in a public domain. Those are internal strategies as to whether we go for volume, whether we go for price, whether we use discounting as a strategy, whether we use the strength of our dossier and data and quality of product.

Shradha Patil: I was just seeing your Fact Sheet and if you could help us understand in a better way how do we interpret the adjustment in the segment sales. So if I am seeing Small Molecules, we have done upward adjustment of Rs.63 crores in the Q1 FY17.

Siddharth Mittal: Current quarter, there are multiple small adjustments, I will just talk about one large number, which is on account of revenue adjustment of Rs.78 crores, of which around Rs.9 crores is towards excise duty gross ups and the balance on account of sales cut-off. Also, there is a cascading impact on material and power cost because of the revenue reversal resulting from change in accounting standards. In March-16 quarter, we had to reverse sales to the extent of Rs.60 crores, which has been recognized in Q1 of this year. That is a one-time adjustment and the impact of this transaction on the bottom line is Rs.20 crores net of tax.

Shradha Patil: So, this Rs.63 crores, which has been adjusted in Small Molecules is what exactly?

Siddharth Mittal: That is as I mentioned, sales reversals in March which got recognized in Q1 of this year. Please consider this as one-time adjustment only.

Shradha Patil: In the Branded Formulations business, we have really seen something changing during the quarter. So I just wanted to understand better as to what exactly you are seeing in the Branded Formulations sales and do we see the current quarter to continue in the quarters going forward?

Siddharth Mittal: Rs.159 crores was the revenue for the quarter and this definitely will go up during the year.

Shradha Patil: So the trajectory has definitely changed?

Siddharth Mittal: It is 15% growth on a like-to-like basis as we had mentioned earlier compared to Rs.138 crores in last year, it is Rs.159 crores this year. Now, if you look at our guidance for FY'19 for this business to be at $200 million, the growth would have to be 15% to 20% and we are confident of achieving this growth.

Shradha Patil: For the Branded Formulations business, should we assume that the Middle East sales have resumed to a large extent during the quarter?

Siddharth Mittal: I think you are referring to the Middle East sales of our APIs where we had credit issues. That is different than the Middle East sales of Branded Formulations, which was earlier captured in NeoBiocon. The NeoBiocon business like most other branded business across the world is mostly cash-carry business, where you do not have too much credit risk. However, in the API business, where we had credit concerns, we still continue to have those concerns, though we have become more judicious, we do sell in those territories but on advance payments or LCs.

Shradha Patil: Just on a broader understanding basis, do you feel this as an improvement over the last year or the last two years?

Siddharth Mittal: Yes.

Shradha Patil: The Small Molecules segment, how have we seen the performance of Rosuvastatin in the EU and also any ANDA sales from the US?

Siddharth Mittal: ANDA sales in the US have not yet begun. We expect the sales to begin in this fiscal year. EU, the markets that have opened up are more the Eastern European countries, the main EU five will open up in Jan '18. The patents expire there in December '17.

Shradha Patil: Do we expect the trajectory to continue for the Small Molecules as well?

Siddharth Mittal: Our guidance has been mid-to-high single digit for Small Molecules.

Shradha Patil: So we stick to the guidance?

Siddharth Mittal: Yes, because again, when you look at the overall guidance for this vertical at $300 million in FY'19, up from $250 million would imply guidance of high single-digit and we are confident of that number.

Shradha Patil: Just to understand the progress on Pegfilgrastim, so what is our expectation of a possible timeline for an approval to come from the EU?

Siddharth Mittal: Paul had mentioned earlier that we expect 12 to 18-months approval timeline in Europe.

Shradha Patil: We do expect to file it in the coming quarters?

Siddharth Mittal: We have already filed and our file is accepted in Europe and we expect to file in US in this fiscal. I cannot specifically say which quarter.

Shradha Patil: Lastly, any update on Lispro and Aspart?

Siddharth Mittal: They are in preclinical stage.

Shreehas Tambe: Those are assets under development at this stage and we will share information on them as we get to a stage which are more material in nature.

Charu Lata Gaidhani: I wanted to know what is the percentage of revenue under price control currently?

Siddharth Mittal: Around 20-25%, because Insulin which as I mentioned Rs.100 crores plus product out of total revenues that we did last year of Rs.437 crores, that itself is around 25% of the revenues and the other products are small.

Charu Lata Gaidhani: My second question pertains to market size for Trastuzumab and Insulin. If you could give me an idea of the market size in India and also in the emerging markets.

Arun Chandavarkar: I think globally we have mentioned that Trastuzumab is a multi-billion dollar product, of which maybe 15%, 20% of that may be in the emerging markets.

Charu Lata Gaidhani: India?

Arun Chandavarkar: I do not think we have given market size number in India, in that sense, but what I can tell you it is a few hundred crores.

Charu Lata Gaidhani: Also Insulin?

Arun Chandavarkar: rh-Insulin in India will be a little between Rs.1000 crores and Rs.1100 odd crores.

Manushi Shah: I had a question on Trastuzumab clinical trial data. So, in the data the primary endpoint when it is compared with Herceptin it is showing quite better. The secondary end point is not met. So, how should we read this -- can it be placed into the Bio better category because primary end point is better than Herceptin or will it be Biosimilar only?

Arun Chandavarkar: The data presented at ASCO is intended to file for the molecule as a proposed Biosimilar.

Manushi Shah: No, because the primary end point is better, so will it be better than Herceptin that is what I am trying to understand?

Arun Chandavarkar: The data says that it is within the confidence interval. So our intent is to file it as a proposed Biosimilar. We met the primary endpoint and so we will be filing as a proposed Biosimilar.

Paul Thomas: I think if you look at the presentation, the secondary end points are also whatever is available at this time point are met and I think as mentioned PFS data that will be coming in the next read out which will be available at ESMO in October.

Dheeresh Pathak: Just to confirm, in India only rh-Insulin and pre-mix is under price control, Glargine is not under price control. Is it correct?

Arun Chandavarkar: That is correct.

Dheeresh Pathak: For Insulin, pre-mix and rh, the formula that government uses for Small Molecules, which is greater than 1% market share simple average, that also applies to Insulin products?

Arun Chandavarkar: That is right.

Dheeresh Pathak: So then why is it that in Glargine over the years we have only had like mid-teens market share and not more?

Arun Chandavarkar: We did not have a complete portfolio, originally we had only vials. As we launched our pen after we commissioned our disposable pen assembly line only in the middle of last year. Now, we have a complete portfolio of all the SKUs - refills, disposable pens and vials. Because of that in our press release, we have seen that our BASALOG has grown 30% this quarter.

Dheeresh Pathak: Large part of the Glargine market would be in pen rather than vials, right?

Arun Chandavarkar: Yes.

Saurabh Paliwal: Thank you, everybody for joining us today. If there are any unanswered questions, please feel free to reach out to me. We look forward to hosting in the next quarter. Have a good day.

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