Biocon Limited Q4 FY18 Earnings Conference Call
April 27, 2018

Participants from Biocon's Senior Management Team

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

Conference Call Participants during Q&A

- Ronny Gal, Sanford Bernstein
- Prakash Agarwal, Axis Capital
- Surya Patra, Phillip Capital
- Dheeresh Pathak, Goldman Sachs Asset Management
- Cyndrella Carvalho, Dolat Capital
- Hem Agrawal, Individual Investor
- Sameer Baisiwala, Morgan Stanley
- Ritika Jalan, Narnolia Securities
- Sudharkar Prabhu, Span Capital
- Harith Ahamed, Spark Capital
- Charulatha Gaidhani, Dalal & Broacha
- Sumit Modi, Arete Investments

Presentation Session

Saurabh Paliwal: Good morning ladies and gentlemen. I am Saurabh Paliwal from Biocon's Investor Relations team and I welcome you to today's earnings call for the fourth quarter of fiscal '18. Today's call is being recorded and the replay of today's discussion will be available for the next few days two hours post the conclusion of this call. The call transcript will be made available on the website of the company in a few days. We have today with us Dr. Kiran Mazumdar-Shaw our Chairperson and Managing Director and other colleagues from the senior management team to discuss the company's business performance and outlook,. Before we get started out, let me remind everybody on the safe harbor related to this call. Today's discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces, that could cause our future results, performance, or achievements to defer 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 get in touch with me. Now, I would like turn the call over to Dr. Kiran Mazumdar. Over to you ma'am.

Kiran Mazumdar-Shaw: Thank you Saurabh and good morning everyone. I welcome you to Biocon's earnings call for the fourth quarter and the full year of fiscal'18, which ended on 31st March 2018. It was certainly an

exciting year for all of us at Biocon as we crossed many important milestones. And I would like to start by sharing with you the key highlights for the year.

- Our partner Mylan received approval for Ogivri™, our partnered biosimilar Trastuzumab from the USFDA in December 2017. We became the first company from India to get its biosimilar approved by the USFDA and our biosimilar Trastuzumab also received approval in Brazil through our partner Libbs Farmaceutica. Subsequently an approval in Turkey was also received. It was the first biosimilar Trastuzumab approval in all the mentioned countries and certainly from a Biocon and its partner point of view, it was certainly a great achievement.
- Mylan and Biocon also received approval from the European Commission and Therapeutic Goods Administration (TGA) Australia, for Semglee™, which is our biosimilar Insulin Glargine. Semglee™ is expected to be launched by our partner Mylan in Australia and Europe in the second half of this year. Biocon's partner in South Korea also received approval for the product which is expected to be commercialized later in the year.
- Biocon and Mylan agreed to accelerate the introduction of biosimilar Adalimumab in Europe through Mylan's in-licensing arrangement with Fujifilm Kyowa Kirin Biologics or FKB. FKB's product is at an advanced stage of review with EMA and could potentially obtain approval in Europe in the second half of 2018. We believe that through this arrangement Mylan could commercialize FKB's Adalimumab in EU around market formation. Biocon retains its economic interest in this arrangement vis-à-vis Mylan in line with its existing global collaboration with Mylan for monoclonal antibodies.
- In January, we announced our global collaboration with Sandoz, a Novartis division and a global leader in biosimilars for developing a set of next generation biosimilar products. This, we believe, will bolster Biocon's existing global biosimilars portfolio, which comprise biosimilar antibodies as well as insulin analogs. The opportunities for this partnership comprising next wave of biosimilar biologics, are expected to open up in the next decade, thus equipping us to address biosimilar opportunities beyond the near term, which are currently being addressed by our existing and very successful global partnership with Mylan.
- Biocon and Mylan have also agreed to expand their longstanding collaboration with the addition of two next generation biosimilar programs with Insulin Glargine 300 units/ml and Pertuzumab.
- Syngene, our Research Services subsidiary, extended its contract and increased the scope of its engagement with BMS, its largest customer. The next phase of the partnership will see the addition of a new facility to support future BMS research and development operations, expansion of the team and the extension of its existing agreement with BMS to 2026.

  Syngene also expanded its ongoing research collaboration with Amgen and signed a multi-year agreement with GSK, which will focus on accelerating the discovery of new drug candidates using Syngene's discovery services platform. The collaboration also involves the setting up of a dedicated or customized research facility for GSK.
- I am also delighted to say that Biocon was ranked among global top 10 biotech employers as per the 2017 rankings released by Science Career magazine. We are the only Asian company to feature in this list. This is a great testament to our work culture and the opportunities our scientists get within, which ultimately result in successful outcomes for the Company.

Now, moving on, I will now present key financial highlights. I will start with the quarter and follow it with the full year.

Financial highlights for Q4FY18:

- **Total Consolidated Revenues** for the quarter of Rs.1237 crores, which is up 27% compared to last year.
- **Revenues from operations** were at Rs.1170 crores, which reflects a growth of 26% compared to last year. This includes licensing income of Rs.2 crores this quarter compared to Rs.16 crores in Q4 last fiscal.

- From a segment perspective,
  - **Small Molecules** segment clocked revenues of Rs.426 crores for Q4, which is up 8%,
  - **Biologics segment** revenue grew 47% to Rs.241 crores, and
  - **Branded Formulations** grew 14% to Rs.149 crores in Q4.
  - **Syngene** reported revenues of Rs.409 crores, up a solid 45% compared to Q4 of last fiscal.

- We incurred **gross R&D spends** of Rs.98 crores this quarter. Of this, Rs.51 crores is reported in the P&L corresponding to 7% of revenues excluding Syngene. We capitalized an amount of Rs.47 crores related to our biosimilars and insulin analogs development expenses. While the gross spends are similar to last year, the amount in the P&L has reduced on account of capitalization of Bevacizumab-related expenses which were reflected in the P&L last year.

- We booked a **forex gain** of Rs.42 crores this quarter as compared to a loss of Rs.17 crores in Q4 last fiscal. This gain is reflected in the '*other income*' line of the P&L statement. Of the total amount, Rs.31 crores comes from gains in Syngene.

- Group **EBITDA** was at Rs.300 crores for this quarter, with **EBITDA margin** at 24%. **Core margins**, i.e. EBITDA margins net of licensing, impact of forex and R&D stood at 26%.

- Reported **Net Profit** for the quarter was Rs.130 crores, which represents a Net Profit margin of 11%.

- The **effective tax rate** at 21% for the quarter appears higher than last year tax rate of 2% last year as we had utilized R&D incentives and deferred tax asset for the full year in Q4 of last year.

Now, coming to the **full year financial highlights**:

- **Total Consolidated Revenues** for the year were at Rs.4336 crores, up 6% compared to the previous fiscal.

- **Revenues from Operations** were Rs.4130 crores, which reflects a growth of 5% compared to the previous fiscal. This includes licensing income of Rs.23 crores as compared to Rs.145 crores the previous year.

- From a segment perspective –
  - **Small Molecules** revenues were Rs.1508 crores, which is down 8% from the previous year,
  - **Biologics** revenues grew 10% to Rs.770 crores,
  - **Branded Formulations** sales grew 11% to Rs.612 crores, while
  - **Syngene** registered revenues of Rs.1423 crores, reflecting a strong growth of 19% compared to the previous fiscal.

- We incurred a **gross R&D spend** of Rs.380 crores this year. Of this amount, Rs.216 crores is reported in the P&L corresponding to 8% of revenues excluding Syngene. We capitalized an amount of Rs.165 crores as compared to Rs.135 crores in fiscal'17, pertaining to our biosimilars and insulin analogs development expenses. While the gross spends are slightly down from the previous years on account of lower spends in our biosimilar development programs, the amount in the P&L has reduced on account of capitalization pertaining to Bevacizumab-related expenses.

- We booked a **forex gain** of Rs.83 crores this year, compared to a loss of Rs.3 crores the previous year. Major gains amounting to Rs.74 crores were booked in Syngene.

- Group **EBITDA** stood at Rs.1035 crores for the year, down 9% with an **EBITDA margin** of 24%. **Core margins** that is EBITDA margins net of licensing, impact of forex, and R&D stood at 27%. The reduction in margins percentage as compared to last year is on account of lower licensing income, we also faced pricing pressure in the small molecules generics segment globally, the impact of shutdown of the fill and finish plant for modifications and requalification post regulatory audits and fixed and operating cost related to the Malaysian facility.

- Reported **Net Profit** for the year was Rs.372 crores, which represents a Net Profit margin of 9%.

- The **effective tax rate** for the full year at 26% again appears higher than last year of 19%. This is largely on account of utilization of R&D incentives and deferred tax asset, as previously mentioned.

- Now, before I move on to discussing individual segment performance, I would like to share with you that the Board of Directors in their meeting yesterday have recommended for approval by the shareholders, a **Final Dividend** of Re.1 per share (20% of face value of each share) for the financial year 2017-18.

Now, coming to individual business segments, let me start with **Small Molecules**. This segment faced headwinds as a result of pricing pressure and channel consolidation by our clients in the US, which impacted our statin sales. Continued demand for immuno-suppressants helped offset some of the pressure in this segment. We launched our first finished dosage formulation in the US market this year, which was Rosuvastatin calcium in a highly crowded market. Despite the pressures, we were able to increase market share for some of our specialty APIs in key markets. Some of our API customers in developed markets received regulatory approvals and we also made regulatory submissions for multiple APIs across developed and key emerging markets. This we believe will help this segment as we move into FY19.

Biologics: Biologic segment revenues grew 47% in Q4 and 10% for the full year. The full year growth was impacted by shut down of fill-finish plant for modifications and requalification post regulatory audits last calendar year and lower licensing income pertaining to this segment. Adjusting for impact of decrease in licensing income, product revenues growth was strong at 68% in Q4 and a decent 29% on a full year basis. Therefore the major impact of growth is on account of a lower licensing income and we could have had a much better performance if the fill-finish facility had not taken a shutdown. The growth was led by insulin sales in Malaysia via the offtake agreement, higher sales in Mexico where our partner won a government tender and traction in the AFMET region contributed to the insulins growth. Antibodies product revenues increased as a result of the expansion of our geographical footprint in emerging markets, with increased offtake of products Trastuzumab and Bevacizumab by our partners for emerging markets and India. Increased product sales growth was partially offset by a decrease in licensing income.

A note on Malaysia operations: Last year we had stated that starting Q1FY18, fixed expenses including depreciation and finance costs related to the Malaysia plant, totaling to approximately $48 million annually would be charged to the P&L account. We also said that while we expected to offset a portion of these costs by product sales in Malaysia and other emerging markets, we expect a loss at the Malaysia standalone level. In FY18, Malaysia reported an operational loss of $5 million at a standalone level, when excluding the impact of R&D. In FY19, the fixed expenses are projected to increase to $50 million on account of increase in operating expenses. Our Malaysia insulin facility is making good progress and receiving approvals for both the facility and the products from various regulatory agencies globally, including the European Medicines Agency and TGA Australia, and we believe this will help us aim for operational breakeven in Malaysia after excluding R&D expenses in FY19.

In FY18, the growth in **Branded Formulations**, which comprises India and UAE, were led by strong growth in the UAE business at 33%, while growth of the Indian business remain muted at 4%, with performance impacted due to various challenges faced by the business. During FY18, Biocon launched biosimilar Insulin Glargine in UAE, under the brand name Glaricon™. This was our first biosimilar launch in the UAE market. We also in-licensed two more innovative brands from Novartis, which will fortify our position in UAE cardiovascular market, where we currently rank among the top 10 companies. The UAE business reported an overall strong revenue growth driven by our metabolics portfolio, which comprises novel in-licensed products like Jalra and Imprida and our own brand of biosimilar Insulin Glargine, Glaricon™. Sales momentum of our other branded generic products also boosted revenues during this fiscal.

In India, we launched Krabeva®, a biosimilar Bevacizumab, our second oncology biosimilar launch in India. Developed for the treatment of metastatic colorectal cancer and other types of lung, kidney, cervical, ovarian, and brain cancers, it is an important addition to our current oncology portfolio in India. While this was a key positive for the India business, we had to take price reductions in some of our products, both mandatory as well as market-based. And there was a temporary volume shortfall for certain biologic products due to the shutdown of our biologics facility in Q2 and Q3 of FY18. Lack of significant new launches and operational delivery has resulted in continued disappointment. We are closely monitoring our strategic initiatives undertaken to bring it back to normalized growth.

Finally, **Research Services -** Syngene's revenues recorded a strong growth this year on the back of an overall strong performance across its businesses. While discovery services and development manufacturing services showed strong momentum, dedicated centers continue to be on a strong footing. Biologic services particularly showed a strong performance during the year. Revenue growth in Q4 was a robust 45%, signaling a full recovery from the impact of the fire incident that happened in December 2016. The damaged facility is expected to be fully operational during the first quarter of FY19.

Product Development updates: The review of our Biologics License Application (BLA) for biosimilar Pegfilgrastim by USFDA is progressing. We have responded to all information requests received till date and our awaiting their response. The target action date for a decision by USFDA is June 4th, 2018.

In Europe, the regulatory review of our Marketing Authorization Application (MAA) for biosimilar Trastuzumab and biosimilar Pegfilgrastim are also progressing, and we expect decisions by CHMP by the end of this calendar year.

In the US, Mylan and Biocon's application for Insulin Glargine under the NDA pathway is under review by the FDA.

The global Phase III trial of our biosimilar Bevacizumab continues. For Insulin Aspart, we has recently completed our global Phase I study and expect a PK/PD readout shortly.

As part of our Novel Biologics, in Q3 we initiated a Phase 2/3 clinical study in India, in Q3 for Insulin Tregopil in type 2 diabetes patients. This, I might remind you, is our oral insulin program. The recruitment for this trial continues.

Now, before I conclude, I would like to summarize our performance in FY18 and provide you with some outlook for FY19.

Fiscal year 2017-18 witnessed significant progress in terms of our global biosimilar pipeline, with first US and EU biosimilar approvals coming through along with the approvals in key emerging markets. We also expanded our biosimilar portfolio with a new collaboration with Sandoz and the addition of Insulin Glargine 300 units/ml and Pertuzumab to our longstanding collaboration with Mylan. Syngene's return to growth, extended its BMS contract, added GSK to its list of marquee clients and continued to make investments to expand its capacities and service offerings.

Prospects for fiscal'19 look exciting with growth in Biologics led by developed and emerging markets and with Syngene continuing to deliver strong performance, in line with our previous guidance for these segments. We expect better performance from Small Molecules and our India Branded Formulations business in the coming year.

With this, I hand over the floor to question and answers. Thank you.

Question and Answer Session

Ronny Gal: **My question is on Pegfilgrastim. First, on Europe. It sounds like the review that you are having with EMA, essentially a review de novo with EMA going through the entire review or is any parts of review already done in the first round? Or essentially is EMA looking at everything from the beginning? And then**

switching over to the US Pegfilgrastim, could you share with us whether you already shared with the FDA your final (not audible) for the biosimilar, and are you expecting another round of questions and answers from them before June?

Paul Thomas: I think your questions were #1) status about EU review and then #2) the same about the FDA review. I think, on the EU review, as you know, we have had both resubmissions last year and to the query of whether it is a fresh review or a repeat of the same review, yeah, there are typically changes in rapporteurs that are handling it and so there is some level of fresh look at it, but clearly we benefit from the review that is already completed. But EU goes through the calendar cycle and so we are working our way through that process.

Ronny Gal: **Essentially de novo?**

Paul Thomas: No, I wouldn't say it is de novo. I think we definitely benefit from not having a lot of fresh items that would be raised up in a review like this. On the FDA side, I think, there is nothing new to report there. We have our action date coming up in June and we are comfortable where we stand in the review process.

Ronny Gal: **Adcom?**

Paul Thomas: No.

Prakash Agarwal: **Just trying to understand the R&D ramp up from here given the fact that you added a couple of molecules with Mylan as well as the Sandoz collaboration and also you have a host of pipeline in the Novel biologics side. So if you could help us on how should we think about R&D spend over this year and next year please?**

Siddharth Mittal: In FY18, R&D expenses were 14% at a gross level of our revenue ex-Syngene. We expect the absolute numbers to go up next year and spends to be in a similar range of 15-16% of revenue. On an absolute basis, we expect gross R&D spend to be in the range of Rs.450-500 crores. The two new drugs that we have added to the pipeline with Mylan and molecules with Sandoz are in early stages of development. Greater spends spends from them will come when these molecules move into the clinic. While the advancement of these new additions is expected in the coming years, the increase in R&D expenses next year will be on account of our novel molecules pipeline and ANDAs. We had slowed down our ANDA development in the last one or two years and are going to resume development again on a very selective basis with increase in activity in the coming years.

Prakash Agarwal: **Perfect, thanks for this. Secondly on the gross margins side, if you look at the quarter there has been some pressure despite the fact the mix has actually moved in favor of the Syngene Research Services as well as the higher margin biologics, so just trying to understand for this particular quarter what really happened given the fact that there is an up move in both the higher margin businesses?**

Siddharth Mittal: Well actually if you are comparing with last year, there was a reduction of 4% and that's mainly on account of Small Molecule pricing pressure. But if you compare it with the third quarter, then both the quarters we had gross margin of ~55% which is in line with the trends we have seen in this year. When you compare with full of last year, drop is margins is mainly on account of reduction of margins in Small Molecules and Branded Formulations.

Surya Patra: **On the Biologic revenue front there is a positive surprise of course, that is also anticipated that emerging markets should pick up after the approval of coming**

in the market but just wanted to know, in whatever product which we have launched in whichever market, what is the market share so far we have achieved in any specific markets?

Arun Chandavarkar: As of now the market share largely seen in emerging markets and as we have highlighted in the past. Couple of examples were illustrated by Kiran as well that in some emerging markets we have a significant market share, having won for example tenders. I think Kiran alluded to the tender in Mexico for insulin which gives us a very dominant market share because that's a tender driven business. So our growth has come from such opportunities in emerging markets. On top of that we have the OTA business which is an on-going business in Malaysia.

Dheeresh Pathak: **I just want to clear my understanding that are there any IP issues that will prevent us from launching or are we waiting for approval in both EU and US?**

Arun Chandavarkar: As you know from Trastuzumab perspective Mylan and Roche are reaching to a global settlement. As far as Pegfilgrastim in the US is concerned, there is an on-going IP process as part of the BPCIA Act.

Cyndrella Carvalho: **Ma'am I just wanted to understand, before the Pegfilgrastim approval, would we be able to see any inspection from USFDA? Is it required? Because some kind of comment similar to this was made on Mylan's last call so just wanted some understanding on this.**

Arun Chandavarkar: Well, as and when an FDA inspection happens and it is concluded, as per our policy we would of course make disclosures and conclusions if there are any observations. At this point in time we do not have any comment on an FDA inspection.

Cyndrella Carvalho: **Okay. And sir in terms of our EU inspection which we have been awaiting for the Bangalore plant, any update on that?**

Arun Chandavarkar: Yeah, again over there, we have been inspected by the EMA, we are now waiting for the EMA to give us the report. EMA unlike the FDA does not issue a report immediately on conclusion. So we would be able to make an appropriate comment once we actually receive a report from the EMA.

Cyndrella Carvalho: **When was this inspection done sir, last month or the month before that?**

Arun Chandavarkar: It was done last month.

Cyndrella Carvalho: **And sir, just some understanding on the Branded India business. If you could help us understand the growth rate has come fairly low. What are the current challenges and what is the way…how are we tackling them and what is the way ahead for this business, typically for the Indian market?**

Suresh Subramanian: Last year's performance was impacted by, as Kiran was saying, shortfall of biologics because of the upgradation and requalification of the plant. We also had the impact of GST and we had some unfavorable pricing which we had to take to face competition. While these are the main reasons, we also had some operational issues leading from attrition which impacted execution. So the next year, we will not have these shortage issues and the impact of GST is behind us. In order to tackle pricing issues, we have installed a key account team, which focuses on business and on key accounts and therefore to be able to guard the business more closely. We have installed some performance management measures and close review and coaching methodologies which will enable prevention of attrition and improve execution. Added to that we will also have new markets contributing which have been delayed; the approvals and listing in markets like Sri Lanka - which is a timing issue. That will start coming in and

our in-licensing efforts will also help shore up business in the coming year. So that in short was what was wrong and what efforts we are putting in to build the business this year.

Hem Agrawal: **First of all hats off to your perseverance to your vision. I have a couple of questions. I wish to understand - are biosimilars and biologics subject to the same pricing pressure as conventional pharma as the biosimilar buyers are the same?**

Paul Thomas: I think it is a good question and I think a valid observation about buyers in many cases being the same. I think the difference that we have here is on the competition side, the number of players involved in the market is quite different. As you recognize the long journey and investments required in order to develop one of these products, the number of competitors tend to be much lower than in those markets and so we see a different dynamic and a much more gradual competitive price dynamic.

Hem Agrawal: **I see, but the illness continue to be the same and the buyers are still the same people. So when you are treating say diabetes, why would somebody pay more for biosimilar biologic compared to a conventional….that is my confusion.**

Kiran Mazumdar-Shaw: I think we need to explain to you that even in the general market, what you refer to as generics or small molecules are a very different drug class compared to biologics or what we call as protein therapeutics. These are very different category of drugs, very different class of drugs and the price points of both these products, whether it is a generic or biologic are very different. So what we are trying to explain to you is that the generics are a crowded market with a number of competitors, and therefore the pricing pressure is very intense and you see a very low price when it comes to buyers being able to negotiate a very competitive kind of bargain. But when it comes to biologics, a) to start with these products are very expensive and b) the bargaining power that the buyer has compared to a generic where there's competition and the number of people offering the products are very, very few, the kind of discount that you are able to negotiate is much lower than for a common generic. I hope you understand that.

Hem Agrawal: **Okay so my follow-up question madam would be that our biosimilar and biologics then subject to a more rigorous USFDA, more stringent than conventional pharma?**

Kiran Mazumdar-Shaw: Well you know the whole regulatory path of bringing a generic to the market and bringing a biosimilar to the market is very different. The cost involved in bringing a generic molecule to the market is significantly lower, generally it is between 5 to 10 million dollars. Whereas when you talk about a biosimilar product, it takes upwards of 100 million dollars to bring a biosimilar to the market. So it is many orders of magnitude higher than a generic molecule and that is why you don't see so much competition and obviously the time to market journey is also much, much longer. So it takes us almost 3 to 5 years minimum to bring a biosimilar drug to the market compared to a generic molecule. So if you think about all these dynamics, obviously it is very expensive and very long drawn out in terms of the regulatory time line to bring a product to the market. And that is just the regulatory approval. You have to then wait for the patent expiry date.

Naren Chirmule: The FDA and the EMA organization are learning along with the industry on how to approve these biosimilars, we in the industry have collaborated with the FDA in developing the guidelines. So all of this is a learning process in the biologics sector, so it is a growth area.

Kiran Mazumdar-Shaw: So we are amongst the front runners. So we are basically setting the path so to speak.

Dheeresh Pathak: **So my second question in my first attempt what I wanted to clarify was that in the adalimumab when Fujifilm's product is being sold by Mylan, in the developed markets, would Biocon get any share from those profit streams or Mylan would just reimburse you for your molecule clinical program?**

Arun Chandavarkar: We are talking about us participating in the profit share arrangement in the European market where Mylan would market the FKB product.

Dheeresh Pathak: **So how do you retain your economic interest because earlier there were two people to share the profit pool, now there are three people? So what do you mean when you say you keep your economic interests?**

Arun Chandavarkar: Whatever economics Mylan has, we participate in Mylan's share of that economics.

Dheeresh Pathak: **Okay so from the earlier part it will be lower but as a percentage of the profit share it would be similar? Percentage sharing would be similar but absolute profits would be lower?**

Arun Chandavarkar: So we participate in, as I said whatever costs and profits Mylan has as part of its deal. We participate in our share of that as per our global arrangement. FKB also would be getting its share, so to that extent it would be a three-way.

Sameer Baisiwala: **On your comment on Malaysian facility, you mentioned that you made a 5 million dollar operational loss in fiscal 18 and in fiscal 19 your expenses go from 48 to 50 million dollar and this year you expect to breakeven. So does that mean there is going to be a delta of 7 million dollar?**

Siddharth Mittal: That's right Sameer. At an operational level the P&L would have a delta of 7 million dollars. I would like to remind you that there are various moving parts, so you cannot necessarily correlate the delta with the top line growth that we have because as I mentioned in the previous call, we also have cost sharing with our partners on the idle time and the facility cost and we also use the facility for a lot of development activities for follow on molecules; so you will not be able to exactly correlate what that means in terms of the revenue growth.

Sameer Baisiwala: **That's fine, I am not trying to come to the revenue growth number Siddharth, the point here is, considering that you are going to launch in Europe and you have got a few of these key emerging market approvals, the delta seems to be way too low..That was my point.**

Siddharth Mittal: That's precisely the point I was trying to make. What Kiran had mentioned in her opening comment was that we are on course to meeting our guidance for biosimilars which is for $200 million for next year and that growth will come from a combination of antibodies, insulin and glargine growth. As far as Europe specifically is concerned, what Mylan has also commented in their call is that they expect to launch the product in later half of this year. What that would mean is that the actual revenue which we'll capture for us in fiscal'19 will only be for a few months and that would be again in launch quantities. We typically expect penetration time to be 1 to 2 years in these markets.

Sameer Baisiwala: **Okay got it. The second question is for adalimumab. What would you do with your own product? I think it has completed phase III clinical in the first half of**

2017 if I am not wrong. So what do you plan to do with that in the US, Europe and emerging markets?

Arun Chandavarkar: I think that Mylan has mentioned in their investor call a few weeks ago that the arrangement with FKB is currently for Europe. However, there are options to extend that to the US or other jurisdictions. At this stage based on what we have seen and if you are aware of the potential launch time lines or market formation timelines in the US, we feel there is time to take a decision on which option to pursue in the US and in other markets. So we have not ruled in or ruled out any option outside of Europe at this stage.

Sameer Baisiwala: **Okay and just a quick one on your fiscal 19, I think a few years back you have given an aspirational target of a billion dollar in top line so do you want to update us on that or do you want to revise it?**

Arun Chandavarkar: I mentioned this in the previous investor call also that when you look at the aspirational target, if you look at what our growth drivers have been and what we anticipate them to be which is our Biologics segment and the Research Services segment; I had mentioned that we certainly expect those segments to be in line with our aspirational targets. We've seen that due to the global dynamics which is not just Biocon specific but has impacted the entire sector in terms of the US landscape for small molecule generics, we do see similar challenges that all other pharma companies in that sector are facing and at this point in time, we can continue to expect in the near term the sort of single digit revenue growth on the Small Molecule business that we've seen in the recent past until we are able to fully sort of capitalize our current investment in small molecules which is basically about growing our ANDA footprint and moving away from purely our dependence on third party API sales to being vertically integrated. That is a work in progress and as we mentioned we continue to file low single digit numbers ANDAs very selectively. In line with what I guess the generic pharma sector has been articulating, we too of course with our differentiated product portfolio which will pan out as many of these ANDA opportunities become commercial, try and play that game of differentiated generics, complex generics, fermentation based generics and things like that which are sort of in line with our capabilities. So that's one trend. In Branded Formulation, clearly there are two pieces to the Branded Formulation, one is the ex-India piece which is growing at a very healthy clip and benefits from the currency movements. India, of course when we gave our original guidance way back in early 2013, the rupee was at 50 to a dollar and the India Business unfortunately has not benefited from that. On top of that we've had some challenges. At this point in time we continue to see the Branded Formulations piece growing more in the mid-teens.

Sameer Baisiwala: **Okay, any update on your Copaxone file?**

Arun Chandavarkar: Well, I think, we had earlier guided that we should be in a position to submit our responses this quarter. I don't want to give a fresh guidance, but there might be some delay in our resubmission.

Ritika Jalan: **I want to know that on the FY19 guidance, which you have given, the $1 billion revenue, I know you are on track to achieve it, but the $200 million will come from biosimilar and $200 from branded formulations, how the things going on, or you want to delay the guidance for one or two years?**

Kiran Mazumdar-Shaw: I think you did not hear the comments being made by our CEO but suffice to say that we continue to track well on Biologics and Research Services. I think, what we said is that we are likely to face some challenges and headwinds in our Branded Formulations numbers and also in terms of our Small Molecules numbers. Because of the kind of market dynamics that are prevailing in the world, there have been

tremendous pricing pressures, price enforcement by NPPA and things like that. So, we will directionally be in that sort of target to address the $1 billion target. But, I think, there are a lot of challenges that we had not anticipated, maybe five years ago, which we are seeing how we can bridge that gap, as much as we can. So, I think, we are very confident on Biologics and on the Research Services aiming to achieve those targets, and we are seeing how we can bridge the gap in terms of the other segments.

Ritika Jalan: **I want to understand that there was a pricing challenges in the generic business, so can you explain me, like, it will prevail going forward because of that gross margin was also affected**

Arun Chandavarkar: Siddharth made a comment earlier that the impact on gross margins in the Small Molecule segment has been on account of pricing pressure.

Ritika Jalan: **Yeah. But it will prevail going forward or, like, just in any other pharma companies…**?

Arun Chandavarkar: Yes. I mean the pricing pressure on the older molecules, like statins, would continue. It would be less on the newer molecules, like the immunosuppressants.

Prakash Agarwal: **Yeah, thanks for the opportunity again. Just trying to understand the capex, given Syngene has also revised capex guidance, what would be our capex for '19 and '20?**

Siddharth Mittal: So, in terms of cash flow, Prakash, it should be anywhere around Rs.500-600 crores per year. Majority of this is coming from our new antibodies facility, construction for which had started last year. But last year, the cash outflow at the Biocon level, excluding Syngene was around 400 crores. A small component of that was for the new facility. We will see majority cash outflows for that in the coming two years. Now, the numbers I am giving are at a gross level. As previously indicated, our partner Mylan will also be contributing on that facility. So the numbers would get reduced. But again, if you look at the combined capex for next two years, at a Biocon level excluding Syngene, you should expect around Rs.1000 crores.

Prakash Agarwal: **Okay, understood, fair enough. And, on Biocon Malaysia plant Phase II, that is not built in here, right, next two years?**

Siddharth Mittal: No, that's not factored in these numbers.

Prakash Agarwal: **Okay, understood. And secondly, there is a comment on increasing ANDA submission, so what are our total ANDA submissions pending approval and we expect approvals starting fiscal '19?**

Arun Chandavarkar: So, we have filed 2 ANDAs in FY18 and our plan is to file more in FY19 and this is, I think, in line with our guidance also on R&D, where the R&D ramp up on small molecules is also likely to be seen going forward, largely because of our focus on submitting some of these ANDAs, some of which would be as I said, not just regular, but difficult to make products.

Prakash Agarwal: **Okay, fair enough. And any color on the tax rates? We have earlier talked about around 25%?**

Siddharth Mittal: We would broadly be in around those percentage, but the absolute number would go up slightly. The reason is that now we have multiple legal entities where we have different business units. Some of these units - to give an example, Biocon Pharma Limited is our entity where we have our entire ANDA business and that business is still in early investment stage. So whatever expenses are there, are not tax deductible.

So, because of that, at a group level, you might see little bit of increase on the effective tax rate and the overall tax amount would go up slightly.

Sudhakar Prabhu: **Yeah, good morning. I had two questions; my first question is on your licensing revenue. What kind of opportunity do you see in next year, FY19 and FY20?**

Arun Chandavarkar: Historically, a lot of our licensing income has been related to local partnering of our biosimilar assets and clearly if you look at the biosimilar asset opportunities, our focus to date had been largely on Trastuzumab. We still have opportunities with the other biosimilar programs to do partnering. I am not referring to the ones, which are in early stage, but the ones which are in late stage developments. So those opportunities continue to exist.

Sudhakar Prabhu: **My second question is on your overall margins. So, this year we saw a fall in your core margin, core EBITDA margins. So, how should we look at it in next year, FY19?**

Siddharth Mittal: You should expect core margins for next year to be at similar levels to FY18. Though they may not be exactly 27%, but should be around that.

Sudhakar Prabhu: **And Siddharth, my last question is on the interest cost and other expenses. So, all the interest costs and everything has hit the P&L or is there something still being capitalized in the balance sheet?**

Siddharth Mittal: The majority of the interest cost is on our debt in Malaysia, we have a debt of almost $180 million and the interest costs on that net of the subsidies which we receive from the Government of Malaysia is in the P&L. Apart from that we have smaller debt facilities for our other plants, and again bulk of that is in the P&L, and a very, very small component is capitalized along with the plant cost.

Sudhakar Prabhu: **And last question is on your capex, you mentioned that you have a capex of Rs.1000 crore lined up for next two years. So, would that be financed largely from debt and from internal accruals or would you need to raise any additional money**?

Siddharth Mittal: We had a net cash balance of roughly Rs.350 crores as of March'18 which gives us a lot of borrowing power to take on more debt. We would also look at the internal accruals. If you look at the EBITDA at the group level this year, it was around Rs.1000 crores. While internal accruals and debt will definitely be there, at some point in time we are also open to divesting a small stake in Syngene to raise additional funds if we prefer not to taking on too much debt on our balance sheet.

Sameer Baisiwala: **Just to confirm, did you say that gross R&D spend for fiscal'19 would be 450 to 500 crores?**

Siddharth Mittal: What I mentioned was that we expect the gross R&D spends to be 15-16% of our top line ex-Syngene. While this year the gross spend was around Rs.400 crores, in FY19, it would definitely inch up. It would be very difficult to give an absolute number but we expect to reach Rs.450-500 crore levels or possibly higher, because in the last two years while we had guided that our gross spends would be in that range, the spends came in lower due to reduction in expenses on our ANDA programs. In the coming year we expect to see an uptick.

Sameer Baiswala: **Kiran your thoughts….I think it was being said that you probably planned to spin off the biosimilar business let's say separately so if you can just update us on that and what's your thinking behind this?**

Kiran Mazumdar-Shaw: That is a work in progress and we certainly believe that Biosimilars is a very valuable part of our overall business. They requires a huge amount of investment to grow and develop the pipeline and take to the market. Therefore, we believe that this is an important opportunity for us to look at the prospect for creating a separate entity for our biosimilars business. We will keep you informed as we progress this particular model.

Harith Ahamed: **On the capitalized part of R&D which was close to 180 crores in FY18 and Rs.50 crores for the quarter, are there any other assets apart from Glargine and Trastuzumab spending for which is getting capitalized because both Glargine and Trastuzumab have been filed and the R&D spending on those assets are likely to have come off, but the capitalized R&D remains 50 crores a quarter, so that's the reason for it.**

Siddharth Mittal: Kiran had mentioned in her opening comments that this year we capitalized expenses relating to Bevacizumab. While you are right that the filing for Trastuzumab and Glargine is over, it does not necessarily mean that the expenses are over. We still have some expenses coming for these two molecules. The bulk of the capitalization is now for Bevacizumab which as you know is in global Phase III.

Harith Ahamed: **Okay and then is there a decision yet on the R&D spending that you will be having for Toujeo and Perjeta? Will you be able to capitalize those?**

Siddharth Mittal: As per our capitalization policy, we only capitalize molecules where we have got an approval for that particular molecule in one of the markets, thereby establishing scientific proof of concept and also the technical and the commercial feasibility. At this stage, we are developing many more molecules apart from the three molecules that we are capitalizing and all the expenses for those molecules are being expensed in the P&L. So for Toujeo and Perjeta, all the initial expenses, till the time we see our first approval will be in the P&L. Only the subsequent development expenses, if any, will be in the balance sheet.

Harith Ahamed: **Is there an update on the new biologics facility that you are planning in Bangalore? The time lines? Have you started the work there?**

Siddharth Mittal: As I mentioned some time back, the construction for this new facility started last year. In one of our previous calls we had said that it will take about two years to commission the facility, a year after that to qualify and file for approvals, and then one year to get the approvals. So by next year, the facility itself should be commissioned and in 2020 we expect to do all the development work to file in various markets. Finally, in early 2021 we expect commercial sales to start from that facility.

Charulatha Gaidhani: **There is a reversal in the Small Molecules business. Do you expect it to be sustainable and what kind of growth you expect in Small Molecules going forward?**

Prasad BSV: Yes, there was a reversal this quarter. We expect on an annualized basis to see low single digit growth in Small Molecules.

Charulatha Gaidhani: **Okay. So you expect some more pricing pressure?**

Prasad BSV: The US pricing pressure is expected to continue. But as more of our API partners start getting approval for new products, we expect the growth to happen through that.

Charulatha Gaidhani: **Yeah, my question pertains to IN105, the trial is being conducted in India, it is in phase III; there was positive data that was when it was last with BMS?**

Naren Chirmule: Yes the program right now is in Phase III, we've initiated the studies. A few patients have been dosed and the dosing will continue for the next couple of years. We will look at the data on an interim basis sometime next year. It is all in discussion with the DCGI office. We are very enthusiastic about this program. Just like any other development program, this is a blinded study. So we won't know what the results are till the study reaches its endpoint.

Charulatha Gaidhani: **My last question pertains to what was the timing of the Glargine launch in UAE?**

Arun Chandavarkar: I think it was in the middle of last year.

Sumit Modi: **Thanks for the opportunity. I actually wanted to understand what are the challenges or milestones on our way to launch Trastuzumab in US market? Where I am coming from is, Trastuzumab will go off patent only in June 2019 in US, so how are we….can you give a color on the timeline for the launch in US and before June 2019 can there be a launch in EU?**

Arun Chandavarkar: So when you say what the challenges are between now and then, from an approval related standpoint, the product is approved in the US. We received our approval on the 1st of December.

Sumit Modi: **When are the milestones?**

Arun Chandavarkar: The launch in US is linked with the dates that Mylan has agreed with Roche in terms of their IP settlement. I cannot comment on that because that is a confidential document between Mylan and Roche and we will not be able to make any comments on the exact launch timing. Suffice to say that that settlement will govern the launch timing in the US. That settlement also applies to Europe and will decide the commercial launch timing there as well. In Europe, as we have mentioned, we have re-submitted our file with EMA and hope to receive approval by the end of this year.

Sumit Modi: **That said, can we fairly assume the launch of Trastuzumab won't be before June 2019?**

Arun Chandavarkar: I cannot make any comment on that because as I said, the launch dates are governed by the IP settlement and that is confidential.

Sumit Modi: **Okay, also on Pegfilgrastim if at all we get an approval with respect to the target action date in June, what is the time line you expect for the launch in the developed market….just a color or flavor on it?**

Arun Chandavarkar: I think Mylan has guided that if we get approval in June then they would target to launch in the second half of this fiscal.

Sumit Modi: **Okay so this would be faster than Trastuzumab?**

Arun Chandavarkar: Well, I won't compare the two, I will just say that Pegfilgrastim will be launched in the second half. I am not making any comment on the Trastuzumab launch date because that I said is governed by the IP settlement.

Cyndrella Carvalho: **Just a follow up, ma'am, this question is to you, asking in terms of how would we look at our FY20 considering a lot will be coming in FY20 and there will be almost three biosimilars which we would be seeing in the EU as well as in the US hopefully, so how should we look at FY20 and the way ahead?**

Kiran Mazumdar-Shaw: With increasing performance of our biosimilars portfolio in the market place, we expect a better contribution from the Biologics. The percentage contribution of the Biologics

segment to the overall business pie is definitely going to trend upwards. Being a high value and a high margin business, our margins should also improve once biosimilars become a significant part of our business.

Cyndrella Carvalho: **And ma'am any color that you can help us in terms of the margin profile, in terms of not only the margin profile but the entire business wherein the biosimilars will become a significant portion if everything falls in place as per the expectations. How then we should be able to look at it?**

Kiran Mazumdar-Shaw: Right now we can't really guide as such. While we expect sales to ramp up in 2020-21 timeframe, at this stage it is very difficult for us to make exact predictions because there are so many unknowns in the market place. Suffice to say, that you will see improving contributions of Biologics and improving margins in this business going forward.

Cyndrella Carvalho: **But just a request, maybe a year later or so, you will be any which ways meeting our Biologics and our Resource Services guidance that we had already guided, so if you could at least after a year provide us with some kind of milestone would be great to look at. And just wanted to pick your thought on the kind of capacity ready….do you feel that we are capacity ready in terms of all these growth engines because our MAb facility will be coming in most expected by 21, so should we be ready for all these levers to play on?**

Kiran Mazumdar-Shaw: Like Siddharth commented, that by 2021 we should have a lot of the capacity requirements in place because we are progressing well on the new biologics facility and we have built scale in our insulin business in Malaysia. So looking at all these, we would be in a state of preparedness as we approach peak market share or peak opportunities going forward. So at least by 2021 we should be able to address a large number of these opportunities but like you said, we will be able to give you better color on these opportunities as we enter the markets, and as we see how the market dynamics play, because it is not as simple as the generics business. I think we need to give you a much more accurate forecast on how we see the market once we get into the market, and see how the market is appearing for us in terms of the opportunities ahead.

Dheeresh Pathak: **Siddharth the 1000 crore capex for two years, does it include capitalized R&D or is it excluding that?**

Siddharth Mittal: It is only tangible assets so it does not include capitalized R&D.

Dheeresh Pathak: **Understood. If you have it handy can you give me Biocon ex-Syngene gross debt and cash?**

Siddharth Mittal: Biocon ex-Syngene gross debt would be approximately 1400 crores with cash levels at roughly 700 crores.

Dheeresh Pathak: **Okay got it thank you.**

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