

**Biocon Limited**  
**Q2FY06 Earnings Conference Call**  
**October 19, 2005 at 2:30 pm IST**

**Moderator:** Good afternoon Ladies and Gentlemen. I am Parimala, the moderator for this conference. Welcome to the Biocon conference call. For the duration of the presentation, all participants' lines will be in the listen-only mode. I will be standing by for the question and answer session. I would like to hand over to Mr. Nitin Tandon of Citigate. Thank you and over to Mr. Tandon. Go ahead sir.

**Nitin Tandon:** Thank you. Good afternoon everyone and thank you for joining us on Biocon's H1 results conference call. Joining us from Bangalore are Mrs. Kiran Mazumdar-Shaw, Biocon's Chairman and Managing Director, and her colleagues from the senior management team. Before we begin, I would like to state that some of the statements made in today's discussion maybe forward looking in nature and a detailed statement in this regard is available in the H1 results announcement release which has been e-mailed to you and has also been posted on Biocon's website. I would now like to invite Mrs. Kiran Mazumdar-Shaw to provide a brief overview of the company's performance for the first half and the second quarter in the current financial year. Over to you Kiran. Thank you.

**Kiran Mazumdar-Shaw:** Thanks Nitin, and welcome everyone to this conference call. I would like to start by saying that our first half performance this year should be taken in context of the market situation. If you were to compare it to what the market situation was last year, there was very little competition and then look at this year, the competition has been intense in the market place, Biocon's performance has been comparatively good.

Secondly, I would like to say that we are very satisfied with the kind of financials that we are seeing for this quarter and what we envisaged for the year ahead based on the fact that we are seeing stabilization in our main business, which at the moment happens to be the statins business. At the same time we are also seeing some very encouraging numbers coming in from some of our new businesses, namely, Insulin and immunosuppressants. Also our research services businesses have been delivering very strongly and in this context you are going to see not just Syngene, but Clinigene also delivering.

In terms of overall performance you all have the numbers in front of you and what I would like to really focus on is, the fact that the PAT margins have been maintained at a healthy 22%, which indicates the ability of Biocon to really maintain its business health as such. It is also very important for me to talk about certain opportunities that we see

going forward. I think biogenerics, follow on biologicals are extremely important for Biocon and in this particularly Insulin and GCSF are the immediate opportunities for Biocon. These are, of course, first looking at unregulated markets where we have already made some very interesting inroads with our Insulin business and then going forward we are looking at the regulated markets where the European regulatory authorities have actually for the first time announced the guidelines for four biologics, Insulin, GCSF, HGH, and EPO, and in this Biocon is definitely preparing itself to launch with GCSF and Insulin where we are in a very good level of preparedness in terms of addressing all the guideline requirements.

Now, in terms of our discovery programs, we are making good progress. We are very pleased to see some interim data coming out of our monoclonal antibody programme, and this monoclonal antibody for head and neck cancers that we are developing is something that we expect to seek fast track approval for sometime next year and therefore the next fiscal should capture some market numbers for this particular product. When it comes to oral Insulin, we are progressing on track in terms of our preclinical development both in the US and in India, and we expect to file IND in India and in the USFDA by this year-end, and by the end of this fiscal respectively.

Now, one of the aspects of our financials that I would like to really focus on is the fact that although we have compared Q1 and Q2 results, this by no means is indicative of the fact that Biocon's business should be done on this comparative basis, but what we are trying to show you is the improvement in our financials after having taken that enormous hit in the first quarter, which was largely a result of significant price erosion that we faced. The US market opportunities are something that will kick in from the last quarter of this year. We have been doing a lot in terms of registering our Insulin in different markets. We have 40 registrations in process. In addition to that we have also started partnering with European companies for the European market entry for Insulin and for GCSF. So all these preparations are being made, while we can't disclose the names of our partners just as yet, you will be able to know this once we get regulatory approval for these products.

In addition to that Clinigene's recently announced strategic partnership with SCIREX is proving to be extremely encouraging because we are beginning to see a lot of clinical trial business coming in from the US for Clinigene and this then will translate into very good growth drivers in the future. Syngene continues to do well and we are trying to see how we can differentiate Syngene's model even further because we do realize that the outsourced research services business is again going to be a competitive business given the fact that FTE type businesses tend to be very prone to price cutting. We are already beginning to do that in terms of taking on more project based kind of contracts rather than just FTE based contracts.

Our SEZ status also is a very important development. In recent times we have seen much higher tax charges than what we have seen in the past, and the SEZ status for our new facilities will definitely allow us to have lower tax levels in the future.

So with that introductory remarks I would like to throw this open to question and answers. Thank you very much.

**Moderator:** Thank you very much madam. We will now begin the Q&A interactive session. Participants who wish to ask questions, please press \*1 on the telephone keypad. First in line we have Mr. Ajay Sharma from CLSA. Go ahead sir.

**Ajay Sharma:** Good afternoon. Kiran, I have one question in two parts. First is, last week there was this announcement by one of the large PBMs in the US that they actually dropped Lipitor from their preferred list and I think this could be a prelude to switching to simvastatin generics. How do you see this impacting your volumes, and are your customers already asking you for higher uptakes?

**Kiran Mazumdar-Shaw:** Well, you are right. We also saw this particular announcement and I think it is clearly indicative of switch to generic simvastatin. There was also a mention about the fact that they were looking at a 35 cents per tablet for a 20 mg Zocor tablet which is also indicative of the kind of price level. So, yes, it is a volume play. I think we are all set for that. We are beginning to get some requests for reserving some capacity, but basically the generics business is such that they are not going to book too much at a certain price level. We have lot of request for quantities for pipe filling but the real kind of capacities and numbers and volumes will kick in once the market actually opens.

**Ajay Sharma:** Okay. And the second question pertains to Teva's acquisition of IVAX, how does that impact you because IVAX was one of the non-integrated players who could have been a big potential customer to yourself?

**Ajay Bharadwaj:** I don't think we will be impacted in anyway because IVAX was always working with Teva on number of APIs. So in that sense it is not going to impact us negatively at all.

**Ajay Sharma:** Okay. One last bit if I could squeeze in is, on pravastatin. Teva has actually challenged FDA stance on the exclusivity issue. Now hypothetically if they were to get the exclusivity on 10, 20, 40, how do you see that impacting Biocon?

**Ajay Bharadwaj:** If they get exclusivity then it gets delayed for everybody except them. Lot of people think that this will not be allowed. In all these matters your guess is as good as mine really because it is legal matter and everybody has an opinion.

**Moderator:** Thank you Mr. Sharma. Next in line we have Mr. Nikunj Doshi from Kotak PMS. Go ahead sir.

**Nikunj Doshi:** Yes. Just wanted to understand Clinigene business model. I believe we were doing only the internal studies earlier, so now have you opened up this service to outsiders also?

**Kiran Mazumdar-Shaw:** Yes, what we did was, we wanted to build up capabilities in the whole clinical development area based on our own trials, but the plan was always to be a third party CRO as well, and so we built up strong capabilities based on our Insulin and based on our antibodies and now this is allowing us to really become very effective as a third party CRO. We have already started a large number of trials for companies like Merck and many others, and now we are beginning to see some requests coming in and some business actually coming in from the US, and this is largely happening because of the partnership we have entered into with SCIREX. As long as you are just an India centric player it was difficult to attract global business. They will give you business for the Indian qualification and registration, but it was becoming difficult for us to really get some of the global clinical trials, and now through SCIREX we are getting a lot of this business.

**Nikunj Doshi:** Okay. With regard to the European guideline for biogenerics can you just explain us as to what would be process to get into that market? Will you be required to do some clinical trials out there or on what basis the registrations would be given?

**Ajay Bharadwaj:** For different products the guidelines are elaborate and quite specific. It is not one guideline for all products. Depending on the complexity of the molecule they have put up different guidelines, but clinical trials are not required. You don't need to do clinical trials in Europe on European subjects, if you develop the data on any other population, but it has to be done as a comparative study.

**Nikunj Doshi:** Okay.

**Kiran Mazumdar-Shaw:** Because Biocon has done comparative studies on Insulin, we are very well positioned to take advantage of this.

**Nikunj Doshi:** Okay. So any time line as to when you can be earliest there?

**Ajay Bharadwaj:** See, at the moment these are draft guidelines, so these first have to be made into the Regulatory guidelines and then one has to submit the DMF after conducting extensive characterization of the molecule. This is an expensive and time consuming process, since there are number of things that have to be done. So they

have kept the bar pretty high which will actually allow only quality players to come in. Depending on how fast you work, we see this not before 2007.

**Nikunj Doshi:** Not before 2007. But could you envisage any litigation out there from the original innovator on this even after the guidelines?

**Ajay Bharadwaj:** See some of the molecules like Insulin are out of patent anyway, so they cannot litigate against the product. Whatever objections will be on process patents, but we aren't infringing on any process patent for these products, and they are only being launched after the product is going off patent. This is not like para IV or any of that kind of thing. So I do not see the same level of litigative activity, but then litigation is a matter of when you feel somebody is infringing on your rights, you sue them, so you cannot really predict whether litigation will not happen at all, but it is not as litigative as doing para IV challenges.

**Nikunj Doshi:** Okay, and just last one. I wanted clarity on your SEZ, Does it mean that we are putting up an SEZ project or it is only we are getting recognition as SEZ for our existing project?

**Murali Krishnan:** Biocon Park project, which is coming up in about 50 acres of industrial land, has been recently approved by the Board of Approvals, Central Government as a SEZ. Thereby all the units coming up at Biocon Park such as the fermentation & chemical synthesis facilities, Syngene facilities and the bio-pharmaceutical facilities for manufacture of Mabs, will be governed by the SEZ laws, once we complete the statutory formalities such as Customs bonding etc., . Following that, the entire site would be registered SEZ, which will entitle all the units within the SEZ for 5 year 100% tax holiday followed by a 5-year 50% tax holiday, and thereafter, the units get a further extension of another 5 years of 50% tax holiday if they meet certain investment criteria.

**Nikunj Doshi:** But what would be investments from Biocon's side in this?

**Murali Krishnan:** In phase 1, we have planned invest about Rs. 650 crore at Biocon Park. that site.

**Nikunj Doshi:** Rs. 650 crore, and how would that be funded?

**Murali Krishnan:** The Projects are being funded out of the IPO proceeds, amounting to Rs. 315 crores and the balance will get funded by the internal accruals. This covers all the Projects envisaged over the last two years and includes Syngene, the Biocon's Fermentation & chemical synthesis facility and the new monoclonal antibody facility. Initially these 3 units will get located in the 50 acres of land at the SEZ zone. All these units are separate legal entities and each of them will be governed & entitled for the tax benefits as per the prevailing SEZ laws.

**Moderator:** Thank you Sir. Next in line we have Mr. Amrit Mathur from Business Standard. Go ahead sir.

**Amrit Mathur:** I just wanted to ask a couple of questions, one is why have your manufacturing expenses jumped so much, and two, can you give us a broad outlook for the statins market? Because in the June quarter there was a lot of pricing pressure, so has there been any easing on that pressure? And my last question was, how many new clients have you added in your contract research business?

**Kiran Mazumdar-Shaw:** Okay, so let me answer one question at a time. In terms of the manufacturing cost, I will ask Chinnappa will answer you.

**MB Chinappa:** We have seen total materials cost climb from 50% last year to about 55% in the current year. This really reflects the price erosion in our statins business between last year and the current year. Over the last three quarters we have seen this remain at the same level.

**Amrit Mathur:** Okay. Is the statins price pressure still continuing, because I thought you were saying this morning that it has stabilized.

**Kiran Mazumdar-Shaw:** The price level of statin has stabilized and that is why you are even seeing that there is not much of a shift in the margins as such, it is just that we have shown better top line and therefore better bottom line.

**Amrit Mathur:** EBITDA margins have fallen considerably by about 3%.

**Ajay Bharadwaj:** That is largely because of the price reduction in our statin business in the European market, when compared to the corresponding period, in FY 2005.

**Amrit Mathur:** How many new clients have you added in your research side in the September quarter?

**Murali Krishnan:** Actually the number of clients doesn't make much difference because there could be some clients with only 2 or 3 FTEs or smaller contracts, but there could be one big client who might add about 30 FTEs. So the number of clients doesn't make much sense, but this business has grown over the last half year by over 40%.

**Amrit Mathur:** Okay. Just a last question, you have set up these new manufacturing facilities to gear up for this simvastatin and pravastatin going off patent in America, can you give us an update on that in terms of how you have actually geared up for that, is there any strategy going forward for that?

**Kiran Mazumdar-Shaw:** The strategy as we shared with you last time was that as far as the main markets are concerned these will go off patent in the middle of 2006, and these are large scale generics opportunities. You just heard Mr. Ajay Sharma saying that there is already been a big sort of focus on shifting people from Lipitor to simvastatin and pravastatin in the US, and so this is going to be a huge market opportunity in terms of just volumes, but additionally, we are also working very strategically with some of the companies who are actually trying to build new molecule business out of combination statins. So that is the way we are trying to at least improve our margins on statins.

**Moderator:** Thank you Mr. Amrit Mathur. Next in line we have Mr. Amit Goel from First Global Securities. Go ahead Sir.

**Amit Goel:** Hello. Two questions on the margin side. The first is, we have been maintaining our EBITDA margin on consolidated basis of around 30% but on a standalone basis there is a huge decline even on quarter-to-quarter basis of 100 basis points. That obviously is due to pricing pressure on statin front and the levelling effect is coming from clinical research services and contract research services. Do you think this trend will continue and do we see further margin erosions in biopharmaceuticals on a standalone basis?

**M B Chinappa:** Actually even on a standalone basis, the numbers when compared with the sequential quarter are the same. In percentage points it appears 25% and 24%, but that is the effect of other income which has come off from Rs. 18 million to Rs. 10 million. So the margins are identical between the two quarters.

**Amit Goel:** Can I know the R&D expenditure on revenue side for the first half of this year?

**Murali Krishnan:** R&D expenditure for this half is about Rs. 42 crores, including the capital expenditure, out of which Rs. 10 crores is the capital expenditure.

**Amit Goel:** Sir, this revenue expenditure includes the cost of research services?

**Murali Krishnan:** Yes.

**Amit Goel:** So going into future when we have such aggressive programmes for monoclonal antibodies and oral Insulin do you think this revenue expenditure on R&D would increase and therefore might affect the margins as well?

**Murali Krishnan:** In the next few years, margins will be affected because of substantial increase in R&D spend.



**Moderator:** Thank you Mr. Goel. Next in line we have in Mr. Surjit Pal from KJMC Capital Market Services. Go ahead Sir.

**Surjit Pal:** Hi, I had a question on Insulin product in the US market and the recent progress. What we have seen is Pfizer is planning to come out very soon with inhaler Insulin. Now what I need to understand is that assuming there will be no litigation proposed and your product will have a smooth sailing to get the approval, now how do you see that inhaler Insulin along with the conventional Insulin will be pitched against the oral Insulin? How will you place your product in the market and how do you think your product will compete with existing Insulin?

**Kiran Mazumdar-Shaw:** See, first and foremost when you look at the conventional Insulin or the injectible Insulin versus inhaled Insulin those are very two different kinds of market opportunities, inhaled Insulin is going to be a very expensive product, and the way they will have to position that product is in a very speciality niche segment. So it does not affect our opportunity in the conventional injectible Insulin segment, Although inhaled Insulin is the product that is likely to be in the market first as a non-injectible Insulin there were some concerns about inhaled Insulin, which have been validated, and my colleague in R&D will answer this question.

**Srikumar Suryanarayan:** I think Exubera, which is the inhaled Insulin of Pfizer has recently received positive reviews from the FDA committee and also from the European committee. It is, of course, subject to extensive post marketing surveillance. While it represents a very important advance in terms of alternative Insulin delivery, there are also concerns, which will be scrutinised, but most probably it will be fine. Oral Insulin is a different way in which Insulin is brought into the body and mimic the natural way in which Insulin comes into the body and targets the liver, so we believe it represents an extremely unique segment. Medically we believe oral Insulin will have a significant advantage, over any of the other alternative Insulin delivery forms including inhaled Insulin. Apart from that there is an issue of convenience. We believe any alternative delivery Insulin that is being developed whether it is inhaled or whether it is spray you have to deal with the device, an inhaler, which is in many cases not very conveniently sized. The way we are planning to develop oral Insulin is in the form of a tablet and its far more convenient to swallow a tablet than to cart around any kind of a device. So to summarize what I am saying we are not just looking at a more convenient delivery form, we are also looking at a more medically superior product.

**Surjit Pal:** Over here, as I know that generally the Insulin which is basically injectible are divided into three, long acting, short acting, and medium acting. Now, how do you see that the tablet Insulin or oral Insulin will be used in which part of the existing Insulin?

**Srikumar Suryanarayan:** We will be targeting oral Insulin in very early intervention and it will more likely to be like a short acting Insulin.



**Surjit Pal:** The last question on the Insulin part at present you are in phase two, so what is the procedure to get the product in the market?

**Kiran Mazumdar-Shaw:** We are at the moment in pre-clinicals. We will only start Phase-I early next year.

**Surjit Pal:** So not before 2007-08, we are seeing the product in the market?

**Kiran Mazumdar-Shaw:** Yes.

**Srikumar Suryanarayan:** We are in phase II - B for our monoclonal antibody for cancer, and we hope to see that in the market sometime next year.

**Surjit Pal:** Right. The other question is on financial terms, what we are seeing is sundry debtors has increased quite a lot. If I compare, by around Rs. 30 crore, compared to the growth in sales your sundry debtors growth is quite phenomenal., Secondly, your secured loans, when you are seeing rampant growth for the Company for the next 2-3 years, which has come down at that position also around Rs. 45-46 crore. Now could you throw some light on these two, different perspective, but action in the different angle?

**Murali Krishnan:** If you just look at the gross sales, it is about Rs. 200 crores +, for the quarter - 2 and the debtors levels are also around the same levels. In terms of number of days it is about 90 days / 3 months approximately and thought it was at slightly lower level, last year. While absolute Debtors has gone up in line with sales in terms of number of days or in terms of the percentage to sales, it remains same.

**Surjit Pal:** How about reduction in loans while you need more of money for feeding your growth?

**Murali Krishnan:** Whatever growth we have planned for we have already tied up either out of the IPO proceeds or from the internal accruals that is getting generated. We do not want to take more money and just put it in investments, it has to be put to better use in business. That is why we have obtained commitments / sanctions from the banks, and as and when we need funds, we can avail the same at short notice.

**Surjit Pal:** How much interest you used to bear on this Rs. 45 crore which you have repaid?

**MB Chinappa:** This used to be export-packing credit, which had an average interest cost of about 3% per annum.

**Moderator:** Thank you Mr. Surjit Pal. Next in line we have Mr. Madhusudhan Bagree from Citigroup Global Markets.

**Madhusudhan Bagree:** Can you give us some idea as to your three main businesses, the biopharmaceuticals, enzymes, and contract research, which way are the margins headed for these three businesses?

**Murali Krishnan:** The margins in each of the individual businesses have been more or less constant. The contract service business contributes about 12% in terms of revenue, biopharmaceuticals about 80% and enzymes business about 8%. In terms of margins contract research contributes about 40% and the other two business segments have an EBITDA margin of about 30%.

**Madhusudhan Bagree:** Okay, so there has been no major change in the profile for other businesses?

**Murali Krishnan:** No, there has been no major change as of now.

**Moderator:** Thank you Sir. Next in line we have Mr. Indrajit Singh from BRICS Securities. Over to you Sir.

**Indrajit Singh:** Hello, I just had a couple of questions, the first one is on your European generics market, as you going to go for a tie up route because the product would not be substitutable at pharmacy level, so you may need to have your own front end, is that right?

**Ajay Bharadwaj:** We plan to work with leaders in various markets in Europe, the major markets. We are definitely tying up with people, because we don't have marketing and sales forces and neither do we intend to create a marketing and sales force in European countries.

**Indrajit Singh:** Can you comment on biogenerics in US? What are you hearing from the regulators there?

**Kiran Mazumdar-Shaw:** What we hear is that early next year they are likely to announce similar guidelines as to what EMIA has announced. So we have to wait for that and then take a call.

**Indrajit Singh:** So, do you expect it to be similar is going to be product by product regulations?

**Kiran Mazumdar-Shaw:** We believe so.

**Moderator:** Thank you Mr. Singh. Next in line we have Mr. Ravichandran M from Unifi Wealth Management. Go ahead Sir.

**Ravichandran M:** I have only one question, did you get the water connection for your new plant, and what is the status?

**Kiran Mazumdar-Shaw:** Yes, we did get the water connection.

**Ravichandran M:** And how are the simva bulk prices moving? Did we have a big drop over the last six months?....

**Ajay Bharadwaj:** Some of it has gone down. Different markets behave differently, but what has happened is, as I was explaining earlier the prices of formulation in major markets have collapsed. In UK and in Germany there has been a very big pressure and these are the major markets in Europe. There has been a very serious collapse in the price of formulations. As a result the whole supply chain all the way back to the API is affected. So the pressure on margins comes from basically overall competition in the market.

**Moderator:** Next in line we have Mr. Rahul Sharma from Karvy Stock Broking. Go ahead sir.

**Rahul Sharma:** Just looking at the quarterly numbers for the sales, we have seen growth of around 6% in biopharmaceuticals. And is it that Insulin and our domestic formulations has been the main driver for the growth? Could you please give some clarity on it?

**Kiran Mazumdar-Shaw:** Yes, you are right, the Insulin and domestic healthcare business has definitely given most of that growth.

**Rahul Sharma:** How much Insulin have we done till date for the current year in terms of revenue?

**Murali Krishnan:** Unfortunately, we can't share those individual numbers, product wise or territory wise, but definitely they have started contributing to the revenues.

**Ajay Bharadwaj:** See, what we have been saying is that our effort to sell newer products and move away from what about year and a half ago was a reliance on just statins is paying off. We are making gains other products other than the statins.

**Rahul Sharma:** How many registrations have we got and in how many countries are we selling the Insulin?

**Kiran Mazumdar-Shaw:** We are selling Insulin in about seven or eight countries right now, but we have got about 40 registrations in the process.

**Moderator:** Thank you Mr. Sharma. Next in line we have Mr. Ashwin Aggarwal from Akash Ganga Investments. Go ahead sir.

**Ashwin Aggarwal:** Hi, I just have one question whether our statin facility would be FDA approved for manufacturing for the Q4 as we indicated?

**Kiran Mazumdar-Shaw:** Yes, we expect it to be.

**Moderator:** Thank you Mr. Aggarwal. Next we have Mr. Alok Dalal from India Infoline. Over to you sir.

**Alok Dalal:** What is the reason behind the higher tax outgo, and after you are accorded the SEZ status, what would be your effective tax rate?

**MB Chinappa:** The higher tax outgo is again because of higher sales in the domestic market including what we spoke about in domestic formulation business. Once the exports start picking up, especially in the US market, you will see the steady decline in the tax rate. Our Insulin profits will also be tax-free. So we should start seeing a decline in tax rate starting from next quarter. However, there would be a one time effect of deferred tax on capitalization of the new facility.

**Alok Dalal:** Can you put a number to the effective tax rate?

**MB Chinappa:** I will get back to you on that.

**Alok Dalal:** All right sir, no problems. Thank you sir.

**Moderator:** Thank you sir. Next in line we have Mr. Rahul Baijal from Voyager. Go ahead sir.

**Rahul Baijal:** The question on the research services front. Do you think that for Syngene and Clinigene as you do more and more third party services, the linkages with Biocon will help or hinder scaling up the business model versus the clients, specially keeping in mind that other competing business models are emerging from India? Can you throw some light on that?

**Kiran Mazumdar-Shaw:** Yes, actually it is helping a lot because many of these companies are beginning to look at Biocon's capabilities as an additional step in this

contract with Syngene and Clinigene. From that point of view Biocon's involvement in these companies is really helping a lot.

**Rahul Baijal:** And what about potential conflicts of Interest, are clients comfortable?

**Kiran Mazumdar-Shaw:** I think all our clients are very comfortable in this respect because we have demonstrated it quite adequately that these are standalone businesses and there is absolutely no question of linkages between Biocon and these companies as far as the businesses are concerned.

**Rahul Baijal:** Right. And one more small question, it was also mentioned that EBITDA margin in research services are around 40% or so. So when the business model evolves from an FTE base to more of a project based kind of a model, do you think margins will go up or margins will go down from here?

**Kiran Mazumdar-Shaw:** No, I think it should be maintained, if at all it might go up marginally, but I do not think it will go down because we are just trying to differentiate our business model.

**Moderator:** Thank you Mr. Rahul Baijal. Next is a follow up question from Mr. Ajay Sharma of CLSA. Go ahead sir.

**Ajay Sharma:** Just one question on the combination products with Zocor, Kiran, I do not actually know which products could be added so if you could just give some highlight, are these the ARVs like Diovan or you are looking at Plavix, what kind of products?

**Ajay Bharadwaj:** Well generally in the cardiovascular area, either anti-hypertensives or anti-diabetics is the typical kind of profile of products which can be combined.

**Ajay Sharma:** And if these were to go through in terms of volumes, could this be around 40 to 50 tons in the US like we have for the pure simvastatin? Just to see a ballpark, where does this take?

**Ajay Bharadwaj:** These are going to be new molecules, so obviously you know they will be branded products. The success of those products is hard to predict. The volumes can be very large, but even in the worst case they will be large.

**Ajay Sharma:** Okay, and do you think pricing for these would be better than pure generic customers?

**Ajay Bharadwaj:** Again, it is reasonable to expect that it would be better than just the brutal pricing that one sees in generics, but as regards the prices, even the branded companies are aware of generic pricing, so it does have a bearing on that as well.

**Ajay Sharma:** Okay. And one more long-term question is that, do you want to get into formulations in the US? You have just filed the DMF for tacrolimus as well, but do you think being just an API player at the back end is enough, or in five to ten years you would have to be a formulation player with a front end in the US?

**Kiran Mazumdar-Shaw:** Not in the generic space. I think we would certainly look at having our marketing in the biotech space if some of our new molecules are successful.

**Ajay Sharma:** No Kiran, just what I was trying to ask is if you had for example the ANDA of tacrolimus and then you gave it to your customer, would there be more stickiness and captivity, is the customer more captive? Can he probably switch during patents through a different DMF, but will ANDA make your customers more captive?

**Ajay Bharadwaj:** What you are saying is, if we were to develop our own dossier and then distribute it through partners. Yes that is something that definitely secures the business. We are looking at that, we have been developing those capabilities. We are putting in place formulation development capability but we do not intend to be marketers of formulations.

**Moderator:** Thank you Mr. Sharma. Next is a follow-up question from Mr. Amit Goel of First Global Securities. Go ahead sir.

**Amit Goel:** Can you throw some light on third party contracts Clinigene is having till date? What kind of revenues we are expecting from Clinigene from coming two-three years?

**Dr Arvind Atingal:** With regard to third party contracts, it can be classified as clients from the domestic pharma sector, multinational pharma clients for Indian registration, and multinational pharma clients for global studies where the Indian part of it is being done here. These are the three categories, and currently we are doing about half a dozen in total and we expect this number to increase rapidly with the SCIREX collaboration. We are in advanced stage of discussion to do trials in India through the SCIREX connection. In terms of revenues, I cannot say at this minute of time.

**Amit Goel:** Can I have a ballpark figure?

**Murali Krishnan:** In terms of exact numbers, we won't be able to provide that, but as a percentage, it could contribute about 3-5% of total turnover in the next 3 years.

**Moderator:** Thank you Mr. Goel. Next in line we have Mr. Nimesh Desai from Motilal Oswal Securities. Go ahead sir.

**Nimesh Desai:** I just wanted you to throw some light on your enzymes business, particularly why it has not performed during the quarter and what is the overall outlook for this business?

**Ajay Bharadwaj:** First of all, I think it is wrong to say it hasn't performed, it has remained flat. It is a business that is profitable. Generally the growth in the enzyme market worldwide is not so high, so it does reflect that, and I think going forward we do expect it to maintain the same level of percentage of our business as it has in the previous year. We are not investing in creating more facilities for enzymes, but the enzyme business is a robust business and we do expect it to keep contributing in the same region of 8 to 10% of our revenues.

**Nimesh Desai:** Enzyme business compared to your biopharmaceuticals business?

**Murali Krishnan:** Yes, the overall revenue contributory is about 8%, and what Ajay was trying to say is that we are not investing in any facilities to create more capacity for building up enzyme business. All the new contributions or investments are happening in the biopharmaceuticals business.

**Moderator:** Thank you Mr. Desai. Next we have Mr. Rakesh Nayudu from Mehta Partners. Go ahead sir.

**Rakesh Nayudu:** Can you throw some light on your statin strategy for the US market considering the fact that there are 11 players in pravastatin and 8 in simvastatin, and it is very likely that we may have a similar kind of pricing pressure that we have seen in Europe. So can you tell me what is your backup plan for this? And two, you have said that you will be supplying combination products also, so is Vytorin a part of that strategy?

**Ajay Bharadwaj:** The strategy, we have is to have many customers who have our DMF on their file, on the ANDA. So far we have some approvals and of course the number of approvals are still awaited, so I do not know how this number has come about ?

**Rakesh Nayudu:** 11 for prava, and 8 for simva.

**Ajay Bharadwaj:** They are filed.

**Ajay Bharadwaj:** But these are not approved yet, but if you look at lovastatin also there were about 20 filings and finally only three or four approvals. So what will happen, all this will become clearer closer to the date of expiry of patent, and we will be there with number of players but it is very difficult to predict what will be the price erosion, what will be the level of competitiveness on the day of the launch. I know for a fact that quite a few of the people who have put us in their ANDAs have passed their bio and are going



ahead with their launch. We also have initial expression of interest on supplying them their launch quantities. So we will be giving them material for launch quantity. After that what happen really is very hard to predict to be very honest.

**Rakesh Nayudu:** Okay, and can you throw some light on the combination products that you are talking of?

**Ajay Bharadwaj:** Well those are products which are branded products, so these are going to come on. They will have to go through or are going through full clinical trials and all the rest of it, and they will be launched subsequently by branded companies in the year 2008-2009 or after that.

**Moderator:** Thank you Mr. Nayudu. At this moment, there are no further questions from participants. I would like to hand over the floor back to Mr. Nitin Tandon for final remarks. Over to you sir.

**Nitin Tandon:** On behalf of Biocon's management team I would like to thank all of you for participating in this conference call. The transcript of this conference call will be available on Biocon's website in about 72 hours. Thank you once again, and I will just pass on the floor to Kiran for her closing remarks.

**Kiran Mazumdar-Shaw:** I would just like to thank all of you, and please if there are any clarifications or further information, do not hesitate to contact us. Thank you very much.

**Moderator:** Thank you madam. Ladies and gentlemen, thank you for choosing WebEx conferencing service. That concludes this conference call. Thank you for your participation. You may now disconnect your lines. Thank you and have a nice day.