



Strides Pharma Science Limited's
Q2 FY'21 Earnings Conference Call"

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- MANAGEMENT:**
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– FOUNDER & NON-EXECUTIVE CHAIRMAN
 - 2. DR. R. ANANTHANARAYANAN**
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MODERATOR: MR. ABHISHEK SINGHAL

Moderator: Ladies and gentlemen, good day and welcome to the Strides Pharma Science Limited Q2 FY'21 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal the operator by pressing '*' and then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Abhishek Singhal. Thank you. And over to you, sir.

Abhishek Singhal: Yes, very good evening and thank you for joining us today for Strides Earnings Call for the Second Quarter and Half Year-ended Financial Year 2021.

Today we have with us, Arun -- Founder and Non-Executive Chairman; Dr. Ananth -- Chief Executive Officer and Managing Director and Badree -- Executive Director and CFO to share the Highlights of the Business and Financials for the Quarter. I hope you have gone through our "Results Release" and the "Quarterly Investor Presentation" which have been uploaded on our website as well as the stock exchange website.

The transcript for this call will be available in a week's time on the company's website.

Please note that today's discussion maybe forward-looking in nature and must be viewed in relation to the risk pertaining to our business.

After the end of this call, in case you have any further questions, please feel free to reach out to the Investor Relations Team.

I now hand over the call to Arun to make the opening comments.

Arun Kumar: Thank you, Abhishek and good evening, everybody. I hope all of you being safe in these circumstances that we live in.

Before I start, like Abhishek mentioned, along with me today, we have Dr. Ananth and Badree, and also other members of the team to support us to address any specific questions.

Given the situation that we were in the last quarter especially being in Bangalore which was a hot bed for the COVID cases in India especially in the South of India, we were impacted by intermittent disruptions in our manufacturing. But having said that, I believe given those circumstances, we have come out with a fairly steady set of numbers. Our strategy is in place, our order books are full. We had some challenges as one would imagine our priority was for safety and health of our people. We are now pleased to say that our plants are back to normalcy and we are executing to plan. Consequently, you will see probably a shift towards H2. Some of it like in the US market would be driven by the fact that we have had improved market share. You will also notice commentary for the first time that the company did have some challenges on a couple of its products on his base products which are the larger commodity products that we operate at the base of our pyramid. Having said that, we have leveraged our recent product

launches in the US, managed to retain our fairly significant gross margin, albeit growth being tepid, we are very confident that you will see significant growth coming back in H2. Given the circumstances, our primary obligations during the quarter was to prioritize key accounts. We did see a depletion of our standard safety stocks in the US given that we had supply disruptions but that safety stock actually played in our favor

The dampener, of course, has been the other regulated markets and especially our businesses to Australia which as most of you know have got significant flow through margins from gross margins to EBITDA. That has been impacted by the fact that our dedicated Australian facility was the most impacted in the cluster of our manufacturing units. Having said that, the plant is now fully operational. We are working extra shifts to ensure that we catch up on lost ground. Given all of these circumstances, we have in my personal view done fairly well coming out from very constrained situations that we all live in.

There would be focus on our US business. I am very confident that we will meet our range that was guided. H2 will be a strong performance. Like I said, our order books are fairly comfortable and we are executing. And considering that now we believe that the COVID cases have come down significantly and we have taken additional precautions to ensure that even with fewer cases we should be able to operate fully. We are quite confident that is behind us and we should have good outcomes in the coming quarters.

With that I am going to request “Ananth to give you More Detailed Opening Remarks” and then “Badree will Comment on Financials” and after that we will open the house for “Questions.” Thank you.

Dr. R. Ananthanarayanan: Thank you, Arun, and hello, everyone. I hope all of you and your loved ones continue to remain safe and well during these challenging times. As Arun mentioned despite COVID-19 related challenges, we have reported a steady Q2 performance. Southern India did see a significant surge in COVID-19 cases during this quarter that did disrupt our operations and impacted manufacturing and supply of products from our India sites. Manufacturing activity was impacted due to the intermittent shutdown. Out of total India workforce of over 3,000 across the facilities, over 400 of our colleagues tested positive through the quarter. We are also saddened by the passing away of one of our colleagues in our Puducherry plant who succumbed to COVID-19. We continue to remain proud of our global workforce for their resilience and their continued commitment and exemplary efforts to curtail this impact during the current crisis period. We continue to pursue a people-first approach and the well-being of our employees remains our top priority

The markets in US, UK and in many parts of Europe continue to witness lower footfalls at pharmacies, lower surgeries in hospitals, leading to lower prescription rates. Disruptions in manufacturing activity led to inventory depletion on few SKUs at our front end as well as stock outs in certain products. Lower order fulfillment predominantly in our partnered business in Europe and supplies to Australia were also impacted. In the light of this, we re-prioritized our

operations to ensure we meet customer commitments and thereby maintained healthy gross margins and EBITDA margins in a constrained environment. The re-inspection of our Puducherry site has not yet occurred as the US FDA is yet to resume offshore audits. Despite these COVID-19 related headwinds, we expect a rebound in H2 of this fiscal year. COVID-19 outbreak is tapering down with significant reductions in number of cases at our sites. Manufacturing across facilities has since returned back to normalcy and we continue to closely monitor the situation. We are pleased with the strong order book for other regulated markets including our supplies to Australia. There is a high focus on inventory replenishment back to our historical level for better customer advocacy.

Let me come specific to the “Results.” We have delivered steady Q2 FY’21 performance that highlights the resilience of our diversified business model. Revenues in Q2 FY’21 at Rs.7,971 million were up 11% year-on-year and in H1 of FY’21 at Rs.15,818 million, were up 12% year-on-year led by continued business momentum. We maintained our gross margins at 61.3% and EBITDA margin at 20.8% in this quarter under the constraints.

Let me take you through the “Performance Highlights across Key Markets.” In the US market: We continue to ramp up our business with the 8% quarter-on-quarter growth to US\$54 million in Q2 FY’21. Our US front end, as you all know, US comprises of partnered business which is the B2B and the front end which is B2C. The US front end grew 25% year-on-year for the quarter and contributes 85% of the total US revenues. Market share for key products continues to be steady and new launches gaining traction. Performance was muted as select products went out of stock during the quarter and we had subdued demand for few products due to COVID. We witnessed price erosion for the first time in very select base products; however, we had significant market share gains on key products that helped mitigate this erosion. Current portfolio build out is well diversified with a basket of market leading products to deliver sustainable growth.

We have received eight ANDA approvals this year. We filed three ANDAs in H1 and expect to file over eight ANDAs in second half of this fiscal year.

Coming to the “Other Regulated Markets”, reported revenues of \$32 million in Q2 representing 30% of our Q2 FY’21 consolidated revenues. The revenues for the first half H1 of FY’21 stood at \$67 million with the growth of 27% year-on-year. Temporary softness in UK and certain European markets along with COVID-related plant shutdowns, led to lower order fulfillment for specific products in the other reg markets during the quarter. Supply to Arrotex in Australia were impacted due to the shutdown of our dedicated plant for a prolonged period during the quarter and we expect to bounce back strongly during the second half of this year. We do have a strong order book visibility and that will continue to drive future growth.

We continue investments in R&D to enrich the portfolio. We have filed eight new products and expect to file 10-plus products in the second half for the other regulated markets.

In line with our previous commentary, Strides regulated market strategy is playing out to plan. Over the years, we have successfully built a diversified regulated market business. The overall regulated markets showed a 15% growth in H1 FY'21 at Rs.12,777 million versus H1 of FY'20 and 20% growth versus H2 of FY'20. We expect to deliver sustainable growth as we unfold a large pipeline of products with market fungibility across our business.

Coming to “Emerging Markets.” Our emerging markets reported a strong performance with revenues at Rs.1,538 million in Q2 FY'21 and Rs.3,041 million in H1 of FY'21, a growth of 34% year-over-year.

The Africa business grew 21% quarter-on-quarter with healthy, primary and secondary sales. While the first half of this year, the H1 FY'21 has seen a strong comeback for Africa, we are witnessing softness in certain therapeutic segment due to lower prescription rates in some markets.

The Institutional business delivered a steady quarterly performance. Country-specific registrations for the key product which is Tenofovir/Lamivudine and Dolutegravir TLD is on track and the product will be commercialized during second half of FY'21.

As indicated earlier, although Q2 has been impacted by COVID-related headwinds, we expect a rebound in H2 FY'21 and our manufacturing has returned back to normalcy with a significant reduction in the number of cases across our site.

I would like to reiterate our focus on people-first approach, continuity in operations and supply chain, continued engagement with our customers and conservation of cash.

With this let me pass on the phone to “Badree to Update you on the Financials.”

Badree Komandur:

Good Evening, Ladies and Gentlemen. Profitability, efficiency and growth have been the three pillars on which the entire Strides is built for the last three, four quarters. So these display consistency across all parameters, the profitability and efficiency has been quite good and the growth will definitely come in H2. The gross margins have been very stable at 61.4%. We have told externally that we will maintain the gross margin for 60%. As of Q2, we have done about 61.4%. EBITDA margins, we have done about 20.8% for the Q2 and 20.4% on a half year basis, 70 basis points expansion over previous quarter. The manpower cost has slightly increased mainly because of a pay hike and also COVID-related insurance cost. We expect to be in the same percentage range. Operating costs are very stable. We had a reasonably good quarter in terms of cost management and our R&D cost is about Rs.280 million for the quarter and together on a first half we spent about Rs.530 million. Depreciation and interest on a half year basis is at a consistent trend. ETR at 6%. We have guided the market that we will be between the range of 10% to 12%. We expect to maintain the same outlook of 10% to 12%.

Another pleasing aspect of this year is that we generated an operating cash of 2,694 million. We had payouts because of Ranitidine returns to the tune of Rs.1,200 million. To reiterate, we generated 2,694 million cash on an EBITDA of 3,250 million as of H1. And we also spent about 1,170 million mainly on maintenance CAPEX as well as we also completed most of our expansion plants in West Palm Beach and we also invested 1,653 million, that is 165 crores in Biotech. We have said that we will invest 40 million over a period of 18- months. We have completed 31 million as of this date.

The debt is very comfortable at Rs.13 billion. We had guided the market that it will be between 2 to 2.2. We are at 2 as of Q2.

And I would also like to draw your attention to two important points from the SEBI results perspective. In Q2 FY'20 on a comparable basis, we had a write-back of some of the obligations which were not required to the tune of 1,063 million. And if you see the comparable quarter, the investors have to take these into consideration to compare the numbers accordingly. And in Q1 FY'21, we had an exception gain of Rs.440 million because of a positive exchange rate impacts on AUD related to deferred consideration receivable from Arrow transaction. And broadly the currency has stabilized at this point of time and we do not expect any major movements from the current levels.

So, with this I will pass it on to Arun to give some updates on Biotech and the Injectable business.

Arun Kumar:

Thank you, Badri. It has been a good quarter for the new businesses that we are heavily invested in, in terms of outcomes. So, from a manufacturing standpoint, four of our five manufacturing units are now fully commercial, validated and available for business. From the IP standpoint, our first Biosim which is PTH has been accepted for review in Europe. As guided, it was filed in September and we are now in the review process and we are obviously hoping for a good outcome here. We moved our Glargine dosing by a month mainly because of availability of patient pool for dosing, but that has now been resolved. And then we have a pre-IND meeting for both PTH and for Glargine schedule for this quarter. So we are chugging along on that front.

As far as our vaccines project is concerned, we are building this block in record speed. We are on schedule to go onstream January 2021. Just to be clear that the last time we mentioned 60 million vials which is approximately 500 million doses of liquid vaccines and 300 million of lyophilized vaccines, just for better clarity, we moved that to doses.

We are in discussions with global companies to partner for manufacturing vaccines but we are obviously very selective about that partnership, and we are waiting for the right partner who is already at an advanced stage of having completed phase-I before we take in those licensing. But I think during this quarter, we will have news flow around that.

With that, I am now opening the house for any questions and all of us are here to address that. Thank you.

Moderator: Thank you. Ladies and gentlemen we will now begin with the question-and-answer session. The first question is from the line of Alankar Garude from Macquarie. Please go ahead.

Alankar Garude: My first question is, if we look at our guidance of \$240 million to \$250 million for US FY'21, so that implies a quarterly run rate of about \$70-odd million and you had mentioned about the VA program starting to contribute from the second half and which broadly in my view would be about \$10-odd million dollars. So apart from the VA program, if you could help me understand what are the factors which will drive such a sharp improvement over the Q2 level.

Dr. R. Ananthanarayanan: So yes, at the beginning of the year, we had guided towards the range that you mentioned, US\$230 to US\$240 million range in the US business. As we went through in Q1, we did indicate that we were cautiously optimistic with some of the impacts that were coming from the COVID with softness in the market and at that point we really did not know how much of impact we would have in our manufacturing facilities. Given some of these situations, are we on the trajectory for growth? The answer is yes. Would we be able to be in the 230 to 240? Probably not, it might be slightly around the 230 regions. So that certainly would have an impact for sure but our opportunity with the new product gaining traction continues. Our ability to gain market share continues and we certainly seem poised for the rebound in H2 to be able to get us closer to that.

Alankar Garude: And maybe just a follow-up to that, even for 230, apart from VA program, if you could just help kind of break that growth down in the second half?

Dr. R. Ananthanarayanan: One is the market share from our base products. Some of our base products we have had an advantage where some of our competitors have had disruptions and we have gained market share. So, that is one that will continue to play out during H2. We have seen that during this quarter that will of course come into play in H2, that is one. Second is the new products that we had launched earlier, that continues to keep building on the momentum. That is the second dimension. And to the point that you mentioned on the VA, yes, it was, some of that was to play out in H2 which we still believe will play out in H2. So, it is a combination of all the three that will help us progress towards that direction.

Alankar Garude: You mentioned about fungibility of portfolio in your opening remarks. Now barring this COVID-19 disruption in the second quarter, where are we currently in terms of progress towards maximization of our US and Australian portfolios in the other regulated markets?

Dr. R. Ananthanarayanan: So we continue to progress on the portfolio maximization. As I said, our R&D focus on filings in the other regulated markets is on an increased level, number one. Number two, we have picked up the filing momentum as I indicated in my commentary just now, we have already filed eight products in H1 and we are going to file able to file another 10-plus products in the other regulated markets. Now all of these are coming in through maximization of the portfolio that we have with the IP from the Australia market.

Alankar Garude: And any ballpark number which you can provide as to how much of this maximization we have achieved till now and how much can play out over the next few years?

Dr. R. Ananthanarayanan: We have significant leeway to do on filings in the other reg market. So there is still a lot of headroom for filing. We will continue to focus on increasing our filings for the other reg market. If you recollect our commentary in the past, we said that the investment that we needed to do to file for the US, we are almost coming towards the end of that investment cycle, and all the investments in the R&D are oriented towards the other reg market. So, there is a lot of headroom still for leverage of that portfolio and we will continue to focus on that... I cannot give a very specific comment on how much percentage but yes, there is a significant number of filings that will continue to happen through the second half of this year, but also into next year and so on.

Moderator: Thank you. The next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: Ananth, on the TLD opportunity, two things; one is how competitive are we on this product and what kind of addressable market size would we be participating in this opportunity?

Dr. R. Ananthanarayanan: So let me answer that in two parts; one is the TLD opportunity that we have currently now, is with the WHO PQ approval that we have received, part one. Because of the WHO PQ approval, we have now already filed dossiers for approval in countries that have WHO collaborative procedures for approval as well as in countries in Africa that follow the (NMRA) National Medicine Regulatory Agency procedures which is individual countries where we need to file. And all of these have been done. We expect the approvals to keep coming during November and December and we should keep getting those and therefore it enables us to participate specific to all the opportunities that come through the global funds into these countries. The second part of the TLD for us is the PEPFAR-related area and that is an area where we are looking to file. The work has progressed significantly. We will be filing pretty soon. And once that is done, then we will also have the opportunity to participate in the PEPFAR-related contracts. The opportunity that will start off in H2 will continue through into the next year as well as all of these approvals come in place.

Nitin Agarwal: Ananth, between the two, what is the opportunity size addressable market for us to sort of participate in, in rough sense?

Dr. R. Ananthanarayanan: The addressable market from the WHO approval perspective is about \$200 million to \$300 million, that is the overall addressable market. And PEPFAR market is at least another 200, 300 million market.

Nitin Agarwal: And we should be able to get some fair share of this \$400, \$500 opportunity over a period of time?

Dr. R. Ananthanarayanan: We will work to get some fair share of that market.

- Nitin Agarwal:** Secondly, on Levothyroxine, any update on that?
- Dr. R. Ananthanarayanan:** So, we did receive an acceptance of the file from FDA, which is a positive news. They did come back with a very initial information request which is a minor clarification on one of these sections which has also since been provided. So, it is under FDA review. The fact that one is acceptance plus the second receiving an information request, gives us a very positive signal that FDA has already started their review.
- Nitin Agarwal:** Arun, you mentioned the Stelis business and SteriScience business, if we take a two, three year view of these businesses, what should one look out for a very high level in terms of value creating opportunities in these businesses, and in the near term until that period of time will we see drag on the consolidated financials once the target is consolidated?
- Arun Kumar:** So, if we look at the business, it has got CDMO part of the business which includes biological, we have now started onboarding customers and validation work is happening, COVID is not supporting, customer audits and stuff like that, but in spite of that we have started onboarding customers, we expect from a manufacturing recovery, that should be in line for next year. We expect SteriScience to file approximately 15 ANDAs in the next financial year. There is a lot of work that is already happening, including the first filing from SteriScience for a proprietary injectable in a device within this financial year and we expect approval flows to happen in nine to ten months, and, of course we have already filed our Meropenem dossier, we expect an approval by May of next year in Europe,. So by second half of next year, I like to believe that we should be aiming at an operational breakeven in the combined SteriScience and Stelis business.
- Nitin Agarwal:** And lastly, Ananth, did we get any opportunities in a portfolio to participate in any of the COVID treatment options in any meaningful way, that has been essentially one, most companies have enjoyed over the last six months or so?
- Dr. R. Ananthanarayanan:** I would not say very specific to COVID treatment but there have been products that have been used in symptomatic treatments from some of the products in our portfolio and obviously some of those products we see some full in those but we do not have anything which is very specific too.
- Arun Kumar:** Nitin, I think you are specifically referring to Favi which we announced first off the block amongst Indian companies. We do not sell in India as you know. I must tell you that we have also become now the first company to have successfully completed a bioequivalent study to the innovator and we are very focused on being able to sell the product at the right price point and in the regulated manner. I am not suggesting what is sold in India is not, it is just that we do not have the infrastructure and capability to sell in India. We are not set up for that. We just want some more clinical evidence to emerge and there is a lot of work happening. I think you will see some news flow around that, give us a couple of weeks and then we will come back to you on that.

- Moderator:** Thank you. The next question is from the line of Anmol Ganjoo from JM Financial. Please go ahead.
- Anmol Ganjoo:** My first question is to Badree. Ranitidine recall, the charge of 60 million, we have seen an impact of that on cash flows. What is the P&L treatment of that?
- Badree Komandur:** It has been taken in Q4. We had accrued for \$21 million in Q4 for recall plus the returns in Q4 results and getting paid in the current quarter.
- Anmol Ganjoo:** Secondly, the withdrawal of export incentives, a) the impact of that for the full year and any impact do you see on a gross margin trajectory in the next year, any thoughts on that and what you are budgeting and what is the incremental impact on that count?
- Badree Komandur:** In the first half, we did not have much of an impact. Whereas the yearly impact is about \$6 million so the half yearly impact will be about \$3 million, that will definitely reflect in H2
- Anmol Ganjoo:** And we would have mitigants to that by the way of process improvements, product mix, etc., or you think that this...
- Badree Komandur:** We have to work on all of that.
- Anmol Ganjoo:** Second question is on the US. Dr. Ananth, is this pricing pressure that you were alluding to broad-based or it is limited to some specific products where we could see some kind of a turnaround going forward, can you just give more color on pricing pressure after many quarters?
- Dr. R. Ananthanarayanan:** Sure, Anmol. So as I said this was pretty much the first time we have really seen a pricing challenge or pricing pressure coming into us. It was certainly in a couple of our base products, we did not see it all across, we did see it in a couple of our base products. Having said that, we had a pretty good market share gains in some of our other key products that we have been able to take advantage of to overcome the pricing pressures that we have. The reason we are bringing it is that this was really the first time that we have seen in any of our products. So this certainly was a new one for us.
- Anmol Ganjoo:** Just a follow-up on this; so basically we did around \$54 million and if you kind of adjust for Ranitidine which is still a degrowth. So you expect this to cool for the rest of the year? I know you alluded to \$220 million, \$230 million kind of a number, but on a sustainable basis, is US now on its way of consistently doing in the neighborhood of around \$60 million quarterly run rate?
- Dr. R. Ananthanarayanan:** So we will be able to show sequential growth in the US business. We are certainly confident of coming back as I said in H2 and demonstrating that. Certainly we should get to an exit run rate that should be able to give confidence of getting towards the guidance that we had said and then further grow beyond that into the Q1 of next year.

Arun Kumar: Anmol, just add to Ananth, Arun here. What one needs to appreciate is that in spite of Ranitidine like you correctly alluded, we have been growing quarter-on-quarter on our front-end business and that has been reflected even in the last two quarters post-Ranitidine. We have a very measured way of introducing products in the market. We have not changed that. It is reflected in the gross margins that we continue to deliver in spite of Ranitidine been one of our largest margin products. So that is very important to understand and appreciate in our model. This is a slow and steady climb QoQ, but what we do is sustainable and there are no one-off in what we present in the US numbers.

Dr. R. Ananthanarayanan: Just to remind, as I said in my commentary earlier, the front end grew by 25% year-on-year for the quarter. So that is something to keep in mind as well.

Anmol Ganjoo: My second question is to both Arun and Dr. Ananth. When I look at the amount of COVID impact for the quarter, 400 out of 3,000 000 employees impacted, that is fairly widespread disruption. Congratulations for navigating that well. But a natural follow-through of that would be that there will be a lot of pent-up opportunities for which there should be a spillover in the next quarter or at least H2. So if you could just directionally quantify what is it that of the business which is permanently lost as a consequence of fairly widespread COVID impact in the organization, one of that is permanently lost or would potentially come back because a lot of that is manufacturing disruption in the reg market, so that would be helpful because I think it is fair to assume that some of the business would just go away?

Arun Kumar: Anmol, to answer your question, no business or no business lines or customers are being lost. What has happened or what could have happened or what may happen is that we will incur some incremental cost which we probably have already done in the last couple of months instead of sending by sea, we send goods by air to maintain a higher level of customer advocacy. So, there is really no permanent loss of any business that has occurred. It is a catch-up that we have to do and now that our plants are back to normalcy, we are very confident that H2 will start reflecting those actions that already we are seeing witnessing in our manufacturing operations. So we do not do any spot businesses as a company, either all long-term contracts based on very measured approval launch strategies and we do not do any opportunistic businesses.

Anmol Ganjoo: Now, moving on to the Biotech part of the equation, so we have Rs.30 crores loss here. I know you alluded to some numbers in terms of what our overall investment is going to be. But what is the key monitorable that we should be looking at in terms of this assuming the critical size that we have been excited about for some time, so any few points that you want us to monitor and which could be around any recent timeframe nearby?

Arun Kumar: Anmol, you must appreciate that the Biotech business is a high CAPEX and extremely long gestation business. We are in the cusp of having completed that cycle. So the heavy lifting, the investment phase, we have taken all that hits, right. We are now commercial in four of our five manufacturing blocks. We are onboarding customers. This is a small operating cost structure but a high CAPEX structure. So it is very light on OPEX, it is very high on CAPEX. We have

completed the CAPEX cycle. You will probably see OPEX leverage. This is a business where gross margins are significantly higher than what the company does today and the line items on OPEX is very low, so the EBITDA margins are significantly higher as is the case for most other companies. I think we are about 15, 16-months away before you can see the hockey stick situation in this vertical. That is mainly to do with the work that we are doing in SteriScience because that is the injectable business that will create quicker outcomes because the cycle time for approval is shorter. Programs like PTH, there is only one generic player in an \$800 million product. So all of that adds this confidence that this is a business that will play out to plan. It is taking a lot more time than what one would like to see but that is the nature of this business, it is a 7 to 10-year investment if you are a pure play regulated market player. We do not have so much of an emerging market strategy as you will know. So, our products developed are for global standards, it takes time to develop products, clinical studies a little more complex, more expensive. I think an operating break even should happen fairly quick followed by an EPS accretion in that 15 to 18-months timeline.

Moderator: Thank you. The next question is from the line of Vinay Bafna from ICICI Securities. Please go ahead.

Vinay Bafna: I have a couple of questions: So firstly, on the Puducherry plant. So I understand that we are awaiting inspection from FDA. And I think earlier you had mentioned that about four to five critical products are filed from this plant. As you have not seen any time from the USFDA for any reinspection, there is a possibility that a clearance for the warning letter on this plant may take some time. So, how long before these products lose viability or the criticality in the nature?

Arun Kumar: I think you were not probably very clear. So for Ananth's benefit I am going to address your question. Puducherry has got only one critical product, that is material, everything else is not so important and we have otherwise found another home for it. So we are not so much concerned about it. The one product that is very critical continues to be in a CGT category in the FDA for the last four years, five years so whenever CGT started. We have a few queries that the FDA has asked us to do. We are continuing to do that work, so that means we are engaged with the agency. We are hopeful that the recently received closure of inspection from Europe for the site after the FDA events would be a document that we could provide to the FDA, FDA has asked us to give more information around that which we have and which we will provide as a supportive, and see if we can try and get an approval quicker. But outside of that one product, nothing is material or that has already not been mitigated. If you recall, when the warning letter was issued, we did mention that we will take those products to other sites, anything which is material, will be taken to other sites which is what we have done.

Vinay Bafna: Another question that I have in the Stelis part. So I understand that we are going to commercialize the vaccine part of the business sometime in Jan '21 and we have a thousand of operational breakeven in H2 '22. How important is the whole vaccine portfolio or the manufacturing unit to perform with COVID for that breakeven, I mean, how critical is that?

- Arun Kumar:** It is not. Just like I mentioned to you that the vaccine, indicative timelines that I mentioned today were the same that were mentioned even before we decided to set up the vaccine line. So the vaccine potentially just accelerates the timeline or creates a different opportunity. Also, for clarity, we have never said that we will be manufacturing vaccines by January. We said our site will be ready. We are working with partners. It is a function of getting the right partner. It is a function of the partner getting the right clinical outcomes on a COVID product. So before we get super excited that we have 500 million doses that we can potentially produce, a billion dollars worth of vaccines, I think we should just be realistic that the vaccine block is designed in such a manner that you can produce vaccines, biologicals or other injectables and we do not make certain types of vaccines like live vaccines for this particular reason. So I would like to believe that this gives us an additional opportunity, but this is not the pivot for that platform.
- Vinay Bafna:** I just need one clarification. So on Meropenem, you said that you are going to file it in May and then we are accepting approval a year later or the approval is expected in May?
- Arun Kumar:** I said the Meropenem dossier has been filed in Europe and we expect approvals to come in from May.
- Moderator:** Thank you. The next question is from the line of Bhaskar Bukrediwala from ASK Investment. Please go ahead.
- Bhaskar Bukrediwala:** Just wanted to understand couple of things on the US portfolio. What is the price erosion if at all we are seeing on the portfolio as of now? And in terms of our existing products, what sort of growth are we seeing and therefore as a combination of price erosion plus the growth into our existing products, what is the sort of growth visibility that we have?
- Dr. R. Ananthanarayanan:** So as it relates to erosion specific to products we do not disclose those. You would appreciate we cannot get into those granular details. In terms of growth, we have said that some of our critical products have had jump up in market share and the jump up has been pretty significant and that is going to help us to continue in our growth trajectory to get the overall business growth that we talked about the US and the other regulated markets put together, the regulated markets growing at 20%. So, the market share gains will help us in that trajectory.
- Bhaskar Bukrediwala:** I understand that you would not like to talk about specific price erosion, but broadly in the US market, has the price erosion largely come down, would it be more in the range of 3% to 5%...?
- Arun Kumar:** I think you should take this in the spirit of our open communication. We have been consistently saying in the last 12-quarters that we have no price erosions, that is a statement of fact. In this quarter, we have seen for the first time price erosions on two or three products. Having said that then there is no erosion on gross margins and there has been growth. You will understand that there has been price opportunities or increased market share that have also occurred. So it is a combination. We are just making a statement because we provide a lot more granularity around price erosion because if you check Symphony for the last 12-quarters, you will not see any price

erosion from us. And if you check now, you will see. So that is the reason why we have been upfront with this information, but that does not mean that the business is at risk or the growth is at risk. It is contrary. We are saying that in spite of that we have maintained our margins and we have increased our growth.

Moderator: Thank you. The next question is from the line of Tushar from Motilal Oswal. Please go ahead.

Tushar: Just would like to understand, given the number of employees that got impacted by COVID, so was there any one-off incremental expense associated to that in this quarter or we will have it in the coming quarters?

Dr. R. Ananthanarayanan: We have taken some insurance for COVID for employees. In the H1 results, it is about 2 million.

Tushar: Just on this net debt number, so any guidance would you like to give?

Dr. R. Ananthanarayanan: Between 2 and 2.2 range. Our net debt is at Rs.13 billion and we hope to maintain that range.

Moderator: Thank you. The next question is from the line of Tushar Bohra from MK Ventures. Please go ahead.

Tushar Bohra: Sir, you mentioned a couple of times in the presentation as well as on the call on product stock-outs or supply related disruptions which impacted your portfolio. Just want to understand if there was any penalty or any kind of payouts related to that or if you could quantify the total opportunity loss for us relates to these product stock-outs across markets?

Dr. R. Ananthanarayanan: Yes, we did have very marginal impact on penalties, nothing very significant to report in it, but the major impact was on our inventory that we hold in market and we have always been saying that has clearly been our strength for ability to turn around and quickly provide products to the market. So our inventory has got depleted quite a bit because obviously the manufacturing was interrupted and in a very limited number of products we had stock outs, but specific to penalties was very marginal.

Tushar Bohra: Just to follow up on that, we see I think about Rs.150 crores inventory rise in September over March. So we are saying that probably the inventory level should have been much higher or has this just been recouped towards the end of the quarter?

Arun Kumar: This is more accounting and Badri will explain. Badri, do you want to take it up?

Badree Komandur: There are three factors contributing to this; one is that there is an increase in the front-end inventory we have to replenish the stocks and we have to keep more inventory in the front-end. We changed our norms. Second is in terms of consolidation of our German business which we acquired in last year, we started consolidating from the current year, that also contributed to the increase in the inventory plus there have also been some increasing in the manufacturing inventory, just to fill in the stocks.

- Tushar Bohra:** Second, sir, I suppose we are typically entering into the stronger part from a seasonality perspective, H2 also in the flu season being there, we have done about slightly more than 10% growth in H1 YoY plus Europe we had this one off in Q2. Should we expect then therefore even other regulated markets along with US a much sharper YoY growth in H2 over the previous days?
- Dr. R. Ananthanarayanan:** We certainly expect the other reg markets showing a better growth in H2. You are right, clearly, our order books reflect that plus our ability to get the supplies into Australia which was impacted as well as the partnered business in Europe which was impacted will all rebound back in H2, so the answer is yes.
- Tushar Bohra:** Sir, one clarification on Stelis and SteriScience. So, what Arun mentioned was that H2 sometime around this time next year, we should break even operationally on the combined portfolio, Stelis plus SteriScience. But Stelis alone, the guidance was for Q4 FY'21 or maybe Q1 FY'22, that still holds for us?
- Arun Kumar:** No, it was not guided like that.
- Tushar Bohra:** But then can we have some guidance sir? It is Rs.30 crores this quarter on Stelis plus CHC. When do we break even on this portfolio?
- Arun Kumar:** Stelis will take at least a year more to break even, that Rs.30 crores to become zero. But what we are saying is that SteriScience will ensure that there would be a positive contribution.
- Tushar Bohra:** Potassium chloride, we had some recall in this quarter. I suppose that was a big product, although I do not know the size for Strides, but overall it was I think about \$200 million product. What is our guidance sir on that one? When should we be back in the market and was there any impact because of that also for the quarter?
- Dr. R. Ananthanarayanan:** It is not a \$200 million product. The one that you are referring to \$200 million is the extended release one. This is not the extended release one. The product that we had was an isolated case; we had two batch recalls that we did, was an isolated case of the specific batches in question which we obviously withdrew and we have got all the corrective actions in place, so we do not see any impact going forward.
- Moderator:** Thank you. Ladies and gentlemen, we will be taking the last question that is from the line of Alankar Garude from Macquarie. Please go ahead.
- Alankar Garude:** One question on the CGT product which was under regulatory review. Any update on that?
- Dr. R. Ananthanarayanan:** We continue to do the work that FDA had asked for given us a deficiency that we needed to respond to. All the work that we need to do to respond is in progress. And as soon as we complete, we hope to respond back to the FDA and continue the review of that.

Alankar Garude: Any broad timeline sir how much time would it take for...?

Dr. R. Ananthanarayanan: Little early at this time because the work is an extended work that we need to do because it has some bioequivalents component into it and we can probably give a little bit more granularity maybe in a quarter or two.

Alankar Garude: Secondly sir, when do we expect consolidation of SteriScience and Stelis with Strides? I think last quarter we had mentioned at least for Stelis fourth quarter or first quarter of FY'22.

Arun Kumar: Yes, we are still maintaining that.

Alankar Garude: And finally how was the capacity utilization at our Singapore as well as the Florida facilities moved in the last one year? Assuming we exclude this recent disruption where do you expect it to be in the next maybe six to 12-months?

Dr. R. Ananthanarayanan: Singapore facility is currently at about 50% utilization and we expect with more of the product transfers that will happen, that will step up and go up. In terms of the West Palm Beach facility, we should start commercial products supplies beginning towards the end either in December or early January. We are waiting for the CBE30 grant from the FDA for product transfers that we have done for the first product. There are subsequently several other products that are in various stages of CBE30 and so Q4 we will see revenues coming in from the West Palm Beach facility.

Moderator: Ladies and gentlemen that was the last question. I now hand the conference over to the management for the closing comments.

Dr. R. Ananthanarayanan: Thank you very much, ladies and gentlemen for joining us together on this call today. As we indicated earlier, despite the challenging quarter, steady performance, we are pretty excited about the second half of the year and look forward to the rebound. We hope all of you and your loved ones stay safe and well, and we will see you back during the next call. Thank you.

Arun Kumar: Thanks, Abhishek. Thank you.

Moderator: Thank you. Ladies and gentlemen, on behalf of Strides Pharma Science Limited, that concludes this conference call. Thank you for joining us and you may now disconnect your lines.
