“Strides Pharma Science Limited
Q1 FY21 Earnings Conference Call”

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MODERATOR: MR. ABHISHEK SINGHAL
Moderator: Ladies and gentlemen, good day, and welcome to the Strides Pharma Science Limited Q1 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 an operator by pressing "*" then "0" on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Mr. Abhishek Singhal. Thank you, and over to you, sir.

Abhishek Singhal: A very good evening and thank you for joining us today for Strides earnings call for the first quarter ended financial year 2021.

Today, we have with us Arun - Founder and non-Executive Chairman, Dr. Ananth - CEO 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. The transcript of this call will be available in a week's time on the company's website. Please note that today's discussion may be forward-looking in nature and must be viewed relation to the risks 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'll now hand over the call to Arun to make the opening comments.

Arun Kumar: Thank you, Abhishek. Good evening to everybody, and thanks for joining in a little late than our standard call time. We do appreciate your availability at this hour.

Before I start, I do hope all of you are being safe and healthy, not only you, but also your loved ones. We all live in very unique times. And in these circumstances, we continue to manage running a business which is a very important part of these challenging times. And I'm glad that with the new leadership that we have with Strides, we have delivered a very stellar quarter. I'm extremely pleased with Ananth and Badree and the rest of the team for having delivered an outstanding quarter especially given a comeback quarter from the fact that we left significant value and profits consequent to the Ranitidine withdrawal. It's been a great performance, especially in tiring times given COVID. And I must say that we had a relatively easy Q1 in terms of COVID cases especially in Bangalore, now Karnataka has become a hotspot, unfortunately, as days go by. And in this quarter, we see those challenges to be a lot more magnified, and we're working our way through all the challenges that go through that most companies face. But we continue to be confident that we will continue to deliver from here on.

And I will now, without taking away any of the thunder from the management team, request Ananth and then Badree to address the meet today. I will then come back on specifics related to our Stelis business and also the current status of our injectables investments. And I'll take
questions around those businesses, while I'll let my colleagues address all of the questions related to the rest of the business.

Thank you, and over to Ananth.

R. Ananthanarayanan:  Thank you, Arun, and hello, everyone. I hope all of you and your loved ones continue to remain safe and well in these challenging times. Q1 has truly been a bounce back quarter for Strides, post the withdrawal of Ranitidine in the U.S. on the last day of March 2020. We have reported strong performance across all our businesses. This performance comes amidst the significant disruptions and ambiguity that exist in the business environment due to COVID-19. I want to specifically call out our global workforce. And we are proud of their exemplary efforts to keep the operations running during this crisis. We continue to pursue our people first approach, and the well-being of our employees remains our top priority.

In line with our commitments to serve the patients, we have demonstrated resilience and agility, and our manufacturing and supply chain remained steady without major disruptions. Our regulated markets grew by 22% over the previous quarter, and our emerging markets have returned to growth after several quarters. We have delivered 920 basis points quarter-on-quarter EBITDA margin expansion with superior cash flows through a healthy operating leverage. This is a significant uplift from the 68 crores that we reported in Q4 post Ranitidine withdrawal to Rs. 158 crores in this quarter.

Our overall revenues grew sequentially by 26% to achieve about 785 crores in the quarter. We are happy to report sustained gross margins, above 60% for the last 3 quarters, which in this quarter was 61.5%.

Let me now share some specific updates about our markets. Our U.S. business had a strong comeback, growing quarter-on-quarter by 28% to report about 374 crores or US $50 million. This rebound back from US $41 million in Q4 has been achieved within a quarter without Ranitidine on the back of a strong product portfolio. During the quarter, we received 3 ANDA approvals and filed 2 ANDAs. In spite of us leaving about 120 crores on the table due to the Ranitidine withdrawal, new products that were launched in Q4 gained momentum, while we continued to maintain market share without price erosions.

Having said that, we do see some headwinds due to COVID led by lower prescription rates, reduction in elective surgeries and lower footfall in the pharmacy as well as lower reordering by our customers. Despite this, our base business continues to maintain a steady market share. As regards to other regulated markets, business continues to scale and grew 53% year-on-year and 15% sequentially, reporting its highest quarterly revenues of US $35 million. Performance was driven by key front-end markets of U.K., Germany, Nordics, Netherlands as well as our partnered Australian business.
We filed 4 new products and received 2 product approvals in Q1. Our portfolio fungibility continues to drive marketing penetration. In our previous commentary, we had indicated that our U.S. business will deliver 25% to 30% growth during the year. Having said that, due to the COVID-related softness on the business, as I indicated earlier, we remain optimistic that our combined regulated markets will continue to scale and are confident to achieve a similar aspirational growth level.

Coming to emerging markets. We are clearly seeing turnaround and green shoots in the performance. Africa business grew 73% year-on-year and quarter-on-quarter, driven by key brands and improvement in primary sales in line with our secondary sales. Although, again, there is some softness that we've seen in acute therapies due to lower prescription rates related to COVID. The institutional business was on track with a 30% growth due to higher order pickup by donor funds. During this quarter, we received a WHO PQ approval for TLD, the ARV product under the new treatment regimen. This product is currently under country-specific registrations, and we look forward to launching this product during H2 of FY ’21.

Coming to some update on our Puducherry facility reclassification. We would also like to provide you with the current status on our Puducherry facility. We have completed and submitted all corrective and preventive actions, which have been verified by external third-party remediation agency. We await the reinspection of the facility by U.S. FDA, which is delayed by the current COVID-related travel restrictions. We continue to engage with the agency on a regular basis and shall update the outcomes as soon as it becomes available.

As indicated earlier, although Q1 has been a strong comeback quarter, we believe challenges around COVID-19 will continue to bear on the industry. We are seeing an increasing spurt in the number of COVID positive cases around us that can potentially create unforeseen challenges in manufacturing and supply chain. Any such situation in our manufacturing facilities can lead to significant disruption in operations. We also continue to see increase in operating costs, including higher logistics cost. The softness in demand will continue to be an overhang in the markets. Given these challenges, we remain cautiously optimistic on the overall business outlook for the year, and we’ll keep closely monitoring the situation.

I would like to reiterate our focus on business continuity measures, which is around people first, continuity in our operations and supply chain, continued engagement with our customers and a high focus on containment of cost and cash conservation without disrupting the business.

With this, let me pass on the phone to Badree to update you on the financial aspects.

Badree Komandur: Good evening, ladies and gentlemen. So, I'd like to spend few minutes on the financial results. We had an excellent start for the financial year ’21. So, we have been saying that profitability, efficiency and growth has been our key pillars and our focus for the last few quarters. And we demonstrated a significant improvement across all the financial parameters in the first quarter of the new financial year with good confidence.
Secondly, in terms of laying a sustainable foundation, we laid a strong foundation for gross margins of about 60% and EBITDA margins of about 20%. And we also expanded gross margins during the quarter and EBITDA margins too expanded by 920 basis points post Ranitidine. The operating leverage is quite solid, and depreciation and amortization have been very steady. The net interest cost also is within a range, which we have guided. The ETR is at 4%. We believe that we will have to do some catch-up during the year and expect to be in between 10% to 12%.

With superior cash flow management, there has been a net debt reduction of Rs. 752 million. And the net debt stands at about Rs. 10.7 billion against 11.47 billion, which was reported. Most importantly, in the last call, we said that our endeavor is to maintain the net debt-to-EBITDA ratio within the range between 2 to 2.2x. We are currently at 1.7. So, we continue to focus on profitability, efficiency and growth. And we hope to build a very sustainable performance.

So, with this, I will forward it to Mr. Arun to make comments on Stelis and Stelis business.

Arun Kumar:

Thank you, Badree. Considering that we had a long opening commentary, I will quickly give an update on the biotech and our other businesses.

So, the biotech business is finally getting traction, as all of us know, it's high CAPEX, long gestation. I'm pleased to report that our first product will be filed in September in Europe. We expect to get an approval for this product in 12 months from filing. The product is already partnered with several partners in Europe and other key markets. As we announced last, Strides will front end this market in the U.S. and is in the process of designing its clinical protocols. It's also important to know that we have now got our insulin glargine to Phase I. We are doing our Phase I trials this quarter in India. And we are now very excited with the fact that there have been significant changes in the regulatory pathways for insulins in the U.S. And consequently, we are now contemplating making the investments ourselves to go to the Europe and then the U.S. markets with our insulin platforms.

It's obviously going to take us 2 to 3 years before we see revenues, but we are pleased with the fact that being a nascent company, we are moving on the right path in as far as this business is concerned. As all of you may know, Stelis has got the BioSource's division, which is our CDMO services division, which is now commercially available to customers. We have onboarded a large pharmaceutical company as our first customer for key peptides to be produced from this plant. And this quarter, we will also commission our microbial capabilities, including large-scale manufacturing of Glargine and other insulin analogs. And the Mammalian facility, unfortunately, will get delayed until April ’21. This is a good 5 to 6-month delay that although the equipment is at site, we are unable to get the engineers from Germany and the U.S. to come and install this equipment. So, we expect validation and commercialization in April’21. Having said that, we are starting to onboard customers for both drug substance and drug products and we're quite excited about the pipeline that we are getting in our CDMO services.
Considering that we have invested significant CAPEX around our Stelis business, we have the ability to quickly kind of bespoke one of our blocks into a dedicated vaccine facility for nonlife vaccines. And I'm pleased to report that we now are getting ready to get into commercial production of vaccines from December 2020. These are very specific vaccines, given the acute shortage of vaccine capacities globally, especially for COVID and others. We have some capabilities to produce some specific highly potential vaccines and we are in discussions with some of the key players who are in the forefront. At this stage, they are very early discussions, but we'll keep investors informed about how we progress.

I think we'll have a better guidance around where we get here in the next quarter. I just want to reemphasize that we are only offering CDMO services, and we are not into the vaccine business ourselves. So, we are currently in discussions with a global company to produce some of the vaccines for the emerging markets and we are at very early stages of discussion. So just in terms of a call out, Strides committed to invest in $40 million and to take control in the biotech business. $15 million of this has already been invested, and the balance $25 million will be invested in the next 3 quarters along with more capital coming in from minority investors as has been envisaged.

When it comes to the injectables business, although we announced in December that we intend to get back to the injectable business. And with the events leading to Ranitidine and also the COVID outbreak, we took a judicious call not to get into any big ticket investments, which are high CAPEX, long gestation, but also not do any M&A transactions until we see how the COVID situation pans out. As was announced and the promoters already were investing in the space, we continue to stay invested. Strides retains an option to take a decision by December 2020 if it prefers to participate in the platform that is being built already at SteriScience or alternatively be in the injectables business on its own. At this time, it's a little early, we would like to see 1 or 2 quarters going before we take a final decision, and we'll keep investors updated based on our performance, cash flows, and if there are no COVID impacts, this is obviously a logical thing for Strides to do to be in this space, given our strong outcomes that we have delivered.

So, with that, may I request that we are open for questions, and we will try and make them efficient by making the questions of 1 or 2, given the time limits that we have. And like Abhishek mentioned in the opening statement, we are more than available to take any specific calls if any of you have paucity of time today to address your questions. Thank you.

**Moderator:** Thank you very much. We will now begin the question and answer session. First question is from the line of Alankar Garude from Macquarie. Please go ahead.

**Alankar Garude:** Sir, emerging markets have done well after quite some time. But going ahead, you have talked about softness in acute therapies in branded Africa. But on the other hand, we also talked about the alignment finally happening between the primary and secondary sales as well as the TLD launch in the second half. So overall, can you comment on the outlook for both these subsegments in FY '21 and even beyond in terms of both topline as well as margins?
R. Ananthanarayanan: So, thank you for the question. Yes, we do see clearly the opportunity for us to continue this growth. As we said, we are seeing the green shoots in performance after all the corrections that we did in Africa and we expect this to be sustained. The fact of the softness in the market is a reality because many of the markets were closed. The general practitioners were not available, the pharmacies were closed. And obviously, there was that softness that we had seen. Some of the countries have started relaxing the lockdowns and have started opening up. But as far as our business is concerned, we continue to be optimistic and we think that the growth will continue from here on. As far as our institutional business is concerned, yes, we took a decision to stay away and not participate in certain products, which would have brought the gross margin at the overall company levels down and would have impacted it adversely. So, we chose to stay with products where we get a benefit of improved gross margin. That is playing out in reality. And with the TLD approval and the approvals that we expect to get from individual countries, with the launch of TLD in H2, we think that will clearly add another fillip to the growth that we are seeing.

Alankar Garude: And in terms of margins, so will we see operating leverage coming into play, especially on the institutional business?

R. Ananthanarayanan: Yes. Because we've chosen to stay away from products that were lower in gross margin, and we chose to have the right product mix where the gross margin improvement did happen. That has clearly resulted in an overall benefit to the organization.

Alankar Garude: Understood. Secondly, sir, on the decision to put on hold investments in sterile injectables. Now Arun sir did mention about the 2 main reasons, Ranitidine as well as COVID-19. So, I just wanted to understand what have been the investments done in this entity till now, till date? And if you could just split that between Strides as well as the promoters, that would be helpful.

Arun Kumar: So, we can't give you those specifics at this time. It's just that there are several pipeline deals that are in the works. We are trying to delay as many as of them for Strides to be participating in that. But at this time, it's very nascent. It's a question of how much capital you need to commit.

Alankar Garude: Okay, fair enough, but any color on what was the planned capital outlay, assuming things had gone as per plan?

Arun Kumar: It will take any business in sterile between $100 million and $125 million till we're breakeven. And of course, we had the ability of leveraging some capacities in Stelis. So therefore, the infrastructure costs would be slightly lower. And in this case, the breakeven point would have been an investment of between $60 million to $70 million.

Moderator: Thank you very much. Next question is from Sriraam Rathi from ICICI Securities. Please go ahead.
Sriraam Rathi: The first question, the U.S. sales in this quarter will be around $50 million. So, I mean our target was around $240-odd million for the full year. Is it fair to assume that additional $40 million gap will be largely coming from the new approvals?

R. Ananthanarayanan: Yes. As indicated in our commentary earlier as well, we clearly expect the new approval to contribute towards that.

Sriraam Rathi: So, we have decent opportunities which may come during the course of the year.

R. Ananthanarayanan: That's correct.

Sriraam Rathi: Okay. Got it. And sir, secondly, particularly on the SG&A costs, other expenses, this quarter seems to be on the higher side. I mean on YoY basis, it is higher by almost 50 crores and QoQ around 30 crores, much higher than the growth in the same. Any particular reason for the same?

Badree Komandur: Yes. So, this is mainly because of 3 things. One is the consolidated Fairmed business into our group. The business in Germany, we started consolidating from Q1 that was one. Second thing is there has been an increase in freight costs that has been alluded by Dr. Ananth's commentary. The third is, there's also an increase in R&D cost from the last quarter to the current quarter. So, all 3 put together is about 30 crores.

Sriraam Rathi: So, this is something which we should expect to continue, except maybe the freight cost may come down?

Badree Komandur: Yes.

Sriraam Rathi: And sir, lastly, on the Stelis side, I mean, by when we are expecting it to consolidate into the numbers?


Sriraam Rathi: Q4, okay.

R. Ananthanarayanan: Q4 or Q1 of next year. It depends upon because, like I said, because of this COVID situation, we are not able to get, the Mammalian site is the biggest site in terms of readiness, and that is what requires a lot more capital. Strides is currently investing need based. So, depending upon I think it will be more Q4 if not Q1.

Sriraam Rathi: And so just with relation to the same, the losses that we are reporting in terms of JV and associates. So, what proportion of that would be because of Stelis?

R. Ananthanarayanan: About 80%.

Moderator: Thank you very much. Next question is from Anmol from JM Financial. Please go ahead.
Anmol Ganjoo:
My first question is to Dr. Ananth. Dr. Ananth, congratulations on a great set of numbers. But I just wanted to understand that you did allude to a lot of COVID-related disruptions. My sense is that if you look at the impact of COVID, again, based on your commentary, what we've seen is the worst of the impact should have been felt this quarter, both on the demand side as well as the supply side. So, any particular reason for the extreme cautious view that you're outlining in terms of the impact of COVID not being true because consistent with other company managements and your performance, you tend to think that you've weathered this rather well. So, any thoughts there?

R. Ananthanarayanan:
First of all, thank you. So, there are 2 aspects here. One, which I talked about from a market perspective was clearly to indicate that, that did play out in Q1, and we still managed to get to the levels that we grew in Q1. As far as the challenges are concerned, it's significantly related to people that I mentioned because if you see the spurt in COVID cases, which is around us particularly in Karnataka, there's significant increase that's happening currently. A lot of people every single day are reporting to be COVID positive. And therefore, any of those, if that plays out into our manufacturing and supply chain is unforeseen and can have an impact. So, I was alluding from that perspective.

Anmol Ganjoo:
Okay, thank you. That's helpful. My second question is to Arun. Arun, we've seen after a long time, quite a few positive things happened in the business consistently and institutional and emerging markets have started turning around. Free cash flow generation has been robust. People are alluding to some kind of a turn as far as the U.S. cycle is concerned in generics. This is hardly a construct for moderating investments. So, with our debt equity at 1.7 and the business environment looking up, what's again driving the extremely conservative outlook in terms of investment? You surely have taken bolder calls than that in the previous cycle. So just wanted to know your thoughts on that.

Arun Kumar:
So, the good result is because we have a good new management. So that's the first point. I don't think it's conservative at all. What we are basically saying is that the ambiguity around people availability to come to work in facilities is a lot more than what one believes. When you sit there in Mumbai and when you see things are getting better, in the southern parts of India, we are now seeing what you guys saw 2-3 months ago in Mumbai. We are seeing a lot of absenteeism, and this has impact because our plant run 24/7, right? They are fully occupied. As we see more and more cases, we are anticipating challenges in manufacturing and all of that. We are consistently using the word, we continue to be optimistic, but we are cautiously optimistic because there are things that are not in our control. Further, to reaffirm what Ananth said, while there has been a frenzy of stocking and stockpiling, then there is no acute demand. Typically, demand across, as you probably see in India and the U.S. and in Europe, the IMS data shows drop in prescriptions. And also, if you look at the number of stores that have been shut down in COVID at Walgreens or CVS, all of that has an impact. We strongly believe that our portfolio and our reach, especially in Europe and other markets will ensure that there is continuity in the business, and there are other challenges that we want to call out. I'm not so sure what the other company say, but this is the reality with which Strides operates. We are not suggesting our order books are not full. We
are not suggesting that we do not have the ability to execute. We have a fairly strong inventory level. So that's not getting impacted. So, our inventory refills are getting all right. Maybe our inventory level days have come down a bit. But it is important to be cautiously optimistic at this time, and that's all we are saying. And we delivered a stellar quarterly number, so that reflects it. Nothing changes from that.

Moderator: Thank you very much. Next question is from Tushar Manudhane from Motilal Oswal. Please go ahead.

Tushar Manudhane: Just one question from me, in the opening remarks, you alluded to making investments for the advanced market on the insulin platform. So how much that amount would be and over what period of time?

Arun Kumar: So, we believe that the new regulatory pathways that the FDA has proposed will reduce the development cost of about $50 million per analog to a typical European study cost which will be about $25 million. So, what would have been $75 million to $100 million is now $25 million to $30 million. That leaves a bigger opportunity for us to develop the product to a later stage licensing, if we want to, so that we get better economics or to take it to market, given all the noise about insulin and the need for being more competitive. So, this is an optionality that we have. Had the regulatory changes not been done, we probably would have gone and licensed this product out much earlier than what we are proposing to do now.

Moderator: Thank you very much. Next question is from Kunal Randeria from Antique Stock Broking. Please go ahead.

Kunal Randeria: So, you actually had started export of Favipiravir in April. Does it have a meaningful contribution in the quarter?

R. Ananthanarayanan: So, we had some contribution from Favipiravir certainly, but nothing material.

Kunal Randeria: Okay. Fair enough. But under this line item, would it be booked?

R. Ananthanarayanan: It would be under the institutional.

Kunal Randeria: So, my second question is regarding those 18 ANDAs that you had purchased in February. So, I was just wondering if you can provide some more details around it. I believe you have also secured marketing rights of levothyroxine. Just wondering where we are in terms of the filing status and what are the plans to commercialize those ANDAs?

R. Ananthanarayanan: So, let me split response in terms of 2 different types of products. There have been one set of products where after acquisition, we have had to do site transfers as well as to do change in the source of API, which we have done, and many of those products are either under stability studies or have been filed with the FDA with those source changes and site changes because that needed to make those products viable. So, we've done that. Some of the products we are awaiting FDA
approval. And on levothyroxine specifically, I'm happy to say that we just filed the ANDA, 1 ANDA during this month.

Kunal Randeria: And have you sort of expect any revenues in this fiscal, approval in revenue this year?

R. Ananthanarayanan: No, not in this fiscal.

Kunal Randeria: And the other 3 R&Ds, when do you expect to file?

R. Ananthanarayanan: Sorry, which one? On the levothyroxine, by the end of quarter 3.

Kunal Randeria: Okay. Sure. And just 1 more question, if I can squeeze in. Can you just remind us on the status of those 2 CGT products that you had?

R. Ananthanarayanan: At this point, a bit difficult because it's under regulatory status. So very difficult for us to give update on that.

Arun Kumar: No, I think one of them, we lost the CGT status, but we launched it just after the other company, and we have a bigger market share than the original seller.

R. Ananthanarayanan: So yes, one of it, when you said 2 CGT, one of the CGT products, as Arun said, it's right, we lost the CGT status and so we launched it on day 181 after our competitor launched. On the other one, it's still under FDA regulatory process.

Moderator: Thank you very much. Next question is from Kartik Mehta from Klay Capital. Please go ahead.

Kartik Mehta: I have a question on the new vaccine business. It is interesting that you speak about 25 million lyophilized vaccines also. So, from commissioning to commercial manufacturing, can you help us in terms of timelines or in terms of regulatory approval or in terms of any other thing which is required to manufacture from now until December 2020? How should we look at this business?

Arun Kumar: Well, if you read the document, Kartik, it says that we started construction of a vaccine line by carving out a part of the facility. It requires dedicated capabilities, which we have. And by December, we'll commission the facility. We are doing this in under 5 months.

Kartik Mehta: Yes. So, are there batches etc. which you have run? And when you say you...  

Arun Kumar: We are not doing any vaccines ourselves. We are offering manufacturing services for companies who are looking for capacities in vaccines. So once the facility is ready in December, we will only start taking validation batches of potential vaccines that we think we would have signed up by then and not before then. So, it's just an incremental capacity, given the acute shortage of vaccine capacity. So, the particular type of vaccines that we have called out in our release.
Kartik Mehta: Sure. Is it fair to assume, Arun, that in FY '21, you could see some amount of revenue for 2 months or so?

Arun Kumar: That is the idea of having ramp-up start to validation in 5 months. That's the idea.

Kartik Mehta: And the nature of companies, are we talking about exporting it because you mentioned lyophilized vaccines. So, one name, obviously, comes to our mind. So, is it only exporting? Or is it a mix of everything else?

Arun Kumar: Well, we will offer the capacity, obviously, depending upon who wants it most. And if we can deliver to India, if that capacity is required, then we'll obviously offer it to India first. But at this time, the idea is to partner with companies who are having challenges on capacities. And if that is the case, then it will be an export business, obviously.

Kartik Mehta: And the second one is on the insulin part of the business, which is there in the biopharma vertical. What is the timeline that one should run with for you to come, assuming that Phase I will actually start in Q2 FY '21? And on the backdrop that insulin prices are coming down, can you have an accelerated trial or an approval in this? Anything on those lines?

Arun Kumar: No, we don't think so. We don't think we'll have revenues in insulin for at least 30 months from now.

Kartik Mehta: Sorry, how many months, you say?

Arun Kumar: 30.

Moderator: Thank you very much. Next question is from Saurabh Shah from AUM Fund Advisors. Please go ahead.

Saurabh Shah: Arun, so the question about Stelis. You mentioned that this could become big, should breakeven in FY '22. Just wanted to get a sense of order of magnitude, what kind of revenues could this imply? And maybe over the next year after that, what kind of headline number we should look at in terms of revenues from Stelis?

Arun Kumar: So, I don't think we can give any specific revenue numbers. Typically, in the BioSource CDMO business, gross margins run at 75% plus, which is a very standard industry as a CDMO order services. And we need to have an OPEX recovery of only $20 million, given this operation is for us. Not including the R&D spend that we will do for the programs that we plan to market ourselves. But from an entire OPEX, that's what it takes, and we think we will get there in the next financial year.

Saurabh Shah: And going forward, do you think that could scale up dramatically, just given the CAPEX split, $25 million, we expect to spend additional in as well. Just trying to see the return on this and what kind of...
Arun Kumar: It takes only about 10% to 12% of capacity utilization to breakeven, and that's not unique to us. It's very typical of the industry and how it operates. It's just that the gestation is significantly longer. And I think we are almost done with the high CAPEX gestation phase, and it's about time that we now get into an operational breakeven and then once we see revenues on our portfolio and the CDMO business is coming, I think this will be a smooth sail and that is where I'm spending a lot of time myself to ensure that we get all the right people and the right outcomes. And I'm quite confident that we are on the right track here.

Saurabh Shah: Any change in perspective, given what we heard about the changes in health care regulation in the U.S., more sourcing inside the country, lowering costs. Any impact on that on the whole Stelis operation?

Arun Kumar: I don't think that any business can be based on what's happening in the U.S. I know we all get a lot fascinated with what happens there. But the whole world, there is currently 300 million people unmet for insulins. The whole world is your market. And we now have an arbitrage, a better arbitrage in the U.S. given the fact that the regulatory pathways have improved. We expect if you have a great Phase I study, we can get a Phase III waiver. So that's really made the business a lot more interesting from the total capital deployed on each of the analogs to what market opportunities you can have. And if it comes directive a couple of weeks ago, the first point is insulin, it's because it's still high price. There's a lot of patients who don't get insulin. But it's just that there are insulin challenges everywhere, which is unmet. And as long as we can make affordable insulin, which we can, given our platform technology, I just think that we will be able to attract a lot more customer and patient fully. It doesn't matter which market it is. So, we are creating a program to meet global standards, but we will be very happy to sell to the emerging markets or partner in the U.S. with other companies. So, it's early days. We'll keep you posted as this business is getting traction.

Saurabh Shah: The next question was just on the overall CAPEX. I don't know if Dr. Ananth or you want to cover that. Except for the $25 million on Stelis and on injectables, if any, decided later, what else is the CAPEX we're assuming for the next 2 years that is until FY '22?

R. Ananthanarayanan: So, in Q1, we spent about Rs. 300 million. So, we expect to maintain a similar range.

Saurabh Shah: Okay. So, nothing major other than this.

R. Ananthanarayanan: In fact in the last few years, we have spent significant money in hard CAPEX. And in the last call also, we highlighted that most of our CAPEX programs in terms of hard CAPEX, except the West Palm beach has been complete.

Moderator: Thank you very much. Next participant is Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: Dr. Ananth, on the Palm Beach facility, where is the status on the facility in terms of revenue contribution from the facility?
R. Ananthanarayanan: So, the West Palm Beach facility has started some initial revenues coming in, but it will start truly flowing in only in H2, more towards Q4. We have completed the tech transfer of products to that site. At least the first product is loaded on stability. Other 2 products as we speak during the course of this month are getting loaded into stability. We will have CB30 submission to the FDA and post that, those products will be out in the market.

Nitin Agarwal: So how many products are we talking about, sort of tech transferring to that facility? And what does that do? I mean, what does this tech transfer do for us in terms of our capacity? Did you take market share in these products?

R. Ananthanarayanan: So, the advantage of the West Palm Beach facility that we have and the reason we are transferring some of these, apart from being in market for the U.S., it also offers us the ability to participate in the VA program. I think that's the key dimension out there. Now in terms of number of products, we've got a series of our Softgel 45:32 lined. So, the products that we have currently in our portfolio, we also plan to qualify that in West Palm Beach, as I said, because then we can start participating in the DoD and the FSS program as a part of the VA supply.

Nitin Agarwal: And for this portfolio, is the VA supply a meaningful opportunity for us on an incremental basis?

R. Ananthanarayanan: Again, I won't say whether it's major or not, but VA supplies are a significant part of the overall market. And so, we would certainly like to participate in that.

Nitin Agarwal: And secondly, on the U.S. business for the year, I mean, balance part of the year, how many new launches are we anticipating in the market?

R. Ananthanarayanan: So, we would anticipate probably between 4 and 5 product launches as we keep looking at the scenario out in the market, plus some of the new product approvals that we get.

Nitin Agarwal: And that should be enough for you to sort of bridge the $40 million, $50 million gap, which is there to meet your full year numbers?

R. Ananthanarayanan: I think it's a combination, right? We launched already products in the last quarter. Now that will get the full year realization of the revenues, plus the new products that we will launch. It's a combination of the 2.

Arun Kumar: But Nitin, if I may add, this is Arun. Don't discount the other regulated markets. So, what we're basically saying is that if for whatever reasons, the U.S. business is not tracking, COVID or other reasons are not in our control. But otherwise, we are well on track to get to the guidance. Between the 2 businesses, we will definitely deliver a very strong outcome in respect of COVID or whatever for that matter given the significant growth, as you probably realize that the other regulated markets are growing at a faster plus than the U.S., but notwithstanding that we still continue to believe that the U.S. would be the market which gives the company to get back to a very significant growth and also margins.
Nitin Agarwal: Arun, linked to that, and if you guys can answer that. On the other developed markets, with the market developments that have happened over the last, say, 3 to 4 months or 3 or 4, 5 months with the COVID situation, how has the market environment sort of changed? Has it become more favorable for our strategy? I mean how is that playing out for us now?

Arun Kumar: So how I see it is that as far as acute prescriptions globally, we see a drop globally and that's not unique for Strides. I must say Strides simply says that you can do your checks. But what happens is that with the velocity of filings that we did in the last 2 years in the other regs, which didn't get any limelight because everybody is so focused on what's happening in the U.S. We are able to improve our basket of offerings, which is leading to this growth. So, from the other regs, we are not so much worried compared to the U.S. because the U.S. is dependent on at least $40-odd million of new product launches like we articulated last. And we are confident that those launches will happen. And we continue to gain that having dropped $25 million of revenues or $20-odd million of revenues in Q4, we continue to believe that market share on our existing products and new launches will gather momentum. And if that happens, then, of course, the 220, 240 is a breeze. But if for whatever reason, it won't happen. And those reasons are not only because of things that are not in our control. Then all I'm saying is that we have a mirrored market in the other regs which is growing faster at the same margin profile, and that is why the gross margins continued to remain robust in the company.

Moderator: Thank you very much. Next question is from Sachin Kasera from Svan Investment Managers. Please go ahead.

Sachin Kasera: Can you just update us on the current status of the Singapore facility, how is it ramping up? Is it now working at full capacity? Or is there still some fair capacity there?

R. Ananthanarayanan: So the Singapore facility continues to operate well, though it's not to the full capacity, but it's operating at a fairly decent level of capacity utilization. Again, that's a site which is an extremely important site for us to support the VA program, given that it's a TAA designated country. And therefore, we continue to keep transferring, tech transferring products there as well as a part of dual site registration. So that we continue to support from our flagship site for the regular retail market, while the Singapore site continues to support for the VA program. But yes, we still have capacity available there and that will be used as we keep getting new product approvals, and that needs to support the VA program, we'll use it.

Sachin Kasera: Sir, my second question is regarding the balance sheet. So this quarter, we have seen significant cash generation and margins because of which the net debt has come down and the return on capital has improved. So how do you see both these 2 numbers maybe by the end of the year?

Badree Komandur: See, the last quarter, we had very robust cash flow generation. We generated about 200 crores in terms of the operating cash flow. And the net cash flow generation has been about 75 crores as opposed to investment in the biotech business of about 50 crores. So we expect to maintain a
decent trend. And we believe that we will have to wait and watch as it goes along, and we'll get a much better picture in Q2.

Moderator: Thank you very much. Ladies and gentlemen, due to time constraint, we will take last 2 questions. Next question is from Ravi Sundaram from Sundaram Family Investments. Please go ahead.

Ravi Sundaram: I have 2 questions. My first question is on the TLD approval that you've got. I think I asked this in the previous quarter concall also. So my question is, what kind of opportunity size are we looking at here? I understand the business is evolving from TLE to TLD, especially on institutional ARV business. So what kind of opportunity does the management look at here for H2 and for the upcoming year?

R. Ananthanarayanan: Yes. So as I indicated, since our receipt of the WHO PQ approval, we have now filed to individual countries for the NMRA process and WHO collaborative process to get country-specific approvals. This is not a PEPFAR approval. So I just want to sort of be very clear that this will not be participating in the PEPFAR approval related procurement. But we expect that during the H2, all these country-specific approvals will come in place, and we will be able to participate in those donors funded programs where supplies to those countries are required.

Ravi Sundaram: And a second question on the pledge side. Now that our group companies’ sales through, when do we have a ballpark number on which quarter likely the pledge is likely to be reduced?

Arun Kumar: When the deal is completed. We haven't got our money as yet. So we'll let you know in the next call.

Moderator: Thank you very much. Next question is from Pritesh Vora from Mission Holdings Private Limited. Please go ahead.

Pritesh Vora: I have this question. While we are in the many businesses like emerging on the regulated market, nonregulated market as well as the biotech vaccine. So in one way you are targeting a long-term growth for the company. But on the other way, if you look at it, where are we focused on which business as of now which will result into a good revenue as well as EBITDA over the next 2, 3 years?

Arun Kumar: Yes. I strongly recommend you connect with Abhishek so that he can take you through the story of Strides and probably have not spent time to understand the company enough. We are very focused on what we do. And we are very focused on the investments that we deploy, which creates significant value over time. But this is not the forum and the time to have this conversation. But please do not hesitate to call us, and we'll be more than happy to spend as long as time as you want for you to have a different view on your thinking on why a diverse business plays a very valuable role for stakeholders.
Pritesh Vora: Right. And my next question is the Puducherry facility, you mentioned about the ongoing inspection. So what sort of revenue comes out of this facility and what will be the impact of this facility when it comes on stream?

Arun Kumar: At this time, Puducherry has got no negative impacts. Whatever business we were doing before FDA issue, we'll continue to do the same numbers. We do not have an import alert in this plant. We only have a warning letter, which allows us to continue to sell products. And all those products are produced in 1 or 2 factories. And therefore, there is no revenue impact. The only impact is that some of our approvals are pending, 4 or 5 approvals are pending, which once this inspection reclassification is over, will come through and which will start improving the numbers from that facility. But at this time, the Puducherry plant runs fully booked, is very busy and is doing things under heightened supervision. So there's no negative impact on the numbers.

Pritesh Vora: And if I can squeeze the last question. We have seen a lot of companies are reporting good sets of turnarounds in the U.S. market. Arun Kumar, what according to you the key reasons behind the superiority performance from the U.S. market?

Arun Kumar: I am not judge of what other companies do. I think the U.S. market is a function of demand and supply. I think there's a lot of rational thinking now on pricing. Because of increased API pricing, supply chain issues, nobody is chasing market share. Everybody's chasing good quality business. And I think that's a very good behavior for the industry. We have been following that for 8 quarters. If you recall in our 8 quarter reports, we have said we have had no price erosion on any quarter. And it's all about product selection and how do you engage with your customers and make them happy. I think there's a lot of discipline global industries brought into all markets, which is good for the industry. And I think that's the reason why everybody is benefiting from it. It's just being more rational and allocating capital and time more efficiently.

Moderator: Thank you very much. I will now hand the conference over to the management for closing remarks.

Arun Kumar: Thank you all. Appreciate your time today. And like we always say, it's a pleasure interacting. We are always available. Please get in touch with us, and we will answer any queries that may have been unanswered of paucity of time. Thank you all, and be safe, and have a wonderful evening. Thank you.

R. Ananthanarayanan: Thank you.

Moderator: Thank you very much. On behalf of Strides Pharma Science Limited, that concludes this conference. Thank you for joining us. You may now disconnect your lines. Thank you.