



“Strides Pharma Science Limited  
Q3 FY2021 Earnings Conference Call”

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– FOUNDER & NON-EXECUTIVE CHAIRMAN  
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**ANALYST : MR. ABHISHEK SINGHAL**

**Moderator:** Ladies and gentlemen, good day and welcome to Q3 FY2021 Earning Conference Call of Strides Pharma Science Limited. As a remainder, all participant lines will be in the listen-only mode and there will be an opportunity for you 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 afternoon and thank you for joining us today for Strides Earnings Call for the third quarter and 9 months ended financial year 2021. Today, we have with us Arun, Founder, and nonexecutive Chairman; Dr. Ananth, CEO and Managing Director; and Badree, ED 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. The transcript of this call will be available in a week's time on the company's website. Please note that today's discussion is forward looking in nature and must be viewed in relation to 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 now hand over the call to Arun to make the opening comments.

**Arun Kumar:** Thank you, Abhishek, and good afternoon, everybody. Much appreciate your time today. While I'm going to let Ananth do the introduction on the call in a bit and also speak about the quarterly performance, there are two significant decision points that have been made today, and I thought I will give a little more color around those decisions and also explain the rationale. On the Biotech business, we have been consistently mentioning that at the appropriate time we would demerge this business and list it separately. We believe the biopharmaceuticals business will need attention that is different from that of a generics business. So, we have taken the decision today to demerge this business and for shareholders of Strides to benefit from a standalone biopharmaceutical business. I'm also delighted to announce that Aditya Puri, who we inducted in the board a couple of weeks ago, will now chair the Board of Stelis. And Stelis, as all of you know, has been a little bit in the making almost 8 to 9 years. But in the last 3 or 4 years, we have had extensive build-outs in terms of its capabilities and the offerings Stelis can offer and can provide to customers. As we see the opportunities emerging, especially because of COVID and the demand for capabilities in the biopharmaceuticals business, Stelis is leaning more and more to become a CDMO player. It does have a few products in its development program, but predominantly, our focus is to offer our services worldwide as we see increasing demand for our capabilities and capacity. We are also in line to breakeven in the next financial year.

Our order books are looking healthy. We should be having significant updates in how those order books will look like, including the potential vaccine opportunities in our next readout, which is expected, as regards to Stelis, in approximately 4 to 5 weeks from now, and we will provide another update. At this time, we are in discussions, fairly advanced discussions in terms of opportunities around the CDMO space. Now incubating a business of biopharmaceuticals, obviously, from our learning curve is significantly greater than the other businesses that we are invested in. It has taken us a lot of time and capital to get here. But we are now delighted that Stelis can live on its own. And consequently, we believe that the delisting will add significant value in the near term to the Strides' shareholders. It is a commitment we made to delist at an appropriate time, and we think the time has come now.

Also, at this time, we see the need for incremental capital as we move from the incubation phase to growth phase. We estimate this capital to be \$100 million based on different types of opportunities that we currently are pursuing. And while we will look at capital raise at the appropriate time and appropriate value, promoters are committing an additional \$50 million to increase their ownership, but also to provide the much-needed capital for Stelis without adding additional burden to Strides. So this is in regards our Biotech business.

We had been commenting on an optionality that Strides had on a business that the promoters had incubated and continue to incubate called SteriScience, which is a domain play in injectables. Strides has not invested any capital into this business thus far. But had an option to participate, taking a controlling stake in a domain play of injectables. Ananth, Badree and the new teams after having done strategic reviews of the opportunities that are available to us, and following the Stelis model of having invested over a long period of time, which caused the balance sheet to stretch and also our focus, have decided that Strides will continue to develop its injectables business on its own, keeping all the economics, but will not play a domain game as we had in our previous outing as in Agila, where we had multiple facilities, 200 ANDAs and instead pick and choose portfolio of products, which are complementary to our strategy of finding niche and complex products, and this is what we will be doing at Strides. This also means that the heavy lifting in terms of continued commitment of capital across Stelis or any new businesses will stop. And opex leverage, balance sheet focused on lighter balance sheet and improved growth will be the key focus for Ananth and his leadership team, given that we believe that although we have come a long way in terms of improving the quality of the balance sheet in the last 2 to 3 years, the opportunity ahead of us in our core business and with opex leverage that is visible when we move our business in our core generics in each of the markets that we called out, for example, U.S. getting to \$400 million. We believe our focus and attention should be dedicated to get that to its end game. So that is predominantly the larger story that I wanted

to discuss. I am available through this call to take other questions. With that, I will pass on the call to Ananth to continue the discussion.

**R. Ananthanarayanan:** Thank you, Arun, and hello, everyone. I hope all of you and your loved ones continue to remain safe and well. At the very outset, I am happy to say that during this quarter, we have been able to successfully run all our manufacturing facilities smoothly without interruptions. And I do want to take this time to thank our global workforce for their resilience, commitment, and exemplary efforts to ensure continued operations during this period. We continue to pursue people-first approach and the well-being of our employees remains our topmost priority. With that, let me talk about the business. We are pleased to report steady performance of our businesses in this Q3 FY2021. Our performance was led by continued momentum in our regulated markets business with consistent growth being delivered by our front-end business over last many quarters now. We are particularly pleased with the strong bounce back in the other regulated markets, which has been led by healthy volume traction. Our portfolio maximization strategy is yielding the desired results, and we continue to invest in R&D to expand our product offering across regulated markets. Our US strategy of building the front end and tapering the partner business is playing out to plan, and our front end now contributes approximately 86% of our U.S. revenues. We are pleased to have received the U.S. FDA approval for generic Truvada recently. Also, during the quarter, we have successfully commercialized TLD, the Tenofovir, Lamivudine and Dolutegravir, from our institutional portfolio. Our revenues during this quarter has grown 34% year-on-year, adjusting for Ranitidine to Rs.8375 million with an EBITDA of Rs.1661 million, up 76% year-on-year. This translates into a healthy EBITDA margin of 20%, increased by 470 basis points year-on-year. The business has generated healthy operating cash during the quarter, which has helped us to reduce the net debt by Rs.683 million quarter-on-quarter. As we continue to build and focus on our core growth business, I am delighted to announce the strengthening of our executive management team with addition of top-notch pharma leaders having a strong pedigree and vast industry experience to enable our next level of growth.

Let me spend a few minutes to talk about performance across key markets. Our U.S. business had a steady growth from our front-end business, as we continue to taper our partner business, as I just indicated. U.S. reported a 10% year-on-year adjusted for Ranitidine growth to \$53 million in this quarter and the 9-month FY2021 revenues were at \$157 million, which is up by 9% year-on-year. Market share for some of our key molecules continue to be steady, and some of our new launches are gaining market share. We also saw some headwinds in this quarter. It has been an extremely weak flu season in the U.S., which has impacted our winter portfolio. Select products continue to witness price erosions and both patient footfalls at hospitals and pharmacies continue to remain below pre-COVID

levels, leading to subdued demand for few products and a softer off take by the wholesalers. We remain confident and optimistic on our U.S. business, and the business will continue to benefit from our focused product collection strategy with relentless focus on supply commitments and customer advocacy. We continued our R&D momentum and received 12 ANDA approvals so far in this fiscal. We filed 6 ANDAs and expect the filing momentum to continue in this Q4 of FY2021. We have so far 127 cumulative ANDAs with the U.S. FDA, 30 of them pending approval.

Coming to other regulated markets. Our other regulated markets delivered a very strong quarter led by growth across key markets of U.K., Europe, Australia, and South Africa. Supply to Arrotex in Australia witnessed a healthy ramp up, driven by increased volumes, while the U.K. front end benefited from improved market share of products. The partners business in EU also saw increased off take. Our other regulated markets reported revenues of Rs.2981 million or \$40 million, in Q3 FY2021, which was up 37% year-on-year and 25% quarter-on-quarter.

Revenues for the 9 months of this fiscal stood at \$107 million, representing a growth of 31% year-on-year. Strong order book visibility continues across key markets and business will continue to benefit from portfolio maximization. So clearly, our other regulated markets are playing up to our strategy and we will continue to invest in R&D to enrich other regulated market portfolio. We filed 12 new products and received 13 approvals so far in this fiscal. Overall, this has been a very strong bounce back for the other regulated market, and the growth outlook remains robust. So if I were to put both the U.S. and the other markets together and look at our regulated markets play, the play continues to remain robust with a diversified portfolio and we have strong pivots in place to deliver continued growth. The regulated markets will be a strategic focus area for Strides, and we will ensure significant focus and attention to this part of our business, which is now over 80% of our consolidated revenues. The regulated markets combined, reported a revenue of Rs.6,857 million, growing year-on-year by 21%. And again, in line with our previous commentary that we would grow this business in the 20%, 25% range.

Emerging markets. Our emerging markets reported a steady performance in this quarter with revenues of Rs.1518 million, and revenues for the 9-month period stood at Rs.4559 million, showing a growth of 61% year-on-year, representing 18% of our consolidated revenues. Institutional business delivered a healthy growth in this quarter, benefiting from successful commercialization of TLD, the Tenofovir, Lamivudine and Dolutegravir. Africa business delivered a tepid quarter due to COVID-19-related temporary softness in acute therapeutic segments. We continue to focus on introduction of new products and line extensions to our branded Africa business to drive growth forward. Given our focus on

growth in key regulated markets, we are pleased to announce the strengthening of our global executive management team. Terrance Coughlin or Terry joins us, effective March 2, 2021, as the CEO for the U.S. business and will be responsible to provide strategic leadership in driving growth, portfolio management and operational efficiency in the U. S. Terry has over 3 decades of rich experience in R&D, supply chain management, manufacturing, sales and marketing, business development and portfolio management. He joins us from Endo Pharmaceuticals, where he was the Executive Vice President and Chief Operating Officer. Terry will be based in our office in New Jersey. Christoph Funke is the next leader who joined us effective January 1, 2021, as the Chief Operations Officer, and oversees global manufacturing, supply chain and quality operations, along with operations excellence. Christoph joins us from Fresenius Kabi in Germany, where he was the Executive Vice President of Global Manufacturing and held several leadership positions for over 20 years. Christoph is based in our offices in Bangalore. Rahul Garella joins us, effective March, as the Chief Commercial Officer for international markets, that is all markets other than the U.S. Rahul brings with him a strong strategic and operational track record built over 25 years of experience across generics, specialty pharmaceuticals and APIs in various international markets. He joined Strides from Endo Pharmaceuticals, where he was the Executive Vice President and responsible for the international business. Rahul will be based in our offices in London. Our fourth executive management team member is Dr. Raviraj Pillai, who joined us as the Chief Scientific Officer and oversees R&D regulatory affairs and clinical affairs. Ravi has over 25 years of rich and diverse pharmaceutical R&D experience in generic, specialty and new chemical entities. He joins us from Abbott Healthcare and has been associated with organizations like Dr. Reddy's, Perrigo, and GSK, both in India and the U.S. Dr. Ravi will be based out of our R&D center in Bangalore. I am very happy to welcome such distinguished names into the Strides family. The buildup of such high caliber team is aimed at ensuring dedicated and expert leadership, who are both driving current and future businesses. Having identified a long-term focus area, we will leverage the vast experience and expertise of these high caliber leaders, making us well positioned to plan our strategy road map for sustainable growth and value creation to continue to give our best to our patients and customers. With this, let me pass on the line to Badree, who will take you through the financials.

**Badree Komandur:**

Good afternoon, ladies, and gentlemen. The profitability, efficiency and growth has been the cornerstone on which the entire Strides has been built in the last 2 to 3 years. So we demonstrated a consistent performance in all 3 parameters, profitability, efficiency, and growth. The growth, predominantly, coming from the other regulated markets, and we are delivered a very attractive growth rate there. As far as the gross margins are concerned, we have stated our position that we will maintain our range, year-to-date basis, we are in that range as has been communicated in the past. This is the third quarter post Ranitidine; we are

delivering an EBITDA margin of 20% and that is also very consistent with our communication in the past. We also have demonstrated to get a Net Debt/ EBITDA ratio between 2 to 2.2 range, so the 5 quarters of demonstration has resulted in a credit rating upgrade for Strides, and we hope to maintain the same range. The effective tax rate, we had guided the market that it will be between 10% to 12%. We are up 7% on a year-to-date basis. We hope to maintain the same range of 10% to 12% going forward. As far as the manpower cost is concerned, the year-to-date is at 16.4%, but this current quarter is slightly low, but we hope to maintain the same outlook of 16.5%, considering the management additions, what we have planned. Overall, we have almost completed the investments in Stelis of \$40 million and we hope to sustain this performance going forward. So, with this, I will pass it on to Abhishek Singhal to open up for questions.

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

**Alankar Garude:** Arun, my first question to you. Now with Strides decision of not investing in Stelis going forward as well as the rollback of our decision of investing in SteriScience, and coupled with all these senior management appointments, including Mr. Puri, as an adviser to Strides. So, looking at all these 3 aspects, is there a structural change in how you are thinking about the core business and consequently, your ownership in Strides?

**Arun Kumar:** Well, that is a good question. So as a group, as you are probably aware that we allocate capital and time across various verticals. The Stelis platform is an extremely important platform. I think at least for certain time that it requires significant new capital. And I think with the new management team, the whole idea, when I set off, as you probably are aware that I have been coming into these calls only to support Ananth and his team during this transition and considering that Ananth and Badree and the rest of the team have done a great job thus far and with the new team that is been built out, just like what I do in a lot of other companies, I believe, after having spent 35 years of operational leadership, it is a good time for somebody else to take over, which is what I communicated with Ananth's team so that has not changed and it is quite logical as the businesses scale up, you set your priorities right, that includes the management's priorities. And I think, rightly so, and then Ananth view of not investing into businesses, which are high capex, long gestation is a decision that board supported and I supported. It is not anything to do with my own aspirations, and I do not think this is the forum for us to have that conversation, Alankar, to be honest.

**Alankar Garude:** Fair enough, Arun. Just a follow-up on that. Would SteriScience be continued to be run by the family office? Because I think there is always...

**Arun Kumar:** Alankar, if you recall, we gave an option to Strides so that if there were any potential conflicts that could be avoided. It always was. It does not have any revenues. It is suboptimal. It is a longer way from getting to where it should be. And yes, so we will continue to say we have more than 7 or 8 different verticals in the pharmaceutical space that we are invested in different forms and formats. And you are aware of that and everybody is aware of it because we have been very vocal and very up front about how we run our businesses. And it is done well for us and for the shareholders, and I guess that is the right thing to do. So yes, we will still stay invested in SteriScience, but not in a public domain for many, many years, considering that it takes a long time for any business of that type to be built out.

**Alankar Garude:** So, my question there, Arun, so because Strides is also planning to invest in some selective injectables on its own. So how would you avoid a conflict of interest between what SteriScience does and what Strides would do?

**Arun Kumar:** Well, I think the market is open for everybody. I mean, if you recall from our earlier conversations and today's press release, what SteriScience does is a domain play, which means it is number of ANDAs for a particular domain of Penicillins or penems or any particular type of products. What Strides is doing is more selectively picking up products that they can add value to the portfolio with this complex niche or whatever it is. So at this time, and you should also understand that Terry, who was the CEO and the Head of Business in Endo, ran a very successful injectable business of revenues with over \$1 billion in less than 10 years. I think we lean on people like him to collaborate in license, work on more complex products as we have completed our program of generic development. So we do have the ability to do all of that. So I think it will be wise for us to wait for a couple of quarters to see what portfolio has been selected. And I have always been able to manage conflicts ensuring that anything that is listed gets a priority. And I do not think that is a concern for anybody for that matter.

**Moderator:** Thank you. The next question is from the line of Nitin Agarwal from DAM Capital Advisors. Please go ahead.

**Nitin Agarwal:** Arun, just a bit of follow-up on the corporate developments. How much stake will Strides be holding in Stelis now, going forward, post the transaction is over?

**Arun Kumar:** So, Nitin, as we speak, Strides owns 54% of Stelis, but not necessarily have invested 54% of the \$145 million because they were invested at different time points and at different valuations. All the other investors in the platform have come at a higher valuation to Strides at some time so 54% does not mean 54% or \$145 million of equity. It could be slightly

more in terms of equity value. Assuming that the \$50 million is coming in at the same round of financing that was done the last round by Strides and by their investors there would be \$75 million on approximately \$200 million of total outstanding capital.

**Nitin Agarwal:** Strides will be a 25% ownership subsequently?

**Arun Kumar:** 25% of \$200 million is a little more than 25%.

**Nitin Agarwal:** Okay. I will get offline with you. Secondly on the...

**Arun Kumar:** Yes, that is what I said, in absolute dollar terms, it is 54% diluting by \$50 million. So, and then what is that value? So, it all depends upon valuation. And that is why I called out that please bear with us for another 4 to 6 weeks as we complete, we will be able to provide more information around Stelis, as we complete certain milestones that we are currently working on.

**Nitin Agarwal:** Okay. And secondly, on the core business itself, now I mean, apparently, in the way the leadership team is now being beefed up versus the size of the current business that we have. I mean, this seems like a very, very large build-out of senior management talent. So, has there something just changed in terms of whether you visualizing the business over the next 3 to 5 years? Because it seems like a fairly heavyweight management team from size of business that we have, right?

**R. Ananthanarayanan:** So clearly, for us, our core business is exciting and continues to be exciting. And as we have been giving commentary, we see significant opportunities going forward, particularly with respect to the regulated market business, which is really the core area of the overall organization. As I said, which is currently now over 80% of the revenues. We clearly believe focusing significantly on that value-creating portion is going to give us the ability to grow better and to create better value. And to be able to do that, and to both generate the velocity as well as to meet the growth aspirations, we clearly believe that having industry experienced leaders that are coming into the management team is going to make a big difference and it is going to help us accelerate towards that growth dimension, number one and number 2 is, also to the point, as Arun mentioned earlier, this will help us also select complementarities that we will look at into the portfolio buildings that will also help further build on to the growth story.

**Arun Kumar:** And Arun here, if I may add. See, with our current run rate of close to about \$500 million you will appreciate that this business was built in the last 4 to 5 years after we sold Agila. It has taken several fine tunings from us. But in the last 2 or 3 years, we have got the model right. It is a business that has been built on deep portfolio, great customer advocacy and the

work. To build the business from the \$500 million run rate to what we think it will be because if we called out \$400 million in the U.S. and that business being mirrored by other regulated markets in probably in the next 4 to 5 years, I am not so sure exactly how long, what we have been missing would be the leadership team. And just like in our first phase, we would have invested heavily on products and infrastructure. In this phase, we are investing, obviously, on people to build the business to the next level. So, like in all pharmaceutical businesses, you have to put money, expenses before the revenue growth. And I think what Ananth has done is brilliant in terms of finding the right team. I mean, a different type of team that probably takes the company from where we are today to where we want to be.

**Nitin Agarwal:** If I can squeeze in one small question. Badree, on gross margin, there is a Q-o-Q pretty sharp dip. Any specific reason why should that be revenue composition is largely the same?

**Badree Komandur:** Yes. So, there are 2 reasons for that. One is the quality of the mix for the business. And second is the abolition of the MEIS scheme, which was not there in the current quarter.

**Nitin Agarwal:** Okay. So, this should be a run rate going forward, 58% or so?

**Badree Komandur:** Yes, that is correct.

**Arun Kumar:** So, there is almost 3% impact on incentives, which, if you adjust for that, it is not very material drop in the gross margin.

**Nitin Agarwal:** Got it. Okay thank you.

**Moderator:** Thank you. The next question is from the line of Vivek Gautam from GS Investments. Please go ahead.

**Vivek Gautam:** Congratulations on good numbers you have been providing. And I just wanted to have information about the pricing situation, especially in US and regulated markets for both oral products and injectables. Has it started feeling the competitive intensity and has it started coming down, I mean as it used to be before COVID?

**Arun Kumar:** So Vivek, this is Arun. We do not yet sell any injectables in any market. So, we would not be able to comment on your question.

**Vivek Gautam:** Oral solid, I'm talking about, also.

**Arun Kumar:** So, I will probably pass that on to Ananth.

**R. Ananthanarayanan:** Yes. So Vivek, on the oral side, as we said, especially in the U.S., we do continue to see some price erosions on certain products. We do not see that all across the board, but we do see that on select products, where certainly, competition is increasing on those. And obviously, that does bring in some element of price erosion. So, we did see that in the U.S. in this quarter. During our commentary in the last quarter also, we had given that indication that we are starting to see that almost for the first time that we had seen, and it has been there in this quarter as well.

**Vivek Gautam:** And Q1, basically, we saw performance, which has improved a lot. So had a sort of a one-off tailwind in form of COVID demand in Q1?

**R. Ananthanarayanan:** Could you repeat that, Vivek?

**Vivek Gautam:** Yes. In the April, May, June quarter, the performance of the company was quite good, as for the sector also it was quite good. So, was it more to the stocking up and other opportunities being done in U.S. and other regulated market for generics, both oral and otherwise injectables?

**R. Ananthanarayanan:** So, Vivek, apologies, but we are simply unable to hear you well and understand your question. Would you mind repeating it?

**Vivek Gautam:** My question is, so the performance of Strides was very good in Q1 of this current year for April, May, June quarter. So, I just wanted to understand the reasons behind the improvement of that particular quarter? Because due to the COVID stocking up, the numbers were very good, and now the situation has started sort of worsening due to the competition intensity?

**Arun Kumar:** Well, this quarter is equally good. It is just that, typically, in this quarter, the flu season place favorably for us. This time, we had a very bad flu season, which means that there were no flu-related sales, it is typically \$4 million to \$5 million for us, and that is the reason why you'll see the quarter to be a little flattish. But otherwise, the growth is within line or within our expectations. We do not see a COVID uptick and a post-COVID downtick. So that is not the case.

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

**Tushar Manudhane:** Just on the U.S. sales, overall sales number for FY2021, while the Q3 got impacted because of the flu season. So overall, FY2021 guidance, does it stand revise and if so, then what is the new sales guidance?

**R. Ananthanarayanan:** Yes, sure. So, as you would recollect in our commentary, the last time we did indicate that we would probably be towards the lower end of our guidance. Having said now, given the way the flu season has played out and the impact of the winter products that we have had as well as some of the price erosions, we do believe that is going to play a little bit forward. So, we expect our guidance to be in the sub-220 level.

**Tushar Manudhane:** Got it and so for FY2022 with new launches lined up, what can be the base case to go with?

**R. Ananthanarayanan:** Yes, we do have new launches lined up that will play out from the end of this year going into the next year. And certainly, that will be one of our pivots for growth going forward.

**Tushar Manudhane:** Got it. And just on other regulated markets, quite a sharp jump up even sequentially. So, this Rs.298 Crores to Rs.300 Crores can be taken as a sustainable number? Or is there any one-off?

**R. Ananthanarayanan:** No. There is no one-off. If you, again, go back to the commentary we had in Q2, we did indicate, pretty clearly, that some of the interruptions that we had during Q2 in our manufacturing facilities, did cause supply disruptions. And our Q2 other reg markets showed a dip and we said, we clearly have the order book visibility, and we will bounce back very strongly, again, in Q3 and going forward. So that's what played out is clearly, when the facilities have come back to normalcy, we have been able to get back to delivering to our order books. We continue to see the order books visibility to be strong. And therefore, there will be a continued growth in this other reg market business.

**Tushar Manudhane:** Alright that answers my question.

**Moderator:** Thank you. The next question is from the line of Sajal Kapoor from Unseen Risks. Please go ahead.

**Sajal Kapoor:** I have a couple of longer-term questions, please. So firstly, what we have seen with some of the Chinese biologics players is that once the long gestation period is over, the sales and profit growth show a very sharp uptrend. So, 90% profit CAGR over 5, 6, 7 years is common there. Wuxi Biologics as an example. When do you think the Stelis can get into that kind of high-growth case sometime in future?

**Arun Kumar:** So, we are at least, 4 to 5 years before we get to that hockey stick growth, biologics takes much longer and to our dismay in our case, because we had to bring the project back from Malaysia to India. We lost about 2 to 3 years in that journey. So, we are at least 4, 5 years away when we get to that hockey stick kind of growth trajectory, both in revenues and in margins, simply from the regulatory timelines and the approvals. And COVID does not

help, while the demand for capacities are high, our plant is new, so regulators are not traveling and visiting. So, obviously, that is a negative. So, we hope that is going to change soon. And we should have inspections happening because we are ready to receive inspectors. But considering that we have the ability to make product season for COVID, we hope that we will have the facility inspected and then we can hit the road for this business. But we are several years away from significant growth.

**Sajal Kapoor:**

Sure, Arun. And secondly, the biologics developments and manufacturing are a relatively new domain for Indian players. So, there will, of course, be a steep learning curve for everyone and challenges will be there in getting the right talent, along the value chain from research and development all the way to commercial manufacturing. So, this more of an industry question for you because you have so much experience. How do you see the risk reward landscape, given that there is an apparent crunch of sorts in India as far as biologics manufacturing is concerned? So, can Indian players get into that sort of high-growth phase starting, say, 2025, not just the Stelis, but the general industry structure?

**Arun Kumar:**

Yes. So, to address your question, which is relevant, but different to your question is the model of Stelis. Stelis is predominantly a service provider of everything from cell line development to improvements and needs, to clinical batches, to undertake the large-scale manufacturing. Like I mentioned in my opening statement, outside of one product that we have filed, we have not invested any capital, significant capital on any new programs. So, your question is very relevant when you have a portfolio of products like some other companies in India have. But our focus is to be more a service provider, be a full services GMP provider right from small-scale to very large-scale manufacturing and also to include vaccine manufacturing in the process. So, the CDMO opportunity is good because most biopharmaceutical companies are virtual. COVID has ensured that large players who provide capacities to smaller players are no more available. Backlog of capacity is 2 to 3 years. So, even a new company like ours, a new facility like us is getting a lot of interest from international players. So, we believe moving away from spending millions of dollars on development, we are better off investing in infrastructure and leveraging capabilities by being a full services provider of services and manufacturing. And that is the shift and that is the reason why the business will not require too much more cash from the incentive, next round of funding, which will be over 3 years and I hope that answers your question because we are not a product company in Stelis.

**Moderator:**

Thank you. The next question is from the line of Sriraam Rathi from ICICI Securities. Please go ahead.

**Sriraam Rathi:** Just 1 question, particularly on the other regulated markets. In the last 2, 3 years, we have seen phenomenal growth in that segment. And the base is also very high. So, going forward, can we still expect that double-digit growth to continue in that business? And what will be driving that?

**R. Ananthanarayanan:** Yes. Thank you for the question. So absolutely, we are certainly bullish about the other reg markets and the growth that we are likely to see in the other reg markets. We certainly see the trajectory continuing. We certainly see the growth pattern continuing, going forward. And we are confident of growing that business.

**Sriraam Rathi:** Okay. And in relation to that only, I mean, particularly the Australian market. Have we already achieved our target EBITDA after the divestment that initially we guided for?

**R. Ananthanarayanan:** Yes. So, we are very much in line with the target EBITDA.

**Arun Kumar:** That is there in the numbers...

**R. Ananthanarayanan:** In fact, it has already been achieved a few quarters back. Yes, we have done it earlier.

**Sriraam Rathi:** Okay. Perfect and Sir, lastly, one thing, I mean, is it fair to assume that the gross margin across U.S. and the other regulated markets would be more or less similar?

**R. Ananthanarayanan:** No, gross margins in the U.S. is certainly higher. And in the other reg markets, you have to understand that there is a mix of front end as well as partnered business. And therefore, as a combination, that business will have a slightly lower gross margin than the U.S. business. The U.S. is as we indicated significantly a B2C or a front-end driven business, and we have tapered off our partners business, and the gross margins are much higher.

**Moderator:** Thank you. The next question is from the line of Kunal Randeria from Edelweiss. Please go ahead.

**Kunal Randeria:** So, a couple of related questions to each other. So, I just wanted to know a couple of things regarding how you're planning on filing ANDAs in the next couple of years? You acquired a facility in Florida a couple of years back. So, I am wondering whether you started to make a filing from that facility and also, we acquired some 18 ANDAs last year, last February. So 11 of which are approved. So, I just want to understand whether they have already been launched and 7 are under development. What is the status?

**R. Ananthanarayanan:** Certainly, happy to provide the detail. So, the facility in Florida, the West Palm Beach site in Florida currently is in the process of having products that are getting tech transferred.

And that are under filing with the FDA for CB30 and we expect the approval, the CB30 approvals to come in, and we should have the ability to start the manufacturing and supply going forward. And therefore, that is going to be one of our important facilities ahead that is number one. Number two is that from a second question that you asked, along with it, was about the ANDAs mix, am I right? Sorry, could you repeat the second question?

**Arun Kumar:** The ANDAs we acquired.

**R. Ananthanarayanan:** The ANDAs we acquired. 18 ANDAs that we acquired. So yes, and we have got a mix that some products where we are doing work on either an alternate API source and/or tech transfer to our site in Bangalore to make us more competitive, which is under process. There are some products that are already approved, and we have already commercialized them, and those products are growing pretty well. In fact, on some of them, we have got very good market share and are gaining further traction. And there are a couple of products where we have got the approval from the FDA. However, they are products that come under the controlled substances category in Schedule II. And therefore, we are in the process of now identifying and finalizing a suitable site in the U.S. where we could do the tech transfer and launch the manufacturing from those sites for those controlled substance products. So that is probably the perspective for your questions. I hope it answers.

**Kunal Randeria:** Yes, that is helpful. Just a clarification, how many products will you be getting approval from the Florida plant?

**R. Ananthanarayanan:** From Florida?

**Kunal Randeria:** Yes.

**R. Ananthanarayanan:** We are looking right now in the first phase, about 6 products.

**Kunal Randeria:** By first phase, I mean, in the next, maybe, 3 or 4 quarters?

**R. Ananthanarayanan:** In the next couple of quarters.

**Kunal Randeria:** Couple of quarters. Great and just lastly, any update on Levothyroxine?

**R. Ananthanarayanan:** On Levothyroxine, it is filed with the FDA, it is undergoing FDA review. So, it is still in the regulatory stages.

**Kunal Randeria:** Okay. Any sort of timeline would you like to share on that?

- R. Ananthanarayanan:** No, it is under regulatory review. So, there is very little we will be able to share.
- Moderator:** Thank you. The next question is from the line of Rahul Veera from Abakkus Asset Manager. Please go ahead.
- Rahul Veera:** I just wanted to understand some details around Stelis Biopharma would be great in terms of topline, what kind of margins we are expecting, when we say that it will breakeven in FY2022?
- Arun Kumar:** No, we do not have a topline now. Stelis does not have revenues or significant revenues, a couple of million dollars. We mentioned that in the next financial year, we will breakeven. And as a policy, we do not give forward-looking numbers.
- Rahul Veera:** Okay and Sir, in the annual reporting that we have done, it shows in the Q3 FY2021, we are showing around Rs.26 Crores of loss from the share of JV and associates. So, is it largely related to Stelis only?
- Badree Komandur:** Yes, it has 2 components. One is the Strides consumer health business, which is also in the investment phase. And the other one is the Stelis, which is expected to breakeven in 2022.
- Rahul Veera:** Okay fair point that is it from my end.
- Moderator:** Thank you. The next question is from the line of Sarvesh Gupta from Maximal Capital. Please go ahead.
- Sarvesh Gupta:** Sir, first question on the U.S. business, we had an aspiration to reach \$100 million run rate. And because we had 2 soft quarters because of external reasons, my understanding was that bulk of the growth was supposed to be coming from new products because our ratio of the products launched to the product approvals was pretty low. So given that, how do we see the softness in the growth in U.S. business in the last 2 quarters? And how should we see your vision of reaching the \$100 million run rate. Earlier, I think it got pushed by a couple of quarters, so what is the timelines for that? So that is number one. Secondly, on Stelis, if you can help me with the post money evaluation for the last round, of which, Strides would be holding 54% stake?
- R. Ananthanarayanan:** Sure. Let me answer your first question clearly. Now I think you have to look at the U.S. business, particularly on 2 fronts. Our U.S. front end business is growing pretty strong and continues to grow quarter-over-quarter. We have, by design, decided to taper our partnered business. And certainly, some of that comes into play. And during our early part of the commentary, we did indicate that during this quarter, we did see a weak flu season that did

have a softness in some of our winter product portfolio that otherwise plays out normally during this quarter. But other than that, you would see that we are constantly growing in the U.S., and we see growth going forward as well. And as you rightly mentioned, new products are great for growth. It does not mean that our ratio of approval to launches will be low because of the way we have also selected products. Some of these approvals will come into play going forward. And as those product approvals come in, we will also be increasing the number of products that we will launch. Obviously, that is to make commercial sense. It has to be in the right commercial ballpark and value ballpark. But having said, new products are going to be a strong pivot for our growth and the portfolio selection that has been done, so far, and the portfolio selection that is being done going forward is all based on the ability for us to continue that growth trajectory. On Stelis, Arun will probably handle.

**Arun Kumar:** So, your question was on pre-money valuation. The last round of \$40 million that Strides invested was at a pre-money valuation of \$115 million, taking the post-money valuation to \$155 million. If that addresses your question.

**Sarvesh Gupta:** Thank you Sir.

**Moderator:** Thank you. We will take one last question, which is from the line of Nitin Agarwal from DAM Capital Advisors. Please go ahead.

**Nitin Agarwal:** Dr. Ananth, in the press release, you have called out the Truvada approval. I mean any specific reason why you called it out? Do we see it as a significant launch for us?

**R. Ananthanarayanan:** Yes. So, the generic Truvada is certainly an important product, and that is why I did call out because we were certainly excited about that approval. As you know, this is a product that is currently under 180-day exclusivity. And the 180-day exclusivity will come off pretty soon. We are gearing ourselves. The generic market formation will happen soon as when as the 180-day exclusivity is complete. And we are certainly getting geared up to be able to present during the market formation. And so, we just called out the generic Truvada approval.

**Nitin Agarwal:** And secondly, you mentioned that TLD approvals now how big an opportunity do you see for yourself in TLD, given the fact that we are not vertically integrated in this product, given the fact that some of our peers have really scaled up massively on this product so far?

**R. Ananthanarayanan:** Yes. So, TLD continues to be an opportunity because of the new regimen, and that is a part of the new regimen. Having said that, we do realize that some of our competition has vertical integration and we will continue to be selectively participating in opportunities or

the global fund tenders or the other tenders that come up, that will make commercial sense. And wherever it makes sense for us from a gross margin and revenue perspective, we will participate. We are not going to go aggressive and try and capture the business for the sake of capturing the revenues.

**Moderator:** Thank you. Ladies and gentlemen, due to time constraints that was the last question. I now hand the conference over to the management for closing comments.

**R. Ananthanarayanan:** Thank you, everyone. Thank you for your time on this call. See you all during our next quarterly conference. Until then, please stay safe, stay well, and have a good evening.

**Moderator:** Thank you. On behalf of Strides Pharma Science Limited that concludes this conference. Thank you all for joining us and you may now disconnect your lines.

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