



## “Cadila Healthcare Limited Q4 FY18 Post Results Conference Call”

**May 25, 2018**



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**Moderator:** Ladies and gentlemen, good day and welcome to the Q4 FY18 Post Results Conference Call of Cadila Healthcare Limited. As a reminder all participants' 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. Ganesh Nayak – COO & Executive Director of Cadila Healthcare Limited. Thank you and over to you, sir.

**Ganesh Nayak:** Good evening and welcome to our post results teleconference for FY18. We have with us Dr. Sharvil Patel – Managing Director; Mr. Nitin Parekh – Chief Financial Officer; Mr. Tushar Shroff – Senior Vice President-Corporate Finance and Mr. Vishal Gor – Vice President-Corporate Finance.

The year gone by was the most successful year for our US formulation business. We received approvals for 77 new products, including 8 tentative approvals, during the year, which incidentally is the highest number of approvals received by us in a single financial year. The launch of Mesalamine 1.2 gram DR tablets in July 2017 with 180 days exclusivity was our first large FTF opportunity.

During the year, we moved one step further in our endeavor to build the specialty pipeline in the US as we received the approval for Pitavastatin Magnesium tablets, the first product filed through 505(b)(2) route, which we recently launched in the US under the brand name Zypitamag™. On the regulatory front, both Moraiya formulations facility and Topical formulations facility successfully completed the USFDA inspections twice without any observations. Our API facility at Dabhasa, also successfully completed the USFDA inspection without any observations.

The year gone by turned out to be a difficult one for our India formulations business on account of the nationwide rollout of the GST Act with effect from 1<sup>st</sup> of July 2017 which resulted in de-stocking of inventories by our stockists, thus impacting the performance of the first quarter adversely. As is known, we continue making sizeable investments in new technologies such as specialty generics, biosimilars, vaccines, transdermals and new chemical entities which are expected to contribute to our future aspirations. With that, first of all let me take you through the broad financial numbers.

During the fourth quarter of the financial year 2017-18, on a consolidated basis our total income from operations was up 29% year-on-year to Rs. 32.5 billion. However, on a like-to-like basis, adjusting for the GST impact the growth was 31%. Our EBITDA was up 87% year-on-year to Rs. 8.7 billion and the EBITDA margin for the quarter improved by 830 basis points



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to 26.8% as against 18.5% registered last year. Profit before Tax was up 79% year-on-year to Rs 7.4 billion.

Net profit was up 53% year-on-year to Rs. 5.9 billion and the net profit margin for the quarter improved by 290 basis points to 18.2% as against 15.3% registered last year.

Coming to the financial year 2017-18, on a consolidated basis, our total income from operations was up 25% year-on-year at Rs. 119.4 billion. On a like-to-like basis, adjusting for the GST impact, the growth was 27%. EBITDA was up 50% year-on-year to Rs. 28.5 billion and the EBITDA margin for the year improved by 400 basis points to 23.9% as against 19.9% registered last year.

Profit before tax was up 44% year-on-year to Rs. 23.3 billion. Net profit was up 19% year-on-year to Rs 17.8 billion and the net profit margin for the year stood at 14.9%. Our consolidated debt at a gross level stood at Rs. 54.1 billion and the debt net of cash stood at Rs. 38.5 billion. Net debt equity ratio was 0.44 as on 31st March 2018.

Let me share some of the highlights of operations for the year. In the US market, we launched 20 new products in the US during the year. Our new launches include Mesalamine 1.2 grams DR tablets which is a generic version of Lialda and Oseltamivir powder for oral suspension which is a generic version of Tamiflu. We also filed 26 additional ANDAs with the USFDA taking our cumulative ANDA filings to 330. These include our first ever ANDA submitted from LIVA which is our injectable facility near Baroda.

We received approvals for 77 ANDAs, including 8 tentative approvals, during the year taking our cumulative number of approvals to 186. These include receipt of final approval for Mesalamine 1.2 grams DR tablet, Mesalamine 800 mg DR tablets which is a generic version of Asacol HD, Oseltamivir powder for oral suspension, Metoprolol Succinate ER tablets, and the tentative approval for Mesalamine rectal suppositories 1000 mg which is the generic version of CANASA.

We entered into an agreement with Medicure International Inc. to commercialize ZYPITAMAG™ which is our first product filed through 505(b)(2) route and recently we launched ZYPITAMAG™ in the US market. Overall, our US business posted sales of Rs. 58.3 billion, up 57% during the year.

On the India formulations front, we launched 64 new products, including line extensions during the year, of which 10 were for the first time in India.

We successfully launched the acquired brands of Organon (India) Limited, which is a subsidiary of Merck Sharp and Dohme and AstraZeneca during the year. Overall, our India



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formulations business, posted sales of Rs. 33.3 billion, up 3%. However, on a like-to-like basis, adjusting for the GST impact, the growth was 6%.

In the emerging markets of Asia Pacific, Africa and Middle East, we retained our number one position in Sri Lanka with 7 brands featuring among the country's top 50 brands. We launched 10 new products in the focused markets of Asia Pacific, Africa and Middle East during the year. These included the launch of two biosimilars, namely Colstim and Pegstim in Philippines and Sri Lanka respectively. Overall, our emerging markets business posted sales of Rs. 5 billion down 1%. Speaking of Latin America, we launched 3 new products in Brazil and 4 new products in Mexico during the year. We filed 3 new product dossiers with the Brazilian Regulatory Authority ANVISA and received approval for one new product during the year. In Mexico, we filed 2 new product dossiers with the Mexican Regulatory Authority COFEPRIS and received approvals for 3 products during the year. Overall, our business in Latin America posted sales of Rs. 2.6 billion during the year, up 7%.

Among our other businesses, we launched 7 new products in France, including 5 from India and 6 new products in Spain, all of them from India. We filed 4 new product dossiers taking our cumulative filings to over 215 and received approvals for 6 new products, taking our cumulative approvals to over 180 for the European market during the year. Overall, our European business posted sales of Rs. 2.4 billion during the year, down 8%.

Zydus Wellness Limited posted sales of Rs. 4.9 billion up 7% and a net profit of Rs. 1.3 billion up 23%. On a like-to-like basis adjusting for the GST impact the growth in sales was 16%. Wellness business continued to maintain its leadership position in SugarFree, EverYuth scrub and peel off categories.

On the animal health front, we commenced exports of products from India to 4 countries during the year. We sold our entire stake in Bremer Pharma, Germany to Alivira Animal Health Limited, Ireland. Overall our animal health business launched 4 new products in India during the year and posted sales of Rs. 4.4 billion, up 11%. On a like-to-like basis adjusting for the GST impact the growth in sales was 14%.

On the APIs front, we filed 6 DMFs with the USFDA during the year, taking the cumulative number of DMF filings to 133. Coming to our JVs and alliances, we sold 25% stake in Bayer Zydus Pharma Private Limited to the other Joint Venture partner.

On the biosimilars front, we received a marketing authorization from the DCGI for 3 more products during the year. We received regulatory approvals to initiate Phase 3 clinical trials in India for one more Monoclonal antibody during the year. We continued to file the dossiers of our first generation Biosimilars and Monoclonal antibodies in the emerging markets. During



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the year we received 5 product registrations in different countries of emerging markets. On the novel biologics front, we initiated phase 3 clinical trials in India for Rabimabs.

On the vaccines front, we completed phase 3 clinical trials in India for one more vaccine and applied for its marketing authorization. We entered into an agreement with Pharm Aid Limited Russia, for the supply and technology transfer of the varicella vaccine.

On the new chemical entity research front, we have received marketing approval from COFEPRIS, to commercialize LIPAGLYN™ for the treatment of Dyslipidemia in patients with diabetes mellitus type 2 and hypertriglyceridemia in patients with diabetes mellitus type 2 not controlled by statins. We initiated phase 2 clinical trials for investigating ZYANI as a treatment for Anemia associated with chronic kidney disease. Saroglitazar Magnesium, a novel PPAR agonist having predominant PPAR alpha activity is currently undergoing phase 2 clinical trials in the US for 3 indications and phase 3 clinical trials both in India and Mexico for 3 indications each.

On the Manufacturing and Operations front, both Moraiya formulation facility and topical formulations facility successfully completed the USFDA inspection twice without any observations. Dabhasa API facility successfully completed the USFDA inspection without any observations. Our biologics unit 1, unit 2 and the Fill and Finish facility and our API manufacturing sites both at Ankleshwar and Dabhasa successfully completed the COFEPRIS audit. Thank you and we will now start the Q & A session. Over to the coordinator for the Q&A.

**Moderator:** Thank you very much, sir. Ladies and gentlemen, we will now begin the question-and-answer session.

The first question is from the line of Rajesh Kothari from AlfAccurate Advisors. Please go ahead.

**Rajesh Kothari:** I have two questions. One, USA market is changing a lot and there are many new regulations and of course the Trump government is also announcing lot of things on the US Pharmaceutical Industry. So if you can give your view on how do you see the US pie of your business to take shape over next 2 to 3 years.

Second question is on similar lines how do you see the India business growth because Indian market also has quite significant changes, of course in terms of sales mix it is not making that big dent to the companies but otherwise government is talking a lot in terms of the generics and overseas formulations. So over the next 2 to 3 years how do you see therefore the sales mix compared to currently where we stand?



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**Sharvil Patel:** On your first question on the impact on the views of the current president Donald Trump, I think generally it is a positive view that, it is for the generics market because he is talking about increasing access of affordable medicines, specifically the generics medicine. So I think generally we look at it as a positive indicator for the generic part of the business. He has also spoken of important things like removing the middle men who are making actually most of the profit in the overall business. So I would say generally it is positive for the business in the generics industry.

For Zydus specifically, I think we continue to have a good filing pipeline as well as a tilt to approve products with FDA and we continue to file different dosage forms. So we see that the US business will continue to remain large and significant which today is 50% of the overall revenue, will remain around that with the current momentum of growth that we have.

**Rajesh Kothari:** So you do not see pricing pressure from here on into the segments in which we are operational, if you can give color on that?

**Sharvil Patel:** Pricing pressures will continue. They are much lower than what it used to be in the preceding earlier quarter. But as the generics competition intensifies there will be pricing pressure but we have a large diversified portfolio of competitive products as well as limited competition products. So we will continue to grow with those portfolios.

Specific to India, India is a home market for us. It is a market where we have significant market share across many therapies. We have done well on new product introduction. So, we are balancing our portfolio between our heritage brands and new brands. So once the new brands become significantly large form of the overall pie, we would see improvement in the growth in the India business. So looking at all of that, portfolio alignment, rationalization and other things, we feel that we should be back on track from the coming quarter.

**Rajesh Kothari:** So are you looking at double digit growth in India business?

**Sharvil Patel:** Yes.

**Rajesh Kothari:** So in terms of therefore sales mix you think the current sales mix over the next 2 to 3 years do you see any significant change to your sales mix?

**Sharvil Patel:** We do feel that in the next 3 years, our India and emerging market portfolio will improve aided by Biologics and Vaccines which today have very little revenue of the overall business. But large part of the development is finished, approvals are here, the regulatory applications are filed and coming up for approvals. So those two businesses will add revenue in the next 3 to 4 years. So you would see those pies of India EM portfolio improving in the next 3 to 5 years.



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- Rajesh Kothari:** So does it mean that you know your overall margins therefore from current levels, how do you see that as those segments grow faster than your overall business?
- Sharvil Patel:** On a normalized basis, with the new portfolio our margins would improve by 1% every year.
- Rajesh Kothari:** What do you mean by Normalized basis?
- Sharvil Patel:** One-off. We have some one-offs like Mesalamine and all. So we will have to see a steady state on that as well.
- Rajesh Kothari:** So what are the steady state margins if you remove those one-offs?
- Sharvil Patel:** We do not give product wise, portfolio wise details. We can just give the overall margin.
- Moderator:** Thank you. The next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.
- Neha Manpuria:** There was obviously a very large one-off component in this quarter, in this year. Now going ahead based on the approvals that we have received which we have not launched and the pipeline visibility that we have, how should you see your underlying business growth? I mean, would it be enough to offset the margin pressure that we would see from Tamiflu and Lialda coming off from this quarter's level?
- Sharvil Patel:** Revenue wise, we would still see good growth because of the amount of products that we will be launching in the coming year. And we also have important launches there, where we have limited competition products coming up.
- Neha Manpuria:** So you expect US to grow even next year from the current base?
- Sharvil Patel:** Yes.
- Neha Manpuria:** And what about margin? How much do you think, you know there was a one-off element, therefore margins across, margin should come off in the next quarter get more normalized. Is that a fair assumption? Or do you think you have certain products in your pipeline which will be able to offset the pressure that you are seeing, you know that you will see from Lialda?
- Sharvil Patel:** So I would say that if you look at it from annual picture, we should be able to manage our margins well but quarter-on-quarter there might be some changes.
- Neha Manpuria:** My last question. Excluding the one-off, did you see margin improvement in FY18 versus FY17 especially because India was weak, EM was weak?



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- Sharvil Patel:** Yes.
- Neha Manpuria:** And what drove that margin improvement?
- Sharvil Patel:** Better products for the US market.
- Neha Manpuria:** Other than Lialda?
- Sharvil Patel:** Other than Lialda and also we continuously work on operational efficiencies so that will also add over a period of time some improvements on margins.
- Moderator:** Thank you. The next question is from the line of Kartik Mehta from Deutsche bank. Please go ahead.
- Kartik Mehta:** Two questions. In terms of approvals for the FCCB and convertible, is that an approval and which assets do you see would be in which type of geographies would be attractive for you?
- Sharvil Patel:** It is an enabling provision only for the moment. We would only exercise that if we have large strategic transactions.
- Nitin Parekh:** We are having these resolutions for last two years also you would have seen these resolutions. These are enabling in nature. If there is a right opportunity which needs the fund raising, then we do not have to wait for funds and miss that opportunity or encashing that opportunity for that only resolutions have been taken.
- Kartik Mehta:** So that is helpful. These are enable?
- Nitin Parekh:** Yes, these are the enabling resolutions.
- Kartik Mehta:** So two quarters ago you had indicated that you expect a growth in FY19 over FY18 so we had a huge base of Lialda and also now in this case higher base for Tamiflu, there has been competition in Tamiflu which you will face competitor now for Lialda. Will assume low double-digit PAT growth in FY19?
- Sharvil Patel:** Yes.
- Kartik Mehta:** And in terms of number of launches have you kept the assumptions for the number is actually the same or is it been now reduced assuming that competition would have increased in many of the products that we would have assumed to launch?
- Sharvil Patel:** It is the same we will continue to launch 50 plus products.





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- Moderator:** Thank you. The next question is from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.
- Nimish Mehta:** Just two questions. How much of the Top 5 products in US are contributing to the overall sales?
- Sharvil Patel:** Unfortunately, we do not give product wise break up.
- Nimish Mehta:** Not really the product wise something like maybe the Top 5 products or top 10 products?
- Sharvil Patel:** It amounts to the same issue.
- Nimish Mehta:** On the gross margin front, I wanted a clarification you mentioned that you will be able to maintain the same gross margin for, I mean that we are maintaining in FY18 and FY19. Is that a fair assumption? Is that what I understood rightly?
- Sharvil Patel:** We can talk about better the EBITDA margin that we can.
- Nimish Mehta:** Yes, fine. No problem. What exactly?
- Sharvil Patel:** Yes, we should be able to without the one-off.
- Nimish Mehta:** With the one-off or without the one-off, sorry?
- Sharvil Patel:** without the one-off.
- Nimish Mehta:** We are talking about FY18 versus FY19 not, not Q4, right?
- Sharvil Patel:** Yes.
- Moderator:** Thank you. The next question is from the line of Kartik Mehta from Deutsche bank. Please go ahead.
- Kartik Mehta:** In terms of your outlook for your Vaccines and your Biosimilars business in emerging markets, would you be able to help us in terms of your arrangement with actually distributors or the number of products that we expect to launch over the next 2 to 3 years?
- Sharvil Patel:** So for the Biologics, we commercialized the Biosimilars in India through our own field forces and where we have very strong market share for all of the Biosimilars where we are either among the top 3 in all of the categories of Autoimmune oncology as well as rheumatology and others and Nephrology. We have followed a business model of being able to license these products for the emerging markets.



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Some markets where we could do directly and some markets we have found and already partnered with the top 3 ranked companies in those markets for the launch of Biosimilars. These have already gone through the first stage of regulatory cycle. So all of the large markets where we have license, we already have been our facilities have been audited and cleared. Now the dosages are decked with all of them and we would see approvals coming through this year.

And likely commercialization will start in the next year, middle of this year to next year. In the next 3 to 4 years we should see a \$150 million business that we can build on that Biologic side and similarly for vaccines, we are in an early stage with the vaccines. We have a large portfolio of vaccines that have been developed nine of which have been approved. We just commercialized recently the vaccine which is the Zydus Typhoid Conjugate Vaccine which is a vaccine with limited competition.

Similarly, we have more vaccines coming up, again we have done some partnership though limited right now, but some partnership with some markets where we have found credible partners who could launch some of these private vaccines. We are also working on qualifying our facilities with WHO for prequalification. And we are lined up to do that in the next 12 to 18 months.

So vaccines also will be an equally \$150 million to \$200 million plus business in the next 4 to 5 years. So these two franchises both within India and emerging markets can be between \$500 million to \$550 million in the next 4 to 5 years.

**Kartik Mehta:** And for this in term of expenses that you would need to incur in terms of distribution, so where are we on that? Will this entail upfront investments may be from next year or is it we then borne by distributors here?

**Sharvil Patel:** The model that we have followed for this, in India we already have a distribution team already built. So there is no further significant investment there. On the other markets, we have licensed out where there is going to be commercial partners who would take care of the distribution, marketing and sales of these businesses. So we would have relatively much better profitability with these businesses because we do not have upfront investment. And we would also have some small percentage of royalty linked licensing fees.

**Kartik Mehta:** Last one is on the Income Tax rate? Could you help us with what rate should we run for the next 2 years on Income Tax?

**Management:** Less than 25%.

**Moderator:** Thank you. The next question is from the line of Saion Mukherjee from Nomura. Please go ahead.



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**Saion Mukherjee:** Can you throw some light on the current dynamics on pricing particularly with respect to Lialda and Metoprolol in the market? And what is your expectation on these two products going forward? Some general color would be useful and have you seen meaningful erosion you would say in Lialda this quarter compared to last quarter?

**Sharvil Patel:** No, Lialda is steady now with one generic competition and the market is stable. So we do not have any significant further price erosion on this with the current competition in the market. And so with TEVA that is the only player who has launched into the market. After more competition you would see more erosion, but currently with the current stage there are only one competitor plus us. And on Metoprolol we have been able to see that there is enough opportunities in the market to gain some share, so we feel it should be positive for us.

**Saion Mukherjee:** As of March 2018, what is the number of pending ANDAs and the broad breakup formulation wise? Is it possible for you to share?

**Sharvil Patel:** Total pending ANDAs is 144. The breakup of the dosage forms, Vishal can give you offline.

**Moderator:** Thank you. The next question is from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.

**Anubhav Agarwal:** Just one question on Metoprolol. When did you launch this product?

**Sharvil Patel:** We have not launched it yet. We will launch it in the coming quarter.

**Anubhav Agarwal:** Why such a long delay? You got the approval in March and almost a quarter delay, what is the reason for that?

**Sharvil Patel:** So Metoprolol, one is obviously it is a high technology based product. It is a large volume product also and it requires specific technology and for any product for us it does take 3 to 4 months, almost sometimes 6 months to get commercially ready because there are various steps of processes that we have to follow before we can commercialize the new product. You must understand that we have a large product approvals come through, so we must do it right the first time.

So we have protocols in place that take care of different formats on validation and engineering batches and all of that. So there would always be a delay unless we have already seen that the product is going to be approved. I mean if we are aware of it earlier we would be prepared otherwise it does take some time after the product approval.

**Anubhav Agarwal:** Just to get it right. Right now this product for you, is it right now in the inventory buildup stage or you already built up the inventory and you dispatched it and marketing stage right now?



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- Sharvil Patel:** No, it is in Inventory buildup stage. It is always the large inventory so that we do not have issues in the market.
- Anubhav Agarwal:** So when you say next quarter, we expect to launch around July, August something around that period?
- Sharvil Patel:** Yes.
- Anubhav Agarwal:** And just one clarity on generic Lialda. You said that after Teva the market is stable but what IMA shows that Cadila has been able to maintain a market share more than 50% that will be right representation of right market share. Basically your market share has not changed after Teva has come in. Is that so?
- Sharvil Patel:** No, the market share has come down after Teva.
- Anubhav Agarwal:** What about pricing? Pricing would have come off typically as it happens when a new generic player enters the market.
- Sharvil Patel:** Let me clarify. Market share wise we are still holding 50% market share but there has been price erosions.
- Anubhav Agarwal:** Last clarity on this other expenses in the quarter? Is there any one-off there or this is now very much, what you mentioned earlier that we have some discretionary expenses that you wanted to increase and you have increased with the higher resources now. Is this the right way? So there are still some one-off other expenses in this quarter?
- Vishal Gor:** There would be certain one-offs, I will provide the exact numbers offline.
- Anubhav Agarwal:** But that number will be less than 5% or more than 5% one-off in this quarter?
- Vishal Gor:** Quarterly number?
- Anubhav Agarwal:** Of the other expenses in the quarter?
- Vishal Gor:** Yes, it would be less than 5%.
- Moderator:** Thank you. The next question is from the line of Alok Dalal from CLSA. Please go ahead.
- Alok Dalal:** The US launches you are targeting 50 launches during the year. So what changes have you made to internal systems and supply chain preparedness that allows for so many launches during the year?



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**Sharvil Patel:** So we have since after closure of our warning letter and with the few successful audits what we have started to do is we have started taking calls on APIs early on and also taking on some production at risk kind of format. We have started the whole process of getting the validation and all those things first time right.

We have a dedicated team that looks at the new products and does this firefighting or technical resolution on PPP basis. So we have been able to what we have been able to do is also get a little bit of better protection to what it all come but more importantly I have been able to take some calls early so that we can prepare for the launches. In terms of capacity we have debottlenecked majority of the areas that we had to but also the good number of filings are from SEZ which is a very new facility so there is lot of capacity available there.

So I think it has been multiple things. The capacity debottlenecking, increase in manpower because we have to setup new lines, taking risk calls on API, taking risk calls on formulations and on manufacturing before approval. And also looking at and obviously having a tactic to fall technical challenges.

**Alok Dalal:** So out of 50 products how many are already approved?

**Sharvil Patel:** We have more approvals. We are pursuing new commercialized 50 plus molecules.

**Alok Dalal:** So some would have already been approved and some you will get approval during the year?

**Sharvil Patel:** Yes. About 70% would be already approved.

**Alok Dalal:** And second question is on the India formulations market. So again we are seeing that out of your top 5 products only one is growing and the other are either flat or declining particularly cardiac products and the market is not declining. So any reason why Cadila is facing these issues?

**Sharvil Patel:** So we have had issues with the cardio-diabeto portfolio. We had to restructure this business unit and also have had issues with performance management in terms of the business. So we did see multiple issues. Lot of that has been corrected. If you look at the last bimonthly prescription data lot of positives are there in terms of improvement which still further needs to improve. But in a chronic segment when you lose certain share of prescription it takes a while to gain it, it will take some time to come back. So lots of things have been put back in place and we would see better momentum in the later part of the year for this particular business.

**Alok Dalal:** And even if you look at Skinlite for example or Gastro those products are also de-growing?

**Sharvil Patel:** Yes, so on Skinlite there is trade means lot of it is trade related issues. Because we have been finding a lot of spurious drugs on Skinlite so a huge crackdown is going on to try and stop the



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inflow of spurious medicines and some wrong practices that are happening in the market. So that is why we do have some issues for the temporary currently which we are trying to resolve. On the GI side broadly some of the brands are doing very well but on couple of products we are slower than market. That is why we are reflecting much lower. GI also we are confident with the bimonthly that things will improve in the next part of second half of the year.

**Alok Dalal:** Sharvil, you mentioned some changes in the system so what are those changes are they leadership related changes, people related changes that you made?

**Sharvil Patel:** Yes.

**Alok Dalal:** And you think those results should reflect in fiscal 19 second half onwards?

**Sharvil Patel:** Yes.

**Moderator:** Thank you. The next question is from the line of Aditya Khemka from DSP BlackRock. Please go ahead.

**Aditya Khemka:** Sharvil, I am a little confused on the guidance for sort of the ballpark profitability indication that you gave. So for FY19 in terms of EBITDA margin you expect to be better than FY18 EBITDA margins including the one-off number, is that correct?

**Sharvil Patel:** Excluding the one-off.

**Aditya Khemka:** Excluding the one-off you expect to be better. But in FY19 also you have a one-off which is Asacol your own ANDA coming through and you will in due course have competition there as well. So when you give this guidance are you giving it like-to-like?

**Sharvil Patel:** No, Asacol was not there in terms of the margin.

**Aditya Khemka:** Which means that you are accounting for Asacol as a part of your base margins?

**Sharvil Patel:** No, we are including Asacol.

**Aditya Khemka:** You are including Asacol in your margin, okay. And secondly, if I just look at your balance sheet for the year so your entire profit for the year is Rs. 1,800 crores and we increase on your inventory and trade receivables if I total the two it would come to Rs. 1,800 crores or roughly Rs. 1,500 crores. And then there is another Rs. 300 crores increase in other financial assets and another Rs. 300 crores increase in other current assets.



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So essentially, we have not generated any cash this year despite such profitability if it is tied in working capital. Could you throw some light as to what is happening here there is no reduction in debt also, our debt is flat year-on-year?

**Management:**

So you know that in US the business model is a little tricky whereby there is a long credit period once and because of the charged back cycle involved while you sale the material you have also first pay a charge back and wait for your credit period to be over to actually receive the money. Now with the growth in US business that we have experienced in the current year you can understand that there has been large working capital cycle which we experienced. But once you know the things get stabilize again it will come down. But otherwise you are right that the large part of the cash accrued have been invested in working capital.

**Aditya Khemka:**

So Vishal, I understand the Rs. 1,000 crores increase in trade receivables. Most of really Aldus is probably will billing trade receivables but I am unable to comprehend the Rs. 500 crores increase in inventory year-on-year?

**Vishal Gor:**

Inventory is also largely again because of US business. Because we tried to keep the inventory there to get maximize out of the market opportunity which may arise. So large part of inventory is also related to US business.

**Sharvil Patel:**

See after warning letter closure and obviously then our inventory buildup happened because we carry 90 days of inventory in the US market. So we had to buildup on to that inventory. And lot of new products approvals came which again led to the buildup of the inventory. So once the base gets stabilized and that is why we always said it will take at least another one year plus before we would see significant improvement on the cash flow.

**Aditya Khemka:**

And can you also elaborate a little on the other current assets and other current financial assets Rs. 300 crores increase in each of them total Rs. 600 crores?

**Sharvil Patel:**

If you are okay Vishal will provide you offline because he does not have all of its breakup right now with him.

**Aditya Khemka:**

Just one last question. On the guidance from US business still growing in FY19 over FY18 again in the base of FY18 are you accounting for Lialda and Tamiflu?

**Sharvil Patel:**

Yes.

**Aditya Khemka:**

And in FY19 you are also including Asacol your own ANDA?

**Sharvil Patel:**

Yes.



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- Aditya Khemka:** And just last one question if I may. In FY19 for Asacol HD are you contemplating or are you expecting any additional competition other than yourself?
- Sharvil Patel:** No.
- Moderator:** Thank you. The next question is from the line of Hari Belawat an individual investor. Please go ahead.
- Hari Belawat:** This is regarding this corporate tax rate is reduced in United States from 35% to 21%. Is there any effect during the FY18 in our balance sheet anymore profits or any tax saving have we got it that way?
- Sharvil Patel:** Not FY18 it will be in FY19.
- Hari Belawat:** It is not there in FY18 any effect?
- Management:** It is a very marginal for one quarter but significant change in US tax impact would be seen in the current financial year.
- Hari Belawat:** How much do you expect in FY19 say?
- Management:** It is a question of the profit mix and business mix but as you rightly said the tax has come down from 35% to 21%. That should help us in terms of saving over tax rate.
- Moderator:** Thank you. The next question is from the line of Rahul Sharma from Karvy Stock Broking. Please go ahead.
- Rahul Sharma:** Earlier part you all mentioned some key approvals which came in. I missed out some of them probably could you just run through them again?
- Sharvil Patel:** So the approvals that we have obviously we launched Mesalamine last year; Tamiflu which is Oseltamivir. Then we had approvals on metoprolol which we still have to commercialize. But there have been more than around 15, 17 critical approvals, many of them are going to get commercialized now.
- Rahul Sharma:** Any others apart from the Mesalamine franchise which probably you have not launched as of now?
- Sharvil Patel:** No.
- Rahul Sharma:** And any others which the critical products which you would launching in the current year?





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**Sharvil Patel:** Yes, there are we have a good portfolio of limited competition products to come up for this year.

**Rahul Sharma:** Would it be a 15 to 17 we should be launched in the current year itself?

**Sharvil Patel:** Yes, at least.

**Rahul Sharma:** And could we say each could be probably around \$10 million, \$15 million opportunity for us?

**Sharvil Patel:** Some of the high impact ones will definitely be higher, it will be a mix of portfolios.

**Moderator:** Thank you. The next question is from the line of Rajesh Prasad from Wealth Spring. Please go ahead.

**Rajesh Prasad:** My question was that your biosimilars business in India and the other parts of the developing world does it establish you and does it enable you to launch that in the developed world?

**Sharvil Patel:** It enables us because we have the capability to manufacture. Currently from nominating development projects for the developed markets we have only decided to invest in PEG-GCSF. Over the next couple of years, you would see some more additions but currently our investment proposal is on only PEG-GCSF for the developed markets.

**Rajesh Prasad:** What I meant was that not only it establishes your manufacturing capabilities it also establishes your trails and stuff like in India over the number of years it is getting tested on so many people. So that should facilitate your launch globally?

**Sharvil Patel:** Not really we would still have to do a specific trial for US and Europe.

**Rajesh Prasad:** But you will be much more confident about the results of those trials?

**Sharvil Patel:** Yes, definitely. We have not been able to do many more because we do not have a commercial front end to do these kinds of products. So it was too higher risk to take both the development as well as the commercial risks. PEG-GCSF we are more confident how it could commercialize so we have nominated that as our portfolio project as such.

**Rajesh Prasad:** So basically, it will involve one the testing there and two having a partner who has a feel for it to takes it to the last mile?

**Sharvil Patel:** Yes.

**Rajesh Prasad:** And how much would it cost the testing part?



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- Sharvil Patel:** It depends product-to-product.
- Rajesh Prasad:** But of the order of magnitude is it \$50 million or \$100 million, \$10 million?
- Sharvil Patel:** It will depend on the therapy and the molecule. So there is no rough estimate I mean ballpark there could be as low as \$20 million, \$25 million and as high as \$60 million to \$70 million.
- Rajesh Prasad:** So you do not see strategically this kind of in the future a big business for you or something which creates a lot of value for your business?
- Sharvil Patel:** It will create a lot of value from India and emerging market's point of view or it can be in the order of \$150 million to \$200 million with the current portfolio. For the developed markets once we are able to find potential partners for our future pipeline the business will be even better.
- Moderator:** Thank you. The next question is from the line of Saion Mukherjee from Nomura. Please go ahead.
- Saion Mukherjee:** Sir, you received approval for cinacalcet recently. You are fighting this case for non-infringement. In case it goes in your favor what you think would be the market opportunity for you? I mean do you think it will be very crowded or there will be limited number of players?
- Management:** I think in my one-on-one with you two weeks ago I have made a mention of it. At this point in time I or we just cannot give you any indication.
- Saion Mukherjee:** No, I was just wondering is this a possibility you think in fiscal 19?
- Sharvil Patel:** We cannot discuss that.
- Moderator:** Thank you. The next question is from the line of Rajesh Kothari from AlfAccurate Advisors. Please go ahead.
- Rajesh Kothari:** Sir, again sorry for confusion. But earlier in the question you mentioned that on like-to-like basis that is before one-off your operating profit margin has improved by about 100 bps per annum kind of thing over next 2 to 3 years. But then in one of the answer you mentioned that FY19 margins excluding one-off of FY18 you will be able to maintain. So I am little bit confused. Can you give some clarity?
- Sharvil Patel:** So what I said I continue to say that other than the one-off we would see an improvement of margin over the next couple of financial years and we are looking to improve it by 1% in the year.



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- Moderator:** Thank you. The next question is from the line of Kunal Randeria from Antique Stock Broking. Please go ahead.
- Kunal Randeria:** Just one clarification on your margin guidance. Is it based on today's exchange rate or last year's average and I was just wondering if you can provide some FX sensitivity to margin?
- Sharvil Patel:** This is based on the last quarter's exchange rate.
- Kunal Randeria:** For every 1% change in dollar to the rupee how does it impact our margins?
- Sharvil Patel:** I do not have that right now because there are multiple issues with import as well as exports. So it will be very tough to say. I mean the rupee is volatile so it is very tough to predict immediately like. But net-net it has a positive effect with the rupee becoming weaker.
- Moderator:** Thank you. The next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.
- Nitin:** This is Nitin here. Sir, on the biosimilars bit in the emerging markets how many biosimilars are you looking to launch over this period over next three to four years that is going to give you the \$150 numbers you talked about?
- Sharvil Patel:** Seven to eight in the emerging markets. In India it will be around 12 to 14 products.
- Nitin:** And sir, how many have you already commercialized in India so far?
- Sharvil Patel:** Eleven.
- Nitin:** And sir, versus this 150 where we would have finished FY18 as cumulative biosimilars revenue for us from the emerging markets?
- Sharvil Patel:** Emerging markets is insignificant. We have just recently got approvals and we have just commercialized for a few lot so it is very small. It will come up more importantly end of this year and more importantly in the next three years. We have launched nine products in India.
- Nitin:** And sir, on Pegfilgrastim for the US by when do you looking to file it?
- Sharvil Patel:** Yes, first quarter of calendar year 2020.
- Nitin:** First quarter of calendar year 2020?
- Sharvil Patel:** Yes, in the calendar year first six months. It is sometimes difficult to predict exactly.



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- Nitin:** So it still taken a couple of years for you?
- Sharvil Patel:** Yes.
- Nitin:** And sir, lastly on these transdermals launches when do you see them starting finally?
- Management:** Yes, we expect our first approval to come towards the end of this year.
- Nitin:** But this is some sort of is there any particular reason for the delay that has happened versus the initial guidance on this?
- Management:** Last time also we had mentioned the USFDA they need so many clarifications because this is a completely new field. So that is why there are quite a few things which have gone back and forth. So finally, we expect before the end of the calendar year one good approval.
- Sharvil Patel:** You see the facility inspection they all have been cleared we are being inspected twice and they have been cleared. The FDA guidance on transdermals is not as clear as it has been for many other dosage forms. I would say it has improved significantly now. So going forward new developments would be far more clearer but it has taken us this long to be able to respond to the FDA.
- Nitin:** And sir, lastly on the US, bulk of our niche filing for this year are largely going to be around oral solids or there are some other newer presentations that you see coming through for us this year?
- Sharvil Patel:** Largely it will be orals. There could be some injectables that is going to come through which are important, a few. And if you are lucky some transdermals and some dermatology products are there.
- Moderator:** Thank you. The next question is from the line of Damayanti Kerai from HSBC. Please go ahead.
- Damayanti Kerai:** Sir, can you share your outlook for R&D spends and CAPEX for next two, three years?
- Sharvil Patel:** So for CAPEX I do not think I can give you a very long term view immediately but we are looking at around Rs. 1,000 crores of overall CAPEX and R&D we have always committed to spend between 7% to 8% of revenue so we continue with that.
- Damayanti Kerai:** Okay and this CAPEX will be mainly towards what kind of facilities or where we are allocating most of the CAPEX?
- Sharvil Patel:** Largely formulations, manufacturing, quality, compliance and some new projects.



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- Moderator:** Thank you. The next question is from the line of Alok Dalal from CLSA. Please go ahead.
- Alok Dalal:** Sir, could you mention pricing pressure has been much lower than earlier. So what kind of price erosion you saw in this quarter as compared to the past?
- Sharvil Patel:** Around 1.5% to 2%.
- Alok Dalal:** And is this something that we can run with for the year for your portfolio?
- Sharvil Patel:** This is quarter-on-quarter.
- Alok Dalal:** Yes, that is correct, but this is something that one can work with for the full year?
- Sharvil Patel:** It is very difficult to answer that question there because it depends on how the competition comes in. But largely speaking we are more confident but it is I would not say 100% commitment to this.
- Alok Dalal:** And what was this the same number for the previous quarter this 2%?
- Sharvil Patel:** That I do not have on me. Vishal can give this to you offline.
- Moderator:** Thank you. Ladies and gentlemen, as there are no further questions from the participants, I would now like to hand the conference over to Mr. Ganesh Nayak for closing comments.
- Ganesh Nayak:** Thank you very much and look forward to interacting with you during the next quarterly results conference call.
- Moderator:** Thank you very much, sir. Ladies and gentlemen, on behalf of Cadila Healthcare Limited, that concludes this conference. Thank you for joining us and you may now disconnect your lines.