



## **Corporate Participants**

### **Dilip Shanghvi**

Managing Director, Sun Pharmaceutical Industries Ltd.

### **Sudhir Valia**

Whole Time Director, Sun Pharmaceutical Industries Ltd.

### **Kal Sundaram**

CEO (India, Emerging Markets & CHC Business), Sun Pharmaceutical Industries Ltd.



**Moderator:** Ladies and gentlemen, good day and welcome to the Sun Pharmaceutical Industries Limited Q1 FY18 earnings conference call. As a reminder, all participant lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal for 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. Nimish Desai. Thank you and over to you sir.

**Nimish Desai:** Thank you. Good evening and a warm welcome to our first quarter FY18 earnings call. I am Nimish from the Sun Pharma investor relations team. We hope you have received the Q1 financials and the press release that was sent out earlier in the day. These are also available on our website. We have with us Mr. Dilip Shanghvi – Managing Director, Mr. Sudhir Valia – Whole Time Director and Mr. Kal Sundaram – CEO (India, Emerging Markets & Consumer Healthcare). Today the team will discuss performance highlights, update on strategies and respond to any questions that you may have. As is usual, for ease of discussion we will look at the consolidated financials. Just as a reminder, this call is being recorded and a replay will be available for the next few days. The call transcript will also be put on our website shortly. The discussion today might include certain forward-looking statements and these must be viewed in conjunction with the risks that our business faces. You are requested to ask two questions in the initial round. If you have more questions you are requested to rejoin the queue. I also request all of you to kindly send in your questions that may remain unanswered today.

I now hand over the call to Mr. Shanghvi.

**Dilip Shanghvi:** Welcome and thank you for joining us for this earnings call after the announcement of financial results for the first quarter of FY18. Let me discuss some of the key highlights. Our overall performance in first quarter is not in-line with our past performance due to the combined impact of temporary disruptions in our India business due to GST implementation, the challenging US generic pricing environment, increasing investments in our global specialty business and the Modafinil settlement in the US. While Sun Pharma has settled its Modafinil litigation with two plaintiffs, litigation with the third plaintiff is ongoing. Also, if you compare with Q1 last year, the expiry of Imatinib exclusivity has impacted year-on-year comparisons. Current profitability is after accounting for all of these factors. As guided before, we are on track to achieve the US \$300 million synergy benefits from Ranbaxy acquisition. We have also guided in the past that we will be utilizing these synergy benefits to fund our evolving specialty business and hence it may not be visible separately in our financial numbers.



Also, some part of the synergy benefits are being lost by the adverse impact of pricing pressure in the US generic business.

Let me update you on Halol. As you all are aware, the US FDA re-inspected the Halol facility in Q3 and has raised 9 observations. The remedial steps to address these observations are now complete and we are now awaiting a re-inspection by the US FDA. Till we have a successful outcome from the re-inspection, we will not get any new approvals from this facility. As indicated before, we are in the process of shifting some of the products filed from Halol to alternate site as a risk mitigation measure. We continue to focus on enhancing our specialty pipeline as well as establishing the requisite frontend infrastructure and talent. We will continue to invest in building our product specialty pipeline in the Dermatology, Ophthalmology, Oncology and CNS segments and create a long base for long term growth.

I will now handover the call to Mr. Valia for discussion of the Q1 performance.

**Sudhir Valia:** Thank you Mr. Sanghvi. Good evening everyone and welcome to all of you. Our Q1 financials are already with you. As usual we will look at key consolidated financials. Q1 sales are at Rs. 6,167 crores, down by 23% over Q1 last year. Material cost as a percentage of sales was 27.2%, higher than Q1 last year mainly due to the year-on-year decline in Imatinib sales in US as well as higher COGS for Taro. Staff cost was at 21.6% of sales, higher than Q1 last year. This increase is due to the year-on-year sales decline in Imatinib and is partly due to the expansion of the specialty teams in the US. Other expenditure was at 34.1% of sales which was higher than Q1 last year resulting from lower topline year-on-year coupled with investments in building the specialty business and partly due to forex losses.

As a result of the above, the EBITDA for Q1 was at Rs. 1,054 crores, with EBITDA margins at 17%. Net profit for the quarter was adversely impacted by settlements with certain plaintiffs related to the Modafinil antitrust litigation in the US, with the settlement amounting to Rs 950 crores. Excluding the Modafinil settlement, our adjusted net profit for Q1FY18 was at Rs. 526 crores, down 74% over Q1 last year, with resulting adjusted net profit margin of 8.5%. Net profit for Q1 last year included the benefit of the 180-day exclusivity for Imatinib which expired in July-2016. EPS for the quarter was negative Rs. 1.80.



Let me also explain the variance in certain key items compared to March-2017 quarter. The India business revenues were down as compared to Q4 mainly due to the GST implementation and Kal will discuss this in detail shortly. The other operating income variance over Q4 is the result of higher income booked in Q4 due to milestone payment from Almirall for Tildrakizumab. Higher finance cost in Q1 versus Q4 is mainly on account of the impact of foreign exchange movement which gets included in finance cost.

Let me now briefly discuss Taro's performance. Taro posted Q1 sales of US\$ 161 million, down by 31% over Q1 last year. Taro's net profit for Q1 was US\$ 55 million down by 50% over Q1 last year.

I will now handover to Mr. Kal Sundaram who will share the performance of our India and Emerging Market business.

**Kal Sundaram:** Thank you Mr. Valia. First let me take you through the performance of our India business.

For Q1, sales of branded formulations in India were Rs. 1,761 crores, a de-growth of 5% over Q1 last year and accounting for approximately 29% of total sales. Growth was impacted by the temporary disruption from the GST wherein the trade channel reduced inventories ahead of the GST implementation. We expect a gradual recovery in the coming quarters. Also, the new GST rate for pharmaceuticals is slightly higher compared to the overall pre-GST taxation. As you all know, the new GST regime does not allow compensation of this increase through price increases except for products under NLEM. This will have some impact on the overall growth for the industry including us, for the next three quarters.

Sun Pharma is the largest pharmaceutical company in India and holds approximately 8.6% market share in the over Rs. 110,000 crore pharmaceutical market as per March 2017 AIOCD-AWACS report. As per latest SMSRC report, Sun Pharma is ranked no. 1 based on share of prescriptions with 11 classes of doctors. For Q1, 10 new products were launched in the Indian market.

Our immediate near-term focus will be on normalizing and to continue to grow our business in the post-GST regime. For the long-term, we will strive to maintain our leadership position in the market and at the same time focus on increasing the productivity of our sales force. We continue to focus on profitable sales growth and on building strong brands.



The demographics of India will be the key growth driver for the industry in the long-term. However, competitive intensity, changing regulations and government mandated price controls are the other key factors which will determine the long term growth trajectory of the industry.

Let me now discuss our performance in emerging markets. Our sales in emerging markets were at US\$ 168 million for Q1, a growth of 9% partly driven by the acquisition of Biosintez in Russia. Emerging markets accounted for 18% of total sales. The growth is broad-based amongst emerging markets. There was a minor adverse impact of currency movement on our growth in emerging markets for the quarter. With this, I will now hand it over to Mr. Shanghvi.

**Dilip Shanghvi:** Thank you Kal. I will briefly discuss the performance highlights of our US and rest of the world's business. Let me start with the US. For Q1, our overall sales in the US were down 42% at US \$351 million accounting for approximately 37% of our overall sales. There are 3 main reasons for the year-on-year decline in the US revenues. Lower Imatinib sales post the expiry of exclusivity, pricing pressure due to customer consolidation and delay in approval of important products from Halol facility. Also supplies were affected after some of the remediation activity during the last quarter. Formulation sales in the rest of the world excluding US and emerging markets were US \$150 million in Q1, a growth of 37% over last year, partly driven by consolidation of Japanese acquisition. RoW markets accounted for approximately 12% of revenue in Q1.

We continue to focus on developing and utilizing APIs for captive consumption for benefits of vertical integration. For Q1 the external sales of our API were at Rs. 309 crores, down 34% over last year. We expect this numbers to stabilize during the year.

We continue to invest in R&D for enhancing our pipeline. Consolidated R&D investment for Q1 was Rs. 522 crores, accounting for 8.5% of sales. This R&D spending enables development of future product pipelines including specialty and differentiated products and we continue to expect increased R&D investments in future. We have a strong pipeline for the US market with 151 ANDAs and 5ANDA awaiting approval from the US FDA. For the quarter 5 ANDAs were filed and 8 approvals were received.

Let me discuss our specialty initiatives in detail. During the quarter we announced acceptance of Tildrakizumab filing by the US FDA for the US market. The European filing was accepted in March last year. We will be gradually filing Tildrakizumab in all key markets in future.



Post the pre-NDA meeting with the US FDA for Seciera, we are in the process of filing NDA by Q3 FY18. We continue to evaluate filing Seciera in other markets. We started marketing Odomzo, our specialty oncology product in the US some months back. We are in the process of ramping up this product and are leveraging both our Oncology and Dermatology sales forces in the US for co-promoting this product to both Oncologist and Dermatologist. Our ophthalmic specialty product – BromSite – which was launched in the US in last year is gradually ramping up.

And finally on FY18 guidance. As indicated in the Q4 call in May, FY18 is likely to be a challenging year for us and we expect a single digit decline in our consolidated revenue. Generally, we do not give any EBITDA guidance, but given various moving parts in our business, we are making an exception this year and giving an indicative EBITDA margin guidance. Our consolidated EBITDA margin in Q1 was 17% as indicated in my comments at the start of the call, there are multiple factors which are pressurizing our margins, some of which are temporary or one-time, while others are more structural. As we move forward in the coming quarters, we expect our business to improve. We expect a gradual improvement in EBITDA margin from the base of Q1 and reaching approximately 20%-22% in the second half of the year. As indicated in the past, our guidance does not factor-in any new approvals from Halol. We also expect a gradual increasing tax rate on the overall basis.

With this I would like to leave the floor open for questions. Thank you.

**Moderator:** Thank you sir. Ladies and gentlemen, we will now begin with the question and answer session. The first question is from the line of Anubhav Aggarwal from Credit Suisse. Please go ahead.

**Anubhav Aggarwal:** One question that if you see US sales for us, just looking at approximately ex Taro, the number is largely flattish when I look at the March quarter and the June quarter sequentially basically, I just wanted to understand that what is roughly the base price erosion that you have seen in this quarter?

**Uday Baldota:** It is difficult to give a specific number here, but I think the pricing pressure that we are seeing is across large number of products. So I think whether it is on account of customer consolidation or on account of new competition with...

**Dilip Shanghvi:** Also we have to consider which specific products we have sold more during the quarter because some products have lower margin.



**Anubhav Aggarwal:** No, but I am just trying to, Uday, if you combine the two, I am not asking for the split at all. I am just asking that total sales are flattish and I am just simply asking that because we can clearly see, you talked about last quarter that there are some deferred sales which you expect to do in future and our sales is flattish that clearly means our base has eroded and I can clearly see from your partner result that Absorica has been sold significantly higher in this quarter. That is the reason I am asking that the result shows that at least we are experiencing double digit price erosion on the base number.

**Dilip Shanghvi:** I think there is a high single digit price erosion. There are certain structural changes that we have done in Absorica which essentially leads to increase in the scripts that you see. But that is possibly not leading to same level of increase into topline or the sales. So that should start stabilizing in next quarter.

**Anubhav Aggarwal:** Okay. And my second question is on the capex intensity in the business. Last quarter you have guided that for FY18 you expect capex about US\$350 million. My own expectation was that after we acquired Ranbaxy and having got the clearance for Mohali facility, we used to do a CAPEX about 1,000 crores earlier. Now we are doing almost 2,000 crores plus. Can you just help which part of the business is large part of this incremental CAPEX going?

**Dilip Shanghvi:** Mainly in dosage form and mainly in creating aseptic manufacturing capability. So because technology has moved on, and it is necessary for us to have new facility which meets new regulatory expectations.

**Anubhav Aggarwal:** You are making this plant in India or US, this injectable plant?

**Dilip Shanghvi:** In India. See, we are investing in the US also, not that all of the investment is in the US. Large investment also is being done in India.

**Anubhav Agarwal:** So this is a Greenfield plant?

**Dilip Shanghvi:** Greenfield and brownfield, both.

**Moderator:** Thank you. The next question is from Prakash Agarwal from Axis Capital. Please go ahead.



**Prakash Agarwal:** On your comment on Halol that we started the process of shifting, so just trying to understand and at the same time we made a comment that we are awaiting the inspection. So what is that leading to, I mean if you start the process anyway it is going to take 6-12 months at least. So what is leading to that kind of decision?

**Dilip Shanghvi:** For many products, it makes sense for us to have two sites because then we can reassure customers that we have stable supply chain. So the kind of products that we are transferring will justify additional cost of transfer and also from a business point of view are justified because of consistency of supply chain.

**Prakash Agarwal:** Understood. And these are for existing and pending products?

**Dilip Shanghvi:** Not so much for existing products, mainly for pending products.

**Prakash Agarwal:** Okay. Thanks. And second question on India business, just trying to understand the GST impact in terms of accounting. In last few calls we made to understand there is an adjustment on the cost of goods sold and that sets off against other expenses. So ideally our gross margins Q-on-Q would have improved if the GST wouldn't have happened?

**Kal Sundaram:** With the change in pricing of product mix and pricing mix, ongoing margins there would have been an expansion but for the GST impact, which will be felt more from Q2 onwards that we wouldn't have felt in Q1.

**Prakash Agarwal:** I didn't understand. So, Q2 onwards it will start to improve?

**Kal Sundaram:** There is an on-going margin expansion in the India business with GST now coming on from Q2 onwards, we will be eliminating excise duty from the topline and at the same time we will be eliminating excise duty from the cost of goods also.

**Prakash Agarwal:** Okay. So net impact on gross margin would be lower sales and lower COGS.

**Uday Baldota:** Lower expenses, not COGS because excise duty was a separate line item.

**Moderator:** Thank you. The next question is from Anmol Ganjoo from JM Financial. Please go ahead.



**Anmol Ganjoo:** My question is around the margin guidance that you gave. You spoke about some of the factors being transitional and more structural. 22% margin for Sun is very long distance from what we have seen in the past. Could you just split up the impact of some of the drivers of margin which you think are more transitional and if you look at FY19, how far do we settle from our previous peaks and from the FY18 troughs?

**Dilip Shanghvi:** One of the reason which is impacting margin is the buildup for the specialty business. The other is the erosion in terms of pricing, which essentially affects both topline, COGS remaining constant, ultimately impacts margin. The third thing is that on a reduced business, our cost has not gone down proportionately. So that also takes away significant margins and all of this you can say our personnel cost is now in excess of 20%, both because of reduction of turnover as well as increase in the cost. So we are creating an organization which can handle much larger turnover and as that turnover starts coming in, the idea for us is that, on a larger base when we start distributing cost, margin will improve. But yes, I think I agree with you, that even post-merger with consolidated margin with Ranbaxy was in excess of 29%. So a 22% margin is clearly not in-line with what we are used to and everybody in the company is very clearly and acutely aware that this is not something which investors expect from us. We will find ways by which we can work towards improving this going forward.

**Anmol Ganjoo:** And just a follow up on that. So the ways of finding would primarily include which focus areas? On the cost side or we think that we will get back to higher revenue which will absorb a lot of these costs.

**Dilip Shanghvi:** For both. We will work towards becoming more efficient and focus on cost control initiatives but more important I think this kind of major shift is feasible only to correct by focusing on growth.

**Anmol Ganjoo:** My second question is on the US formulations base including Taro. I understand that first half we had the benefit of Imatinib, but if we look at the third quarter 17 base, we have lost close to 30% of our sales or one-third of our business including Taro. So I know non Taro sequentially has been flat given some drivers, but what is the new base on the US that one should work with and this virtual collapse of the US base on formulation side does it force a rethink as far as the long term attractiveness quotient of that market is concerned?



**Dilip Shanghvi:** I don't want you to look at structural reasons for the lack of attractiveness of the US market in our perspective. I think the reason why we are suffering is because of our inability to execute and only solution is our focus on improving execution. As we start getting new product approval, as we start getting approval from facilities which till now do not have approvals or we have not started launching products. All of that will start adding to topline like what I answered about creating manufacturing investments. So a large part of manufacturing infrastructure which is created is still not contributing to any kind of topline in the company. So when these facilities will start getting approved and start getting new products they will also start adding to the topline and also unabsorbed overhead will keep on falling. That also is one of the reasons why margins are suffering. We have so many facilities which are operational contributing to cost, but not contributing to topline. But as they start contributing to topline I think they will start adding to profitability and also that will improve margins.

**Moderator:** Thank you. The next question is from Sameer Baisiwala from Morgan Stanley. Please go ahead.

**Sameer Baisiwala:** What should be our expectation from Halol facility post remediation? Is it going to, can change US revenues and approvals quite dramatically or would it be a very small step incremental improvement?

**Dilip Shanghvi:** This question is linked with specific products that we will get approval for. So sometimes the approvals don't come because the facility is not ready, but sometimes the approvals don't come because of the inherent deficiencies in the filing which we need to address. So our focus is to find a way to get back into our growth rhythm and we still find generic business attractive and we continue to invest in R&D for this generic business and large part of our investment in R&D continues to be focused on generic product development.

**Sameer Baisiwala:** Okay. And just shifting gears to specialty platform, I mean for last several quarters you have been mentioning that as a key reason why the margins have come off and you are investing in this area. My guess is by now if I total, you must have spent few hundreds of millions of dollars in this direction. So what is the kind of sales expectation that you have to justify this kind of spend? And any big component of this platform that you can cite us.

**Dilip Shanghvi:** What I will end up giving you is a long term guidance.



**Sameer Baisiwala:** I mean, not necessarily it is, but it is important for us to understand what is it that you are creating in this specialty front and I am not trying to...?

**Dilip Shanghvi:** I understand. I think theoretically if you look at say Tildra and if you look at IL-23 as a product or IL-17 as a product for other people and clearly those are very big companies and those companies have far more experience in launching specialty biologic at high price than we have and we may not be able to meet the kind of success that they have. But we have a good product and there is no reason for us to aspire to not try and match those kind of revenues. Now clearly our spend today is not geared to handle that kind of volume and upside. But that decision we will have to take as we come closer to market. So Tildrakizumab clearly is a potentially very interesting product. If I see Seciera also, it is an interesting product and unlike Restasis, we think that with the kind of clinical outcome data that we have, we have potential to register this product in other large markets also. So I think that can be an interesting product. For Odomzo, if you look at Erivedge, globally it is around US\$200 million product and we have a good product. And the US\$200 million is also growing. So it is expected to become much bigger than what it is now. And we can also look at adding to new indications. So that can be a short term, product that can help us grow. I am quite happy with the way which our specialty business is building up. We should have done better. If we had Xelpros and Elepsia in the market, then we would clearly be much better off than what we are today.

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

**Sion Mukherjee:** Just continuing on the specialty question. I mean, there is some revenue cost mismatch that you are alluding to, now as we go forward, get approval for MK-3222 and probably even Seciera sometime next year, how should we think about this mismatch? Will there be further investment in field force, commercial expenses and you may add few more products on development, so this mismatch I mean how long do you think this would continue? Thanks.

**Dilip Shanghvi:** It is an important question that you are asking and there will be a build phase and during that build phase it will have an impact on our margins for sure. But then these products are potentially long term cash flow generation products. So once they start generating revenue, they will justify the spend.



**Sion Mukherjee:** And sir, any timeline you are thinking of, 3 years, 4 years?

**Dilip Shanghvi:** A typical let us say peak sales for a good product, if you are looking at finding a way to fully leverage the product, very aggressively if you want to invest then you can look at peak sales in 3 years. Typically, most of the companies achieve peak sales in 5-6 years. So if you invest with them you to get peak sales in 5 years, then there is a certain amount of buildup cost. If you want to achieve a peak sale in 3 years, then it will be disproportionately large investment. And we haven't taken a decision as to what is the kind of focus that we want to have so that we can achieve peak sales in 3 years or in 5 years.

**Sion Mukherjee:** Okay and just one last question. If I join back on your margin guidance that you have indicated going forward, what is your assumption on erosion in Taro and your current US business, I know you said no expectation from Halol as such. But on your base are you factoring in from erosion or you think most of the impact has already come through now?

**Dilip Shanghvi:** Whatever that we have given is after factoring business realities. That is the reason why we wanted to give guidance about EBITDA for the first time because it is something we haven't given in the past. But looking at dramatic reduction in our EBITDA, it is necessary for us to walk the investors and all of you through what are our plans because business has become very complex and within the constraints of not disclosing business secrets, we want to help you understand it as best as we can.

**Sion Mukherjee:** Will it be possible for you to share like how many ANDAs from Halol are pending which are stuck because of warning letter, probably 150, just a number?

**Dilip Shanghvi:** I don't have the number right now. But we will discuss internally and if we decide to then we will share. But as on today, we have decided not to share that information.

**Moderator:** Thank you. The next question is from Nishant Chandra from Temasek Holdings. Please go ahead.

**Nishant Chandra:** Couple of points. So there has been some sort of DOJ inspection relating to opiates business. Is that something that we had seen on that front and you also notice that there has been some focus on opiates business in general for us? So any concern that we have on that front?



**Dilip Shanghvi:** You have some specific information. Because I am not aware of a DOJ inspection with reference to opiates product.

**Nishant Chandra:** Okay. Because there has been some press over the last couple of days on that front.

**Nishant Chandra:** Not for Sun, but definitely in the industry in the US?

**Dilip Shanghvi:** Okay. SPARC has a product which has a multiple abuse deterrents technology that they are developing. But that is a different product. I don't think we have any issue with DOJ.

**Dilip Shanghvi:** I think it is a major healthcare issue there, and also I think issue with affecting young people in the US. So government wants to find a way to address and it is not only issue related to licensed opiates but it is also issue of street drugs and easy availability of fentanyl citrate and many other things. So it is a very complex current situation.

**Nishant Chandra:** Understood. And in terms of just the industry evolution from a distribution consolidation perspective, what do you think would be the response of the pharma companies, I mean what do you think the industry will look like, let us say a couple of years down, what is your view on that front?

**Dilip Shanghvi:** Till I actually understand a little bit better as to what finally happened in case of Teva and also of Mylan, I do not want to respond because then it will not be a measured response. But clearly consolidation in distribution cannot be matched by consolidation of the manufacturing because consolidation in manufacturing hasn't helped Teva at all.

**Nishant Chandra:** Got it. And the third one is just from a roll out of specialty/brand platforms in the US. What is your timeline view on steady state because even let us say by end of financial year 2018 our estimate was at, we may not be hitting steady state from a profitability perspective, the investment that is going in the form of sales force creation does not exactly match with the productivity and topline. What is your sort of broad, I mean it may be 1-2 years, maybe 2-4 years how are you thinking of trying to steady state on that front?



**Dilip Shanghvi:** Actually I think you have to look at it slightly differently, is that historically we have only participated in the generic business which has been less than may be 10% of the total US pharma business. We are making first tentative step into the specialty and NCE business. So as we becomes successful in that business, then I think depending on how successful we are, will determine what will be our investment in risk appetite for that business. But philosophically we will look at investing part of our profit, part of the new growth that we get into that business; so that that business can become bigger and increasingly help drive the other businesses also grow the company.

**Nishant Chandra:** Understood and just one last question if I can slip it in is, are you thinking of let us say, looking at the Rx to OTC switch market in the US which sort of provides better pricing while at the same time utilizing the same strength of a generic company. Is that something how you explored in the last year?

**Dilip Shanghvi:** My understanding is that Rx to OTC switch generally is possible only for the brand company to do. So if somebody has a Rx product then FDA will only allow that company to do a biostudy or additional clinical study to switch it to the OTC.

**Nishant Chandra:** Okay. The point I had was something similar to what perhaps a Perrigo is doing, right, where they are essentially looking at powering the same store or the store brand of generics. And that way they are at least aligned with the frontend companies while at the same time utilizing the strength of generic company. And there are complexities in that business in terms of ...

**Dilip Shanghvi:** So what you are saying is how do we look at store brand for future Rx to OTC switches?

**Nishant Chandra:** Yes, correct.

**Dilip Shanghvi:** We started looking at it. So we have projects on those kinds of products. But there is no certainty about which product will switch. So there is a certain element of risk that we have to take.

**Moderator:** Thank you. The next question is from the line Neha Manpuria from JP Morgan. Please go ahead.



**Neha Manpuria:** Just to get an update, we have talked about looking at starting trials and new indications to Tildra. Any update on that?

**Dilip Shanghvi:** The trial is on-going. It is too early to give you an update.

**Neha Manpuria:** So we have started work on that?

**Dilip Shanghvi:** Yes, we have started enrolling subjects.

**Neha Manpuria:** Okay. And the two in-license SPARC product, site transfer, you mentioned that in the last call, by when should we expect approval from a complete site transfer and therefore approval for these products?

**Dilip Shanghvi:** I mean, hopefully they should get approved from Halol before.

**Neha Manpuria:** In the eventuality, since we... Could this, even if Halol irrespective of what happens...?

**Dilip Shanghvi:** Even if Halol becomes available I think these products can benefit from having two sites supplying them. So I think hopefully in next maybe one quarter or two quarters at the most we should have the stability batches filed and then we will negotiate with FDA as to many months of stability we will need to submit.

**Neha Manpuria:** Okay. And my last question on other expenses. Is it fair to assume that there is no one-off in other expenses in this quarter and this is the base or I think in the opening comments you mentioned some effects in this number.

**Uday Baldota:** No, there is no one-off but typically some of the foreign exchange components get here. So to the extent that we have that impact every quarter I think there will be some variability around that.

**Neha Manpuria:** So this is the new base for other expenses?

**Uday Baldota:** No. I do not think we are saying that. I think what I am saying is that there are always Forex related expenses also that occur here. So to that extent every quarter is not necessarily



straightaway comparable. And even in the current quarter there are some foreign exchange losses that are included in the other expenditure.

**Dilip Shanghvi:** Yes, my sense is that in any quarter, in the significant dollar rupee change or if there is an emerging market currency change, then that will be there in the...

**Neha Manpuria:** So then that would indicate that there is a significant amount of FX loss in this quarter given how rupees moved?

**Dilip Shanghvi:** I wouldn't quantify, but I think when you are looking at establishing a base or comparing with the prior period just want to sort of indicate and caution you that there is other expenses and amalgamation of a lot of expenses. We have material at one place and the staff at the other and everything else is in to the other expenses. So there are a lot of moving parts including the foreign exchange component. So not necessarily that we will be able to explain each and every moment very precisely.

**Moderator:** Thank you. The next question is from Abhishek Sharma from IIFL. Please go ahead.

**Abhishek Sharma:** Just a couple of quick questions. Do we have a PDUFA date for Tildra now?

**Dilip Shanghvi:** Yes, I am sure we have.

**Abhishek Sharma:** What is the date?

**Dilip Shanghvi:** Though we haven't announced it. But there is a typical cycle for approval because within the goal date then that depending on when we have announced the acceptance, it is possible for you to calculate.

**Abhishek Sharma:** So 11 months or thereabout?

**Dilip Shanghvi:** And yes, there is this PDUFA guideline.

**Abhishek Sharma:** And just the, I mean I am sure you would have shared Tildra's profile with payers and they have seen the other competitor products on the market as well. So what kind of response are you getting from the payers on Tildra?



**Dilip Shanghvi:** I have said in the past that we have a very good profile for the product, both in terms of efficacy as well as in terms of side effect and that is one of the reason why we feel that the product is likely to do well.

**Abhishek Sharma:** Yes. But these are the competition because if you look at competition, the efficacy profile at least seems to be better as compared to Tildra.

**Dilip Shanghvi:** I understand. We have access to information that is different from your information. So after evaluating that information we believe that we have a competitive product in the market place.

**Abhishek Sharma:** Okay. And just one question around Halol. Has FDA intimated any date or their desire to come and they inspect Halol?

**Dilip Shanghvi:** They haven't indicated a date.

**Abhishek Sharma:** But I mean there has been some communication regarding possible inspection in the near future?

**Dilip Shanghvi:** What I have said is that we have requested them to inspect the facility.

**Moderator:** Thank you. The next question is from Chirag Talati from Kotak Securities. Please go ahead.

**Chirag Talati:** Firstly, I couldn't really understand this statement about facilities being unabsorbed, because there are so many products that have been approved and we have been seeing a consistent decline in unit sales in the US. So what is really stopping the company from getting volumes that would help you to fully absorb or in fact you know even add to profitability from the current sites. And as a follow up to that, if your model is around low volume, high value product why don't you divest some of these facilities?

**Dilip Shanghvi:** We have to find a way to gain market share in many products where we see an opportunity and that should be the focus. What I said about the unabsorbed overhead, is the facilities that have been set up, are validated, but not yet approved for sales to regulated market.



**Chirag Talati:** But even amongst your existing approved facilities, I mean you unit sales have practically halved in the past 3 years and there are so many approved products. So is there a plan in place to get market share in these products, because we are just not seeing any pickup happening?

**Dilip Shanghvi:** Yes. I think there is a plan to gain market share in many of the products.

**Chirag Talati:** And finally if I can squeeze in one, I mean we have seen few hits on the Ranbaxy side on Valcyte and Nexium in the past. How are you viewing the return profile of the acquisition? I mean how has it changed, how has our thinking changed from 3 years back?

**Dilip Shanghvi:** So, last time also I think on the call I had said that some of the potential upside value like ability to sell some products in exclusivity likeesomeprazole where we had exclusivity, would have been factored in our valuations. To that extent I think that is something that was factored. Some of the potential liabilities we had estimated as a part of the valuation.

**Moderator:** Thank you. The next question is from Shyam Srinivasan from Goldman Sachs. Please go ahead.

**Shyam Srinivasan:** Just on the EBITDA margin guidance and the related comments on COGS, we have had about gross margins of 73% this quarter consolidated. Just why do we think that we can maintain gross margins because the COGS comment seems to suggest we can keep it there, given where price erosion has been, given where even in Taro we have actually seen gross margins come off, so what gives us the kind of confidence on that line item?

**Dilip Shanghvi:** Where have we said anything about gross margin? We have said about EBITDA.

**Shyam Srinivasan:** Because I got a sense that COGS would, if something that is where it is?

**Dilip Shanghvi:** I don't think we said anything about COGS.

**Shyam Srinivasan:** Okay. Thank you. My second question is on Halol again and do you foresee that these supply constraints that you have mentioned, can they be actually kind of unmount or no supply constraints before an inspection and the clearance happens or you think the facility needs to be cleared before we come out of all these constraints?



**Dilip Shanghvi:** Some of the constraints we can fix even before the facility is re-inspected.

**Moderator:** Thank you. Next question is from Dhires Pathak from Goldman Sachs. Please go ahead.

**Dhires Pathak:** Thank you. For your content infrastructure is it fair to understand that the field force infrastructure is currently not there for Tildra and Seciera, it is only there for Odomzo and BromSite?

**Dilip Shanghvi:** So field force is not there. Marketing organization is there.

**Dhires Pathak:** Okay. And can you just highlight like what size of field force would be needed for this?

**Dilip Shanghvi:** I think these are competitive sensitive information. So it is better for me not to share specific number. But we will have a field force which will allow us to leverage the full value of the product.

**Dhires Pathak:** And that investment will happen in this year, if for these two assets? Or it will happen later in next year?

**Dilip Shanghvi:** One of them will happen this year.

**Moderator:** Thank you. The next question is from Rahul Sharma from Karvy Stock Broking. Please go ahead.

**Rahul Sharma:** Just wanted clarity, you were talking about 22% EBITDA margins for the current year, so does it take into account, we are yet maintaining the 6%-8% guidance on the R&D and any cut backs on any of the other cost which are there?

**Nimish Desai:** Rahul, this is Nimish here, I think the guidance that we gave on EBITDA margin was 20%-22% range for second half. We didn't say 22% for the full year.

**Dilip Shanghvi:** I think to your question is that whether we are cutting R&D cost, then the answer is no.



**Rahul Sharma:** And we are doing almost 2,000 odd on other expenses which is there per quarter, so with the new specialty product coming next year, did you see at least 15%-20% jump in that expense next year per quarter.

**Dilip Shanghvi:** I think we will give that guidance. Currently, I am not telling you anything about next year. But in answer to earlier question what I said is that there is an investment phase for these products and our effort will be how do we find a way to invest on these products while maintaining our EBITDA margin, that should be our focus.

**Moderator:** Thank you. The next question is from Ketan Gandhi from Gandhi Securities. Please go ahead.

**Ketan Gandhi:** You give lot of importance to specialty products, I think SPARC has two drugs which are in late stage clinical trials or almost on the finalization, how do you see the opportunity there, how fast it can be accepted?

**Dilip Shanghvi:** This is not a SPARC call, but I think SPARC updated investors on some of the status of the product in their last AGM. So that should be there on their website.

**Moderator:** Thank you. The next question is from the line of Surya Patra from Phillip Capital. Please go ahead.

**Surya Patra:** Over the last few years that we have seen multifold growth in the revenue and similarly multi fold jump in the R&D spend and now at this juncture if you see R&D spend is either seen a kind of a continuous up move whereas there are challenges from the revenue front. So how should one look at the R&D productivity in the current juncture?

**Dilip Shanghvi:** Clearly, I think the R&D cost have gone up, partly as a result of additional requirement from agencies about the type of work that we need to do while we file the product including 3 batches, 6 months stability and various other issues. But also part of this is because we are now focusing on more complicated product, so that increases the investment required to bring these products to market. But if we look at per ANDA cost then there is significant per ANDA cost increase over 10 years.



**Surya Patra:** And is that possible to share what is the mix between the generic R&D and other R&D towards the Novel molecules or biologics or whatever specialty product area?

**Dilip Shanghvi:** There will be a certain cost related to clinical development of Tildra in this R&D cost, also some cost related to the other products for which we are developing new indications. There will be a few 505(b)(2) products that we can potentially market in future and rest of the products will be I think generics. So more than 50 plus percent will be the generic R&D cost.

**Surya Patra:** Just one thing, any update on Dadra?

**Sudhir Valia:** We do not have the inspection report yet.

**Moderator:** Thank you. The next question is from Nimish Mehta from Research Delta Advisors. Please go ahead.

**Nimish Mehta:** On the cost front on the impact on performance, as we mentioned there are several factors like sales disruption, delayed launches, cost related to specialty and price erosion. If you were to rank order the severity of these, how would you rank order, so that we know which are temporary and which can actually be overcome, that will be helpful.

**Dilip Shanghvi:** It is difficult to give you a rank order answer, but I think I am paid essentially to solve all the problems. Now also many of the problems, there are different set of people who are responsible for solving them. So, they will have their own priorities. Somebody asked about market share for some of our products, so this some set of people will need to work on improving market share. And then there are products that we are not in market, even though we have approval. So there are different set of people who have to work on that. The priorities is actually based on the theoretical potential of the upside in case we are successful and the biggest project is what we focus on.

**Nimish Mehta:** To what you mention if I were to ask that which is the top priority in terms of you are addressing all the issue at hand.

**Dilip Shanghvi:** Clearly bringing Halol back in compliance is the most important priority for us.

**Nimish Mehta:** Okay, fine. And secondly if I were to, I just wanted to know are we expecting this abuse deterrent technology products any time in the near future, obviously not in FY18, but let us say in



FY19-20 what is the outlook there essentially now that a lot of noise is there around those products, some outlook will be helpful.

**Dilip Shanghvi:** This is a SPARC product, when SPARC wants to share something specific they will share it within them. So it is an exciting product. It is a product which has a very important unmet need in the market. It really save lives, but what update they want to give, I think is which they will decide.

**Nimish Mehta:** We also have one in Ranbaxy, right oxycodone which if I am not wrong it can be also launched with this technology.

**Dilip Shanghvi:** No, that is a generic product.

**Nimish Mehta:** There is an oxycodone which is with this technology as well, I do not know whether we have that or not?

**Dilip Shanghvi:** That is a generic product. Ranbaxy had filed a product and they had a settlement with the innovator, it happened much before we took over the company, so I do not know what they have disclosed.

**Nimish Mehta:** That is not with this technology is what I understand, right?

**Dilip Shanghvi:** It is not an innovative technology, it is a technology for abuse deterrence, but it is not innovative enough to qualify for a new product.

**Nimish Mehta:** So I was actually hinting to that only. So if we can copy that technology as well and is there a possibility of that happening in the near future?

**Dilip Shanghvi:** Sun does not have an abuse deterrant product in development right now.

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

**Anubhav Aggarwal:** One question on the injectable sales, IMS shows a very sharp decline in IMS injectable sales for Sun Pharma. In the fourth quarter, you mentioned there were some deferred sales, I am assuming some of that were injectable sales. Now we have already seen almost half a quarter gone



by, now we are sitting almost middle of August. Have you seen those sales normalizing now or did they normalize in June quarter or they have not normalized as yet?

**Dilip Shanghvi:** It is difficult to give product level information, but what I said earlier, there have been some product disruptions. Once we are able to bring those products back to market, we will start seeing revenue gain on account of those products.

**Anubhav Aggarwal:** But some idea will be useful because we are very confused with very low sales that you guys are reporting that whether those deferred sales had seen some contribution in June or have not seen at all. I am not asking about the quantum.

**Dilip Shanghvi:** So what do you mean by deferred sales?

**Anubhav Aggarwal:** So for example in fourth quarter you mentioned that there were some products where....

**Dilip Shanghvi:** No, that is not related to that.

**Anubhav Aggarwal:** That comment was not for injectables?

**Dilip Shanghvi:** That is not for those products, no.

**Anubhav Aggarwal:** So now for the injectable sales like if I am assuming IMS is right, that our sales have dropped. So with Halol remediation complete now, you expect that revive in the current quarter?

**Dilip Shanghvi:** Yes. That would be the focus.

**Anubhav Aggarwal:** And second question was on your gross margins. Gross margins have expanded dramatically if you see from the March quarter to June quarter, now this is very peculiar because if you see broadly, India's sales is down sequentially and we had the INR appreciation impact as well. The gross margin for the total company is expanded 500 basis points sequentially. What is the big driver for that?

**Dilip Shanghvi:** I think in the previous quarter I think in the end this authorized generic which had low margin.



**Anubhav Aggarwal:** But you mentioned in the previous quarter that other generic sales have dramatically reduced from third quarter to fourth quarter?

**Uday Baldota:** No, I think Anubhav it is again a mix of things. So if you see the overall mix of the businesses changed quite dramatically in the current quarter. If you see also in the midst itself there was some kind of an authorized generic in the last quarter plus I think we had indicated some inventory charge that we had taken in the last quarter. So I think it is a mix of all of these things.

**Anubhav Agarwal:** So there is no one-off in this quarter. So fourth quarter was one-off, but this quarter is more normal.

**Sudhir Valia:** Yes, at least from that standpoint there is no one-off.

**Anubhav Agarwal:** On Dadra facility, have we finished our remediation completely?

**Dilip Shanghvi:** I do not have an update, but there was no major remediation issues in Dadra right now that I am aware of.

**Anubhav Agarwal:** Have you received any approvals on that facility after inspection in April?

**Sudhir Valia:** It is not a remediation, it is only observation needs to be closed.

**Dilip Shanghvi:** So FDA needs to recertify the facility in their internal record or we need to get EIR report.

**Moderator:** Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

**Sameer Baisiwala:** Towards I guess at the end of the call, I will trouble you a little bit with math's. I was just doing looking at the sales guidance and you did last year 31,000 crores and this quarter you have done 6,200 crores and your topline guidance for this year is single digit decline which almost suggest that even if I take 10% decline, 7300 crores per quarter sales, so how do you bridge from 6,200 to 7,300 crores in the next 3 quarters?



**Dilip Shanghvi:** I think part of it may be India business will grow. Part of it is that the API business which is very lumpy, during the year, we should see some kind of growth. So whatever guidance that I think we have given, we have looked at. But also some of the issues like what I said regaining market share of some of the products in the US. So all of that should help.

**Sameer Baisiwala:** Okay sir. The second question towards the early part of the call you mentioned that will get back, you look at getting back into the sales momentum for the overall business going forward. I am sorry just I will take a quick second, so pre-Ranbaxy, your topline growth expectation used to be (+/-20%), after Ranbaxy 10-12%. So now it is a completely new world and you are looking a specialty build out. So it is not looking at this year, I am not looking at next year, but you take 3-5 years whatever timeframe. How should we think about your topline growth as you go forward?

**Dilip Shanghvi:** If you see historically what as a company we have tried to do, is that in each of the businesses that we are competing, we want to find a way to grow faster than the market and we are now getting into specialty business so that idea is to reach a certain amount of critical mass in next 5 years. So if you see the major markets that we are present in, one is India, second is emerging markets, rest of the world, API, US, Europe, Japan. So these are the markets that we will want to find a way to grow faster than the market. Now if overall, if say it the generic market has come down significantly, then we may not be able to grow topline, but we will find a way to at least grow slower than the de-growth of some of the other players.

**Sameer Baisiwala:** Sir this is very helpful, but just because US is a biggest part of your business, US generic. I am keeping specialty out, and if that market for generics is growing at 3%-4%, you have been looking to beat that number and that is the way we should model your businesses?

**Dilip Shanghvi:** It will come back and bite me after 2 years because I am then giving a long-term guidance. I think I am telling you philosophy. Now what happens is that in specific year, there may be challenges because let us say, you see major erosion in some of your important products. So in that year, it may or may not happen. But our effort will be to find a way to grow our business faster than the overall industry rate of growth in each of the market. Clearly, if I see this year, we have significantly underperformed the industry in the US and we have to find a way to fix it. That is an intention, but that is not fully baked in into our projection.



**Sameer Baisiwala:** Okay. This is a company which had spin out really high quality, high technology products such as Doxil, such as auto injector, sumatriptan and many other such products. Is it fair to assume that for your current pipeline, the unapproved products, there are many such winners sitting out there that you will be able to get to market over next few years?

**Dilip Shanghvi:** That is the effort.

**Sameer Baisiwala:** No, they are part of your filings already done?

**Dilip Shanghvi:** Yes, some of them will be yes.

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

**Nimish Desai:** Thank you everybody for being on the call and if any of your questions remained unanswered, please send them across. We will have them answered. Thank you and have a good evening.

**Moderator:** Thank you very much members of the management. Ladies and gentlemen, on behalf of Sun Pharmaceuticals Industries Limited that concludes today's conference call. Thank you all for joining us and you may now disconnect your lines.