Sun Pharma Q3 FY16 Earnings Call Transcript 06:30 pm February 12, 2016



## **Corporate Participants**

**Dilip Shanghvi** Managing Director, Sun Pharmaceutical Industries Ltd.

**Sudhir Valia** Whole Time Director, Sun Pharmaceutical Industries Ltd.

**Abhay Gandhi** CEO India Business, Sun Pharmaceutical Industries Ltd.



**Moderator**: Ladies and Gentlemen, Good Day and Welcome to the Sun Pharmaceutical Industries Limited Q3FY16 Earnings Conference Call. As a reminder, all participant lines will be in the listenonly 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. Nimish Desai. Thank you and over to you, sir.

**Nimish Desai**: Thank you. Good Evening and a warm welcome to our third quarter FY16 earnings call. I am Nimish from the Sun Pharma Investor Relations Team. We hope you have received the Q3 financials and the press release that was sent out earlier in the day. These are also now available on our website.

Let me introduce the management; we have with us today Mr. Dilip Shanghvi -- Managing Director; Mr. Sudhir Valia – Whole Time Director; and Mr. Abhay Gandhi -- CEO of our India business.

Today, the team will discuss Performance Highlights, update on strategy and respond to any questions that you may have. As is usual, for ease of discussion, we will look at consolidated financials.

Just as a reminder, this call is being recorded and the replay will be available for the next few days. The call transcript will also be put up on our website shortly. The discussion today might include certain forward-looking statements and this 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 will now hand over the call to Mr. Shanghvi.

**Dilip S. Shanghvi:** Welcome and Thank You for joining us for this Earnings Call after the announcement of Financial Results for the third quarter of FY16. Let me discuss some of the key highlights:



The Ranbaxy integration is on track. We are implementing synergies as scheduled and some of them even ahead of time. Some of these synergies will be visible in FY17 while we remain committed to a target of US\$ 300 million in synergy benefits by FY18.

Let me now update you on Halol: As all of you are aware, in December 2015, we received a warning letter from US FDA for the Halol facility. We have undertaken some incremental remedial measures to address this and we are progressing well on the implementation of these measures. We understand that investors need clarity on the time-line of the Halol resolution. While, it is difficult to predict such time-lines, we expect to put in a request for re-inspection of this facility sometime in Q1FY17.

I will now hand over the call to Mr. Valia for discussion on the Q3 performance.

**Sudhir V. Valia:** Thank you, Mr. Shanghvi. Good evening everyone and welcome to all of you. Our Q3 financials are already with you. As usual, we will look at key consolidated financials.

Before we discuss the financials, let me highlight that the US dollar for the quarter and the 9 months was at a higher rate as compared to last year.

Q3 net sales are at Rs. 7,047 crores, up by 2% over Q3 last year. Material cost as a percentage of the net sales was 25% same as Q3 last year. Staff cost was at 16.3% and other expenditure was at 28.5% of net sales, both slightly higher than Q3 last year.

As a result of the above, the EBITDA for Q3 was at Rs.2,134 crores with EBITDA margins at 30.3%. EBITDA Margins have improved sequentially from 28% to 30.3% for Q3. Net profit for the quarter was at Rs. 1,417 crores with Net profit margin at 20%. EPS for the quarter was Rs. 5.9 on the expanded equity capital post Ranbaxy merger.

Now, we will discuss the 9 month performance.

For first 9 months, net sales were at Rs. 20,376 crores, a decline of 3.6% over 9 month last year. Material cost, as a percentage of the net sales was 24.7% almost same as 9 month last year. The staff cost for the 9 month was at 17.7% of the net sales while other expenses were at 30%, both higher than 9 months last year.



As a result of the above the EBITDA for the 9 months was at Rs. 5,656 crores a decline of 20% over the 9 month last year. EBITDA margins were at 27.8% for 9 month compared to 33.2% for 9 month last year. The 9-month period last year had the benefit of high margin supplies of generic Diovan under the exclusivity period.

Net profit for the 9 month FY16 was adversely impacted by one-time items as well as exceptional charges of Rs. 685 crores in Q1FY16. These exceptional charges relate to impairment of fixed assets and goodwill and other related costs and have arisen on account of integration and optimization measures. As a result, the net profit for the 9 month FY16 was at Rs. 3,002 crores resulting in EPS of Rs. 12.5.

Taro posted Q3 FY16 sales of US\$ 258 million, up 9% over Q3 last year. For the 9 months, sales were US\$ 686 million, up by 11% over 9 months last year. Taro's net profit for Q3 was US\$ 189 million, up 33% YoY. Net profit for 9 months FY16 was at US\$ 426 million, up by 28% over 9 months last year.

I will now hand over to Abhay Gandhi, who will share the Performance of the India business.

**Abhay Gandhi**: Thank you Mr. Valia. Let me take you through the performance of our India business.

For Q3, sales of branded formulations in India were Rs. 1,890 crores, a growth of 8% over Q3 last year and accounting for approximately 27% of total sales.

We are seeing a gradual recovery post the soft performance experienced in September-2015 quarter. However, we continue to witness the adverse impact of withdrawal of bonus offers on certain acute care products, which we believe is temporary.

For the nine months ended December-2015, sales were Rs. 5,493 crores, a growth of 7% over nine months last year.

Growth in the second-line sales, as well as prescriptions for the quarter and the nine months continued to be strong.



Sun Pharma is ranked No. 1 and holds approximately 8.8% market share in the Rs. 96,000 crore pharmaceuticals market as per December-2015 AIOCD-AWACS report. As per latest SMSRC report, Sun Pharma is ranked no. 1 based on share of prescriptions with 12 classes of doctors.

The integration between the India businesses of both Sun and Ranbaxy is on-track. Competition and government mandated price controls are the other key factors which will determine the long term growth trajectory.

I will now hand over the call to Mr. Shanghvi.

**Dilip S. Shanghvi**: Thank you Abhay. I will briefly discuss the performance highlights of international business. Let me first start with the US business.

For Q3, our overall sales in the US were at US\$ 486 million accounting for approximately 45% of our overall sales. Sales for the quarter were impacted primarily due to competitive pressure on some products and temporary supply constraints arising from remediation efforts at the Halol facility. The Company had benefitted significantly in same quarter last year from the 180-day exclusivity on Valsartan tablets in the US resulting in a higher base.

During the quarter, we received the final approval for generic Gleevec from the US FDA. We have launched our generic version in the US on 1st February 2016. We expect this product to be a key contributor to our revenues and profits in the exclusivity period.

Our sales in emerging markets were at US\$ 151 million for Q3, accounting for 14% of total sales. Sales were impacted due to volatile currency movements in certain emerging markets and a strategic decision of not participating in low margin businesses.

Formulation sales in Rest of World (ROW) markets excluding US and Emerging Markets were US\$ 85 million in Q3, accounting for approximately 8% of revenues. We have made a conscious effort at reducing the participation in non-remunerative businesses which has contributed to the degrowth in the business.

The API business is of strategic importance to us due to benefits from vertical integration. We continue to increase the API supply for captive consumption significantly for key products. External



sales of API for Q3 were at Rs. 441 crores, up 78% from the corresponding quarter last year. This strong growth was partly driven by the consolidation of the opiates business in Australia.

We continue to invest aggressively in R&D. Consolidated R&D expense for Q3 was Rs. 583 crores, accounting for 8.3% of sales. This was up by almost Rs. 85 crores over Q2FY16 and by Rs. 268 crores YoY.

For 9 months, R&D spend was Rs. 1,591 crores at 7.8% of sales. This includes significant investments on account of funding the clinical development of Tildrakizumab. This R&D spending enables development of future product pipeline including specialty and differentiated products and we continue to expect increased R&D investments in future. Current profitability is after this increased investment in R&D.

We have a strong pipeline for the US market with 156 ANDAs awaiting approval with the US FDA. Our comprehensive product offering in the US market consists of approved ANDAs for 435 products. During the 9 month period, ANDAs for 11 products were filed and 9 approvals were received.

Our overall results for Q3 indicate sequentially improving quality of business despite adverse currency movements and a significant increase in R&D investments. The synergy benefits of the Ranbaxy acquisition have begun to reflect in our financials. This improvement is despite the US\$ 40 million one-time revenues booked in Q2FY16.

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

**Moderator:** Thank you very much. We will now begin the Question-and-Answer Session. Our first question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

**Neha Manpuria**: My first question is on the US business. So I understand that there was \$40 million impact in the second quarter. But even after including that given Taro performance was so strong in the quarter, is it fair to assume that the additional remediation at Halol has impacted dispatches in the quarter?



**Dilip S. Shanghvi**: I do not see a trend which indicates a weakening of business. There may be some impact on account of some products that we would have undersold or sold less in this quarter because of some time mismatch, but otherwise, overall business continues to be in line with the earlier period.

**Neha Manpuria**: So is it fair to assume that the supplies from Halol are still improving quarteron-quarter all things remaining equal?

**Dilip S. Shanghvi:** Yes, I think supplies are improving.

**Neha Manpuria**: My second question is on India. We are seeing gradual improvement from the soft second quarter numbers that you have reported. Could you tell us two or three things which are driving improvement? Is all of that fully reflected in our number or you see more improvement coming through as we go ahead?

**Abhay Gandhi**: I think the basic changes which we made is reduce the dependence of India business on things like bonus offers and discounting, and that had led to the soft earlier quarter. These corrections have been made and the focus on building relationships with doctors, focusing on prescriptions, investing for the long-term, these are the prime changes that we have brought in and it took some time for everybody to get aligned and start actually delivering on that and gradually we are seeing the impact of this happening on the business.

**Neha Manpuria**: So we should see this continue to improve our performance in India in that case?

Dilip S. Shanghvi: I would like to think so, yes.

**Moderator:** Thank you. The next question is from the line of Girish Bakhru of HSBC. Please go ahead.

**Girish Bakhru:** If you could just update on the remediation efforts at Halol after seeing the warning letter more carefully if you have come out with some more stronger timeline on when you basically assume this will complete and when you can re-invite FDA for inspection?



**Dilip S. Shanghvi**: I did indicate in my opening remarks that we hope to be able to request USFDA in the first quarter of next year, which is first quarter of FY17 to re-inspect.

**Girish Bakhru**: his basically assumes that whatever your assessment from the warning letter was there was not much incremental remediation required or would you have done significant changes post that also?

**Dilip S. Shanghvi**: I think we would have done. We have initiated additional remediation as a response to the warning letter, but the timeline that I am giving is after factoring those remediation efforts.

**Girish Bakhru**: Second question is bit of a broader question again on MK3222. When we basically wait for the top line data, are we basically looking for Tildrakizumab to show more delta in terms of efficacy or in terms of safety, where do you get more confidence on? Just subsequent to that, what basically will bring this product closer to say Cosentyx or better than that in terms of the data?

**Dilip S. Shanghvi**: What we have with us is Phase-II data. We hope that at least the top line data of Phase III should be available with us by April or May and that will give us greater clarity. But, if I see the overall performance of Tildrakizumab in terms of its efficacy, both at PASI-75 and PASI-90, then they are decent numbers. On top of that we expect a fairly benign side effect profile if what we have seen in Phase-II also is reproduced in Phase III and once every three month dosing. So I believe that if I see the overall package that we will be able to submit, we should be able to aspire to get a sensible market share.

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

**Anubhav Agarwal:** One question on this product Sumatriptan Autoinjector. IMS shows that Sun sales have almost become zero in this quarter. So I want to check, is this a product specific issue that we are facing here?



**Dilip S. Shanghvi**: It is a product which is also referred to in the warning letter. So there is a certain amount of remediation that we are addressing and we hope to be able to get back to market soon.

**Anubhav Agarwal:** This warning letter to us came in December and sales for this product almost had become zero even before that. So we have already taken this product out of the market before warning letter came in?

**Dilip S. Shanghvi**: As a part of the remediation effort, we were upgrading and modifying the aseptic facility. So during that period of time, there was a disruption in supply.

**Anubhav Agarwal:** If I look sequentially September 2015 quarter to December 2015 quarter, other expenses as you report they are down about Rs.100 crores. What will be prime driver of that because R&D is also high, but absolute other expenses are down Rs.100 crores?

**Uday Baldota**: When you look at the other expenses is sort of a collection of a large number of expenses, so I think difficult to sort of segregate, but broadly, I think we mentioned in our opening comments that we are beginning to see reflection of synergy in our financial. So I think some of these numbers are sort of getting impacted by what you see in terms of absolute change.

**Anubhav Agarwal:** So, you mean to say that this other expenses what we are seeing this quarter is more sustainable probably we could see some more reduction going forward then?

**Uday Baldota**: Necessarily every quarter-on-quarter you would not see similar reduction, but I think directionally if we have to deliver on synergies, then the expenses will contribute part of the synergy and revenues will contribute part of the synergy. So directionally I would say that we are in the right direction, whether Q4 will be similar to this or subsequent quarters will be similar to this, I think we need to wait for the trend to emerge, because there are a large number of expenses that were grouped in the other expenses.

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



**Sameer Baisiwala**: On Gleevec, during these 180-days, is there any volume restriction on Sun Pharma given the settlement? Is the innovator Novartis competing in any which way with your product through discounts or any such thing?

**Dilip S. Shanghvi**: There are no restrictions as a part of our settlement. However, this is not a typical generic product because it is a product which is essentially distributed through specialty pharmacy and Novartis would have special pricing arrangement with many of the payors. So it is not something that I would classify as a typical generic product. I would expect that the pickup will be gradual. However, we are seeing reasonable traction with the product in the early days and we are quite happy with the way in which the product is progressing.

**Sameer Baisiwala**: You mentioned in your opening remarks that this would be a big contributor to your sales and profits during 180-days. What happens after 180-days -- do you think that the competitive dynamics would be weak for a few more quarters?

**Dilip S. Shanghvi**: If I say what Novartis has publicly stated, that they are expecting significant loss of sales globally on account of loss of this exclusivity and that would essentially reflect that they are expecting many competitors to come. So I would expect that post six months, the generic competition will be there, we do not know how many people, but over time, I am reasonably sure that there will be quite a few.

**Sameer Baisiwala:** On the emerging markets side of the business, your sales have been pretty good quarter-on-quarter, but even if I take it back three, four quarters or even just a quarter before Ranbaxy acquisition, it is holding out pretty nicely and despite the currencies being down a lot in these markets, so what is really helping us over here and what is the outlook?

**Dilip S. Shanghvi**: There are countries like Romania, where there is no major impact. There are other geographies where price and currency erosion is not very significant. Some countries like let us say Russia or Brazil or South Africa have seen significant erosion in value of currency. It is a mixed bag.

Sameer Baisiwala: How do you see this trend forward for your constant currency growth?

Dilip S. Shanghvi: I think we expect business to do well.



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

**Prakash Agarwal**: Trying to understand Doxil market share decline. Was it largely due to the competition picking up or it could be due to the Halol remediation as well?

**Dilip S. Shanghvi**: I do not think generic Doxil supplies were disrupted. So it must be because of the competition.

**Prakash Agarwal**: With this the prices would have also corrected, is that fair to assume?

**Dilip S. Shanghvi**: I do not have that level of granular information.

**Prakash Agarwal**: Secondly, on India business, just trying and understand one comment you made was some adverse impact still continuing because of the bonus offers, a couple of quarters back we had seen some inventory correction measures largely due to Ranbaxy portfolio, but also our portfolio. Would that be totally done now and we should expect a better growth going forward?

**Abhay Gandhi:** It is difficult to estimate exactly, but I think most of it would have been liquidated and we should see normal sales going ahead.

**Moderator**: Thank you. The next question is from the line of Kartik Mehta from Deutsche Bank. Please go ahead.

**Kartik Mehta**: I just wanted to understand from you, would you do less amount of site transfer of products in anticipation of re-inspection in Q1? The reason I ask this is we seem to have tentative on Vimpat but one of the OCs which we were to get approval we seem to have missed that. So I just wanted to understand your thought on which of the key products would you do site transfer assuming they were originally there from Halol?

**Dilip S. Shanghvi**: We are currently not pursuing an aggressive site transfer plan for Halol products. The focus is on getting site re-certified.

Kartik Mehta: Yes, on that we did manage to get Vimpat or is it ...?



Dilip S. Shanghvi: That is a different site product.

**Moderator**: Thank you. The next question is from the line of Manoj Garg from Healthco. Please go ahead.

**Manoj Garg**: Two questions; the first on Gleevec. Can you provide any color on the pricing or the share you expect to garner during your exclusivity period?

**Dilip S. Shanghvi**: I think Kal Sundaram has indicated that he is expecting over time to reach 30% market share. That is based on the visibility that he has today. So that is the kind of numbers that we are looking at.

**Manoj Garg**: A more macro question. So your equity has held in very strong in the background of significant market volatility worldwide, it sounds like you are comfortable with the way remediation is going at Halol, you are going to get basically a one-time bolus of cash from Gleevec. Just wanted to better understand what your appetite would be for additional assets especially at distressed prices?

**Dilip S. Shanghvi**: Our focus is to consolidate our own business, focus on improving our overall service level performance and R&D efficiency throughput.

Manoj Garg: So it just sounds like you are not looking externally?

Dilip S. Shanghvi: We are not looking externally.

Manoj Garg: Looking forward to hearing updates around Halol in the coming quarters.

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

**Surya Patra**: On the API business front sequentially there is a kind of improvement of around Rs.125-odd crores and you are saying it is largely because of the integration of the Opiates business. So is it fair to assume that this Opiates would be adding incremental around Rs.500-odd crores annually?



**Dilip S. Shanghvi**: We have given separate numbers for Opiates. So this number includes part of the Opiates, but also there is an underlying growth of the API business.

**Surya Patra**: My second question is on the ANDA filing side. Of course the R&D expenses have increased sequentially led by both possibly for building the ANDA pipeline as well as for our new molecules. But around 11-odd filings that we have done, so is it a kind of muted number that we are seeing compared to the earlier trend?

**Dilip S. Shanghvi**: Major increase in the R&D spend is on account of clinical studies of Tildrakizumab. However, the focus is to file more complex products rather than products which are easy to file.

Surya Patra: This is excluding of this Taro filing, right?

**Nimish Desai:** The number that we gave in our press release is all inclusive.

**Surya Patra**: Just last one clarification; you said something on the Taro side 30% something like that, can you just please repeat in the previous query?

**Dilip S. Shanghvi**: I gave 30% in context of generic Gleevec market share.

**Moderator**: Thank you. The next question is from the line of Abhishek Sharma from India Infoline. Please go ahead.

**Abhishek Sharma**: Just wanted to delve on Gleevec a little more. You were saying that it is a product where you will get market share only gradually. So I just wanted to understand is that because Novartis is giving you fierce competition or would you find it difficult to switch existing patients who are already on Gleevec?

**Dilip S. Shanghvi**: I think this will be due to multiple reasons, some of them you have listed, I think some resistance of some of the patients to switch, some may also be special pricing to some of the insurance plans that will make it attractive for the plan to stay with the brand. So a series of reasons which would make this a very different product from a typical generic product.



**Abhishek Sharma**: Then is it fair to say that people who come in after your exclusivity expires would find it increasingly difficult to penetrate the market given the fact that they are coming at a later date?

**Dilip S. Shanghvi**: We are entering the market at a point of time that there is no generic. So it is being treated very differently. What you are asking me is that post few generics into the market, whether the market will remain the same or will change, and it is difficult to respond.

**Moderator**: Thank you. The next question is from the line of Nimish Mehta from Research Delta Advisors.

**Nimish Mehta**: I just wanted to understand now that we have this Opiates facility integrated. How will it change in terms of our getting more licenses for the controlled substance, does it go the way that if you have more access to the facility we will get a larger license, is that how will it happen?

**Dilip S. Shanghvi**: No, it makes us an integrated player in the market. License in the US is a function of DEA quota and that process is very independent from whom you are importing.

**Nimish Mehta:** So how does this help us in terms of ensuring that our market share or penetration is better than the competitor? I guess that is the rationale behind this acquisition.

**Dilip S. Shanghvi**: I think we capture the full value chain and that gives us cost advantage, exactly the same logic why integrated players then potentially compete in the other small molecule products.

**Nimish Mehta**: When you are talking about re-inspection of Halol facility in the first quarter, so you will be back to full production in Halol in the first quarter itself?

**Dilip S. Shanghvi**: No, I do not think I said that it is re-inspection in first quarter, I said that we should be able to request FDA for inspecting the facility in first quarter. We cannot influence their decision to inspect. So, I do not know when they will inspect. We also do not know how long it will take for them to recertify the facility. Those are the things which are not in our hand.



**Nimish Mehta**: Yes, sorry, actually my question is just wanted to understand before that, will we be reaching full production in Halol before the request is made to the USFDA?

**Dilip S. Shanghvi**: I have actually in the past also explained is that, for some of the products that we may have lost market share, we will build gradually. So supplying the product once again does not necessarily mean that we get back our market share.

**Nimish Mehta**: Yes, that could be more a market function. I am just talking from production function.

Dilip S. Shanghvi: Yes, clearly, I think it will improve.

**Moderator**: Thank you. The next question is from the line of Ashish Rathi from Infina Finance. Please go ahead.

**Ashish Rathi**: It was just a clarification on the one which was just asked. So basically in a call earlier before the warning letter came, you had indicated that you would look to increase the capacity utilization at Halol irrespective of re-inspection timelines or request. That part still holds, right?

**Dilip S. Shanghvi**: Yes, the idea is to gradually improve the capacity irrespective of reinspection.

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

**Anubhav Agarwal:** Two questions for synergies; one is we have given absolute number of \$300 million to achieve by FY18. With the emerging markets currency volatility that we have seen, is there any impact to the \$300 million number or we are not expecting much from emerging markets in that, so there is no impact?

**Dilip S. Shanghvi**: There will be some synergy also from emerging markets. To that extent, I do not think we have done that level of recalibration, let us say hypothetically we were expecting some synergy in Russia, then that synergy we would have converted and put as a part of \$300



million. That synergy if it was expense in dollar terms, then it will remain the same. If it was spent in ruble terms, then that synergy would go down. But that level of detailing, we have not done.

**Anubhav Agarwal:** You mentioned in your remarks that some part of Ranbaxy synergies is visible in this quarter. Would you just to help us putting some context that when you acquired Ranbaxy, till the time Ranbaxy's last financials were available to us, Ranbaxy had a certain base margins, are we at least back to that base margin with the kind of synergies that we have seen?

**Dilip S. Shanghvi**: Let me share with you what we intend to do. We will possibly get out of very competitive and low margin products so that will have an impact on top line, but it will also potentially improve the overall percentage of cost of goods. We will try to improve the cost, we will try and increase the usage of the facility. So what is being bought from outside will be produced in-house. So all of these are potential synergies that we can see and those are the plans that we have.

**Anubhav Agarwal:** But you have mentioned, but I am not able to put in context, how good are we at Ranbaxy right now. So I was just trying to ask that with the stage we are, are we worse off, or better from the stage that we acquired Ranbaxy? If I put absolute EBITDA that Ranbaxy was making at that time when you acquired it and you know the absolute EBITDA today. Is it better or worse off or equal?

**Dilip S. Shanghvi**: I think it is difficult to respond, but I do not see any part of our combined business which has run more poorly than what it was run in the Ranbaxy days. But that is my overall judgment.

**Anubhav Agarwal:** One more question on the warning letter. I just still have not understood that the FDA has not acknowledged any Sun Pharma's response post May 2015. Have you pursued with them that why none of your response post that were acknowledged?

**Dilip S. Shanghvi**: I think FDA decides what it wants to do and what is appropriate. So, I do not think that we have taken up with them as to why they have not acknowledged our response or whether they have not considered our response. We have looked at the context of the warning letter and learnt from the warning letter their additional concerns and we work towards adding to the remediation process, those activities, which will address the concerns.



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

**Prakash Agarwal**: Just one clarification on the Opiates business. Sir, apart from the cost advantage, because of the integration from back end to front end, would this be fair to understand that this also brings in additional quota and our filing work would be dependent on quota and we would start increasing filings on this?

**Dilip S. Shanghvi**: It does not change the quota in the US.

**Prakash Agarwal:** The filings for controlled substance, would that increase because of this or you have to do a separate exercise?

**Dilip S. Shanghvi**: I think filing is more a function of our ability to develop the product than our availability of raw material because otherwise the material is available from somebody else.

**Prakash Agarwal**: Just trying to understand this better, sir, how does quota increase in this case?

**Dilip S. Shanghvi**: It is a function of our performance in the marketplace. So if we have bigger market share and in the next year we will have bigger quota.

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

**Sameer Baisiwala**: On Ranbaxy synergy benefits, your P&L is going to change a lot in next 6-9months, Gleevec and many other things. So, would you be sharing very transparently where these synergies have come, would be easy for us to see and measure how you get to \$300 million?

**Dilip S. Shanghvi**: We will share what I think is required for us to say without sharing things, which can potentially hurt business interest of the company. Now, as to our ability to achieve the kind of synergy number that we are talking about, I think it is such a significant number looking at our current turnover, that it should be independently measurable and the guide post is FY18. So, by that time I think you should have clarity. Even with our current disclosures, it should not be a big challenge for you to measure.



**Sameer Baisiwala**: On Halol, would you say that over last whatever 15-18 months, for all your pending ANDAs, FDA has been reviewing them, has been giving you target action dates, CRLs being issued. So would you say all of this has been in motion? As and when your facility gets a green signal, then you will have a bunch of these new approvals flow through?

**Dilip S. Shanghvi**: That is generally my understanding of how FDA works.

Sameer Baisiwala: You have been getting TADs and CRLs?

Dilip S. Shanghvi: That is true.

**Sameer Baisiwala**: You mentioned that you are investing a lot R&D in Complex Generics and Specialty pipeline. Just on the second part, Specialty pipeline other than MK3222, what work is being done in this regard?

**Dilip S. Shanghvi**: There are a few other delivery system-based products, there are products that we have now as a part of our acquisition of InSite. We can potentially license some of the SPARC products which are under development.

**Sameer Baisiwala**: So you are including SPARC, InSite etc., it is not really Sun's own R&D engine that we are talking about?

**Dilip S. Shanghvi**: InSite will be Sun's, because it will get consolidated in Sun.

Sameer Baisiwala: But that is what you had in mind when you talked about Specialty?

**Dilip S. Shanghvi**: Yes, plus there are some existing delivery system based Dermatology products, both in Sun and Taro pipeline.

**Moderator**: Thank you. The next question is from the line of Tushar Manudhane from IndiaNivesh. Please go ahead.

**Tushar Manudhane**: Just with respect to the warning letter, there is one point which mentions about performing the dynamic smoke studies. So just would like to know, has the study started and how long this study takes?



**Dilip S. Shanghvi**: I think when we have said that we should be able to put in a request for reinspection, these are basic issues that we should have addressed.

**Tushar Manudhane**: The same point highlights about any major equipment or facility upgrades to be planned or maybe done. So just would like to understand if this is going to be requiring costly equipment and that would add to the...

**Dilip S. Shanghvi**: Whatever that is being done is factored in our numbers that we have shared with you.

**Moderator**: Thank you. The next question is from the line of Chirag Dagli from HDFC Mutual Fund. Please go ahead.

**Chirag Dagli**: On Tildrakizumab, you said that there is a dosing difference, ours is a once a month dosing. I was not actually clear on that point sir so?

**Dilip S. Shanghvi**: What I said is ours is a once every three months dosing.

Chirag Dagli: Versus competitors being?

**Dilip S. Shanghvi**: Not competitors, Cosentyx, it is once a month dose.

**Chirag Dagli**: The other point was that generally speaking empirically whatever we have seen, does the safety profile in Phase-II and Phase-III appear similar in a large number of cases?

**Dilip S. Shanghvi**: Generally people expect the profile not to be very different, but if there is let us say very rare side effect, then you may not see it in a smaller study, but you may see it in a larger study. But looking at the biological activity of this product, I am not expecting that to be a surprise. I think reason why there is always an associated risk with drug discovery and new products is some small probability or uncertainty and risk that we are not anticipating.

Chirag Dagli: Which happens in a very small number of cases is what you are saying?

**Dilip S. Shanghvi**: No, what I am saying is that you may not get what you are expecting.



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

**Saion Mukherjee**: Just on R&D front, you made a comment that we filed 11 ANDAs and you are focusing on more Complex and Specialty. So should we assume that you would be filing more high value, less number of products on the Generic side?

**Dilip S. Shanghvi**: I think whatever our filing target is for next year we will share with you at our next year's guidance.

**Saion Mukherjee**: I was just wondering if there is a change in strategy vis-à-vis the past years when the number of filings were a lot higher?

**Dilip S. Shanghvi**: No, I think it is both. Now that we have multiple approvals and significant manufacturing volume, it also reduces our ability to find more products from the sales. So we are looking at Complex products.

**Saion Mukherjee**: One question on tax rate with Gleevec coming in. How should we think about tax rates going forward?

Sudhir V. Valia: Currently tax rate is increasing gradually.

Saion Mukherjee: From the current levels?

Abhay Gandhi: That is right.

**Moderator**: Thank you. The next question is from the line of Praful Bohra from Religare. Please go ahead.

**Praful Bohra**: The Merck JV for emerging markets, which has been called off, so what is the kind of investment we have made there in the past 4-5-years. Also, if you can provide some color on why the JV has been called off?



**Dilip S. Shanghvi**: First of all it is not very significant and it is already factored in whatever numbers that we have been sharing with you over time. The second thing is that, as we have explained, it is basically difference in the strategic direction of both the companies.

**Moderator**: Thank you. The next question is from the line of Abhishek Sharma from India Infoline. Please go ahead.

**Abhishek Sharma**: Would you be sharing the top line data around Tildrakizumab when it comes out?

**Dilip S. Shanghvi**: Typically what companies do is that they share the top line data in a global subject clinical meet or something like that and that is what we will follow.

Abhishek Sharma: Target filing date with NDA if you have frozen on that?

**Dilip S. Shanghvi**: Yes, I think we have shared some dates with you in the past and those are not likely to change.

Abhishek Sharma: So, December 2016 is what I remember?

Dilip S. Shanghvi: What we have said is calendar 2017.

**Abhishek Sharma**: The procurement-related synergies around Ranbaxy, have they started to kick in already? Would they be somewhere in the numbers if only to a small extent?

**Dilip S. Shanghvi**: To some extent, there will be, but they will also have some long-term contracts. All of these take time and that is why we are guiding for up to FY18.

**Moderator**: Thank you. The next question is from the line of Manish Jain from SageOne Investment Advisors. Please go ahead.

**Manish Jain**: Just one request on Tildrakizumab, InSite and primarily the innovative set, if you can hold a separate call, that will actually enable us to get a good feel on Tildrakizumab especially?



**Dilip S. Shanghvi**: Sure, I think once we maybe publish or share the data for Tildrakizumab, then we will definitely look at your suggestion.

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

**Nimish Mehta**: Once again on the Opiates facility, you mentioned that your gaining quota is a function of your existing market share of the product. But how will it happen for a product which is not yet approved and you are kind of seeking approval. Typically having oxycodone or oxycontin in mind which is where I think the nearest opportunity would be?

**Dilip S. Shanghvi**: I think there is a process, over time people have established a process that when there are no generic, then a generic comes out, market share moves, and DEA works with those kind of processes.

**Nimish Mehta**: But in that also our access to the raw material does not have any impact on our gaining quota, right?

**Dilip S. Shanghvi**: No, it does neither positively nor negatively impact us.

**Nimish Mehta**: I am still trying to understand the rationale, it is only the cost advantage of being inflated that you have acquired that facility or it is because of our gaining full control over raw material which is critical?

**Dilip S. Shanghvi**: I think strategically it gives us access to material, better strategy flavor, but otherwise, I do not think that from quota point of view, we have an advantage.

**Nimish Mehta**: Now that we are kind of getting through the Halol issue. Are we planning to have re-inspection done for the Ranbaxy facilities or how do we look at the resolution status of a troubled facility at Ranbaxy, if you can just give some color that would be great?

**Dilip S. Shanghvi**: I think as we have said, first and primary focus for us is to have Halol recertified.



**Nimish Mehta**: But we also mentioned that GMP compliance is something that is of prime importance?

**Dilip S. Shanghvi**: I agree totally and the facilities are compliant, they are only not certified for US, they have approval for Europe, they have approval for many other regulatory agencies in many other countries.

Nimish Mehta: But any color from the Ranbaxy facility specifically on the US FDA compliance?

Dilip S. Shanghvi: I have already responded.

**Moderator**: Thank you. I would now like to hand the conference over to Mr. Nimish Desai for closing comments. Over to you, sir.

**Nimish Desai**: Thank you all for joining us on this call today evening. If any of your questions have remained unanswered, I would request please do send them over and we will try to get them answered. Have a good evening.

**Moderator**: Thank you very much. On behalf of Sun Pharmaceutical Industries Limited, that concludes this conference call.