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Full Year 2016 Glenmark Pharmaceuticals Ltd Earnings Call

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Corporate Participants

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* Jason D'souza

Glenmark Pharmaceuticals Ltd. - VP & Head, Corporate Strategy & IR

* Glenn Saldanha

Glenmark Pharmaceuticals Ltd. - Chairman & MD

* Bob Matsuk

Glenmark Pharmaceuticals Ltd. - President, API & North America

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Conference Call Participants

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* Prakash Agarwal

Axis Capital - Analyst

* Girish Bakhru

HSBC - Analyst

* Neha Manpuria

JPMorgan - Analyst

* Sudarshan Padmanabhan

Sundaram Mutual Fund - Analyst

* Abhishek Sharma

IIFL - Analyst

* Manoj Garg

Bank of America Merrill Lynch - Analyst

* Deep Master

ENAM Holdings - Analyst

* Nitin Agrawal

IDFC Securities - Analyst

* Kartik Mehta

Deutsche Bank - Analyst

* Dheeresh Pathak

Goldman Sachs - Analyst

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Presentation

Operator [1]

Ladies and gentlemen, good day and welcome to the Glenmark Pharmaceuticals Limited Q4 FY16 results 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. (Operator Instructions) Please note that this conference is being recorded.

I now hand the conference over to Mr. Jason D'Souza. Thank you, and over to you, sir.

Jason D'souza, Glenmark Pharmaceuticals Ltd. - VP & Head, Corporate Strategy & IR [2]

Thanks, Inbha. Welcome to Glenmark's Q4 earnings call. Before we begin the question and answers, a review of the operations for the organization.

So, for the fourth quarter ended March 31 2016, Glenmark's consolidated revenue was at [INR23,066 million], recording growth of 29.89%. For the year ended March 31, 2016, Glenmark's consolidated revenue was at INR76,495 million, recording an increase of 15.12%.

India business, sales for the formulation business in India for fourth quarter was at INR5,397 million, recording growth of 22.52%. As per IMS MAT, March 2016, Glenmark

maintained its rank at 17 as compared to March 2015, with increase in market share by 0.12%, exhibiting value growth of 20% vis-a-vis IPM growth of 14%.

For the month of March 2016, the business registered growth of 13% vis-a-vis market growth of 10%. Glenmark presently has nine brands in the top 300 and is one of the fastest growing companies in the Indian market.

The India business strengthened themselves in the following therapeutic categories. The cardiac segment market share increased from 3.72% to 3.97%, the respiratory segment market share rose from 3.80% to 4.12%, the anti-diabetic market share rose from 2.03% to 2.19%, and the derma market share rose from 7.92% to 8.59%.

Glenmark Pharmaceuticals USA registered revenue from the sale of finished dosage was at INR6,519 million, recording an increase of 21.56%. For the fourth quarter of FY 2016, Glenmark was granted final approval for eight products and tentative approval for two products.

In the fourth quarter, Glenmark filed six ANDAs with the US FDA, and for the financial year the Company filed 12 ANDAs. Glenmark plans to file seven additional applications in the first quarter of FY17. In the fiscal year 2016, Glenmark was granted approvals for 24 ANDAs, comprising of 19 final approvals and five tentative approvals.

Glenmark's marketing portfolio through March 31, 2016 consists of 112 generic products authorized for distribution in the US market. The Company currently has 59 applications pending in various stages of the approval process with the FDA.

Africa, Asia, CIS region; for the fourth quarter, revenue from Africa, Asia and CIS region was at INR2,980 million, recording an increase of 35.57%. In the fourth quarter, secondary sales for the Russian subsidiary showed 40% growth versus the same period last year, with YTD growth at 13% in constant currency.

According to IMS Health, Glenmark ranks 49th in the Russian market. The Asia subsidiary recorded secondary sales growth of 29% for the fourth quarter. The region continues to do well. The Company launched five products in the region. The Africa subsidiary recorded secondary sales growth of 11%, the Company launched five products in the region during the quarter.

Glenmark's Europe operations, revenue for the fourth quarter was at INR2,705 million, recording an increase of 11.18%. The UK and Germany business recorded good growth in the fourth quarter and the CE region also witnessed double-digit growth for the quarter. During the quarter, Glenmark launched three products in the European region, driven mainly by in-licensed products. Glenmark launched two products in UK and one product in Germany. During the year, Glenmark launched 24 products in the European region, including 16 in-licensed products from several companies.

During the fourth quarter, Glenmark also concluded the licensing deal with Celon for generic Seretide Accuhaler in Europe. Glenmark obtained semi exclusive marketing and distribution rights for the product in 15 European countries, including Great Britain and Germany upon commercialization. During the last few months, Glenmark has filed the product in seven European countries, namely Nordic countries and Germany. Glenmark intends to complete the filing in the remaining countries in FY17.

Latin America, Glenmark's revenue from its Latin American operations was at INR2,416 million, recording an increase of 33.47%. The Brazil business recorded 25% growth in constant currency during the quarter. The Mexico subsidiary grew [60%] in the fourth quarter. We continue to sell our existing inventory present in the Venezuela subsidiary in that market. Shipments to the Venezuela market from India have been stopped since November 2015. During the quarter, most currencies in the Latin American region bounced back, which also enabled the region record good growth. Glenmark launched eight products in the region during the quarter.

API, revenue from the sale of API semi-regulated business was at INR2,228.66 million, recording an increase of 44.04%. During the quarter, Glenmark filed four US DMS, two CEPs and two Canadian DMS. The launch quantities Olmesartan for the US market contributed to the overall growth of the business.

Research and development, the Company has a pipeline of seven molecules, two NCEs and five NBE molecules in clinical trials, or ready to enter clinical trials soon. GRC 17536 TRPA1 antagonist has proven to be highly efficacious in treating inflammatory and neuropathic pain in animal models. 17536 has shown positive data in Phase IIa proof of concept study in patients with painful diabetic neuropathy, conducted in Europe and India. Phase II enabling toxicology studies have been completed and GRC 17536 has shown good safety profile, supporting further development. Glenmark has submitted an IND for a Phase IIb dose-ranging finding study with the US FDA. The agency has requested for

additional information with some changes to clinical protocol. Glenmark is working to address the questions to ensure minimal delay in the startup of the study.

GRC 27864; Glenmark's NCE, is a potent, selectively and orally bio-available inhibitor of the mPGES-1, a novel therapeutic target in pain management. Glenmark has successfully completed preclinical studies and Phase I enabling toxicity studies for GRC 27864. A Phase I, first-in-human, single ascending dose and a multiple ascending dose study has been completed in the UK with no safety concerns. A relative bio-availability study with a tablet formulation has also been completed.

Vatelizumab GBR 500, a monoclonal antibody is an antagonist of the VLA-2 integrin. GBR 500 has been licensed to Sanofi for testing in multiple sclerosis Phase II clinical study. Sanofi has made the decision not to pursue further Vatelizumab as a potential relapsing-remitting MS theory, following the results of a pre-planned interim analysis that revealed the primary efficacy endpoint was not met. The decision is not due to safety concerns. Glenmark will continue to pursue the relicensing of GBR 500 as it is returned from Sanofi.

GBR 900; Glenmark licensed the exclusive intellectual property rights for monoclonal antibodies against the neuronal growth factor TrkA from Lay Line Genomics, Italy. TrkA is part of the NGF-TrkA axis, a validated and novel pain receptor system for the treatment of chronic pain. Phase I enabling toxicity studies for GBR 900 have been completed successfully. A Phase I clinical trial has been initiated in the UK. GBR 900 is the first anti-TrkA monoclonal antibody to enter clinical development.

GBR 830; the first anti-OX40 monoclonal antibody was discovered at Glenmark's Biological Research Center in Switzerland. The development of OX40 antagonist has been very challenging and Glenmark has achieved a significant milestone with the successful generation of an antagonist OX40 monoclonal antibody, coupled with generation of data validating the role of OX40 in autoimmune diseases.

GBR 830 completed the preclinical Phase I dosing successfully in the Netherlands. GBR 830 was well tolerated and its safety and pharmacokinetic profile in healthy volunteers fully support the transition into a clinical Phase II study. Glenmark has an open IND at the US FDA and Health Canada approval under which a Phase II study in atopic dermatitis is currently ongoing.

GBR 1302, a HER2xCD3 bispecific antibody is the first clinical candidate based on Glenmark's proprietary best-in-class BEAT platform, and also, GBR 1302 is Glenmark's first clinical candidate targeting oncology indications. GBR 1302, a HER2xCD3 bispecific antibody has successfully completed the preclinical evaluation phase. In preclinics, GBR 1302 has demonstrated superiority over current antibody therapies against most HER2 positive cancers, including breast cancer. Glenmark has an approval to conduct Phase I clinical trials for GBR 1302 from Paul Ehrlich Institute, Germany and expects to initiate dosing in Q1 FY17. If confirmed in clinical trials, GBR 1302 should constitute an innovative treatment for HER2 positive cancers, potentially superior to the currently available monoclonal antibody treatments.

GBR 1342 is a CD38xCD3 bispecific antibody, based on Glenmark's proprietary BEAT platform. GBR 1342 is the second clinical development candidate based on the BEAT technology. It is also Glenmark's second clinical candidate targeting oncology indications. GBR 1342 targets CD38, a target for multiple myeloma and potentially other malignancies of hematopoietic origin. Glenmark has initiated an IND-enabling studies for GBR 1342 and is committed to moving GBR 1342 rapidly into clinical trials.

With this, we'd like to read some notes from the accounts. First, translation losses on account of currency depreciation was INR94 crores for the quarter. The primary reason was Venezuela, which had a ForEx loss of INR84 crores on account of receivables from the subsidiary to the parent company. For the entire year, translation losses which hit the balance sheet were to the extent of INR301 crores. Besides, in other expenditure, one-time cost pertaining to Sitagliptin litigation in India and Azelaic Acid litigation was to be extent of INR65 crores. The EBITDA after considering these two items was INR460 crores for the fourth quarter.

For the fourth quarter, R&D expenditure was INR254 crores, resulting in an increase of 31% for the quarter and 11% as percentage to net sales. The total R&D for the year was INR725 crores, translating to 9.6% of sales for the year. The innovative R&D expenditure was at INR321 crores and the generic R&D expenditure was INR403 crores, respectively. Depreciation for the full year was at INR269 crores. Reported tax rate was at 30.1%. Cash tax paid for the year was around INR470 crores.

Balance sheet, net debt as on March 31, 2016 was INR3,126 crores and gross debt was INR3,988 crores. Net cash was INR862 crores. Nearly $45 million of cash is on account of Venezuela.

Asset addition, fixed asset addition for the [year] was INR475 crores and intangible asset addition was INR298 crores. The intangible asset addition is primarily on account of in-licensing product, namely the deal that we did with Celon. Around INR60 crores of this is spent towards upgradation of IT infrastructure and Project Disha, which is the implementation of the global ERP solution.

The FCTR for the year was around INR301 crores, arising from the Venezuelan subsidiary to the extent of INR115 crores, the Swiss subsidiary to the extent of INR118 crores, the Argentina subsidiary to the extent of INR58 crores, the Brazil subsidiary to the extent of INR20 crores and Russia subsidiary, which was around INR18 crores.

Net working capital; receivables was at INR2,493 crores as against INR2,606 crores for the six months ended September 30, 2015. Receivables in number of days was 120 days for the year as compared to 141 days for the previous year. Inventory was at INR1,568 crores as compared to INR1,539 crores for the first six months of this financial year. In number of days, inventory was at 75 days. Total payables was at INR2,006 crores as against INR2,131 crores for the six months ended September 30, 2015. Total NWC, net working capital, was at 99 days for the year as compared to 97 days for the previous year.

For Venezuela, the overall net sales was around INR320 crores for the year. The EBITDA for Venezuela was around INR127 crores and the PAT was INR75 crores.

For FY 2017, Glenmark's guidance. On our guidance, Glenmark expects to report sales growth to be in excess of 25% for the financial year 2016-2017.

With this I would like to introduce members of Glenmark management team on the call. We have Mr. Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals Limited. We have Mr. Rajesh Desai, Executive Director of Finance, IT and Legal; Bob Matsuk, who is President, API and North America; and we introduce P. Ganesh, who is President and Global Chief Financial Officer at Glenmark Pharmaceuticals Limited.

With this we would like to open the floor for question and answers. Over to you, Inbha.

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Questions and Answers

Operator [1]

(Operator Instructions) Prakash Agarwal, Axis Capital.

Prakash Agarwal, Axis Capital - Analyst [2]

Sir, question is on gross margins. If we look at 4Q numbers, we are at about 68%. Understand, you already mentioned in the past that you're normalizing it, so I'm not comparing it YoY. But even if I see on a Q-on-Q basis, despite the strong growth across regions, I think your gross margins has seen a dip. This is despite you taking export benefit accretion for the whole year. Can you explain that, please?

Unidentified Company Representative [3]

I think the reality is, there is definitely pricing pressure in most of the geographies that we're operating in. So there is a slight hit in terms of the gross margin on account of that. I think a lot of it is going to be product [dependent] from Europe. So as the product mix changes, hopefully once you see product launches like generic Seretide in Europe, or in -- as far as the US, some more [down] products getting launched and the product mix changes, you'll see the gross margins improve dramatically. But for the current year, let me just conclude it, there's definitely some erosion in the overall gross margins on account of the pricing pressure that we're facing in most of the markets, including the US.

Prakash Agarwal, Axis Capital - Analyst [4]

Anything specific for 4Q, sir?

Unidentified Company Representative [5]

No, not really. As, Glenn said, it is a business mix, as well as product mix, and some exchange -- rupee depreciation is reflected in the import cost, so it is a combined thing.

Prakash Agarwal, Axis Capital - Analyst [6]

And sir, how do we read this other revenue? I mean what I understand is export benefits, but how come for the whole year has been clubbed in for the quarter?

Unidentified Company Representative [7]

Yes, it is -- because this -- if you will see these incentives, we require to get accounted, because of accounting -- to meet accounting standard requirement. These incentives we'll get only on the realization of export. So we are of the opinion that we will not take that into account, but then to meet accounting standard we need to take that, because since we have done export and there is a certainty of, say, realizing the export proceeds, so incentives need to be taken as per the accounting standard. And that is why we have taken that in Q4 for entire year. So in subsequent quarters, you will see that entry in quarter-over-quarter.

Prakash Agarwal, Axis Capital - Analyst [8]

And sir, if you could help us with the EBITDA guidance also, which we normally do every year?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [9]

Still we're not guiding to any EBITDA. All we can say is, the core business we see at about 15% for the -- and if you add Zetia to that total sales will be in excess of 25%-plus growth. These are the only two numbers we think we can put up. As far as the EBITDA goes, there is too much of volatility in the environment right now, so it's extremely hard to guide to any specific EBITDA.

Prakash Agarwal, Axis Capital - Analyst [10]

And any target debt to equity, sir?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [11]

Clearly, obviously as we launch Zetia all our capital will go towards delevering the balance sheet. So from that perspective, the debt will come off significantly in the current year. Outside of Zetia, the business will make cash but not any significance. So the significant reduction will come on the launch of Zetia. So, I think we're not putting any specific number out there, but clearly the debt equity will improve dramatically going forward.

Operator [12]

Girish Bakhru, HSBC.

Girish Bakhru, HSBC - Analyst [13]

Just following on the growth outlook, Glenn if you could comment on the US, particularly ex-Zetia, given that you've had some really good launches and approvals and there is more out there in terms of pipeline, how do you see ex-Zetia core US growth next year?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [14]

Hey, Bob, you want to take that?

Bob Matsuk, Glenmark Pharmaceuticals Ltd. - President, API & North America [15]

Yes, sure. Next year we're looking at between 15% and 20% growth based on the factors that you've just mentioned.

Girish Bakhru, HSBC - Analyst [16]

So, I mean, if I look at in terms of nascent launches, like Frovatriptan and you have had potassium chloride, some good growth continuing in Mupirocin, would it be fair to say that

the overall quarter number would be in excess of say [100, 110]? Would you reach that new base or would the base would be still somewhere around $100 million?

Unidentified Company Representative [17]

So I think on the base, clearly what Bob is guiding towards, I mean, we'll get to a 15%, 20% growth. You have to give us some leeway in terms of quarterly performances. A lot is depending on what approvals keep coming through on a quarterly basis. So yes.

Girish Bakhru, HSBC - Analyst [18]

And have you filed Gleevec in the US market, given that you have the product in Europe?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [19]

We don't comment on any of our filings.

Girish Bakhru, HSBC - Analyst [20]

And just on the technology income, what was the nature of technology income in the quarter?

Unidentified Company Representative [21]

Sorry, can you repeat that?

Girish Bakhru, HSBC - Analyst [22]

Nature of this INR82 crores income?

Unidentified Company Representative [23]

As we explained, it pertains to incentives against the export.

Operator [24]

(Operator Instructions) Neha Manpuria, JPMorgan.

Neha Manpuria, JPMorgan - Analyst [25]

My first question is on the US business. We've heard a lot of the US peers talk about generic pricing over the last week and the two pockets of weakness that they mentioned is -- one of them being the derma. Glenn, what have we seen in our portfolio and how would you characterize generic price erosion as we go into the next fiscal year?

Bob Matsuk, Glenmark Pharmaceuticals Ltd. - President, API & North America [26]

You want me to take that Glenn? We definitely see deflationary pricing pressures existing in the market right now and I think to some of the earlier points that are made, as we get new approvals, as well as the product portfolio changes over time, we'll definitely see some improvements, especially on the derm portfolio of the business.

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [27]

But I think Neha, to just add to what Bob was saying, the reality is you are seeing significant pricing pressure in the US market right now and we anticipate if this trend continues you could see close to 8%, 10% on the base business eroding on account of pricing. So unless those new products keep coming through and you're able to get some quality approvals, it's going to be a tough environment going forward.

Neha Manpuria, JPMorgan - Analyst [28]

Second on Latin America, we saw a very strong quarter in the fourth quarter. Should I assume, given we've pretty much nil sales in Venezuela now, should I assume this as the new base as we go forward to next year, which would give us a very good strong number for growth in Latin America going forward?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [29]

My perspective is Latin America, despite Venezuela, Y-o-Y should grow in excess of 20%, somewhere thereabouts. So I think -- and this is mainly ex Venezuela, we'll grow in excess of 20%. I think with Venezuela also you can see something like 10%, 15% kind of growth coming out of Latin America, Y-o-Y. So I think the other geographies continue to do exceedingly well for us and we are seeing strong growths in markets like Mexico, Brazil, Argentina, Peru, Ecuador, Colombia and some other newer markets. So I think my perspective in Latin America should do well, assuming, obviously the currency stays stable and continues to appreciate, like it's been doing in the last few quarters. So these are the two basic assumptions.

Neha Manpuria, JPMorgan - Analyst [30]

Glenn, is it fair to assume that now the Latin America business will be a profitable for us, ex-Venezuela, as we go into FY17?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [31]

Absolutely.

Neha Manpuria, JPMorgan - Analyst [32]

And if I may squeeze in one last question. On the R&D, we saw a spike up there, as we are focusing on specialty and our innovative portfolios increasing. How should we look at this number in FY17?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [33]

Our view is 11% of sales is where we'll cap it in terms of R&D spend, so we won't go beyond 11%. I think in Q4 we were at 11%. So I think on a full year basis from here on you should assume us spending close to 11% of sales on R&D.

Operator [34]

Sudarshan Padmanabhan, Sundaram Mutual Fund.

Sudarshan Padmanabhan, Sundaram Mutual Fund - Analyst [35]

Sir, can you explain the nature of the write-off in Venezuela? I mean have we taken the full write-off or do we have some more write-off sitting in the books?

Jason D'souza, Glenmark Pharmaceuticals Ltd. - VP & Head, Corporate Strategy & IR [36]

So Sudarshan what we have done is that the receivables which the parent -- which the subsidiary owes the parent, on that we have taken a write-off to the extent of the new currencies, which has moved from [6 to 10]. As you would have read in the newspapers, we feel pretty optimistic with the recent discussions that we can get the cash back out from the subsidiary. The second nature of write-offs, if you look at the FCTR is when you -- outside these receivables if you were to calculate the other receivables, the inventory net of all the commitments and arrive at all the -- the balance amount, on that balance amount, after you net it at all off, we have taken the market rate, which is about [272] and that is the hit which

we have taken on the FCTR amount on the balance sheet. So all contracted rates that we have is at the [tech]currency, which is at [10] and anything which is non-contracted is at the market rate, which is about [272].

Sudarshan Padmanabhan, Sundaram Mutual Fund - Analyst [37]

And second thing, going forward, as you pointed out that the US terrain is becoming more difficult in terms of competition. I mean we have in the past been very successful in monetizing our derma assets. But going forward, when we will see the new class of filings and what are -- in terms of thought process over the next two to three years, where do we see us building our capabilities into?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [38]

So I think -- I mean derm is a core segment for the Company, will continue to remain a core segment. We've completely exploited the filings in the oral contraceptive space. Injectables, we continue to file oncology injectables out of Argentina. These are the three segments that we've publicly talked about. In addition to this we continue to file products in other categories. We have some complex injectables also which have been filed. Currently we're still waiting to put out our new strategic direction for the firm, which we'll probably do at the next Analyst Meet. But for now, these are the three, four segments where we are filing into.

Sudarshan Padmanabhan, Sundaram Mutual Fund - Analyst [39]

Sir, on the NCEs, I mean we have seen some kind of progress in this quarter and this year. Can you give some light on what are the progress that we can see in FY17?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [40]

I think the key highlights out of the innovative portfolio is probably going to be some of the data points that will come out like the 830 Atopic Dermatitis trial, which is on in the US. GBR 1302 being lowest in patients in Germany, in cancer patients in Germany. GBR 900 progressing, continuing to progress in Phase I, Phase Ib clinical trials and 1342 getting into clinical development, which we think is a very exciting product. So I think these are the four. Besides that some of the small molecule work will continue on 27864 and 17536.

So this year is a year of gathering more data, in terms of clinical data on most of our development products. I mean that's the way we see this year panning out. It's only next year that you would see some serious progress by way of monetizing some of these assets.

Sudarshan Padmanabhan, Sundaram Mutual Fund - Analyst [41]

And in terms of R&D, I would assume that between generics and complex it would be similar, but if you're generating a lot of data wouldn't it mean a bit of shift towards your NCEs in FY17?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [42]

Not really, actually. So our innovative -- I mean our generic expenditures will continue to exceed what we're spending on the innovation side.

Sudarshan Padmanabhan, Sundaram Mutual Fund - Analyst [43]

Sir, can you also throw some light on the domestic market, especially in light of Sitagliptin and also with the light of Teneligliptin which is doing well for us. So how big is this product and how do we see the prospects of the domestic market, as well as specifically to these products?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [44]

So, Teneli, I think domestically continue to do pretty well as an organization. I mean, last year was a huge year for us. So Teneli, we are recording close to INR9 crores of sales as of last month -- per month. So it's over INR100 crores annualized sales already, the whole franchise in the first year of launch, which is pretty remarkable. And I think we will continue to see growth being very strong on the whole Teneligliptin franchise. This year, of course, on account of some of the NLEM impacts and some of the FDC impacts that's taking place in the market, and especially if you see in April and May we think Q1 will clearly be a muted quarter for most companies, because of all these impacts coming through. On a full year basis, I see India growing at about 10% to 15% this year, mainly because of all these different hits that are there from the external environment, by way of NLEM, by way of FDCs, all that. So I think for India, I feel this year could be quite a muted year, because of some of these impacts. But over a long-term, India continues to look very strong for us, because we continue to launch into some new franchises, which will help us get that propulsion as an organization.

Operator [45]

(Operator Instructions) Abhishek Sharma, India Infoline.

Abhishek Sharma, IIFL - Analyst [46]

Glenn, you would have followed these recent events around this Semler CRO. I just wanted to understand, do you have any exposure to that CRO? Where do you typically get your bio-studies done, is it in-house or elsewhere? And if you do have any exposure to Semler, how would that pan out?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [47]

We have absolutely no exposure to Semler as an organization. So we don't do anything with them. The bulk of our bio studies are done in-house. We've worked with a couple of external vendors every once in a while, but the bulk of the work is done internally.

Abhishek Sharma, IIFL - Analyst [48]

And in terms of this being outsourced versus in-house, and this is just a hypothetical question, do you believe there is some sort of a conflict of interest or there are adequate Chinese walls to protect the impartiality of the study?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [49]

I'm sorry, I didn't get your question.

Abhishek Sharma, IIFL - Analyst [50]

So, I mean you're doing the bio study in-house, right, would that not lead to some conflict of interest?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [51]

Why? I mean everybody does bio-studies internally. I think it's -- obviously you get audited by all the regulatory agencies and you maintain the highest standards like everything that we do, whether it's manufacturing, whether it's bio-studies, whether it's clinical trials, clinical development, all of that is done in-house, but we maintain the highest standards, in terms of frequent audits, making sure we are compliant and this is part of the core business.

Abhishek Sharma, IIFL - Analyst [52]

And just one more question on Celon partnership, what kind of investments do you envisage and what are the timelines for bringing the first product to the market?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [53]

So we are not guiding to any timeline. Obviously the fact that we've filed in seven countries, it could be a huge opportunity for us and we're pretty excited with this product, because we filed already in seven countries, including Germany, we have another eight filings going out in the next -- hopefully, during the course of this year. And we could technically be among the first wave of launches on a generic Seretide, with a multi dose device, which is huge for Europe. Seretide is probably about $700 million, $800 million in sales across Europe. So could be a substantial launch for the Company.

Abhishek Sharma, IIFL - Analyst [54]

And you are going ahead with the original Celon device, or have you tweaked that around too?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [55]

We cannot comment on the device, except that it's a multi dose device. And Celon already has approvals, as you're probably aware, Poland and one more country.

Operator [56]

Manoj Garg, BofA Merrill Lynch.

Manoj Garg, Bank of America Merrill Lynch - Analyst [57]

Glenn, just taking forward the previous participant's question on Seretide, do we also need to do some incremental clinical trials on and around this product or you feel that the current product is fileable in all the European markets?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [58]

So currently we are ready to file in all the markets with the data that we already have. I cannot comment on what data we have and what is required. The data we already have, the product can be filed in all the 15 markets.

Manoj Garg, Bank of America Merrill Lynch - Analyst [59]

And out of INR285 crores intangible, which we have capitalized this year, are you sharing what amount you've paid to Celon initially as a milestone?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [60]

No we are not commenting on that.

Manoj Garg, Bank of America Merrill Lynch - Analyst [61]

Second one, your comments about the US pricing scenario, Glenn, like we clearly understand that obviously there is a deflationary trend at this point of time, but just want to pick your mind from a long-term perspective that as we see the acceleration in the approval from the FDA and obviously with the kind of pressure through the channel consolidation and the possible merger of Express Scripts Walgreens, how do you see the dynamics changing in the US market over the next few years and how you're preparing yourself for that?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [62]

Clearly you are seeing a lot -- with the channel consolidation the pricing pressure is going to be high. I think, we as an organization have looked at differentiating ourselves in terms of product portfolio and what we're doing, to be able to counter that, because if you don't have uniqueness in terms of product and the prices are just getting thrashed and with every new player coming on it's just getting much more competitive. So I think that's a trend which everybody is witnessing, but as an organization, we continue to differentiate ourselves in terms of the product portfolio, the quality of filings and what we're doing on the generic side, which is driving the US growth and we still continue to remain optimistic about its growth. Of course, FY17 and FY18 will be heavily driven by Zetia and Ezetimibe and our success with Ezetimibe. So I think that's going to be a critical element for us.

Manoj Garg, Bank of America Merrill Lynch - Analyst [63]

And across the portfolio are you seeing some higher pressure on your derm per se in terms of pricing pressure, or it's like more or less uniform across the products?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [64]

Obviously, oral solids you're seeing the maximum pressure on all the OSD products. Derm --

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Bob Matsuk, Glenmark Pharmaceuticals Ltd. - President, API & North America [65]

Yes, this is Bob. I think derm are more differentiated, the oral solid doses, though, is certainly high pressure.

Manoj Garg, Bank of America Merrill Lynch - Analyst [66]

So there is high pressure on the pricing out there?

Bob Matsuk, Glenmark Pharmaceuticals Ltd. - President, API & North America [67]

Yes, I say, oh Bob, but I think we're a bit more differentiated on the derm side.

Manoj Garg, Bank of America Merrill Lynch - Analyst [68]

And the last question, just would like to understand from a cash flow perspective, Glenn, at what kind of an annualized sales we will start seeing the core business will be generating free cash flow? Obviously Zetia is one-time kind of an opportunity, but when you look at from a core perspective, because we remember that in earlier interaction we used to say that when we touch around INR1,700 crores to INR2,000 crores kind of topline, probably we will start seeing the cash flow generation. I understand the currency challenge in emerging market and so and so forth, but at what level you feel that our core business would start throwing the free cash flow?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [69]

Our perspective is even at the current level we are generating free cash and going forward, you will continue to generate free cash out of the core business. Obviously, the challenge is how much money you put in R&D, and how much money you put in CapEx towards

continuing to drive this 15%, 20% growth for the organization. So those are the trade-offs which we are constantly debating on. Do we actually go after higher growth rates and continue to reinvest in the business and take some of that cash and invest in the short term to get long-term gains, or do you compromise on the long term to show higher free cash generation in the short term and those are the decisions that we continue to debate with everyday. But even at the current level the businesses is generating free cash and I think next year, on the current year, FY17, you will see free cash generation, even out of the core. It may not be substantial, because we think if Zetia plays out -- I mean if Ezetimibe plays out and we are able to get that cash, then automatically it continues to make sense to invest in the future of this business.

Operator [70]

(Operator Instructions) Deep Master, ENAM Holdings.

Deep Master, ENAM Holdings - Analyst [71]

My first question was on Venezuela, just in terms of your INR320 crores in FY16. Could you give some sort of guidance for FY17? Would it be the same level or slightly lower, given that you're only selling inventory now?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [72]

Obviously, Venezuela will come off very significantly. FY17 will be hardly anything, $10 million or $15 million, I would guess at the most of whatever remaining inventories are there.

Deep Master, ENAM Holdings - Analyst [73]

And the export incentives, was that booked in other income or in the NCE income?

Unidentified Company Representative [74]

It is shown separately, if you'll see this in the Q4 numbers, in the MD&A.

Deep Master, ENAM Holdings - Analyst [75]

Okay, because it's not the NCE, right?

Unidentified Company Representative [76]

No.

Deep Master, ENAM Holdings - Analyst [77]

So, what was the nature of the NCE out-licensing income?

Unidentified Company Representative [78]

It's NCE only.

Deep Master, ENAM Holdings - Analyst [79]

It's just your normal NCE?

Unidentified Company Representative [80]

Yes.

Deep Master, ENAM Holdings - Analyst [81]

And could you comment on the Russia market? So how is that sort of shaping up now, and what's your outlook?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [82]

So, Russia I think continues to do well for us. In the local currency terms we anticipate this year we will easily grow at, I would say, 15%, 20%, or in excess of 20% in terms of topline sales, because of some of the recent approvals that we've got, particularly in the respiratory

side, which will be major drivers of the Russian business this year. So, in local currency we will grow in excess of 20-odd-percent. The question is obviously what happens to the currency, which nobody knows.

Deep Master, ENAM Holdings - Analyst [83]

And is your deal with Celon, does that also include Russia?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [84]

No, it does not.

Deep Master, ENAM Holdings - Analyst [85]

And also pertaining to Celon, is the device substitutable?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [86]

See, we can't get into any further details on the Celon product, for obvious reasons -- competitive reasons.

Deep Master, ENAM Holdings - Analyst [87]

And just on the marketing, could you comment with the sort of -- are you tying up with Celon for the marketing as well?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [88]

Currently, in most of the markets, we will be selling it on our own.

Deep Master, ENAM Holdings - Analyst [89]

And just lastly on the R&D, so the absolute amount in Q4, about INR250 crores, is it safe to sort of annualize that for next year or do you see that going up further?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [90]

You need to take 11% of sales, actually.

Deep Master, ENAM Holdings - Analyst [91]

Including Zetia?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [92]

Currently, excluding Zetia, just to keep the cap of 11% of sales and give us the luxury of including Zetia.

Deep Master, ENAM Holdings - Analyst [93]

And then, over and above that you would still be capitalizing a certain part?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [94]

We don't capitalize any R&D spends.

Deep Master, ENAM Holdings - Analyst [95]

I mean the intangibles.

Unidentified Company Representative [96]

No, so this is -- what Glenn is giving you is the total R&D spend which will come to 11% of sales on the P&L and this all will go through the P&L .

Deep Master, ENAM Holdings - Analyst [97]

And this will be 11% ex Zetia, as a cap?

Unidentified Company Representative [98]

As of now we're saying ex Zetia. In case we are doing some new R&D investments, we will inform you all accordingly, but that also if we're doing it, will again go through the P&L.

Operator [99]

Kartik Mehta, Deutsche Bank.

Kartik Mehta, Deutsche Bank - Analyst [100]

Just trying to understand from you, Glenn, would any M&A interest you, and if yes, which geographies or actually will it be anything like to acquire some entity which has some understanding of some technology, just to understand your thought process on M&A?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [101]

So we have no M&A plans until we complete the launch of Ezetimibe and make sure we kept the cash out of Ezetimibe.

Kartik Mehta, Deutsche Bank - Analyst [102]

And on the tax rate, can you help us what is the number we should take for next year, assuming there are high value launches in the US, and also for FY18?

Unidentified Company Representative [103]

We are expecting in the range of 22% to 25% next year.

Operator [104]

(Operator Instructions) Nitin Agrawal, IDFC Securities.

Nitin Agrawal, IDFC Securities - Analyst [105]

Glenn, I just wanted to just check myself. On Venezuela, we mentioned that we have $45 million in cash right now still in the books?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [106]

Yes.

Nitin Agrawal, IDFC Securities - Analyst [107]

So sir, how do we see this thing going forward now? So what are the events to monitor in terms of -- to see any potential -- in terms of any potential write-offs and all, which can potentially accrue on this cash?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [108]

I mean we're waiting for the government. I mean, there is a big government intervention. You must have been seeing in the newspapers to try and set off some of these exposures against the oil payables that India has to Venezuela. So hopefully if that comes through we should get our money in the coming year.

Nitin Agrawal, IDFC Securities - Analyst [109]

That essentially are the events we are really waiting for before we take a view on this cash in terms of -- it is all marked-to-market at VEF10 to a dollar right now?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [110]

Yes.

Nitin Agrawal, IDFC Securities - Analyst [111]

And Glenn, for the year, apart from [monetrable] perspective, so we have obviously the Zetia launch is coming in the second half of the year. And likewise Seretide launches in Europe. I mean, what are the other sort of key events from a business perspective over the next two years that we should be really watching out for?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [112]

Look, we have a number of product launches, hopefully, that -- I mean product approvals that should come over the next one or two quarters, which should be very exciting for the business. So I think from a business growth perspective we feel pretty good about where we are today and how the business is shaping up. Obviously, you should see some strong growth numbers coming out of the core business in the current year, and even in FY18, overall the business should look good. Also, the other thing is, assuming all goes well with Ezetimibe launch, you will see probably margins a new normal for the margin profile of the Company, which will initially come out of Ezetimibe, but subsequently, hopefully we can sustain that, even in a post Ezetimibe scenario. That's what we're trying to target as an organization.

Nitin Agrawal, IDFC Securities - Analyst [113]

And secondly, on CapEx, what kind of numbers we should look at for the next couple of years?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [114]

CapEx, about INR100 million is what we anticipate per year for the next couple of years.

Nitin Agrawal, IDFC Securities - Analyst [115]

Because this year we were a little on the higher side, maybe more towards INR900 crores.

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [116]

Yes.

Nitin Agrawal, IDFC Securities - Analyst [117]

But, going forward like INR700 crores thereabouts that should be possible?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [118]

Correct, yes.

Nitin Agrawal, IDFC Securities - Analyst [119]

And Glenn, how has been this MDI -- we did launch the MDI -- Seretide MDI in few of these emerging markets over the last year or so. How has been now the traction on that?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [120]

Overall, it's done well in some of the markets. In some of the markets it's been challenging, because the tender cycles are annual tender cycles. We'll see what happens in this year on some of those annual tenders. But in some of the markets it has done pretty well. I mean overall our respiratory franchise continues to do exceedingly well for us.

Nitin Agrawal, IDFC Securities - Analyst [121]

And then lastly, I think this year we've probably seen -- adjusted for the ForEx losses and other sort of one-offs, some sort of moderation really coming through on our staff expense, on some of the overhead costs like staff cost, as well as the SG&A. Are there any particular initiatives that we will be working on through the year and how do we see some of these costs playing through going forward?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [122]

Look, ForEx losses, it's extremely -- it's possible to predict what's going to happen in the global environment. As far as staff costs goes, I think going forward, obviously staff costs also -- there is a currency impact to staff cost, because we employ so many people around the world, which has a direct bearing on the overall staff cost. But assuming on a constant currency basis staff cost will -- we'll see some operating leverage starting to kick in, where you'll see staff cost as a percent to sales over the next two, three years coming down as we go forward.

Operator [123]

(Operator Instructions) Prakash Agarwal, Axis Capital.

Prakash Agarwal, Axis Capital - Analyst [124]

Sir, just trying to understand US business better, you did mention that base business ex of Zetia you would expect about 15% plus growth. What kind of number of approvals are you factoring, given that the GDUFA has really accelerated the approval process and what kind of filing that we are looking of, since we've already mentioned about 1Q filing?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [125]

So I think from an approval perspective, we still remain conservative and take 10, 12 approvals this year and from a filing perspective we will hit over 20 filings in the coming year.

Prakash Agarwal, Axis Capital - Analyst [126]

And any color that you could give us, I mean derm, oncology, injectables you did mention, but anything else that we're doing?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [127]

At this point, Prakash, we're not talking about any of our other filings.

Operator [128]

(Operator Instructions) Dheeresh Pathak, Goldman Sachs.

Dheeresh Pathak, Goldman Sachs - Analyst [129]

I might have missed the number for the full year, what was the mark-to-market loss on foreign currency [your net monthly] assets?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [130]

That was around INR135 crores, which was impacted on the P&L. The FCTR which hit the balance sheet was around INR301 crores.

Dheeresh Pathak, Goldman Sachs - Analyst [131]

Of INR135 crores, how much was Venezuela and of INR301 crores, how much was Venezuela?

Glenn Saldanha, Glenmark Pharmaceuticals Ltd. - Chairman & MD [132]

INR80 crores was Venezuela of INR135 crores and INR115 crores of INR301 crores was Venezuela.

Operator [133]

(Operator Instructions) Deep Master, ENAM Holdings.

Deep Master, ENAM Holdings - Analyst [134]

Just want to clarify the export incentive portion in your MD&A, is the entire other income the export incentive?

Unidentified Company Representative [135]

Yes, almost.

Operator [136]

Thank you. Ladies and gentlemen, this was the last question. I now hand the conference back to Mr. Jason D'Souza for closing comments. Over to you, sir.

Jason D'souza, Glenmark Pharmaceuticals Ltd. - VP & Head, Corporate Strategy & IR [137]

Thank you. Thanks, Inba. Just before closing the call, we'll read the disclaimer. The document, which has been prepared in the call that has been organized by Glenmark Pharmaceuticals Limited. The information statement and analysis made during this call describing the company's objectives, projection and estimates are forward- looking statements and progressive within the meanings of applicable security laws and regulations. The analysis contained herein is based on numerous assumptions. Actual results may vary from those expressed or implied depending upon economic conditions, government policies and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this presentation. This presentation should not be regarded by recipients as a substitute for the exercise of their own

judgment. With this we end Glenmark's Q4 earnings call. Thank you, everyone.

Operator [138]

Thank you. Ladies and gentlemen, on behalf of Glenmark Pharmaceuticals Limited that concludes this conference. Thank you for joining us, and you may now disconnect your lines.