Full Year 2018 Glenmark Pharmaceuticals Ltd Earnings Call

Mumbai May 30, 2018 (Thomson StreetEvents) - Edited Transcript of Glenmark Pharmaceuticals Ltd earnings conference call or presentation Wednesday, May 30, 2018 at 3:00:00am GMT

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Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications

* Robert Matsuk

Glenmark Pharmaceuticals Limited - President of North America and Global API Business

* V. S. Mani

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Operator [1]

Ladies and gentlemen, good day, and welcome to the Q4 FY '18 Earnings Conference Call of Glenmark Pharmaceuticals Limited. (Operator Instructions) Please note that this conference is being recorded.

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

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [2]

Thanks, Irma. Welcome to Glenmark's Q4 earnings call. Before we start the call, I would like to introduce the management at the call. We have with us Glenn Saldanha, Chairman and Managing Director; Robert Matsuk, President, North America and API business; Mr. V. S. Mani, Executive Director and Chief Financial Officer.

Before we start the call, we would like to give a brief on the various businesses of the company. So I would like to hand it over to Bob for a brief on the U.S. business.

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America and Global API Business [3]

Thank you, Jason, and thanks, everyone, for joining us today. Before I give the quarterly update for the U.S. business, I'd like to mention on May 21, Glenmark submitted the company's first ever New Drug Application to the FDA for Ryaltris, our investigational fixed-dose combination nasal spray of an antihistamine and a steroid as a treatment for seasonal allergic rhinitis in patients in 12 years of age and older.

Ryaltris, formerly known as GSP 301 nasal spray has been conditionally accepted by the FDA as the brand name. We expect the FDA will determine whether the NDA is complete for filing within 60 days. If the NDA is accepted, the Prescription Drug User Fee Act, PDUFA, target action date will be assigned to that time.

The North American finished dosage form business, which includes Canada and the U.S, closed the fourth quarter with record -- recorded revenues of USD 108.87 million or INR 6,995 million. The revenue for the entire fiscal year was INR 32,075 million or USD 498 million. We believe that for the U.S. business, the first quarter sales of the financial year will remain at the same levels as Q4 FY 2018 or improve further.

On the approval side of the fourth quarter of FY 2017/'18, the U.S. was granted one approval, Clobetasol Propionate Spray, 0.05%. In addition, since the first quarter of FY 2018/'19, the U.S. was granted 4 additional approvals: Tacrolimus Ointment 0.1%, on April 16; Clobetasol Propionate topical solution USP, 0.05%, April 18; Clobetasol Propionate cream, 0.05%, May 10, 2018; and Colesevelam Hydrochloride Tablets 625 milligram, May 18, 2018.

For generic Welchol, or Colesevelam, we are at currently 10% to 15% market share, and we expect to reach market share of 25% to 30%. For Tacrolimus Ointment, we are currently at 15% to 20% market share and expect to reach up to 25% to 30% in market share.

The U.S. business expect to launch an additional 10 to 12 products in the financial year, including 5 to 6 differentiated/limited competition generics. Glenmark continues to gain market share in both new and existing products, building new businesses for both new and current products.

In total, we have 21 ANDA approvals year-to-date, with 18 final approvals and 3 tentative approvals. The company also filed 7 ANDA applications with the U.S. FDA this quarter and plans to file an additional 3 applications in the forthcoming quarter. The company has filed a total of 16 ANDA applications with the U.S. in this financial year.

Glenmark's marketing portfolio consists of 134 generic products authorized for distribution in the U.S. market. The company currently has 63 applications pending in various stages of the approval process with the U.S. FDA, of which, 26 are Paragraph IV applications.

The global API business had a good quarter. Revenue for the sale of API in regulated and semi-regulated markets globally was INR 2,048.62 million for the fourth quarter ending March 31, 2018 as against INR 1,997.24 million for the previous quarter, recording an increase of 2.57%.

From a market perspective, we want to make note of several things. First, price erosion continue to be a challenge for the business. Price erosion for the quarter edged up to 12% from the previous 10% to 12% guidance. As most of us are aware, this was primarily due to ongoing consolidation of purchasers and as an industry.

Despite ongoing price erosion in the business as well as those of many of our generic manufacturers, we continue to see more initiatives to regulate the pricing and/or implement pricing transparency. This will continue to be a challenging environment, and we should expect it to remain that way for at least next 4 quarters until we launch Ryaltris.

With the diversification of our business segments, including complex generics, specialty branded products and innovative products, we are optimistic regarding our strategy to create growth and value for the company.

And with that, I will turn the call back over to Jason to talk about the progress we are making on our innovation pipeline.

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [4]

Thanks, Bob. Just for the innovation pipeline, a brief on the other businesses. Both the India business, the India business -- sale from India business for the fourth quarter was at INR 608 million, recording a growth of 5.5%.

As per IQVIA MAT March 2018, Glenmark Pharmaceuticals is ranked 13th in market share. Glenmark is the second fastest-growing company as per MAT 2018. The India business strengthened itself across the segments, which is the Cardiac segment, where the market share increased from 3.97% to 4.26%; the Respiratory segment, the market share rose from 4.52% to 4.75%; and in the Dermatology segment where the market share increased from 9.17% to 9.20%.

During the quarter, Glenmark launched the biosimilar of Adalimumab, brand name ADALY under the licensing agreement with Cadila Healthcare. The company also launched Nourkrin Woman tablets through an exclusive licensing agreement with Denmark-headquartered firm Pharma Medico.

Besides this, Glenmark continues to remain a leader in dermatology, and we have been at the forefront of introducing new products. Recently, the company introduced Aprezo, which is Apremilast for psoriasis.

The launch of ADALY and Nourkrin Woman further re-emphasizes the company's focus towards developing treatments for unmet medical needs in the area of dermatology.

Glenmark Consumer Care business. Glenmark forayed into the OTC business space over a few years ago. In a short time, the company has built a sizable OTC business driven by 3 major brands operating in the consumer space now; Candid, VWash Plus and Scalpe Plus. Candid Dusting Powder, the 30-year-old flagship brand for the company has been a prescription leader for the treatment of antifungal infection and is now a leading product even in the OTC business.

Through the introduction of its brand, VWash Plus, Glenmark has successfully created the female intimate hygiene category in India. The company further expanded its product offering through the introductions of VWash Wow San Naps. VWash's extension in to the INR 3,500 crore sanitary napkin category further propels the brand towards the vision of Owning the Intimate Hygiene Space. VWash Wow has been well received across the sales channel within 3 months of launch.

Over a short period of time, Glenmark Consumer Care business has grown its top line in excess of INR 150 crores. As per MAT March 2018, Glenmark's leading brand, Candid, recorded 18.1% value growth with market share of about 56%.

Scalpe is also ranked #1 in its operating market with a market share of 15% as per MAT March 2018. VWash (sic) [VWash Plus] brand recorded value growth of 24% with market share of 42% across all sales channels.

Commenting on the recent inspections, the Pithampur plant at Indore was inspected by the U.S. FDA from May 14, 2018 to May 24, 2018. The plant received 5 observations, which was communicated via the Form 483. The company will respond to the observations within the stipulated time frame. Further, the company received the approval for Colesevelam Hydrochloride Tablets, the generic version of Welchol tablets, which is manufactured at the same plant on May 2018. Glenmark was also granted the final approval of Tacrolimus Ointment, 0.1%, which is also manufactured at the same plant.

On the North Carolina facility, Glenmark's manufacturing facility in the U.S. was commissioned in 2014 by Monroe, North Carolina. The Monroe plant in the U.S. also underwent an inspection by the U.S. FDA from May 14, 2018 to May 18, 2018. The plant received the Form 483 with 2 observations. The company will respond to the observations within the stipulated time frame. This was the first inspection by the U.S. FDA at the Monroe plant. The company expects to begin commercial supplies of oral products from H2 FY '19. The company, Glenmark, also plans to file injectables and nebulizers from the Monroe facility during FY '19.

Moving on to the other region, the Africa, Asia and CIS region. For the fourth quarter, revenue of Africa, Asia and CIS region was INR 2,985 million, recording an increase of 3.32%. As per March 2018, Glenmark Russia showed a de-growth of minus 5.7% in value

versus overall market growth of 3.3% and ranks 41 in the retail segment of the Russian pharmaceutical market. The lower than market growth being attributed to the decline in demand for 2 key products, Ascoril and Oflomil nail lacquer, followed with the launch of new amorolfine generics. Glenmark continues to be a strong player in dermatology segment in Russia and continues to rank 9 among the top 10 players in the derma space.

The Asia region, the secondary sales growth was led by key subsidiaries, such as Malaysia and Philippines. The Glenmark Africa region also posted strong secondary sales growth in the fourth quarter aided by a good performance across most of the subsidiaries.

Europe operations. Glenmark Europe operations revenue for the fourth quarter was INR 3,189 million, recording an increase of 38.81%. The Europe subsidiary performed well during the quarter. The Western European business continued to expand through increased penetration in the U.K., Netherlands, Spain and further expansion of the sales and product portfolio in Germany.

The overall regional growth was led by multiple new product launches across key markets. Maloff Protect, which was launched in the U.S -- in the U.K. through a pharmacy license continues to perform well even in the fourth quarter of the year.

During the third quarter of FY '18, Glenmark successfully closed the decentralized registration procedure for generic Seretide Accuhaler in the Nordic region, including Sweden, Denmark, Norway, Finland and Iceland. This will be Glenmark's first inhaled Respiratory product approval in Europe and reinforces Glenmark's commitment in the respiratory area. Subsequently, Glenmark is the first generic company to receive regulatory approval for the substitution in Denmark for its generic Seretide Accuhaler and has subsequently launched this product.

Latin America. The Latin America region continues to remain challenging. Revenue was INR 1,276 million, recording a decrease of 4.75%.

The API business. The revenue of sale from the API business recorded an increase of 2.57% to INR 2,048.62 million. Glenmark forayed in to the API business in 2003 and over the last 15 years has built a large business based on strong product selection, focused on key regulated markets, maintaining high operational efficiency and a strong compliance culture.

The company has robust R&D capabilities in the API for developing an attractive pipeline and achieving cost efficiencies to overcome external market challenges. During the quarter, Glenmark also successfully concluded the U.S. FDA audit of the API plant at Mohol and is awaiting the EIR from the agency.

Moving on to the R&D side. In our innovative research and development pipelines, I'd like to highlight a number of highlights during the quarter. As you may be aware, the company has 7 pipeline assets, including 2 NCEs and 4 NBEs and a biosimilar candidate in various stages of development focused on 3 therapeutic areas, oncology, dermatology and respiratory. Of particular note, as Bob mentioned, Glenmark announced our first NDA filing submission for Ryaltris by the U.S. FDA on May 21, and is a major step in our company's transition into an innovation-led discovery and life sciences company.

On some of the other highlights of the oncology portfolio, our lead immuno-oncology candidate from our proprietary BEAT platform is GBR 1302, or HER2xCD3 bi-specific antibody and a potential treatment for HER2 positive cancer. GBR 1302 Phase I first-in-human study to determine MTD in patients with HER2 positive cancer is actively enrolling. Dose escalation continues in 9 participating clinical sites across Germany and the U.S. The study is currently dosing patients in Cohort 9 and will continue until MTD is reached.

We recently announced the study for GBR 1302 will be expanded to explore higher doses and to examine potential clinical benefit of the once weekly dosing regimen. Additionally, based on the predictive response rates observed in ex vivo translational studies, a Phase Ib/II study is being designed and will include an expansion cohort of HER2 positive metastatic breast cancer patients.

In addition, translational data in trastuzumab-resistant cancers will be presented at the 2018 Annual Meeting of the American Society of Clinical Oncology. Herceptin is the brand name for trastuzumab.

Our second investigational immuno-oncology candidate from our BEAT platform is GBR 1342, a bi-specific antibody targeting CD38 as well as CD3 T cells co-receptors. CD38 is an antigen target implicated in multiple myeloma and other malignancies of hematopoietic origin as well as a variety of solid tumors. A Phase I study in human -- a Phase I first-in-human study to determine MTD in patients with multiple myeloma dosed its first patient in December 2017.

The study is currently dosing patients in Cohort 5 with patients already being identified for enrollment into Cohort 6. Clinical sites continue to identify patients for possible enrollment into the study. Up to 10 cohorts are planned for this MTD portion of the study. The study's primary objective is to assess the safety and tolerability of increasing doses of GBR 1342. Additional study objectives include assessment of biomarkers and measures of antitumor activity.

Looking now at our innovative Dermatology pipeline, the company's leading biologic candidate is GBR 830, an anti-OX40R monoclonal antibody, which was discovered at Glenmark's Biologics Centre in Switzerland. The molecular target of 830 is to inhibit pathologically activated T cells and effector memory T cells, which are involved in a variety of autoimmune and chronic inflammatory disorders. The lead indication being evaluated for GBR 830 is moderate-to-severe atopic dermatitis.

Glenmark delivered through its presentation new data analysis of the GBR 830 Phase IIa trial completed last year at the IID Meeting in May. New data from the study demonstrated that treatment with GBR 830 resulted in observable modulation of biomarkers with both acute and chronic stages of atopic dermatitis. In addition to the oral presentation, Glenmark also presented 3 posters at the IID Meeting. We're currently evaluating GBR 830 for a study in patients with SLE.

For our Respiratory candidates under development, as we mentioned, the NDA filing submission for Ryaltris has happened. We expect FDA to determine whether the NDA is complete for filing within 60 days in and around July. Additionally, 2 manuscripts on the pharmacokinetics of Ryaltris were accepted for publication in the journal of Allergy and

Asthma Proceedings, and Glenmark presented Phase III on Ryaltris at the WAO Joint Congress in March 2018.

So those are our biosimilar candidates for XOLAIR, GBR 310 for the treatment of atopic and chronic idiopathic urticaria or hives finished the Phase I study's last subject, last visit on April 30, 2018. Top line results are expected in July 2018 and the company is planning to initiate a Phase III study in H1 CY 2019. GBR 310 has the potential to be among the first biosimilar candidate to be submitted to the FDA for approval for respiratory or allergic disease in the U.S.

With this, I would like to read the notes on the P&L and the balance sheet. Gross debt as of March 31, 2018, was at INR 4,639 crores as against INR 4,723 crores. Cash was at INR 1,235 crores as against INR 1,056 crores. The cash Includes a refund of GST to the extent of INR 90 crores, which was received in the last months of the financial year.

Net debt was at INR 3,404 crores as of March 31, 2018 as against INR 3,667 crores, a reduction of INR 263 crores as compared to the previous year. The company had guided to INR 250 crores to INR 300 crores debt reduction for the financial year.

ForEx gain for the quarter, which is included in other income was at INR 65 crores. Inventory was at INR 2,030 crores as compared to INR 2,139 crores. Receivables was at INR 2,332 crores as compared to INR 2,404 crores. Payables was at INR 170 crores for the year.

Net worth accretion for the year was at INR 665 crores. The (inaudible) for the year was INR 70 crores. The total net worth for the company stands at INR 5,135 crores as per Ind AS.

Cash tax for the year was INR 330 crores, thus cash tax for the year was 29% to PBT. Reported tax for the year was at 28% to PBT. In the last FY, cash tax was at 46.4% to PBT.

R&D for Q4 was at INR 320 crores translating to 14.04 percentage to net sales. For the year, total R&D was at INR 1,122 crores translating to 12.33% to net sales. R&D for the last year was at INR 1,262 crores. Of the INR 1,122 crores, INR 432 crores was spent on generics R&D, which constitutes 38% of total R&D spend and INR 690 crores was spent on innovations from speciality R&D, which constitutes 62% of the overall R&D spend.

The company in the financial year has generated free cash flow of approximately INR 240 crores after -- INR 250 crores after working capital and total asset addition. This free cash flow has gone towards the reduction of net debt.

Fixed asset addition was to the extent of INR 699 crores. Intangible asset addition was to the extent of INR 297 crores comprising of INR 265 crores of products in license -- towards licensing agreements and INR 32 crores of computer software.

Amortization for the year was to the extent of INR 152 crores, which is reported as part of depreciation, which was at INR 301 crores.

Guidance. For FY 2018/'19, top line guidance will be in the range of 10% to 15% at constant currency. We believe that the U.S. margin will continue to remain under pressure. The R&D expenditure for the organization will be at 12% to (inaudible).

The company will continue to focus on free cash flow generation, monetize it's R&D to out-licensing by (inaudible) it's innovative and speciality molecule and continue to rearrange the balance sheet to enable cash generation and cost reductions.

With this, I would like to open the floor for question and answers to the Glenmark management team. Over to you, Irma.

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Questions and Answers

Operator [1]

(Operator Instructions) We have the first question from the line of Neha Manpuria from JPMorgan.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [2]

My first question was on Ryaltris. Now that we've submitted and we await FDA's acceptance of our application, how do you look at commercialization of the product? And would this be through own sales force, conducted sales force, any color there?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America and Global API Business [3]

Sure. So we still haven't made a final decision whether we're going to offer this to a partner. But if we decided to do this ourselves, this will be a classic-branded product model in which we have a sales force that goes in details, physicians. And we also discuss the benefits of the products with managed care to make sure reimbursement occurs.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [4]

But this is not -- that we would do it ourselves or through a partner?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America and Global API Business [5]

Not yet.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [6]

Okay. Second question is on the U.S. business. Overall, you've got a couple of good approvals to start the year off with. How do you look at the U.S. trajectory? A lot of our peers have been indicating stabilization in the price erosion trajectory. So what's our view, and how we should look at U.S. business growth, particularly given the 10% to 12% constant currency revenue growth that you mentioned?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America and Global API Business [7]

Yes. We feel like the Q4 was pretty much the trough, we'll start seeing better top line sales numbers moving forward. That being said, we still see some headwinds with price erosion. But overall, we forecast growth positively for this coming fiscal year.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [8]

And this is assuming competition in Mupirocin?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America and Global API Business [9]

Yes.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [10]

Okay. Thank you so much And my last is, Jason, I think you mentioned that you would look at reducing debt through the sales generation and corporate action. Any color on what do you mean by corporate action?

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [11]

I think it will be difficult for us to give -- comment on that front. I mean, the objective is to clearly reduce debt. I think that is the focus for us and deleverage the balance sheet.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [12]

And any amount you would want to mention here?

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [13]

We don't have any specific amount at this time (inaudible).

Operator [14]

(Operator Instructions) Our next question is from the line of Prakash Agarwal from Axis Capital.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [15]

So first question is on the R&D spend, just trying to understand this better. Now with Ryaltris being filed in Q1, and you talked about GBR 830 progressing to Phase IIb, so would the share on the innovative R&D spend would substantially increase within your 12% R&D budget?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [16]

So Prakash, I think it will keep switching between the speciality portfolio and the innovative portfolio, okay? Because we also have XOLAIR Phase III coming up next year. So this year, I think the GBR 830 Phase IIb, we may end up spending most of the R&D spend on. Next year that will switch to the XOLAIR biosimilar Phase III, right? So I think if we can sustain a 12% overall R&D spend, I think we're in good shape.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [17]

Okay. And this does not includes any netting up with respect to any licensing income that we might receive this year given that these are out-licensing possibilities?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [18]

No. It does not.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [19]

Okay. And any color on how we've progressed in terms of discussion like, last time, we talked about that fiscal '18 at least one molecule we'll look to out-license. So any progress in any of the molecules because all are progressing well, we need to monetize one at least?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [20]

So I think very clearly, that's a big objective for us for this year, right, to out-license -- to do some out-licensing deals. Now as I mentioned last time, we are looking at possible regional out-licensing deals, partnering some of our products, maybe for markets like China, Japan as opposed to global deals, right? We're pursuing both. But in all likelihood, this year could be - you could see either regional deals or a global deal. And clearly, from a portfolio perspective, we've got multiple discussions on both the oncology assets, GBR 1302, 1342 and GBR 830. So I think licensing is clearly a key priority for us this year.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [21]

Okay. And secondly on your comment in the press release where you said that you expect pricing erosion to continue. By 2019, we expect much better versus last year given the launches that you're seeing in the beginning of the year. I think there is a comment made that you're expecting about 10 to 12 launches. Would that be enough to grow on that base given that one quarter you already had big impact of Zetia sitting at last year?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [22]

So, I mean, I think both Colesevelam and Tacrolimus itself, right, if you just compute the market share that Bob talked about, right, should give us a big upside on where we were last year. I think all in all, the U.S. business will grow, but we can't guide to any specifics, right? And from here on, we think Q4 was the trough end. From Q1 onwards, the sales will start inching up on account of some of the new approvals. But to answer your question, specifically, to -- I mean, all our calculations are without Zetia, okay. That's the bottom line, Prakash, okay, because we're keeping Zetia...

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [23]

Zetia from Q1. Okay.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [24]

Absolutely. We're keeping Zetia out of the equation, right.

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America and Global API Business [25]

And that's the last headwind we'll have is Q1. After that, we're done with the headwinds with Zetia.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [26]

Understood. And lastly, see that you've done one more deal with SCD Pharma. Last year, we had done for CONCERTA and SUBOXONE with another partner. This one is for ophthal. So I mean, what is the rational partnering it? I mean, is it faster to market? Is it better R&D, I mean, cost efficiencies there? What is the rational? I mean, because we'll have to actually share the profits as well, right?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [27]

So I think, strategically, the way we've approached licensing for the U.S, right, is we've gone out and looked for products where we don't have capabilities internally and which are high-technology products or in areas where we just don't have a presence, ophthalmics is a classic example. Last year, we did deals on NuvaRing, for instance, with a company called Evestra, that's moving forward nicely.

We also have a nano-paclitaxel deal with Particle Sciences. We have a deal with Evonik on one of the products. So I think there's a number of different licensing deals that we've done with companies who are truly experts in the area of technology, right? And we've done this before. We have the capabilities. And because we don't have the capabilities internally, we've gone and licensed it. I mean, some of our competitors have actually gone and bought these compounds, right? Bought similar products from some of the divestitures that happened and things like that. Our approach to it has been to license because thereby

we're getting more of the upside. And even though, it's taking longer, the upfront money is much smaller. So we're just augmenting our portfolio of products by licensing, whether it's ophthalmics, for instance, where we don't have any presence or it's some of these complex generics, right, where we think we don't have the capability to do that.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [28]

And profit share would be equal, or?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [29]

No. I mean, we get the bulk of the profit on these partnering deals. I mean, that's the way it's structured.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [30]

And we have to pay initial milestones to them or?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [31]

There is some small upfront payments, right, on each of these deals.

Operator [32]

(Operator Instructions) Our next question is from the line of Nitin Agarwal from IDFC Securities.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [33]

Glenn, on the U.S. plant, the new U.S. plant that you said you're going to commission sometime during the year, I mean, what are the thoughts in terms of how strategically important is that plant for our U.S. business? And what can we expect going forward from there?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [34]

So clearly, we've invested a substantial amount in that -- in the U.S. plant, right. And now we have 3 lines running. The oral solid line, we have the FDA and we're pretty positive about the inspection. And I think we should start commercial supplies in the second half of this year on oral solids. We also -- the purpose of that line is to also file C2s out of that facility, right, And that's something we're working on. The second line is a nebulizer line. And the nebulizer line, clearly, helps both our generic business as well as we're looking at eventually taking some specialty products there. And then, the third line is on the injectable side, right. Injectables, we're doing both vials and prefilled syringes there. We have products like -- various products in the injectable space, which we're currently doing at the CMO, which we may actually movie in-house on the injectable side. In addition, eventually, a lot of our biologics or biosimilars, a lot of that could be made internally. So I think, overall, that plant is of key strategic importance to the company from a long-term perspective, right, for assisting not just in the generic side of the business, but also in our -- in the work we're doing on the biologics and the biosimilars and products of those nature, right.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [35]

How much -- sorry. How much you've invested in the facility?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [36]

Nitin, we've invested about INR 590 crores so far.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [37]

Okay, sir. Okay. And sir, secondly, Glenn, on the European business, it's done pretty well for the year. I mean, now with this approval Seretide approvals finally getting -- I mean, those approvals -- those products getting launched in Nordic countries, so two things. One is, A, on Seretide how do you see it playing out across -- in terms of launches across various countries? And secondly, overall, on Europe, how do you see it over the next 2 to 3 years?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [38]

So I think the generic Seretide is a great opportunity for us, right? I mean, we've started with the 3 Nordic countries, and we started getting substitution, which is a huge positive. And that's reflective in the sales, right, and I think going forward, that will play a major role. Over the course of this year, I would even expect 1 or 2 of the major markets like Germany to come through, especially in the second half of this year. And that could be a big launch for us, right? So we are -- right now, we're very, very optimistic on this product. It's a very large opportunity, as you know, it's about $700 million in sales across our markets. And between this year and next year, we should be able to commercialize in all the markets that we have a presence in. So I think, overall, continues to remain a pretty big opportunity overall.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [39]

And on the Europe growth in general, apart from Seretide-driven component, what else do you see interesting in the geography going forward?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [40]

So I think from an in-licensing perspective, we continue to in-license a number of products. We have a number of Respiratory launches coming up in the Europe in the course of this year and next year. And that's another exciting opportunity. So I think Europe growth will continue to remain strong for the next few years.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [41]

And lastly, some of the key parts and products that you mentioned, can you update us on in terms of what could be probably potential filing sort of timelines of some of these bigger products like SUBOXONE, NuvaRing and CONCERTA?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [42]

I mean, our thinking is, starting this year, we will start filing some of these partnered products, right, some of the complex stuff. And between this year and next year, right, you should see a host of filings going out on -- particularly on the complex products.

Operator [43]

(Operator Instructions) We'll take our next question from the line of Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [44]

For this -- for fiscal '18, I think you mentioned about 18 ANDA approvals in the U.S. So how many of these have been commercialized or that you want to commercialize?

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [45]

Sorry, Sameer, we didn't get the question.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [46]

I think you mentioned for fiscal '18, you received 18 ANDA approvals, I think 3 were tentative plus. And of these 18, how many have you commercialized or want to commercialize?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [47]

I think most of the products, Sameer, that we get approval on, right, we commercialize.

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America and Global API Business [48]

Yes, I'd say about 15-or-so.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [49]

Okay. Okay. That's fine. And the next question is, how do you see the competitive outlook for Welchol as you go forward? I mean, right now, it's 2 generic, 1 outside generic, 1 innovative, if I'm not wrong. So how do you see this play out in the ensuing months?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [50]

I mean, Sameer, there are a lot of filers, right? We have no visibility to who is going to be approved next or what the time frame is. But right now, it's a pretty clear market, right.

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America and Global API Business [51]

Yes.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [52]

Okay. And any color you can share on the pricing as it stands now? Is it a typical 3 player pricing? Or is it better or worse?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [53]

I mean, I would consider it a typical 3 player market at this point.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [54]

Okay. Perfect. And one final one, Glenn, for my side, which is beyond XOLAIR, how are you -- a similar pipeline? How many candidates, what type and what's the timeframes?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [55]

So Sameer, we have some other work going on, but it's relatively early. So I don't think we're talking about what we're doing next. So for now, it's fair to say that from an investment perspective, the investments are all behind XOLAIR, behind -- now that Ryaltris is done, right, the investments are all going behind XOLAIR. GBR 830, we think can be pretty transformational for us, particularly having seen a positive Phase IIa. And we are moving that forward in atopic dermatitis, running possible trials in lupus nephritis, SLE and some other indications. We think it has broad immunology capabilities, right, as a molecule. And then, of course, the oncology assets, right, I mean, the 1302, 1342, right, I mean, these are the 4 which are ahead, right, from an investment perspective going forward.

Operator [56]

(Operator Instructions) Our next question is from the line of Aditya Khemka from DSP BlackRock Mutual Fund.

Aditya Khemka, [57]

Glenn, could you speak about the potential growth? So I'm sort of intrigued by your guidance on the total top line of 10% to 12%, or was it 10% to 15%?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [58]

Sorry, can you just repeat that?

Aditya Khemka, [59]

Yes. So your top line guidance for the year FY '19 is 10% to 15% or is it 10% to 12%?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [60]

10% to 15%.

Aditya Khemka, [61]

10% to 15%. So could you talk about how much growth are you expecting in the India business given that this has a GST quarter?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [62]

So Aditya, we're not breaking it out. But I mean, ex-U. S. right, clearly, the other geographies, including India, right, will grow between 10% to 15%, right? So that's the way we look at it. The U.S. business is the only wild card there. We don't know how the pricing environment will play out. And although we started the year very positively, right, with the 2 approvals on Colesevelam and Tacrolimus, right, which should give us a big bump up in the U.S. business, right? But it's always hard to predict what's going to happen in the U.S.

environment. But outside of U.S., if you take all our other markets, we feel pretty comfortable that the business will grow at 10% to 15%.

Aditya Khemka, [63]

Okay. That's fair enough. And secondly, on the U.S. pipeline, so any updates on Voltaren and any other key products that have been stuck forward of R&D issues?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [64]

So I think -- I mean, starting, we believe that there are a host of the 6 products that Bob talked about, which are differentiated. A lot of them -- some of them belong to the derm side of things. And you should see some pretty exciting approvals if it all plays out, right, over the course of this year.

Aditya Khemka, [65]

Right. But when you get CRLs then you generally get a sense of whether it's a preliminary inquiry or is it a more deep or last-stage inquiry. So all these 5, 6 approvals that you're expecting this year, would -- how many of them would be in your judgment, I won't say judgment call, but in your judgment, how many of these would be like on the stages of final inquiries? And how many of them would be on a preliminary stage?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [66]

So Aditya, we wouldn't put it out if we didn't think that these would get approved, right? So we feel pretty good about the possibility of some of these getting approved. However, it's extremely uncertain, okay, and in this environment, it's very hard to predict specifically, right, when these will get approved and at what stage they are.

Aditya Khemka, [67]

Fair enough. And Glenn, just another question on your R&D spend the way you treated. It's more of an accounting question. Some of our peers were also big on biosimilars tend to capitalize some of their R&D saying that, they'll amortize it as and when new products gets launched. Why aren't we on that page? I mean, why are we taking a more conservative approach of writing off the entire R&D in the year it is incurred?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [68]

Actually, Aditya, Mani here. This actually helps us. In a way, it's much better to clean up the balance sheet -- I mean, clean up the expense item and more It's much better that way.

Aditya Khemka, [69]

Okay. So -- but your accounting standards allow you to capitalize your...

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [70]

Yes. That will be at a much later date, but today -- as of today, we don't do that.

Aditya Khemka, [71]

Fair enough. Lastly -- last question for my side , Glenn. This entire Chinese situation on the chemical side and the API side where they are shutting down capacities and probably, there is some price situation in basic chemicals and API that we're sourcing from China. How much is Glenmark's exposure? So what percentage of your API/basic material import, key static material import comes from China?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [72]

I don't know the exact number, Aditya, but there is a substantial amount that virtually every company actually imports from China, right, in terms of intermediates and KSM. And there has been some escalation that we're seeing, right, in raw material prices.

Aditya Khemka, [73]

And with regards to our ability to pass on that to our end consumer; I mean, if it's captive, obviously, it's internal, but external sales, are you be able to pass it on to our customers?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [74]

Absolutely. I think we're able to pass on a lot of it to the end consumer.

Operator [75]

(Operator Instructions) Next question is from the line of Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan, Goldman Sachs Group Inc., Research Division - Equity Analyst [76]

Just team, if you can update us on the cost efficiency program that we've talked about in the past? And a related question is on the margin outlook. I think you've seen margins actually come off in the second half of this year. How should we be looking at margins? I remember, a few years back, we had a aspirational goal of going back to 20% to 22%. So if you can give us a quick update on how should we'll be looking at margins? Those are my 2 questions.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [77]

So I think cost efficiency, as you can see, we've done quite a lot of work on that, right. Last year, some of it was evident. I think this year, even more you will see further improvement in the cost structure, right? So there is a substantial amount of effort going on in improving our overall efficiency. We have a number of consulting firms working closely with us, whether it's on SG&A, whether it's on plant cost, whether it's on the GC procurement line items, supply chain. So we have a number of consulting firms who work closely with us on improving the cost efficiency. So that is really helping substantially. And some of it was visible last quarter -- last year, but I think the bulk will come in this year. And some of it even next year. So we have ongoing cost efficiency program currently on within the firm. As regards margins, we don't guide -- we're not guiding to any specific margins for this year, just given the volatile environment that exist in the U.S.

Shyam Srinivasan, Goldman Sachs Group Inc., Research Division - Equity Analyst [78]

So the only guidance we have is in the R&D line you're seeing, right, 12%?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [79]

Correct, and top line growth, right? I mean, we've given top line growth and R&D number.

Operator [80]

(Operator Instructions) We'll take the next question from the line of Anubhav Aggarwal from Crédit Suisse.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [81]

Just one clarity on the sales guidance of 10% to 15%. Are you already knocking out the Zetia sales in 1Q, or you are including them?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [82]

I mean, we're looking at the total number, Anubhav, right, and then we're guiding

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Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [83]

Okay. And what would the CapEx would be, down by almost $150 million this year or for FY '19, what you're thinking about the CapEx?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [84]

It should be in similar lines. It should be in similar lines.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [85]

About INR 1,000 crores intangibles, fixed assets, all put together?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [86]

All put together, yes.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [87]

And Glenn, one question on GBR 830. Now you're planning Phase IIb here. Like in Phase IIa, you've done a small efficacy test. So Phase IIb, what you're planning will be a full phase IIb trial, or you're planning to do a little more -- let's say, a smaller version of Phase IIb, but with a larger samples at what you've done in Phase IIa?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [88]

No. This is a full-blown Phase IIb dose range finding study with 3 doses and placebo and -- so it's a full-blown Phase IIb. I mean, the next step for us is to go and do a Phase III.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [89]

Okay. So how -- just a rough idea, how long will this Phase IIb trial take? Whether it's 6 months, 1 year, including recruitment of patients?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [90]

So it will be around 12 to 18 months spread over 2 years, this year and next year.

Operator [91]

(Operator Instructions) Next question is from the line of Mohnish Dave from Temasek.

Mohnish Dave, [92]

Just 2 questions. One is, if there's any update on Mupirocin that you can provide? And the second one was GSP 101, where are we on that in terms of getting the product sale?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [93]

So on Mupirocin, we continue to sell the product. We're expecting one more competitor, maybe towards the second half of this year is what we anticipate. As far as GSP 101, we continue with the development with the new FDA guidance that came out, I think it was last year. We had to relook at our entire development, but we're hoping to file 101 next year, next financial year.

Mohnish Dave, [94]

That will be FY '20?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [95]

'20, correct.

Operator [96]

(Operator Instructions) Our next question is from the line of Alok Dalal from CLSA.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [97]

Glenn, the press release says about business restructuring, that is API and Consumer Care. Can you help us understand the rationale behind these, please?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [98]

Yes. So I mean, we're subsidizing the API business and the Consumer Care. It's basically helping us with a better focus on the business, also better structure and accountability overall. And there are some financial efficiencies, which we hope to derive by subsidizing these 2 entities -- these 2 businesses.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [99]

Okay. And by when do you expect the board to kind of give the report on this?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [100]

It should be pretty quick.

Operator [101]

(Operator Instructions) The next question is from the line of Harith Ahamed from Spark Capital.

Harith Ahamed Mohammed, Spark Capital Advisors (India) Private Limited, Research Division - VP [102]

Can you give a breakup of the other income for the quarter, because that seems to be on the higher side? And is there a ForEx-related gain or loss in the other expenses?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [103]

Yes, Harith this is Mani here. So the other income is largely the ForEx gain this quarter is about INR 65 crores.

Harith Ahamed Mohammed, Spark Capital Advisors (India) Private Limited, Research Division - VP [104]

Okay. And is there a ForEx component in the other expenses?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [105]

No. There is no major component of ForEx in the other expenses. This is basically only the income.

Harith Ahamed Mohammed, Spark Capital Advisors (India) Private Limited, Research Division - VP [106]

Okay. And is there a tax guidance for FY '19?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [107]

Yes. It'll be about 27% to 28% on a full year basis. Quarter-to-quarter, there could be some variations. But on a full year basis, it's about 27%. Effective tax rate, okay.

Harith Ahamed Mohammed, Spark Capital Advisors (India) Private Limited, Research Division - VP [108]

Yes. Got it. And is there a bid on the filing timelines for some of the products that you've talked about in the past like NuvaRing and ABRAXANE and SUBOXONE?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [109]

So as I said, I think the bulk of it will happen between this year and next year, right, you should see a host of these getting filed.

Harith Ahamed Mohammed, Spark Capital Advisors (India) Private Limited, Research Division - VP [110]

And that includes even CONCERTA -- generic CONCERTA?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [111]

I can't give you the specifics. All I'm saying is from a complex product perspective. The most of the partnering that we've done, the products will get filed during the course of this year and next year.

Operator [112]

(Operator Instructions) Next question is from the line of Cyndrella Carvalho from Dolat Capital.

Cyndrella Carvalho, Dolat Capital Market Pvt. Ltd., Research Division - Senior Analyst [113]

Would you be able to help us with the domestic OTC outlook? And how we are perceiving this particular segment?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [114]

Sure. I think so on the OTC side, most of the products that we have are all Rx/OTC switches that we do, right? And I think from a business perspective, it continues to do well for us. And we're seeing some high growth in the OTC space, especially, I think this year, you should see the OTC business growing pretty aggressively on account of some of the new launches. So the strategy there is all Rx/OTC switches. So we don't get into completely new products on the OTC side. So far, we haven't done it.

Cyndrella Carvalho, Dolat Capital Market Pvt. Ltd., Research Division - Senior Analyst [115]

Any like ad spends that would increase with these activities that you...

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [116]

Nothing out of the ordinary. I mean, it's all built into our numbers. For the last 3 years, we've been spending on this business substantially. And now we're up to about INR 150-plus crores of sales. And we see this business continuing to grow pretty nicely And I think, over time, now the profitability of this business will keep escalating because of the scale that we're getting out of this business.

Operator [117]

(Operator Instructions) We have a next question from the line of Bharat Shettigar from Standard Chartered Bank.

Bharat Shettigar, Standard Chartered PLC, Research Division - Head of Asia Ex-China Corporate Credit Research [118]

A couple of questions. First is, you mentioned a couple of line items in the cash flow. Can you provide a few more, for instance, what is the net working capital change in FY '18? And what is the overall operating cash flow for the year?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [119]

Yes. So Mani here. So as far as the working capital is concerned, if you really look at it, our inventory has kind of gone down about INR 108 crores. The debtors have again gone down by about INR 72 crore. Our creditors have improved by about -- I mean, increased by about INR 126 crores. So overall -- on an overall basis, if you look at it, there's absolutely about INR 300 crores improvement in our working capital lines. And if you look for some color in terms of the overall cash flows, the EBITDA was about INR 1,615 crores. And we had a cash interest of about INR 190 crores, cash tax of INR 330 crores and we had about INR 990-plus crores of asset additions. So all put together in the end, we ended up with about a improvement in our debt position by about INR 260 crores.

Bharat Shettigar, Standard Chartered PLC, Research Division - Head of Asia Ex-China Corporate Credit Research [120]

Okay. That is helpful. Second question is, you mentioned plans to reduce debt. Now given that the dollar bonds, which you have issued, the $200 million issuance, that's trading below par, roughly at around $93 kind of levels. Is there any plan to consider a buyback of the bonds?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [121]

No. As of now, nothing like that, yes.

Operator [122]

(Operator Instructions) Our next question is from the line of Neha Manpuria from JPMorgan.

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [123]

My question has been answered.

Operator [124]

We'll take our next question from the line of Prakash Agarwal from Axis Capital.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [125]

Just a clarification, I missed that part. So the guidance is -- 10% to 15% guidance is ex-U. S.?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [126]

It's on total revenues, Prakash.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [127]

Total revenue. So when we say U.S. is probably going to be similar or a little better exit year, I'm trying to understand this 10% to 15% growth for the other businesses has to grow much higher, right? So it doesn't add up.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [128]

So Prakash, I don't think we can give any more color on the guidance. I mean, we've -- in terms of...

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [129]

Would that be the right way to think? I mean, you're expecting other business to grow 20% plus or?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [130]

That's correct. I mean, the other businesses will grow faster. Yes.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [131]

Okay. And the other number I missed was on the debt reduction for fiscal '19. What are we looking at? Like last year, you gave a number.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [132]

We're not giving. All we're saying is the business will generate free cash, okay, the core business, right, in FY '19, like it did last year, the core business will generate free cash. We're not giving any specific number for '19. And then, over and above whatever corporate actions are there, we'll bring out -- bring down the debt.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [133]

Okay. And would it be fair to say that India business, which you got little impacted due to GST, this year will be much better and would also thus improve gross margins?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [134]

So I think India business would continue to grow at about whatever, I mean, overall about 10% to 15%. And obviously, the margins are much better there. So -- but really speaking, it's difficult to really give a call on the entire business, okay.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [135]

Okay. And lastly, what was adjusted growth if we add back the GST impact for India business for the year and the quarter?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [136]

Yes. It will be about 11% for the full year.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [137]

And for the quarter, sir?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [138]

2% extra you should just add.

Operator [139]

(Operator Instructions) We'll take our next question from the line of Aditya Khemka from DSP BlackRock Mutual Fund.

Aditya Khemka, [140]

So just on the U.S. business, again, sorry to harp on that a little bit, but in terms of our projections, are we taking constant currency growth in U.S.?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [141]

Yes. It will be constant currency growth only.

Aditya Khemka, [142]

Okay. And Glenn, how much do we benefit from a strong dollar? So let's say, INR 1 strengthening of dollar, how much does that percolate to our gross profit or our EBITDA given that you have costs in the USD as well, right, you have some R&D spend, you have a facility there?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [143]

So on a very broad basis, Aditya, for every INR 1 improvement, we would gain about INR 30 crores to INR 40 crores, okay, because we have receivables as well as we have borrowings, but we have some overseas loans given. So on a broad basis for every INR 1, we could gain about INR 30 crores plus.

Aditya Khemka, [144]

Okay. Fair enough. And Glenn, on the innovator pipeline that we had -- that you had discussed, so just trying to understand as to eventually, would you like to have your own field force across these segments to market these products? Or would you look at partnering as a more lucrative strategy when it comes to these innovator products, be it 505(b)(2) (b) (inaudible) how would you look to market them?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [145]

So I think, look, partnering is our first preference as far as, especially, the innovation drugs go, right? On the specialty side, also, we're evaluating both options. In markets where we have a commercial presence, we may market it ourselves. But in markets where we don't, particularly the U.S. and some of them major markets, partnering will always be our first option.

Operator [146]

(Operator Instructions) Our next question is from the line of Surya Patra from PhillipCapital.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [147]

Just one thing on the margin front, so this -- basically, the quarterly margin has come down a bit because of the higher other expenses it seems. So anything that is -- any specific reason that is higher? And that particular other expense item is very volatile over the quarters. So some sense on that and about the margin guidance also if you can give some sense about it going ahead?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [148]

So for the other expenses, if you look at it on a year-to-year basis, actually, it is lower than about a good 10%, okay. So last quarter, it's a little bit higher because obviously -- compared to the previous year, it is much lower. Compared to the last year -- last quarter, it's a little bit higher. Obviously, our R&D expenses were a little higher in the last quarter about INR 40 crores or so. That's the reason.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [149]

Okay. Even adjusted for that also, this -- the other expense number is much higher it seems.

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [150]

No. If you look at last quarter to this quarter, it's about INR 65 crores. So if I knockoff INR 40 crores, it's just INR 20 crores to INR 25 crores. These are normal expensive that keep

moving. But if you look at the previous year, it was well in excess of INR 800 crores for the same quarter.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [151]

Okay. And one more question on the kind of observations what we have witnessed for 3 of our plant recently, the Pithampur plant, API plant as well as the Monroe plant, U.S. So whether that will hurt our approval timeline or expectations what we're building in our guidance, sir?

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [152]

So we have already mentioned that regarding the Pithampur plant, we already received an inspection on Welchol. And second is, for the Monroe plant, this is the first inspection

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Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [153]

Yes. But during the inspection only that approval has come, Jason, I think?

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [154]

Correct, which is -- which I think it will -- you can try to read into that part.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [155]

Okay. So that means we are not really bothered about -- say why, because since there is a little clarity about the...

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [156]

I think that is all we can comment on the inspections Surya. I think everything is mentioned in the MD&A. You can see the approval and when having received it from the same (inaudible) all we can say.

Surya Narayan Patra, PhillipCapital (India) Pvt. Ltd., Research Division - VP & Pharma Analyst [157]

Okay. So that means it is from our understanding about the observations and the CAPA of we would have submitted that gives us the confidence that we are on track?

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [158]

As I said, Surya Patra, that's all we can comment, that the approval has commenced (inaudible) that's all we can say.

Operator [159]

Ladies and gentlemen, that was the last question. I now hand the floor back to Mr. Jason D'souza for closing comments. Over to you, sir.

Jason D'souza, Glenmark Pharmaceuticals Limited - VP of IR, Strategy and Communications [160]

Thanks, Irma. Just before we close the call, we'd like to mention disclosure. The call has been organized by Glenmark Pharmaceuticals Limited. The information statement and analysis made during this call describing the company's objectives, projections and estimates are forward-looking statements and progressive within the meaning of applicable security laws and regulations. The analysis contained herein is based on numerous assumption.

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 [161]

Thank you, members of the management. 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