

Q3 2019 Glenmark Pharmaceuticals Ltd Earnings Call

Mumbai Feb 19, 2019 (Thomson StreetEvents) -- Edited Transcript of Glenmark Pharmaceuticals Ltd earnings conference call or presentation Friday, February 15, 2019 at 3:00:00am GMT

Corporate Participants

* Glenn Mario Saldanha

Glenmark Pharmaceuticals Limited - Chairman, MD & CEO

* Jason D'souza

Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy

* Robert Matsuk

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

* V. S. Mani

Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director

Operator [1]

Ladies and gentlemen, good day, and welcome to the Q3 FY '18/'19 Earnings Conference of Glenmark Pharmaceuticals Limited. (Operator Instructions) Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Jason D'souza. Thank you, and over to you, sir.

Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [2]

Thank you, moderator. Welcome to Glenmark's Q3 earnings call post the review of the operations for the quarter ended December 31, 2018.

For the third quarter ended December 31, 2018, Glenmark's consolidated revenue was at INR 2,550 million (sic) [25,550 million] recording an increase of 15.95%. For the 9 months

ended December 31, 2018, Glenmark's consolidated revenue was at INR 7,309 million (sic) [INR 73,019 million] recording an increase of 7.02%.

Formulation business, India. Sales from the formulation business in India for the third quarter was at INR 6,675 million recording growth of 15.39%. As per IQVIA MAT December 2018, Glenmark is ranked 14th with a market share of 2.16% in IPM. Glenmark India business has consistently grown ahead of industry. Glenmark now has 9 brands among the top 300 brands in the Indian Pharmaceutical Market.

India, Glenmark's Consumer Care business. Glenmark's Consumer Care business grew in excess of 33% in the third quarter FY '2019. As for IQVIA MAT December 2018, Glenmark's leading brand, Candid Powder recorded 7% value growth highest among the top 3 brands which account for majority of sales. Candid Powder continues to be a market leader with share of about 44.70%. VWash Plus continues to hold the leading position in its respective category. As per IQVIA, VWash Plus recorded 57% growth and has 50% market share in the third quarter of FY '19. Together with the recently launched extension VWash Wow Sanitary Pads, the VWash franchise has registered sales growth of 72.9% in FY '19.

U.S. sales. Glenmark Pharmaceuticals Inc. U.S. sales registered revenue from the sale of finished dosage formulation was at INR 8,556.75 million, recording an increase of 16.28%. This translates to the U.S. sales of \$119 million. In the third quarter of FY 2019, Glenmark was granted approvals for 9 products in the U.S. market including 8 approvals and 1 tentative approval.

Africa, Asia and CIS region. For the third quarter, revenue from Africa, Asia and CIS region was INR 3,401.20 million as against INR 3,221.30 million, recording an increase of 5.58%. Glenmark Russia business was moderate -- our performance was moderate in the third quarter. According to IQVIA MAT December 2018 data, Glenmark Russia business grew by 4.8% in value and 8.6% in units.

For Asia, Africa. Asia and Africa region continue to perform well growing in excess of 15% in secondary sales in the third quarter. The Asia region recorded secondary sales growth was also led by key subsidiaries such as Malaysia, Philippines and Sri Lanka. The Africa region also posted strong secondary sales growth in the third quarter aided by robust growth in key markets such as Kenya and South Africa.

Europe. Glenmark Europe operations for the third quarter was at INR 3,217 million recording an increase of 43.15%. The Western European business continue to expand through increased penetration on the overall commercial portfolio in the Nordic region, Germany, Spain and Netherlands. Overall, both the Western European and the Central Eastern European region recorded strong secondary sales growth. The overall regional growth was led by multiple new product launches across markets. Glenmark launched 5 products in the Nordic countries, 2 products each in Netherlands and Germany, and also 3 products in Poland.

Latin America. Glenmark's revenue from its Latin America and Caribbean operations was as at INR 1,014 million recording an increase of 12.91%. For the third quarter, Glenmark recorded good growth in constant currency especially in key markets such as Brazil and Mexico.

Before we go on to the specialty and the R&D business, I would like to hand it over to Bob Matsuk for overall comments on the North America and also on the API business. Over to you, Bob.

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

Okay. Thank you, Jason , and thanks, everyone for joining us today. Before I get into the quarterly performance of the North American business, I'd like to provide a few updates.

In December of 2018, Glenmark announced that Glenmark Therapeutics, Inc. USA, a wholly-owned subsidiary of Glenmark Holding, SA, will be dedicated to developing and commercializing specialty branded medicines in Dermatology and Respiratory. This represents Glenmark Pharmaceuticals' first foray into the branded segment in the U.S., an important step in the company's long-term strategy to build a robust specialty branded business in the U.S. alongside the company's existing and successful generics business.

In support of this new business, Glenmark Therapeutics recently acquired the rights to 7 branded dermatology products from Exeltis USA, Inc. and expects to launch additional dermatology products over the next year.

For NDA filings for Ryaltris, during the second quarter of calendar year 2018, Glenmark announced the acceptance of the company's first NDA for Ryaltris intended for the treatment of seasonal allergic rhinitis in patients 12 years of age and older. The FDA has notified Glenmark that it requires additional time for a full review of the submission and has extended the March 31, 2019, action date by the standard extension period of 3 months. The extended PDUFA is now June 21, 2019. The extension

(technical difficulty)

Sorry, the extended PDUFA -- Fee Act is now June 21, 2019. The extension requested no additional studies. We will continue to work closely with the FDA with the goal of meeting the new PDUFA date.

In terms of this quarter's business performance, the North America finished dosage form business, which includes Canada and the U.S., closed the third quarter with recorded revenues of \$119.36 million or INR 8,556.75 million, an increase of 16.28% from last year's corresponding quarter which was \$113.7 million or INR 7,358.89 million. On the approvals side, the U.S. was granted 8 approvals for the U.S. market during this quarter. This includes 8 final approvals and 1 tentative approval. The final approvals were as follows: Azelaic Acid, 15% gel; Atovaquone Oral suspension; Hydrocortisone Valerate Cream, 0.2%; Hydrocortisone Valerate Ointment, 0.2%; Fluocinolone Acetonide Topical Oil, 0.01% body oil, Scalp Oil and eardrops; (inaudible) tablets.

In total, we have fiscal year-to-date 22 ANDA approvals with 17 final approvals and 5 tentative approvals.

Glenmark's marketing portfolio through December 31, 2018, consists of 148 generic products authorized for distribution in the U.S. market. The company currently has 54 applications pending in various stages of the approval process with the U.S. FDA, of which 28 are Paragraph IV applications.

On the API side, revenue from the sale of API and regulated and semi-regulated markets globally was INR 2,392.47 million for the third quarter ended against INR 2,316.48 million for the previous quarter recording an increase of 3.28%.

And with that, I'll turn it back over to Jason.

Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [4]

Thanks, Bob. Just further updates on Ryaltris in terms of licensing. Glenmark announced an exclusive licensing agreement with Yuhan Corporation commercializing Ryaltris in South Korea. Under the terms of the agreement, Glenmark will be responsible for manufacturing and supplying of the product, while Yuhan will be responsible for regulatory, filing and commercialization of Ryaltris in South Korea. Glenmark will receive an upfront payment, regulatory and commercial milestone payments as well as royalties from Yuhan.

Recently, Glenmark also announced an exclusive licensing arrangement with Grandpharma China for commercializing Ryaltris in China. Under the terms of the agreement Glenmark will again be responsible for manufacturing and supplying Ryaltris while Grandpharma will be responsible for regulatory filing and commercialization of Ryaltris in China. Glenmark will receive an upfront payment regulatory and commercial milestone payments as well as royalties from Grandpharma.

Ryaltris represents the continued commitment towards building a global branded business in the specialty Respiratory segment. The company plans to commercialize Ryaltris in several key markets globally and has already initiated product filings in key markets.

GBR 310, during second quarter FY '19, Glenmark announced results from a Phase I study that suggests similarly in pharmacokinetic, pharmacodynamics safety and immunogenicity profile between GBR 310 and the reference product, omalizumab marketed in the U.S. under the brand name Xolair. The company targets to initiate a Phase III study in FY '20.

GSP 304. GSP 304 is currently in Phase II and the company is targeting to continue development as a treatment of patients suffering from COPD.

Just an update on Glenmark Life Sciences Limited. Glenmark forayed into the API business in 2003 and over the last 15 years has built a large business based on product selection focused on key regulated markets, maintaining high operational efficiency. The API business has grown almost at a 14% CAGR over the last 3 years maintaining consistently high EBITDA margin. In order to further its potential in the global market, Glenmark has transferred its API business into a wholly-owned subsidiary named Glenmark Life Sciences

Limited. Subsequent formalities related to the business transfer were completed on 1st January 2019.

For the 9 months FY '19, the unaudited consolidated revenue for Glenmark Life Sciences Limited was at INR 10,860 million recording growth of 10.2% over the corresponding period.

Innovative R&D. Glenmark yesterday announced that its Board of Directors has given an in-principle approval to spin-off the innovation business into a new company in the U.S. Setting up of the new company will provide enhanced focus to the innovation business and help accelerate the pipeline towards commercialization. The new innovation company will be a wholly-owned subsidiary of Glenmark and will be based in the U.S. It will have an independent board and a new Chief Executive Officer. The other members of the management team and the team remain unchanged. All the innovative molecules in the pipeline, including preclinical assets and technology, the R&D centers in Switzerland, the R&D center in Paramus, the innovation R&D center in Navi Mumbai, India and the biologics manufacturing facility in Switzerland, along with all the employees associated with the innovative R&D will be part of the new company. The transfer of assets and employees to the new organization is expected to be completed in the next 6 to 9 months.

Highlights on the innovation pipeline. Glenmark's current innovation pipeline consists of 8 assets, including NCEs and NBEs in various stages of development of the area of immunology, oncology and pain management.

Oncology. GBR 1302 HER2 CD3 bispecific antibody. GBR 1302, the Phase I first-in-human study to determine MTD in patients with HER2 positive cancers is ongoing in the U.S. and Germany. The study is currently enrolling patients in cohort 9. Pharmacokinetic data from the trial was presented at ESMO Immuno-oncology Congress in December 2018.

GBR 1342. CD38 CD3 bispecific antibody. For GBR 1342, a Phase I first-in-human study to determine the MTD in patients with refractory multiple myeloma is ongoing. Cohorts 1 to 8 have been completed and the study continues to enroll patients into cohort 9. Glenmark also recently announced the decision to launch a Phase I trial in solid tumors based on noninterventional human translational data. The company intends to file an IND application and initiate clinical trial in CY 2019.

GBR 1342, an EGFR CD3 bispecific antibody. GBR 1372 is progressing well in preclinical development as a potential treatment for colorectal cancer.

MAP4K1 inhibitor. Glenmark obtained exclusive global rights into a small molecule oncology compound based on antigen presenting cell biology through a licensing arrangement signed with APC Therapeutics Inc. in 2017.

The compound is currently progressing well through preclinical studies and the company is targeting FY '20 to initiate clinical development.

GBR 830, OX40 antagonist. A Phase IIb study of GBR 830 has been initiated and will enroll 312 adult patients with moderate to severe atopic dermatitis. As of February 2, 2019, 68 patients have been recruited with 37 sites actively open to recruit, enroll patients in the U.S., Canada and Poland. Site initiation in Germany and Czech Republic is expected by end

February 2019. Top line results of the Phase IIb study are expected to be available in H2 FY 2020.

In addition to atopic dermatitis, a Phase IIa proof of concept study are being planned in patients with SLE and ulcerative colitis.

GRC 39815 RORy gamma inhibitor. GRC 39815 is an NCE currently being evaluated as an inhaled compound for the possible treatment of COPD. The compound is currently in preclinical development, and the company plans to initiate a Phase I study in H1 FY '20.

GRC 27864 mPGES-1 inhibitor. GRC 27864, there's currently enrollment for Phase IIb studies that's going on in 624 patients with osteoarthritic pain of the knee and hip. This is progressing well as per the plan with 29 active sites in India and 241 patients recruited so far in the study. Glenmark plans to complete trial recruitment by end H1 FY '20. Top line results of the Phase IIb study are expected in H2 FY '20.

GRC 17536, TRPA1 antagonist. The positive phase IIa proof of concept study of GRC 17536 conducted in Europe and India in patients with painful diabetic neuropathy has been completed. Glenmark is targeting to initiate a Phase IIb dose range finding study in neuropathic pain in FY '20.

With that, we'd like to give some overall comments on the P&L. The R&D expenditure for Q3 was at INR 345 crores. The R&D expenditure for 9 months was at INR 895 crores. The exchange loss and other income was at INR 130 crores. We have -- the gain in other income was INR 15 crores. And the other income was INR 6 crores.

With that, I would like to introduce the members of Glenmark's management and then hand it over for Q&A. We have Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals; we have V. S. Mani, our Executive Director and Chief Financial Officer, Glenmark Pharmaceuticals; Bob Matsuk, President, North America and API; Utkarsh Gandhi, Senior Manager, Investor Relations.

With that, moderator, we would like to open the floor for questions and answers. Over to you.

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Questions and Answers

Operator [1]

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

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

My first question is on the U.S. business. We have had a couple of good launches but the revenue does not seem to be reflecting that fully. Would that be a fair assumption that your market share in the launches that you've made will probably flow fully in the fourth quarter?

And the second part of the U.S. question is what's our idea for the branded Dermatology business that we've acquired? How do you see that? Because the products that you've acquired are currently small. So do we see products being added to that portfolio over the next, let's say, 1 year, 2 years? Any color there?

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

Yes. So on the U.S. business, I mean, I think that we're making good progress in terms of either getting to or realizing our market share. The pricing environment continues to be a bit challenging. But I would kind of classify it as kind of the new normal in pricing. On the Dermatology side, yes, we do plan on adding at least a couple of products -- launching a couple of new products in the next year.

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

And these would be from our own pipeline or are these -- there are certain potential assets that we're looking at?

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

These would be our own pipeline.

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

Okay. Understood. And my second question is on the innovative business that we've decided to subsidiarize. What's the idea there? I mean, what drove this action of sort of separating the innovative business and have -- into a separate subsidiary?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [7]

So Neha, there, we are looking at 3 different things value drivers, right, for why we are doing this. One is we think it will bring a much better focus in terms of what we're doing on the innovation side and with the new CEO joining and a new board to drive it, right, we think that focus will be very strong. We are also looking at benchmarking with some of the best biotechs in the U.S. at an overall level. We are also, being a U.S.-led company, we think we'll be able to recruit the best talent on the innovation side. And lastly, of course, we think this can be a significant value unlock for the parent company shareholders as and when we go out and do a capital raise or a strategic tie up with an investor or a partner.

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

And in terms of your time lines, I'm assuming this would take at least a year of the entire subsidiarization process?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [9]

The process will take us 6 to 9 months. We've made a lot of progress already on the whole process. So I think within the next 6 to 9 months, we should be -- I mean the newco should be effective.

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

So how does the value unlocking look? I mean, we have assets in our portfolio which obviously we're looking to outlicense. And then you're talking about potential investment at the subsidiary level for the innovative business.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [11]

So again, it's a little early to discuss that. And I think the newco board will take a decision on what's the best way to unlock value. But as I said, I mean, longer term, we are open to bringing in either a strategic investor or looking at different ways of either capital raise or bringing in a strategic partner or investor.

Operator [12]

(Operator Instructions) Next question is from the line of Saion Mukherjee from Nomura.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [13]

Can you explain the high amount of ForEx loss that you have in the P&L and high -- maybe high other comprehensive income? If you can explain why these numbers are so high.

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [14]

Sure, so Saion this is Mani. So actually the closing rate of rupee to the dollar as of December 31, was lower, okay, as against 30th September. So it was at about 69.4 vis-a-vis 72 odd, okay, 0.3 in the September end. Therefore, you have your export data and any loan data going to your subsidiaries. And also your loan that you've taken. So which in our case these are higher than the loans taken so therefore when they are revalued, obviously the receivables exceeded -- versus the rupee appreciation, this comes to a negative, okay? So if we look at it in the previous quarters when it goes the other way around, we had a positive of INR 134 crores, okay? So if we look at year-to-date you have positive INR 138 crores. This is principally normal accounting that is done so assets and liabilities as of the quarter end are revaluated based on the closing rates. That's why it is there.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [15]

So all the assets and liabilities gets revaluated in the quarter...

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [16]

So broadly in most cases the assets and liabilities that have led to your net exports and loans, et cetera, those are the ones that will impact that, yes.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [17]

And what about the other comprehensive income?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [18]

So we also -- other comprehensive income in the sense. If you are looking at our other -- basically we got about -- when we bought back our FCCBs, we got about INR 15 crores benefit out of that. And also we have other income which is about INR 6 crores, INR 7 crores, this was broadly the overall income. And if we look at the line -- when we look at there also obviously there are some benefits that we get overseas so the other way around. So therefore, put together, this activity.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [19]

Just on the India business, the transfer of pain business to True North is that reflected in this quarter?

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

Yes, it is, yes.

Operator [21]

(Operator Instructions) Next question is from the line of Ranvir Singh with IDBI Capital.

Ranvir Singh, [22]

In this quarter, was there any element of that branded business acquired in the U.S. is there? Dermatology portfolio.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [23]

It's very, very insignificant.

Ranvir Singh, [24]

But we have started booking it in our P&L?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [25]

Correct. I think from Q4, it will reflect.

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [26]

Yes. It will reflect more from the Q4. As of now, it's absolutely very, very insignificant.

Ranvir Singh, [27]

And what was the contribution of branded business in India, that consumer business in India?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [28]

So on an annualized basis, right, the consumer care business is about INR 200 crores in total revenues.

Ranvir Singh, [29]

Okay, fine. And what would be the debt as of now, gross and net if you could?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [30]

Yes, I will give you. So the net debt is about INR 3,430 crores and the gross debt is about INR 4,705 crores.

Ranvir Singh, [31]

Okay, fine. And I guess another one. Employee cost side and other expenditures and sales seems to have pick up on sequential basis, so what are those?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [32]

Employee cost has really not gone up that much. It's about an 8% increase. So that's normal whatever because after the July everybody gets an increment. And the last quarter obviously you had the bonus payouts. As far as the other expenses are concerned, we had a little extra spend on the R&D part partly and also we were also working on a couple of launches, et cetera, for which goods are getting shipped so there are some extra expenses on that.

Ranvir Singh, [33]

So versus that, then this is likely to continue?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [34]

Yes. So this is sort of like basically over a period of time it I mean in the full year it levels out. There are some quarters where there's a little excess, that's it.

Ranvir Singh, [35]

Okay. And on European -- the European business, this run rate, should I take it going forward?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [36]

No, I think the European business, I think you should take this quarter-by-quarter basis.

Operator [37]

Next question is from the line of Alok Dalal from CLSA.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [38]

Mani, can you give CapEx number and inventory receivable and payable number?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [39]

So I have the CapEx number, Alok, so this quarter it's about total both tangible and intangible put together about INR 390 crores.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [40]

Okay. And the other ones, the working capital ones?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [41]

The -- so as of -- again these are unaudited, but it was around INR 2,100 crores. Receivables around INR 2,519 crores and payables around INR 2,170 crores.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [42]

Okay. And one question on U.S. So now that your approval cycle has been fairly good, should one expect fourth quarter and fiscal '20 to see a much stronger pick up in U.S. as compared to the first 3 quarters?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [43]

I think, Bob, do you want to take that or...

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [44]

Yes. I think you'll see steady progress on that. Glenn, you can add color commentary to it.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [45]

Yes, absolutely. I think sevelamer is sure to help Q4. And I think going forward, this becomes the new run rate basically.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [46]

Okay. And what is the price erosion that your portfolio is witnessing today?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [47]

Yes, for U.S., we're about 8% to 10%.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [48]

Okay. So that has come off by 2, 3 percentage points over the previous quarter?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [49]

Yes. It's not a rate but I mean there's still significant and heavy price competition.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [50]

Sure. And for fiscal '20, are there any products that you would like to highlight which could be a good contributor to the portfolio?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [51]

So typically we don't comment on the pipeline. All I can say is we continue, all our filings continue to be either first generic, second generic, right, across the portfolio.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [52]

Right. But Glenn, are you satisfied with the market share that you're getting with the first generic, second generic kind of products?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [53]

I think so far we continue to perform exceedingly well as far as gaining market share, right? I mean, if you see all the new launches, whether it is Colesevelam, whether it is VAGIFEM generic, we continue to gain some significant market share on a continuous basis. So yes, I think we continue to do very well as far as being able to penetrate the channel and being able to gain market share on all the launches that we have. And you'll see a similar situation with sevelamer also.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [54]

Okay. And last question, Glenn, any guidance on how your net debt number could be like towards margin?

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

I think it should come off a little bit. I mean...

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [56]

Again, it depends a little bit on the currency movements also, Alok, so therefore I think broadly it should come off a little more, yes.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [57]

Okay. And which areas are you looking at improvement? You mentioned working capital is one area. Are there any other areas that can bring down the net debt levels?

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

I think across Glenmark, we have significant cost improvement initiatives ongoing. So I think that'll definitely help this Q4 and next year, right, which should help the overall leverage come off.

Alok Dalal, CLSA Limited, Research Division - Research Analyst [59]

Okay. In the past, you were given some numbers on net debt-to-EBITDA. Do you stick to those numbers for fiscal '20?

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

Yes, that is what we are trying I think to ensure that the net debt to EBITDA keeps coming down and try to reach that 1.25 -- 1.25 to 1.5 number.

Operator [61]

Next question is from the line of Nitin Agarwal from IDFC Securities.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [62]

Glenn, on the branded business, is there any -- it's a small acquisition that we've done and I'm not sure how big those brands that you're talking about launching now. So is there any thoughts as to why we started doing launches business at this point of time?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [63]

So Nitin, I think the primary purpose of doing this is not for Exeltis but it's more for the next 2 launches that are coming up right in the branded portfolio -- in the branded derm portfolio, right? And we think there is an opportunity to gain from both in terms of market share and in terms of value, right, through these subsequent launches and that's the reason why we're doing this.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [64]

Okay. And secondly on the generic business in the U.S., as you mentioned, you should have gained decent amount of market share in VAGIFEM. But it doesn't reflect in our Q-o-Q growth in the business for the U.S. We had a couple of these pretty decent launches over the last 6 months, right?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [65]

Yes, but the -- go ahead, Bob.

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [66]

Yes, I think we continue to get our market share on some of these products like VAGIFEM and Colesevelam. We see increased price competition as well.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [67]

Okay. And lastly in terms of R&D, how do you see -- there's been a lot of reads in the industry on the investments you're making towards generics R&D. I mean, how are we looking at our sort of generics R&D spend structurally going forward?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [68]

We continue to maintain the proportion of spend towards generics, right, pretty stable. So I think our goal is we file 15, 20 ANDAs a year. And we will continue with that run rate. But I think one of the things we've done is we have improved the quality of filings and we rationalized some of the products, especially some of the complex generics where we've discontinued some of the developments and things of that nature, right, where we think we won't o be competitive.

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [69]

Okay. And lastly, Glenn, on the innovation business. The value unlocked should be like a (inaudible)?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [70]

Sorry, Nitin, you got cut off. Can you repeat that?

Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [71]

I'm saying the valuation business value unlocking that you referred to this should be FY '20 or FY '21 event?

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

I don't think we can guide to that, Nitin. But I mean, we're working on it.

Operator [73]

Next question is from the line of Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [74]

Glenn, just under NCE spinoff plan. Until we get a strategic partner, nothing changes at -- here in terms of the resource allocation, the R&D spending, et cetera?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [75]

That's correct.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [76]

Okay. And hypothetically, over whatever time frame once you get a financial partner or some capital infusion, how do we see it then? Would the capital resources come down for the parent company?

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

I think there'll be a significant reduction, right, of in the capital resources, I think, that the parent will, over time, right, will have to invest. Between the partnerships, the licensing as well as any capital raise that we do, right, the capital intensity of the investment from the parent should come down.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [78]

Okay, great. So that's very helpful. And Glenn, do you have any updated thoughts on Advair for the U.S. markets, especially the way the first launch has happened?

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

As I mentioned the last time, Sameer, we are rethinking our whole investment in Advair, right? And we continue to be at the same place. And that's clearly on account of what you're seeing in the market, right. It's very evident that there's been significant erosion, right, in terms of value and in terms of price, right, as far as the product goes. So it automatically becomes much less attractive.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [80]

So this is to read that you would probably be taking it off the pipeline?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [81]

There's a possibility we'll do that.

Sameer Baisiwala, Morgan Stanley, Research Division - Executive Director [82]

Okay. And any thoughts on Mupirocin for -- any action from the competition?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [83]

So far we are not aware of any competitor who's close. However, in our next year's plan, we continue to build 1 competitor coming onto the market.

Operator [84]

(Operator Instructions) Next question is from the line of Aditya Khemka from DSP Mutual Funds.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [85]

A couple of questions from my side. Firstly, Glenn, if you could talk about the Chinese API situation for many of your peer companies. When they reported results there was a hit on gross margins because of India business margins sort of trimming down because of raw material cost pressure. Would you comment on that side of your business? How it is shaping up?

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

I think this year was a challenging year in terms of the cost side, right? Because of the escalation that we've seen from the Chinese APIs. But I think some of that has begun to

moderate now. And our view is next year, in FY '20, right, that should come -- that should reverse to some extent.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [87]

Right. So when you say moderate, are you seeing actual price decline in API prices or you think they will not increase further?

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

I think they're coming -- they're declining. They're coming back to -- closer to the original levels, right? So if I look back FY '18, FY '19 saw a big escalation, right, in prices. So FY '20 we are expecting prices to come closer to where it was in FY '18.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [89]

Okay. Fair enough. Also on the -- again, the (inaudible) business again on the growth side, so given the last 3-years-odd we have seen challenges in terms of obviously ban, pricing regulation, et cetera, et cetera, DST. In your perspective then, what could be the next year market growth and what would Glenmark aspire to grow at?

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

So I think -- I mean, for us, the next 2 or 3 years in domestic should look very exciting in terms of growth. And I think a lot of that is driven by some of the new launches that we are anticipating. So I think the market, my view will -- it will continue to grow at low double-digit, high single-digit, low double digit as far as the India market goes. But for Glenmark, you should see significantly higher numbers in terms of growth purely coming on the back of some very good launches.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [91]

So your aim is to, right, to be in about a 15%-plus growth in India. Would that still be a valid number given that the market seems to have sort of slowed down?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [92]

I think 10% to 15% right for us India growth should continue.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [93]

Okay. I get that. And lastly on the U.S. business side, Glenn, how many launches should we expect -- I know you're not talking product specific but could you guide us to the number of launches that you expect to do in terms of next year, FY '20 and '21 if possible?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [94]

Typically, we should anticipate that we will launch about 12 to 15 products a year.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [95]

Okay. And how many of these would be sort of large ticket or difficult to make limited competition products?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [96]

I think at least 4 or 5 should be really exciting products from Glenmark.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [97]

Perfect. And on in a nutshell so could you comment on the competitive landscape? I see you are about to launch a product in (inaudible) AG or do you expect another competitor approval sooner?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [98]

Yes. There's an AG that's in the marketplace right now but no other generics.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [99]

Sorry, I couldn't get that comment. Is it that there is an AG in the market already?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [100]

Yes, there is an AG in the market, yes.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [101]

And the pricing, the erosion in the molecule, ideally, what you would see in the 2 rare molecule -- or is it worse, better?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [102]

Yes. I mentioned kind of in general that there's kind of a new dynamic now. It's consistent with what we've seen in the most recent past, say, in the past year or so.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [103]

Okay. Just another question for you, Bob. When you look at the U.S. market, again, many of your peer companies tell us that the focus of the bios has now sort of shifted from a price point to consistency of supply and on getting a good quality product and avoiding disruption in supplies. Could you comment on how that has shaped up for you? Are you seeing incremental volumes in certain commoditized old products where competition is walking away. And in the same line, could you also tell us as to -- if you had any FTS penalties this year or last year? And hence, what is attractive on the supply with your customers?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [104]

Yes. So I mean, on the product supply side, I mean, I think we kind of see, depending on the product, right, certain times we'll see a need to supply more depending on the situation. But in general, based on limited competition, we don't see any problems or we -- on the commoditized side, sometimes we'll see an ability to increase market share because of some supply problems. But it's individualized by product. You can't just categorize things overall. We're not -- I don't want to make any comments on failure to supply.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [105]

Okay. But is there are failure -- Glenn, is there a failure to supply penalties would we net it off the revenue or does it come into other expense?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [106]

Sorry, I didn't get that. Can you please repeat again?

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [107]

Yes. If there are any failure to supply penalties even if INR 1 crore or \$1 million or whatever, would you generally net it off revenue as an accounting practice or would you put it in other expenses?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [108]

No, we'll directly make it off in the revenue.

Operator [109]

(Operator Instructions) Next question is from the line of Nishant Chandra from Temasek.

Nishant Chandra, Temasek Holdings (Private) Limited - Associate Director, India [110]

I had a question on the net debt numbers. So from a quarter-on-quarter perspective, what has been the increase in and does it include the cash inflow from the sale of the branded business?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [111]

No. Basically compared to the previous quarter, our net debt has actually gone lower, okay? So about -- they're worth 60 at most, okay. So partly the benefit of the currency movements also. And the branded business is really insignificant this quarter so I don't think that really has much to do with that.

Nishant Chandra, Temasek Holdings (Private) Limited - Associate Director, India [112]

No, the divestment for True North, you said that that's reflecting in the numbers. The cash inflow is coming or not really?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [113]

So that happened in the last quarter itself, the inflow that came in, it came in the last quarter itself. But there was a big currency movement if you look at it from the beginning of the year. So therefore actually speaking, the net debt from a year-to-year basis should be much lower but because of the movements of the currency, it's there. Otherwise on a broad basis, it's much -- I mean in the dollar terms is lower.

Operator [114]

(Operator Instructions) Next question is from the line of Surajit Pal from Prabhudas Lilladher.

Next question is from the line of Anubhav Aggarwal from Crédit Suisse.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [115]

This is Anubhav here. So one question on VAGIFEM. The last time we talked about it, our market share is north of 25%. IMS still raised effectively somewhere about 17%, 18%. I just want to check is IMS not representing it correct or we will gain further share or has already gained share in this quarter, in quarter 4?

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

I mean, clearly IMS is -- go ahead, Bob.

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [117]

Yes. I think that you'll see a lag but I think it -- internally, that's what we're projecting to get.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [118]

Bob, what really reflected in this quarter, the quarter 3, would have been what IMS reflected. Quarter 3 has been representing 17%, 18% share right now.

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [119]

I think we're a bit higher than that.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [120]

Okay. Glenn, question on this innovative business spin-off. Just a couple of questions over there. One, putting this business headquarter in U.S. versus Switzerland, any thoughts there?

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

So, I think we strategically decided that the leadership team, right, the CEO and a lot of the independent board members will be based in the U.S. And they will come out of the U.S. pharma and biotech environment. And since that's where the leading biotechs are housed, right, we think that's the best location. Because Switzerland obviously will be a part of newco, right? So Switzerland, India, all of them, right? So it's basically nothing is going to change as far as the locations, all the developments, all the people go, right? It's just adding a couple of people on the leadership and looking at the business very differently.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [122]

Okay, that's helpful. On this business, how much R&D annually we would have spent like something like \$50 million, \$60 million, would that be a right representation?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [123]

No, we actually spend close to, I mean, \$100 million to \$120 million.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [124]

On an annualized basis, \$120 million?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [125]

At the current run rate.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [126]

Only on the Innovative business?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [127]

That's correct.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [128]

Okay, and just one. If we receive any outlicensing income, let's say, we get some delay in getting a strategic partner over next 1 year or something, would that cash flow be available to reduce debt or you would say that no this is our new subsidiary so outlicensing...

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [129]

Yes, definitely it will be available to reduce the debt, yes.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [130]

And just last question on the U.S. growth rate, last time we talked about we expect FY '20 U.S. growth rate to be single digit. And we're talking about 2 derma products for the branded business, the 505(b)(2)s. So would you still maintain that even with the inclusion of those 2 derma products it will still add -- it would be about high single-digit?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [131]

No, actually we've not included the branded business in that, okay? I think the last time when we mentioned it was related to the generics business, okay? Right. The branded business is completely separate.

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [132]

Okay, okay. So even those 2 derma new NDAs you have not taken there.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [133]

No. We've not taken any of the Derm portfolio or Ryaltris or any of the specialty stuff that we're doing in the U.S.

Operator [134]

Next question is from the line of Saion Mukherjee from Nomura.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [135]

I have just a follow-up. Can I get the nine-month CapEx number and the breakup of intangible and tangible, please?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [136]

Want to come back. Saion, do you want the nine-month CapEx? I won't take long. I will give it to you right away. So what we just say it is INR 390 crores -- for Q3. So 9 months -- somewhere in the INR 459 crores and intangible is INR 380 crores. So INR 844 crores is the total.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [137]

Sir, can you repeat it again? INR 459 crores is?

Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [138]

(inaudible) addition and intangible is INR 380 crores and then INR 844 crores is the total CapEx (inaudible).

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [139]

Okay. And Glenn, you mentioned about cost control measures. Can you give us more specific -- how should we think about it? Because at this point even if we look at adjusting for R&D, the orders seems to be growing at a pace which is at least similar to how the revenues are growing, right? So any indication on quantum? How should we think about it? How big can that be for you?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [140]

So I think next year you should see a substantial improvement at the EBITDA level, right? At least a couple of percentage points should come on account of there is cost improvements between 1% to 2% improvement at the EBITDA level.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [141]

So the entire exercise will be in FY '20 or is it like over a period and when we think about FY '21 is the scope of this to go further?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [142]

I think over time, all I can say, Saion, is because of all the things that we're doing, right, over time, you should see a significant improvement in the parent's margin profile, right, between the spinout of the R&D business along with certain cost improvements that we've undertaken, right? So overall parent's margin profile should improve substantially.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [143]

Yes. Yes, of course, it means spin-off of R&D and if you need funding I understand it will be a significant boost. But excluding that thought, I'm just saying the base business you think 1 to 2 percent point would be possible next year?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [144]

That's correct. That's correct.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [145]

And the weapons, I mean 1 issue is about the branded business, right, when you roll it out, I don't know what the plan for Ryaltris realtors in the U.S. is but there would be overhead costs that will start building on that, right? I mean, I'm just wondering how -- I mean, how difficult will that be to get this 1% to 2% improvement given that overheads.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [146]

So this is, Saion, we've baked everything in our numbers right and then I'm guiding it, so yes.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [147]

And Glenn, on Ryaltris, any -- have you decided on how to roll out it in the U.S. And also for markets like Japan and Europe are out licensing a possibility? What are your thoughts there?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [148]

Clearly, I think the U.S. we still haven't taken a call between working with a partner or going through a contract sales organization. So there are different models we're still looking at. I think Ryaltris we have now partnered in 3 geographies, right? Australia, South Korea and China. And clearly we are working on additional partnerships right and especially in places where we don't have a footprint.

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Equity Research [149]

And what is the -- is there any licensing income there from Ryaltris this quarter? And how much has been the licensing income with 3 deals that you have done so far?

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

Saion, in this quarter there is no licensing income. So far I mean the major amount of Ryaltris outlicensing income will come in the next quarter, yes, the Chinese one and the other one.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [151]

South Korea.

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [152]

Yes, South Korea will come in, in next quarter.

Operator [153]

(Operator Instructions) Next question is from the line of Surajit Pal from Prabhudas Lilladher.

Surajit Pal, Prabhudas Lilladher Pvt Ltd., Research Division - Assistant VP & Senior Research Analyst [154]

Glenn, could you throw some light on how the ongoing inhaler business is growing on the European market?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [155]

So I think we continue to make good progress, right, on the Respiratory side in Europe. I mean, we've launched [Baclo] in the U.K. And as far as SALMEX goes, we continue to sell it in some geographies in Europe. So I think the pipeline continues to remain strong on the Respiratory side.

Surajit Pal, Prabhudas Lilladher Pvt Ltd., Research Division - Assistant VP & Senior Research Analyst [156]

Okay. Any color on your generics retired business in Germany because though it is equivalent to it or reaching it but do you think it will be easier to penetrate over there in generic?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [157]

We have an injunction right now in terms of sales of SALMEX in Germany. So I can't comment because of the ongoing litigation.

Surajit Pal, Prabhudas Lilladher Pvt Ltd., Research Division - Assistant VP & Senior Research Analyst [158]

And you have mentioned there are 4, 5 interesting product in U.S. Could you name the products?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [159]

No. I -- I mean, we can't disclose what the products are.

Surajit Pal, Prabhudas Lilladher Pvt Ltd., Research Division - Assistant VP & Senior Research Analyst [160]

And (inaudible) or injectable if you...

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [161]

No, we can't give any further visibility.

Operator [162]

Next question is from the line of Aditya Khemka from DSP mutual funds.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [163]

Glenn, just a couple more. Firstly on Ryaltris, why was the PDUFA date delayed and I know you mentioned no further clinical data but what was it that FDA wanted to then follow?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [164]

Well, I mean, I can't comment on -- all I can say is there's nothing outstanding from our side okay, Aditya. It's just a matter of reviewing the data which is already with the FDA. As you know, there was a government shutdown and a lot of things happened in the U.S., right? But there is no -- none of it is related to the data or anything pending from our side.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [165]

Got it, okay. And you made a comment -- I think Jason made a comment on the European side that we should take the Europe revenues quarter by quarter and the growth can be lumpy. Certain quarters (inaudible) that's what you mean. So what you think this quarter instead of a more higher growth and what really should we expect from that geography on still FY '20 or FY '21 over the base that we have in FY '19?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [166]

Sure. I think Europe, we continue to grow, right, Q-over-Q. And I think you should see that trend continuing, okay, at least for this year. FY '20, again, we will continue to grow the business but obviously a lot depends on the product approvals and the pipeline coming through.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [167]

Right. But there is no guidance per se on how much we should be transferring for growth for the Europe in geography.

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [168]

No, we can't give any visibility to that, Aditya.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [169]

Got it. And lastly the APIs (inaudible) revaluation I think what's mentioned the nine-month growth for the business has been 10%, 11% with a healthy margin profile. Could you talk to us as to what's leading to that growth in the API external sales then what could be the projected there going forward?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [170]

I think we are able to gain significantly on some of the new product supplies, right, that they're making into some of the other generic companies, right? Additional sales for products like Perindopril, Lizolid, Lercanidipine, (inaudible), Aprepitant. These are some of the products which we continue to drive sales.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [171]

Right. But is the majority of sales done domestic or is the majority -- or can you give us a split of the domestic and exports within the API segment?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [172]

So we do very little domestically. It's all export-based.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [173]

And primarily the synergy and geographies in U.S. and Europe or other emerging markets as well?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [174]

I think the big chunk is still U.S., Europe. But we do supply some EMs also.

Operator [175]

Thank you. Well, ladies and gentlemen, that was the last question for today. I would now like to hand the conference over to Mr. Jason D'souza for closing comments. Over to you.

Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [176]

Thank you, moderator. Just to read the disclaimer. The information, statement and analysis made during this call describing the company's prospectus, projection and estimates are forward-looking statements and progressing within the meaning of applicable securities laws and regulation. The analysis contained herein is based on numerous assumptions. Actual results may vary from those expressed or implied, depending upon economic condition, government policy 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 Q3 earnings call. Thank you, everyone.

Operator [177]

Thank you very much. Ladies and gentlemen, on behalf of Glenmark Pharmaceuticals Limited, we conclude today's conference. Thank you for joining us. You may now disconnect your lines.