## 79-100 minutes

Mumbai Nov 14, 2018 (Thomson StreetEvents) -- Edited Transcript of Glenmark Pharmaceuticals Ltd earnings conference call or presentation Wednesday, November 14, 2018 at 3:00:00am GMT

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

\* V. S. Mani

DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare

Nomura Securities Co. Ltd., Research Division - Head of India Industrials Research

Ladies and gentlemen, good day, and welcome to the Q2 FY '18/'19 Earning Conference Call of Glenmark Pharmaceuticals Ltd. (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. Thank you, Janice. Welcome to Glenmark's Q2 earnings call. Before we begin the call, I would like to introduce the members of Glenmark's team that is here on the call. We have with us Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals; V. S. Mani, Executive Director and Chief Financial Officer, Glenmark Pharmaceuticals Ltd.; Robert Matsuk, President, North America and API business; and Utkarsh Gandhi, Senior Manager, Investor Relations.

A quick review of the operations for the quarter ended September 30, 2018, and then I will hand it over to Bob for a overview on the North America API business and the specialty business.

For the second quarter ended September 30, 2018, Glenmark's consolidated revenue was at INR 25,813 million recording an increase of 14.39%. For the 6, months, Glenmark's consolidated revenue was at INR 47,469 million, recording an increase of 2.76%. Other revenue for the second quarter includes out-licensing income on account of the exclusive license arrangement signed with Harbour Biomed for the Greater China territory to develop manufacture and commercialize GBR 1302. With this, I would like to hand it over to Bob for an update on the North America and the API business. Over to you, Bob.

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

Thank you, Jason, and thanks, everyone, for joining us today. The North American finished dosage form business, which includes Canada and the U.S., closed the third quarter with recorded revenues of USD 116.05 million or INR 8,102.47 million, an increase of 11.44% for last year's corresponding quarter, which was USD 113.24 million or INR 7,270.95 million.

On the approval side, the U.S. was granted 2 approvals in Q2. They were as follows: Colesevelam Hydrochloride for Oral Suspension approved 16th of July 2018; and Estradiol Vaginal Inserts USP, 10 micrograms, approved 14th of September 2018. While no ANDA applications were filed during this quarter, the company plans to file 2 applications in the forthcoming quarter. In total, we have 12 ANDA approvals in fiscal year 2018/'19; 11 final and 1 tentative.

Glenmark's marketing portfolio, through September 30, 2018, consist of 139 generic products authorized for distribution in the U.S. market. The company currently has 61 applications pending in various stages of the approval process with U.S. FDA, of which 29 are Paragraph IV applications.

On the API side. Global API business had a solid quarter. Revenues from the sale of API in regulated and semi-regulated markets globally was INR 2,512.08 million for the quarter ending September 30, 2018, against INR 2,366.14 million for the previous corresponding quarter, recording an increase of 6.17%.

Sales were mainly contributed by Lercanidipine Aprepitant, Etoricoxib, Olmesartan and Perindopril. During the third quarter, Glenmark filed 1 U.S. DMF and 2 DMFs in the EU.

And with that, I'll turn it back over to Jason to talk about the progress we're making on our innovative pipeline.

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

-----

Thanks, Bob. Before the innovative pipeline, a quick wrap-up on the other businesses. The India business. Sales from the formulation business in India for the second quarter was at INR 7,783.57 million, recording growth of 9.52%. As per IQVIA MAT September 2018, Glenmark is ranked 13th with a market share of 2.30%. Glenmark's India business has consistently grown ahead of industry, and Glenmark continues to remain one of the fastest-growing companies as per MAT September 2018.

The India business strengthened its sales across its core therapy areas. The cardiac segment market share increased from 4.30% to 4.56%. The respiratory segment share rose from 4.63% to 4.69%. The anti-diabetic market segment changed from 1.62% to 1.63%, and the derma segment market share changed from 9.22% to 9.11%.

During the second quarter, Glenmark announced that it has entered into a collaboration agreement with leading home-grown private equity firm, True North, for its orthopedic and pain management business for the India and Nepal market. Glenmark's orthopedic and pain management business, consisting of brands such as Esoz, Bon K2, Collasmart and Lizolid, clocked revenues of INR 1,558 million. Under this collaboration, Glenmark's orthopedic and pain management business will be transferred to a new entity incorporated by True North, which will market the product portfolio in India and Nepal. Subsequent formalities related to the transaction was successfully completed in the second quarter.

Glenmark's consumer care business in India. Glenmark's consumer care business in India grew in excess of 25% in the second quarter of FY '19. As per MAT September 2018, Glenmark's leading brand Candid recorded 9% value growth and market share of about 55.8%. Furthermore, Candid powder transformed itself from a brand to a brand franchise with the launch of 2 new products, Candid Activ and Candid Renew, which have gained immediate share of voice.

Moving on to the Africa, Asia and the CIS region. For the second quarter, revenue from this region was at INR 3,051 million, recording an increase of 21.03%.

Glenmark Russia business performed moderately in the second quarter. According to IQVIA MAT, September 2018 data, Glenmark Russia business grew 3.8% versus overall market de-growth of minus 2.7% in units. Glenmark Russia continues to sustain its top 10 rank in the dermatology segment in Russia.

The Asia, Africa region performed significantly well, growing in excess of 25% in the second quarter. The Asia region recorded strong growth sales -- sales growth which was led by key subsidiaries such as Malaysia, Philippines, Myanmar and Sri Lanka. The Glenmark Africa region also posted strong secondary sales growth in the second quarter aided by robust growth in key markets such as Kenya and South Africa.

Europe formulations. Glenmark's Europe operations for the second quarter was at INR 2,607.76 million, recording a growth of 30.37%.

The Western European business continued expanding through increased penetration in the Nordic regions, Germany, Spain and the Netherlands. The Nordic region recorded very high growth due to the launch of the generic version of Seretide Accuhaler in Sweden, Denmark and Norway. Overall, the Western European business continues to record strong secondary sales growth in the second quarter. The Central Eastern region recorded good secondary sales growth during the second quarter, too.

The overall regional growth was led by multiple new product launches across all key markets. Glenmark launched 4 products in Germany and the Nordic countries; 2 products in U.K., Netherlands, Germany and Spain. The company also launched 2 products each in the Czech and the Poland market. Maloff Protect, an anti-malarial medication launched as a pharmacy license in the United Kingdom, has attained 20% volume market share.

During the second quarter, Glenmark received marketing authorization for Fluticasone/Salmeterol dry powder inhaler, DPI, a generic version of GSK Seretide Accuhaler in Germany. Glenmark will sell the product in Germany under the name SALFLUTIN.

During the quarter, the company also announced that it has entered into a strategic, exclusive licensing arrangement for marketing generic Tiotropium Bromide dry powder inhaler in Western Europe.

Latin America. Glenmark's revenue from its Latin American and Caribbean operations was at INR 985 million, recording a decrease of 5.94%. Glenmark recorded good growth in constant currency. However, performance of the overall region was impacted due to currency devaluation in major markets.

Just a quick update on the API business. During the second quarter, Glenmark received approval from the shareholders for the transfer of its API business to a fully owned subsidiary entitled Glenmark Life Sciences Ltd. Subsequently, a Business Purchase Agreement for the transfer of the API business has also been executed between Glenmark Pharmaceuticals Ltd. and Glenmark Life Sciences Ltd. The formalities related to the transfer of the business are ongoing and expected to be complete by Q4 FY '19.

The reorganization is -- this reorganization is targeted towards improving the service to our customers through enhanced focus on the API business and building capabilities in research and development, manufacturing and marketing to accelerate growth in this business.

R&D. Glenmark has a pipeline of 7 innovation assets; 5 in clinical; 2 in preclinical; and 2 specialty assets currently in development. In addition, Glenmark also has a pipeline of complex generics currently in various stages of development.

Quarterly highlights, most on the innovation asset. Glenmark has 2 innovative assets currently in Phase IIb studies, GBR 830 and GRC 27864; 1 asset entering phase IIb, GRC 17536; and 2 oncology assets in Phase Ib. Glenmark also has 2 assets in preclinical development, 39815 and MAP4K1 inhibitor. Of the 7 assets, Glenmark has positive proof -- clinical proof-of-concept on 2 assets, GBR 830 and GRC 17536.

Update on the oncology assets, GBR 1302. GBR 1302 Phase I, first-in-human study to determine maximum tolerated dose in patients with HER2-positive cancers is ongoing. Dose escalation continues at 9 participating clinical trial sites across Germany and the U.S. The study is currently enrolling patients in Cohort 9 and will continue until MTD is reached. Pharmacokinetic data from the trial will be presented at ESMO Immuno-Oncology Congress 2018 in December 2018.

GBR 1342. For GBR 1342, a Phase I, first-in-human study to determine MTD in patients with multiple myeloma is ongoing. The study is currently enrolling patients in Cohort 8, with patients being already identified for enrollment 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.

MAP4K1 inhibitor. Glenmark obtained exclusive global rights to a small molecule oncology compound based on Antigen Presenting Cell biology, through a licensing arrangement signed with APC Therapeutics in 2017. Glenmark's lead compound is currently progressing well through preclinical studies, and the company is targeting to initiate clinical development in FY '20.

Immunology. GBR 830. A Phase IIb study of GBR 830 in 392 patients has been initiated in adults with moderate to severe atopic dermatitis, with 30 trial sites actively open to enroll patients in the U.S. and Canada. Glenmark has also initiated activities in the EU, and enrollment is expected to start by January 2019. Top line results of the Phase IIb study are expected to be available in Q3 FY '20.

Data from a Phase IIa, proof-of-concept study of GBR 830 was presented at the Fall Clinical Dermatology Conference in Las Vegas in October 2018. In addition to atopic dermatitis, Glenmark is currently evaluating GBR 830 for a study in patients with SLE. The company has also initiated preclinical ex vivo translational studies to evaluate GBR 830 in patients suffering from ulcerative colitis.

GRC 39815. 39815 is a 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.

On the pain assets. GRC 27864. A phase IIb study of GRC 27864 in 624 patients with osteoarthritic pain is progressing as per plan, with 33 active sites in India and more than 100 patients recruited for the study. Glenmark plans to complete trial recruitment by end of FY '19. Top line results of the Phase IIb study are expected to be available in H1 FY '20.

GRC 17536. A small molecule has been proven highly efficacious in treating inflammatory and neuropathic pain in animal models. GRC 17536 has shown positive data in a Phase IIa proof-of-concept study in patients with painful diabetic neuropathy conducted in Europe and India. Phase II enabling toxicology studies are currently ongoing, and the compound has shown a good safety profile supporting further development. Glenmark is targeting to initiate a Phase IIb dose ranging finding study in neuropathic pain in FY '19 20.

Quarterly highlights on the specialty assets. Glenmark has 2 specialty assets currently in development, which includes Ryaltris, Glenmark's first NDA filed in the U.S.; and the biosimilar for Xolair.

Ryaltris. During the second quarter, Glenmark announced the acceptance of the company's first NDA for Ryaltris indicated for the treatment of seasonal allergic rhinitis in patients 12 years of age and older. The PDUFA target action date for completion

of the FDA review is March 21, 2019. 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 its key markets.

GBR 310. During the second quarter, Glenmark announced results from a Phase I study that suggested similarity in pharmacokinetic, pharmacodynamics, safety and immunogenicity profiles between Glenmark's proposed biosimilar, GBR 310, and the reference product omalizumab, marketed in the U.S. under the brand name Xolair. Glenmark expects to meet the U.S. FDA in H2 CY 2018, with the goal of advancing the development of GBR 310. The company targets to file, initiate a Phase III study in H1 FY '20.

On the generic assets. Glenmark has multiple complex generic assets, both in-house and in-licensed, currently in development, including 2 generics respiratory inhalers.

In-licensed assets, Glenmark has discontinued development of the following in-licensed complex generic assets as the overall business case for these assets has significantly weakened due to the intense competitive landscape. Generic ABRAXANE, generic NuvaRing, generic CONCERTA, and generic SUBOXONE.

Before we continue the call, a quick update on some of the financial numbers. Gross debt as on September 30, 2018, was at INR 4,807 crores as compared to INR 4,639 crores as on March 31, 2019. Net debt was at INR 3,491 crores as on September 30, 2018, as compared to INR 3,404 crores as on March 31, 2018. The MTM impact on net debt was to the extent of INR 450 crores, thus, on a constant currency, net debt reduced for the organization by INR 363 crores in the first 6 months.

ForEx gains during the second quarter was account of the rupee depreciation, was at INR 125 crores recorded in other income. Out licensing income was INR 40 crores for the second quarter FY 2019, primarily due to the outlicensing deal of 1302 with Harbour Biomed for Greater China territory. R&D expenditure for the second quarter was at INR 305 crores, which was 11.82% of net sales. R&D expenditure for the first half was at INR 550 crores which was at 11.65% of net sales. Fixed asset addition for the first half was at INR 310 crores, and intangible assets was at INR 140 crores for H1 FY '19, of which INR 120 crores was product in-license primarily for the European region.

Depreciation was at INR 79 crores for H1 FY '20 and amortization was at INR 83 crores for H1 FY '20 -- FY '19. Inventory was at INR 2,058 crores as compared with INR 2,030 crores in March 31, 2018. Receivables was at INR 2,561 crores as compared to INR 2,332 crores in March 31, 2018. Payables was at INR 2,160 crores as compared to INR 1,870 crores in March 31, 2018.

Employee wages includes a onetime bonus incentive component in the second quarter which was to the extent of INR 95 crores. Exceptional items during the quarter recorded in the consolidated income statement was a net income of INR 1,671.82 million.

At this point in time, we would like to inform all on the call that all our manufacturing facilities are compliant, and we have received the EIRs for all our previous inspections. With this, we would like to open the floor for question and answers.

Questions and Answers

\_\_\_\_\_

Operator [1]

\_\_\_\_\_

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

\_\_\_\_\_

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

\_\_\_\_\_

First, in the U.S. business. We have seen a good improvement in the U.S. aided by the launches in the quarter. As we look ahead, some of the launches have seen competition come through. How should we look at the trajectory of the U.S. business? And the second question on that. We saw Glenmark taking write-off of intangibles related to a lot of large generic in-licensed

product, and these were so-called complex products. How are we looking at our R&D strategy when it comes to complex generic in the new environment given these large write-offs?

-----

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

\_\_\_\_\_

Yes, I'll take the U.S. question. I think from the U.S. perspective, as we look at Q3, we'll expect this to be above Q2, and that's the guidance we're giving. And from here until the end of the year, we're expecting a couple of good approvals as well. For the second part of the question, I'll let Glen take that.

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [4]

-----

Yes. So I think, Neha, the way we're looking at the U.S. business, I mean, the competitive intensity, especially on the complex generics also has increased substantially over time. And we constantly reevaluate our portfolio to look at the competitive intensity, and then we make certain key strategic decisions around whether to continue development or to discontinue. And this is part of that exercise, right? Based on that, we've discontinued some -- the development of these 3 or 4 complex generics. I think, as a strategy, we have a very strong pipeline. We continue to have some very exciting launches. Yet this year, we have 2 big launches coming up. And I think we are much more focused on opportunities, where we can be first or second to market as opposed to being a part of the crowd, right, in most of our launches. And that's the way we are looking at the U.S. strategy.

\_\_\_\_\_

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [5]

\_\_\_\_\_

Glenn, just on that. For example, in respiratory, you mentioned in your release that you're working on 2 respiratory assets, generic respiratory assets. Is there a risk of a similar situation like you've seen with the other large products, in-licensed products, especially with a product like Advair where given that it's fast declining and the competition couldn't be higher by the time we enter?

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [6]

-----

Well, Advair is -- given the changing landscape of Advair, I mean, it's something we constantly keep reevaluating as a project, right. Right now, we still continue the development. But you're right, I mean, the landscape is constantly changing as far as Advair goes. So Advair may not be the best example, but I think there are some other respiratory products that we have in development where we feel pretty comfortable we'll be in the first wave of launches, which could give us a good flip in the U.S. business.

-----

Neha Manpuria, JP Morgan Chase & Co, Research Division - Analyst [7]

-----

Understood. And my second question is on net debt. We have seen some reduction in the quarter. With the inflow from True North for the India business and now a potential sort of sale of the API business or stake sale of the API business, is there a - how should we look at net debt reduction going forward?

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [8]

-----

So I think net debt, the way we look at it is not really an issue. Our debt will keep sliding between now and the end of the year. I mean, this time, unfortunately, because of the currency move, right, we -- the debt went up but then we use the True North capital to knock it down again. So -- but I think if you take a strategic view, we don't see net debt as an issue going forward. Mani, you want to add something?

\_\_\_\_\_

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [9]

-----

No, that's fine. So on a broad basis, if you look at it in the current quarter, the net debt could have been, as earlier Jason pointed out, could have been much, much lower. But because of the rupee swings, it went up, but that's the nature of how it works.

-----

Operator [10]

\_\_\_\_\_

(Operator Instructions) We would take the next question from the line of Abhishek Sharma from India Infoline.

-----

Abhishek Sharma, IIFL Research - VP & Head of Life Sciences [11]

\_\_\_\_\_

I just have one question around the API business. Is there a plan to monetize the API business? What kind of structures are you looking at, and at what stage are we presently?

\_\_\_\_\_

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [12]

-----

So publicly, we've stated that we are looking at bringing in a minority investor, right, into the API business. So we're still on that process, right. And we are hoping to do something in the near future.

-----

Abhishek Sharma, IIFL Research - VP & Head of Life Sciences [13]

-----

This would be a strategic partner that you're looking at or...

\_\_\_\_\_

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [14]

-----

I cannot give any more visibility other than saying that it will be a minority investor.

-----

Abhishek Sharma, IIFL Research - VP & Head of Life Sciences [15]

And this would be money into the company or would this be like a secondary?
V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [16]
This should be like broadly, it will be an inclusion into one of the parent, okay.
Abhishek Sharma, IIFL Research - VP & Head of Life Sciences [17]
So the money to the parent?
V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [18]
Yes, that's correct.
Abhishek Sharma, IIFL Research - VP & Head of Life Sciences [19]
And it will be selling a stake.
V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [20]
Yes, somewhat like that, yes.
Operator [21]
(Operator Instructions) Next question is from the line of Saion Mukherjee from Nomura.
Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Industrials Research [22]
Can you just throw some light on the U.S. outlook? You mentioned you expect Q3 to be better than Q2.

Can you just throw some light on the U.S. outlook? You mentioned you expect Q3 to be better than Q2. I mean, the existing launches, especially VAGIFEM, was that a contributor this quarter given that it came towards the end of the quarter? And how do you see that market given that limited competition? And your earlier expectation on Welchol, have you been able to achieve what you expected in terms of market share and the pricing environment there?

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [23]

-----

Yes, so I think on the Estradiol, you'll see more -- we'll have more in effect in Q3 because it's towards the end of Q2 that we had the launch. On the Colesevelam, I think we're -- we have our strategy down to defend what we currently have and we'll look to stay about at the same level that we currently are moving forward.

\_\_\_\_\_

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Industrials Research [24]

-----

So you're indicating that the market share is probably lower than what you had initially expected. Is that right?

-----

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

-----

No, no. Saion, I think we are north of 25% on both these products in terms of market share. So I don't think we've actually -- our market share estimations have diminished or anything of that type.

\_\_\_\_\_

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Industrials Research [26]

-----

Okay, okay. And in general for the U.S. launches, I mean, you have a fair bit of competition coming in, derma, et cetera, which has been one of the core of the pipeline. How should we see ramp-up from these levels if I take a, let's say, 2-year view? I mean, any color you can throw? Would it be a lot granular, like, each and every product will contribute? Or there are some big opportunities, which could have a meaningful element of growth in the next 2 years? Dependent on a few products to deliver that growth or it would be more spread?

-----

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

-----

So I think, Saion, as I said, right, we've got some -- a primary interest, as in products where we can be in the first wave of launches, right. And that's where our entire focus is. And with that backdrop, right, we said we have a couple of good launches coming up this year and then again next year and in the future. I mean, we've got a great pipeline of products coming through where we will be in the first wave of launches. I mean, that's the only visibility I can give you at this point.

\_\_\_\_\_

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Industrials Research [28]

-----

Okay, okay. No problem. And finally, one last question before I join back, is on your experience with the inhaler launch in Europe so far. The growth numbers are good. So I'm just wondering is it this product that is contributing? And especially for the German opportunity, how should we think about it? Any expectations there?

\_\_\_\_\_

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

-----

So I think, look, on the inhaler launch, right, I mean, first of all, our European business is not completely driven by the launch of the generic inhaler, right. We're still in the process of rolling it out in various countries, so it's still early days for the launch. As far as Germany goes, I think in the last -- over the weekend or in the last 2, 3 days, we received -- GSK was able to get a preliminary injunction in Germany against us, which we are right now trying to vacate as we speak. So I think we have not launched the product or we had barely launched, started the launch phase, so it's not having any material impact to anything. But it's something which we will have to vacate before continuing the launch.

-----

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Industrials Research [30]

-----

Okay. And this injunction is, I mean, with respect to some patent issue?

\_\_\_\_\_

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

-----

It's a trademark, trademark.

-----

Saion Mukherjee, Nomura Securities Co. Ltd., Research Division - Head of India Industrials Research [32]

-----

Trademark issue. Okay, okay, okay. And any time line, Glenn, on this, by when we should be able to get a clarity?

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [33]

-----

I mean, we can't guide to it, Saion. But again, I mean the takeaway, our European growth will still continue to remain strong in Q3 and Q4 despite this injunction in Germany because we have several other launches in Europe. So we don't see this as a material impact to any of our numbers for Europe or for the business as a whole.

-----

Operator [34]

-----

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

-----

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

\_\_\_\_\_

Glenn, over the last couple of years, U.S. business hasn't -- versus U.S. business and non-U. S. exports have meaningfully grown especially in Europe as well as ROW markets. And this quarter is pretty much in line with that. I mean, in general, when you're looking at the business, over a 2-, 3-year view, I mean, how are you looking at these different pieces now the India -- if you were to divide the business, India, U.S. and non-U. S. export, please?

\_\_\_\_\_

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

I think, I mean, you'll see growth across all 3 segments, Nitin. So I think India, we are strongly focused on derm, respiratory, cardiovascular, metabolic, and we have some great launches. I anticipate India growth to be very strong, particularly next year, because we have 1 or 2 major launches in India. So I think next year, we will really outperform in the India business. If I look at the U.S., clearly, our focus is in addition to the generics and the generic growth because of our low base in generics, we will continue to grow quarter-over-quarter, right, with every new launch that comes up. But we are also very focused on building a specialty business, which will play out starting next year with the launch of Ryaltris. So that's another big event for us in the U.S., and that should change the trajectory. In the rest of the world, I think you will see growth pretty much across our different segments. We have some good launches coming up in Russia. We have some good launches in countries in Asia. And Latin America, now we've pretty much hit the bottom. And from hereon, I mean, the only spoiler could be currency, but I think if you keep the currency aside, the market growth, even in emerging markets and in Europe, continues to be strong. So I mean, we feel pretty good about the business at this point in terms of our growth going forward.

\_\_\_\_\_

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

\_\_\_\_\_

Okay. And secondly on your -- from a profitability perspective, I mean, how do you treat different broad pieces back up? I mean, how lowdown is this non-U. S. export piece right now as a -- in terms of contribution to profitability versus the overall corporate profitability?

\_\_\_\_\_

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

-----

I think from a margin perspective, they're all above the company average. Almost -- we are spending almost, I would say, 7%, 8% on [generic] and specialty, right? If you add that back, I mean, the company margins or north of 25%, right, in terms of EBITDA margin. So I think all our businesses are very, very profitable, right. And they're all the stack up at pre-R&D expenses of 30-odd percent, right. So it's -- I think across the board, it's a good margin business overall for us.

-----

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

-----

Okay. And secondly, Jason, what was the inflow on the [2] booked in H1 on the slump sale for the India business?

\_\_\_\_\_

Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [40]

-----

Nitin, you're talking of the orthopaedic?

-----

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

-----

Yes, orthopaedic, yes.

\_\_\_\_\_

Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [42]

Yes. We got about INR 600 crores.
Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [43]
Okay, INR 600 crores has been and
Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [44]
Obviously, there were payments with [severance] and transaction cost that is part of all the assets, et cetera. So that's all.
Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [45]
So the net interest to INR 600 crores?
Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [46]
Yes, I mean, INR 600 crores is a top number. Then obviously, we have some other transaction cost, severance pay, all that comes lower. Some of them are also paid in the quarter.
Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [47]
And Mani, what's the net inflow in the for H1 then from this transaction?
V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [48]
So we got a net gain of about INR 350 crores, primarily from this.
Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [49]
I mean that's cash flow or there's a P&L impact.

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [50]

-----That is basically a P&L. And broadly, the cash flow will be a little higher than that. \_\_\_\_\_ Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [51] -----Okay. And on CapEx, how are we looking at now? I mean, the CRM they are going after? \_\_\_\_\_ V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [52] \_\_\_\_\_ CapEx, so far, we have done about INR 310 crores in the basically tangible CapEx. INR 700 crores, INR 800 crores. \_\_\_\_\_ Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [53] \_\_\_\_\_ INR 700 crores, INR 800 crores is our average, Nitin. Next year will be -- may come up a little bit but will be in the INR 700 crores mark overall. \_\_\_\_\_ Nitin Agarwal, IDFC Securities Limited, Research Division - Analyst [54] \_\_\_\_\_ And lastly, Glenn, on R&D, we did [550] in H1. I mean this is a run rate of to sort of extrapolate for the second half also and going forward? \_\_\_\_\_ Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [55] \_\_\_\_\_ I think about 12% of revenues is what you should look at for the full year. \_\_\_\_\_ Operator [56] \_\_\_\_\_ (Operator Instructions) Next question is from the line of Shyam Srinivasan of Goldman Sachs. \_\_\_\_\_ Chandramouli Muthiah, Goldman Sachs Group Inc., Research Division - Research Analyst [57]

This is Chandra in for Shyam. First question on the U.S. business. I understand that Tacrolimus and Welchol have helped number this quarter. I'm just curious what the base business of these products have done Q-o-Q? And what is the level of base businesses versus what you have seen in an annual basis?

-----

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [58]

-----

Sorry, Glenn, I couldn't hear.

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [59]

-----

Okay, let me take that. So I mean, the base business erosion is roughly 10%, right, on the core business. So I don't know if that helps.

-----

Chandramouli Muthiah, Goldman Sachs Group Inc., Research Division - Research Analyst [60]

-----

Okay, that's helpful. Okay, that's helpful. Second question on (inaudible) I think is the product that you have talking about a couple of years back. It could be part of kind of opportunity FY '19 second half. So just wondering if there's any update on the litigation status there and how we should think about in the FY '19 ramp in the U.S. business?

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [61]

-----

I don't think we have any update on that specific product. And clearly, it seem -- it will be probably a competitive situation so...

-----

Chandramouli Muthiah, Goldman Sachs Group Inc., Research Division - Research Analyst [62]

-----

Right, right. Next question is on the products that you mentioned that you're discontinuing the development the in-license products ABRAXANE, et cetera. Just wondering if you could give us an estimate of what some is cost there and if there's any recovery you mentioned in the licensing payments that were made related to these products?

\_\_\_\_\_

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [63]

\_\_\_\_\_

We announced it, Chan, we said that we had taken this into consolidated P&L which was to the extent of INR 1,780.03 million.

-----

Chandramouli Muthiah, Goldman Sachs Group Inc., Research Division - Research Analyst [64]

\_\_\_\_\_

Perfect. Perfect. Last one on the exceptional gain this quarter, it looks like the press release states that the exceptional gain -net exceptional gain before tax is about INR 167 crores. I'm just wondering if there's any tax that's just displayed on that item and what the post-tax gained issue on the net income line?

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [65]

-----

If you look at 2, basically, in the stand-alone, you have a net gain and there is a tax element which will be whatever -- 20% plus. And the consolidated, you've taken that right down for intangibles. So on a broader basis, that's how we look at it.

\_\_\_\_\_

Chandramouli Muthiah, Goldman Sachs Group Inc., Research Division - Research Analyst [66]

-----

Right, right. Just last one is on Mupirocin. So I think a couple of quarters back, there was a competitor who got approval. But so far at least on our U.S. numbers, we haven't seen any entry by thae competitor. I'm just wondering how are you thinking about it going forward in the second half?

\_\_\_\_\_

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [67]

-----

Yes, we expect...

\_\_\_\_\_

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

-----

No, no. Bob, go ahead.

-----

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [69]

\_\_\_\_\_

We expect competition at a certain point both -- to date, we've seen nothing on it.

-----

Operator [70]

-----

(Operator Instructions) Next question is from the line of Chirag Dagli from HDFC Asset Management.

-----

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [71]

-----

Please excuse me there is an echo. I'm actually logged on to a cell phone. Am I audible?

\_\_\_\_\_

Operator [72]

\_\_\_\_\_

Excuse me, sir. So sorry to interrupt. My you please request you to please the handset mode.

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [73]

\_\_\_\_\_

So on this product discontinuations, on the 4. For each of these products, if can you sort of give us a sense of what exactly has changed, Glenn? Is it that the pricing in the first wave has been far inferior than what you thought or is the number of competitors higher than what you initially envisaged? Or is it that in your own development plan that there has been some delay and hence you think when you enter the market, it may not be effective.

\_\_\_\_\_

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

\_\_\_\_\_

So we do a complete portfolio review, Chirag. And based on our portfolio review, 1 or 2 of them are related to products which are already commercial right. So obviously, CONCERTA is commercial, and SUBOXONE, NuvaRing. But when we look at landscape and the timing that will be able to enter the market and we map it against the estimated erosion that we see on these products, right, it just doesn't make rational sense the continue development. And that's why we pull out.

-----

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [75]

-----

So that changes expected pricing environment.

\_\_\_\_\_

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [76]

-----

Absolutely.

\_\_\_\_\_

Chirag Dagli, HDFC Asset Management Company Limited - Senior Equity Analyst [77]

\_\_\_\_\_

Okay, fair point. And Jason, you gave out the depreciation and amortization numbers definitely for the first half. Can you repeat those?

-----

Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [78]

-----

Yes, the depreciation was INR 79 crores and the amortization was INR 83 crores.

\_\_\_\_\_

Operator [79]

-----

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

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [80]

-----

Just trying to understand R&D better. So if we hear most companies commentary, everybody's talking about rationalizing, especially the generics piece. I understand we have a rich pipeline on the specialty side. So a, how is the mix changing versus last 2 years now? And have you also looked at rationalizing the generics India pipeline or withdrawing some of the NDAs?

-----

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

-----

Okay. So Prakash, we just mentioned the 3 or 4 NDAs that we've...

-----

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [82]

-----

That was the license that you bought. I'm talking about in-house developments, sir.

-----

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

-----

Well in house, we keep doing -- we keep, rationalizing our portfolio. We keep dropping products, we keep adding products. I mean, that's all part of the ongoing a portfolio review that we conduct, right, on a regular basis. I don't know if that's helpful.

-----

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [84]

-----

But in terms of the share that you are doing now what generics versus innovative spoke speciality?

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [85]

\_\_\_\_\_

I don't think the share has changed. We keep the same mix and the same share, but we keep reaching in the portfolio based on the competitive landscape, and where we are in the development.

\_\_\_\_\_

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [86]

-----

Last time I think you mentioned 40% generics or something like that versus 50-50.

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [87]

-----

Correct, correct. Absolutely.

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [88]
That's correct.
Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [89]
Okay. So that will be likely the case for our couple of next couple of years or you think specialty as these developments pick up, it would require as a percentage moves up. And as a percentage of sales, you'll probably be around 12%?
Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [90]
Correct.
Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [91]
I'm talking about '20, '21.
Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [92]
That's correct.
Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [93]
Okay. And secondly on the gross margins, which are pretty steady for last few quarters, trying to understand your run rate on the SG&A side. And when do we start seeing our old EBITDA margins of 20%? Some outlook would be helpful.
Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [94]
We think margins will keep getting better as we gain more scale, number one. Number two is because of the currency impact, right, our margins will look better in the next few quarters. I'm suspecting. Because I mean the rupees this time, obviously, the P&L was at 68 or something like that, whereas the

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [95]

The quarter end was about INR 72 for that.

-----

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

-----

To margins will keep looking better as we go forward in the subsequent quarters.

\_\_\_\_\_

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [97]

-----

But color on the SG&A expense, would that continue to expand given the fact that all the geographies are growing well and you continue to do investments and especially, next year, Ryaltris, (inaudible) and stuff like that?

-----

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

-----

I think SG&A as a whole, we will continue to get operating leverage because of the scale, okay. So we anticipate SG&A to remain flat or come up a little bit as a percent of sales.

-----

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [99]

-----

So what I understand the revenue growth will be higher SG&A. So that will result...

\_\_\_\_\_

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [100]

-----

Exactly. The margin expansion as we go along.

\_\_\_\_\_

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [101]

-----

Yes. And lastly on U.S. outlook. You've mentioned about a couple of quarters which will be better than Q2 given that you have a couple of products expected. But any color for '20, because 20, '21, '22, we have then these products a little bit on the side. But how many launches and approvals you are expecting for '20? If you can give broad color that will be helpful.

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [102]

\_\_\_\_\_

I think every year, we launch about 12-plus products, right? That will pretty much sustain what we anticipate the run rate of launches will be similar.

Prakash Agarwal, Axis Capital Limited, Research Division - Executive Director of Pharmaceuticals [103]

-----

That would be good enough to -- because you are reaching a good base and that would be a good enough to do a 10%, 12% kind of growth?

\_\_\_\_\_

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [104]

-----

I can't comment on that, Prakash, for next year. Everything depends on how the operating landscape plays out going forward. We can only give you visibility for the next few quarters. As far as the Q-over-Q growth, rate. For next full year, I mean, I would anticipate the generic business to be may be single-digit, right, for next year in terms of growth, yes.

-----

Operator [105]

\_\_\_\_\_

(Operator Instructions) The next question comes from the line of Aditya Khemka from DSP Blackrock.

-----

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [106]

-----

Glenn, couple of questions on what this withdrawal from some complex generic in place. So basically, as you've mentioned with the previous participant, you basically anticipate a very -- most severe competitor landscape than you were originally anticipating, which will lead to probably lower realizations and lower ROE. Is that the case to be for production, particularly, are you seeing sort of a similar trend across many complex generics that you were originally hoping of developing and sort of making a good hurdle on?

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [107]

-----

I think, Aditya, this is -- you know the generic landscape is not easy, right? I mean, the whole environment is such that you're seeing more and more competition on virtually every product. So automatically, when we do a portfolio review, right, some of the products we think are less attractive, right, and that's why we've taken these 4 out of the development grid. I'm sure going forward also, there will be a few which may come up, but that's just the operating reality. And if we can't do the development in a timely manner, we will have to take some strong decisions, right.

-----

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [108]

-----

Right. So it isn't just a function of the competitive landscape. It's also a function of how soon you can you hit the market. Is it fair to assess that the development of this pipeline projects was probably not in a timely fashion as we would have originally anticipated?

-----

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

-----

Possible in some cases, but I think the bulk of it is on the the account of the operating environment.

-----

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [110]

-----

Okay, got it. Fair enough. On the other side, Glenn, what we have been understanding from a few companies, sort of contracting supply and be plain vanilla segment, again this is not a copied statement particularly products in the plain-vanilla segment for now, are seeing contracting supplies and that is helping the price better, as in people are saying that prices are not falling anymore, if not increasing. Is that something that you've seen in your business as well?

-----

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [111]

-----

Glenn, I will.

\_\_\_\_\_

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [112]

-----

Yes, go ahead tomorrow.

-----

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [113]

\_\_\_\_\_

Yes. I think we're seeing selective opportunities for price increases but nothing like it might have been several years ago.

-----

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [114]

-----

Right. But if you were to box, segregate your business into a slightly more complex products that you're currently marketing including the cell called (inaudible) or any other complex product (inaudible) versus your base business which should be fairly competitive already and will be largely plain-vanilla order solids. Could you give us some sense on how the price erosion on these 2 segments have behaved over the past quarter?

-----

Robert Matsuk, Glenmark Pharmaceuticals Limited - President of North America & Global API Business [115]

-----

Yes. I think overall, I mean, it's been around 10%. I think some of the more specialized stuff has been a bit lower. But in general, we're -- some opportunities for price increases, it's more some product specific issues versus whether it's a complex generic or a simple or a solid.

-----

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [116]

-----

Got it. And Glenn, on your guidance, on the spend of being 12% of revenue. So could we take a similar number when it comes to FY '20 or '21 projections?

\_\_\_\_\_

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [117]

-----

Yes, Aditya.

-----

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [118]

\_\_\_\_\_

And this will include your Xolair biosimilar Phase III if it goes to that?

-----

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [119]

-----

So right now, we continue to maintain the same targets, right?

-----

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [120]

-----

Fair enough. Okay, money, sir, how do we manage the currency of these various geographies? So for instance, what I wanted to understand was this rupee depreciation that happened versus the USD. Would the full benefit of the depreciation be reflected in this quarter or we had hedges and therefore the benefit would reflect some...

-----

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [121]

-----

No. We -- as a policy, we never -- we don't hedge, okay. So I mean the rupee depreciation, whatever happens in terms of business will -- I mean, assuming rupee remains at 72 plus, you will see the benefit in the next couple of quarters because then you will get the full benefit of the rupee.

-----

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [122]

-----

For the full quarter?

\_\_\_\_\_

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [123]

-----

Yes, yes. For the full quarter. Whereas in the past quarters, the averages rate is only about 68, so that wasn't too much compared to the base rate that we have.

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [124] \_\_\_\_\_ Fair enough. Is a policy similar across the geographies, let's say, Russia. \_\_\_\_\_ V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [125] \_\_\_\_\_ Yes, yes. Because some of the geographies outside, when you imagine hedging the cost is too high, you probably -- doesn't make sense. \_\_\_\_\_ Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [126] \_\_\_\_\_ Okay. And Glenn, on the Chinese API price situation, has this situation stabilized somewhat in terms of price inflation of raw materials or is it still inflating? \_\_\_\_\_ Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [127] \_\_\_\_\_ Well, I think -- I mean, right now, it seems to be stabilizing and our guess is by Q3, you should see some stability in the price inflation. -----Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [128] \_\_\_\_\_ Right. Have we changed the procurement strategy from a more Chinese oriented type procurement to somewhat indigenous procurement? If yes, what is the cost differential that you are paying there? \_\_\_\_\_ Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [129] \_\_\_\_\_ It's very marginal. We have changed. Obviously, we really look at the procurement consistently, but I don't think from an impact perspective, we are seeing a significant impact. \_\_\_\_\_ Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [130] \_\_\_\_\_ Right. And sorry my last question is on the business strategy. Glenn, you mentioned that next year can be significant growth over this year because you're launching some a couple of very big products. What we want to understand from you is given

the government stance on these (inaudible) combinations and your any rupee irrational combinations and the European Russian combinations and the agencies is now pursuing [to pit in things] strategy more aggressively. Many companies it seems are not doing very well on the India front in terms of growth rates and for the past 2 guarters or so. What is your take on how this business can grow from this point onwards? And what will be the key strategy? How will you grow this business in the absence of the ability of making fixed dose combinations?

-----

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

\_\_\_\_\_

Well, I think, Aditya, fixed dose combinations have virtually no impact on our current business. So we see very strong growth coming from dermatology, respiratory, cardiovascular and metabolic. In fact, we think -- I think this will be -- we're anticipating some great product approvals which can be transformational, particularly in the diabetic space. So the next year or 2 years looks very strong for us as far as India goes.

\_\_\_\_\_

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [132]

\_\_\_\_\_

Right. So the strategy is going to be what? Because you don't invent products, right? So you either copy what is existing for the NMC Pharma campaigns when they go off patent or we in license whereas some companies that are not currently present in India. Are these 2 levers enough to drive like 10% to 15% growth in India for the foreseeable 3 to 5 years?

\_\_\_\_\_

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

\_\_\_\_\_

We think so. In addition, of course, our OTC franchise, right, I would add to that, right. So between these 3 levers, right, I think the OTC business are -- we've done a great amount of in licensing. The AKYNZEO the product, we in licensed from Helsinn and continues to go well. So we bought a bunch of things in the works as far as in licensing goes. And of course, there is some of products going off patent. And of course, there are some combinations also. I would put all of that in the mix, right? And that's what gives us the confidence that I think the next 2, 3 years, looks very strong for India.

\_\_\_\_\_

Aditya Khemka, DSP Investment Managers Pvt. Ltd. - Assistant VP Healthcare [134]

\_\_\_\_\_

Right. Sorry, Glenn, one follow-up on this as well. So on the OTC side, can you talk a bit about what we are doing currently? With regard to the OTC side business in India? What are the growth levers that you are looking at, and what is the profitability of that segment? Because I understand that the advertising and promotional costs will be up-front and the revenue sort of come later.

-----

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [135]

\_\_\_\_\_

The OTC business is at INR 200 crores plus business for us. Just 3 brands, Candid Powder, VWash, the franchise and Scalpe shampoo. And we continue to -- that business is seeing 25%, 30% growth. So we think the growth will continue to remain very strong. The margin -- we've been investing in this for the last, I would say 3 to 4, 5 years. And every year, we see margin improvement. So you're looking at mid-teen margins continuously improving on a consistent basis, right. So every year, you'll see the margin improvements coming through. So it's a strong business for us.

\_\_\_\_\_

Operator [136]

-----

(Operator Instructions) Next question is from the line of Anubhav Aggarwal from Credit Suisse.

-----

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [137]

\_\_\_\_\_

Just a question on these 4 products that we discontinued. We spent about INR 1,178 crores. The question is if we have continue the development of this, how much incremental spend was required to complete then?

\_\_\_\_\_

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [138]

\_\_\_\_\_

I mean, the expense will be substantial, Anubhav, right, for -- given where we were at in the development. So I mean, that's the reason why it just didn't make any strategic sense to continue.

-----

Anubhav Aggarwal, Crédit Suisse AG, Research Division - Associate [139]

-----

I remember earlier discussion like per molecule, participant would not have been more than \$10 million here, right. I mean we already spent \$25 million on 4 products so that's why I was asking that maybe the spend will incrementally would have been 2x of what we have spent so far or it could have been even higher.

-----

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

-----

So some of our competitors, Anubhav, paid close to \$350 million for 4 products, right. So you should -- I mean, just keep those benchmark. This complex generics can be substantial in terms of the spend. So again, I think when we took a call, it was purely a strategic call based on the pricing environment that exist versus what return we would make, right, on this product. And that's the only visibility we can give you, Anubhav.

\_\_\_\_\_

V. S. Mani, Glenmark Pharmaceuticals Limited - President, Global CFO & Executive Director [141]

-----

Anubhav, also just remember one thing that the expenditure that we have done on these products also includes up-front payments that we've made to the in licensing departments.

-----

Operator [142]

-----

(Operator Instructions) We would take the next question from the line of Saion Mukherjee from Nomura.

-----

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

\_\_\_\_\_

One question on the licensing deal with Harbour Biomed for GBR 1302. Just wondering what's the time line you see from this product for registration in China?

-----

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

\_\_\_\_\_

So right now, Anubhav, (sic) [Saion], Harbour is filing their IND for initiating clinical trials in China. And again, in China, we think there's an accelerated approval process, right, for oncology products. So it could be pretty quick. I mean, I can't comment specifically on a specific time line, but it could be much faster than most of the other geographies.

-----

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

-----

Okay. You mean, in 2 years, you think is it possible to do to file? I mean, given the extent of trial that is required?

\_\_\_\_\_

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

-----

I mean, 2 years is very aggressive. But yes, I mean, China is constantly evolving, Saion. So we don't know how it's going to play out.

\_\_\_\_\_

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

-----

Okay. And general question on this out-licensing strategy. Because Glenn, the thing is, you mentioned about 7% to 8% of sales is going to specialty and innovation. So that's a big drag on the P&L. How do you think about this out-licensing strategy which gives you the cash flow in a way to make those business all sustainable. I mean, are there any thoughts around that because there is a significant drag on the P&L?

-----

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

-----

We clearly recognize that, Saion, and we are aggressively working on various partnerships for the innovation pipeline.

-----

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

\_\_\_\_\_

So we would -- we can expect more licensing like these -- those smaller ones, for smaller geographies for all of the other products? (inaudible) constant phenomena because we haven't seen deals very frequently.

\_\_\_\_\_

Glenn Mario Saldanha, Glenmark Pharmaceuticals Limited - Chairman, MD & CEO [150]

-----

Sure. I think you should expect both smaller deals and larger deals, both happening, right in the next 12 to 18 months, on the pipeline.

-----

Operator [151]

\_\_\_\_\_

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

-----

Jason D'souza, Glenmark Pharmaceuticals Limited - Senior VP & Head of Corporate Strategy [152]

-----

Thank you. Before we end the call, we'd like to read our disclaimer. The information statement and analysis made during this call, describing the company's objectives, projection and estimates are forward-looking statements and progressive within the meaning of applicable security laws and regulation. The analysis contained herein is based on numerous assumptions. Actual results may vary from those expressed or implied, depending upon economic conditions, government policies and other incidental factors. No representation or warranty either expressed or implied is provided in relation to this presentation. This presentation should not be regarded by recipients as a substitute for the exercise of their own judgment. With this, we would like to end the second quarter of Glenmark earnings call. Thank you, everyone.

Operator [153]

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