

Novo Nordisk A/S CPSE:NOVO B

FQ4 2011 Earnings Call Transcripts

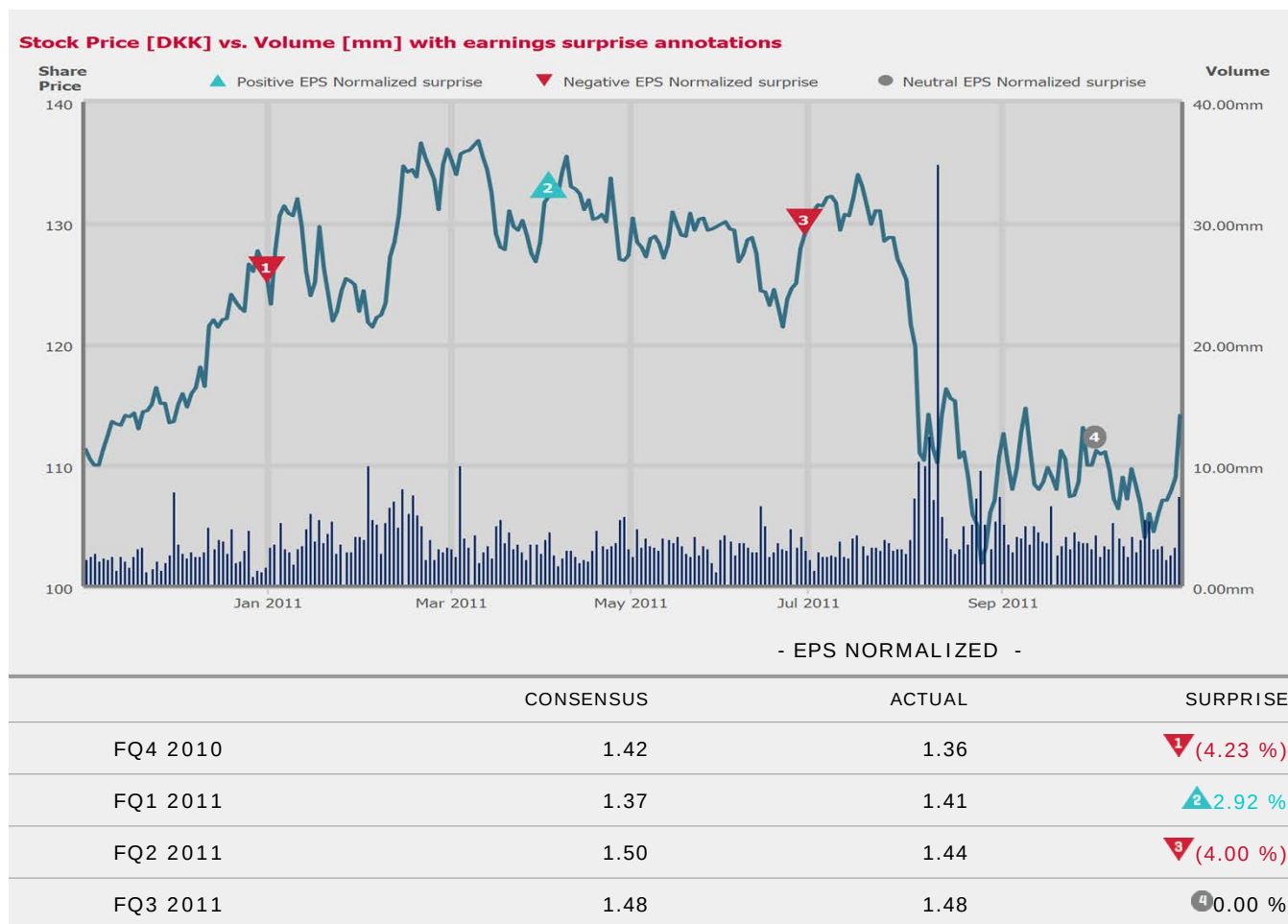
Thursday, February 02, 2012 1:00 PM GMT

S&P Capital IQ Estimates

	-FQ4 2011-			-FQ1 2012-	-FY 2011-		
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	ACTUAL	
EPS Normalized	1.43	1.67	▲ 16.78	1.57	5.78	6.00	
Revenue (mm)	17663.01	18120.00	▲ 2.59	17575.50	65749.51	66346.00	

Currency: DKK

Consensus as of Feb-02-2012 7:54 AM GMT



Call Participants

EXECUTIVES

Jesper Brandgaard

CFO & Executive VP

Lars Rebieen Sørensen

Former Chief Executive Officer and President

Mads Krogsgaard Thomsen

Executive VP & Chief Science Officer

ANALYSTS

Carsten Lønborg Madsen

Carnegie Investment Bank AB, Research Division

Luisa Caroline Hector

Crédit Suisse AG, Research Division

Mark Dainty

Citigroup Inc, Research Division

Mark Douglas Purcell

Barclays PLC, Research Division

Martin Parkhøi

Danske Bank Markets Equity Research

Richard Vosser

JP Morgan Chase & Co, Research Division

Vincent Ollivier

Presentation

Operator

Good day, and welcome to the Novo Nordisk Full Year 2011 Results Conference Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Lars Rebieen Sørensen. Please go ahead, sir.

Lars Rebieen Sørensen

Former Chief Executive Officer and President

Thank you very much and welcome, ladies and gentlemen, to this conference call regarding our performance in 2011 and our outlook for 2012. I'm Lars Rebieen Sørensen, the CEO of Novo Nordisk. With us, we have Chief Financial Officer, Jesper Brandgaard; Mads Krogsgaard, Chief Science Officer; present are also our Investor Relations Officers.

Today's earnings release and the slides for this call are available on our web page, novonordisk.com. The conference scheduled to last as usual approximately one hour. Let's start with the presentation as outlined on Slide #2. The Q&A session will begin in about 25 minutes.

Please turn to Slide #3. As always, I need to advise you that this call will contain forward-looking statements. Such forward-looking statements are subject to risks and uncertainties that could cause the actual results to differ materially from expectations. For further information on the risk factors please see the earnings release and the slides prepared for this presentation. Also note, this conference is being webcast live, and a replay will be made available on Novo Nordisk website after the call.

Turn to Slide #4. 2011 has been the good year for Novo Nordisk. Sales increased 11% in local currencies and the key sales drivers were Victoza and modern insulins. The solid sales performance has been realized in a challenging economic environment, where healthcare reforms impacted sales growth negatively by approximately 2 percentage points.

A very significant milestone in 2011 was the filing for approval of a new ultra-long-acting insulin Degludec and DegludecPlus in major markets including Europe, United States. The regulatory review of Degludec and DegludecPlus are on track in the U.S. A PDUFA action date of 29 of July this year has been issued by FDA.

Further Novo Nordisk has completed 2 extension trials of this Phase IIIa development programs for Degludec providing 2-year data on efficacy and safety of insulin Degludec [indiscernible] type I and type II diabetes respectively.

The data from the extension trial are very encouraging and confirm the safety profile of Degludec compared to insulin glargine and Mads will elaborate on this during his R&D presentation. Finally, Novo Nordisk has successfully completed the Phase IIIa program for Turoctocog alfa, a recombinant FVIII for the treatment of haemophilia A and currently expects to file for marketing authorization in major markets including United States and Europe in the second half of this year.

Turning to the financials, reported operating profit grew 18% and diluted earnings per share grew 22% in this year – in 2011. For 2012, we expect sales growth between 7% to 11% local currencies and operating profit growth of around 10% in local currencies.

Go to Slide #5. Victoza continues the steady growth performance and modern insulins continue to exhibit double-digit growth rates. In 2011, diabetes care franchise grew 13% while the biopharmaceutical franchise grew 8%, both measured in local currencies. Diabetes care now represents 76% of overall sales.

Victoza was the prime growth driver, accounting for 55% of growth in local currencies, followed by modern insulins accounting for 41% of growth. Sales in NovoSeven increased 7% in local currencies. All regions contributed to growth with international operations being the primary contributor.

Sales of Norditropin increased 5% in local currencies. Sales growth was driven by international operations, North America, Japan, Korea, partly offset by a decline in Europe.

Turn to Slide #6. 2011, North America accounted for 61% of growth followed by international operations, with 21% of growth both measured in local currencies.

Sales growth in North America was 18% in local currencies reflecting strong performance of Victoza and continued market penetration of the modern insulins. The sales growth in North America 2011 was negatively impacted by approximately 3 percentage points, due to the U.S. healthcare reform enacted in March of 2010.

European sales grew 2% in local currencies, supported by the continued solid performance of Victoza and progress for the portfolio of modern insulins. Sales growth is negatively impacted by a decline in sales of human insulin and NovoNorm and by healthcare reforms implemented during 2010 and 2011.

Sales within international operations grew 17% in local currencies driven by continued penetration of modern insulins, higher NovoSeven sales and Victoza sales. Sales in Region China increased 12% in local currencies in 2011, the main contributor of growth, sales of modern insulins especially NovoMix. Sales growth in Region China has in 2011 been negatively impacted by price reform on human insulins and NovoNorm enacted in September of 2011. Sales in Japan and Korea increased 5% in local currencies, mainly driven by Victoza and Norditropin.

Turn to Slide #7. In the last decade the global diabetes care market has grown more than 8% in value, with injectables growing close to 14% annually. Novo Nordisk continues to expand the leadership position within diabetes care and currently holds more than 24% value share of the global diabetes medication market.

Turn to the next slide for an update on Victoza. Sales of Victoza reached DKK 2.1 billion in the fourth quarter making total sales in 2011 nearly DKK 6.0 billion. The performance reflects steady penetration across key markets including United States, U.K., Germany, France, Japan, and certain countries in our international operations.

Turn to Slide #9. In the U.S. Victoza sales continues to be encouraging. We estimate that more than 270,000 people with type II diabetes are treated with Victoza in the United States today. We own the market share of close to 55% of the total GLP-1 restrictions in the U.S. and we're capturing around 62% of new GLP-1 patients. Since the Victoza launch in February 2010, GLP-1 class has grown more than 60% and now constitute 5.5% of U.S. diabetes care market measured in value.

Turn to Slide #10. In Europe, we continue to see strong uptake of Victoza in several key markets. The GLP-1 class has more than doubled since the launch of Victoza. Victoza is the leading GLP-1 product in all 3 key markets: in Europe, mainly Germany, U.K. and France. We now estimate close to 160,000 people with type 2 diabetes is treated with Victoza in these markets.

With this, I'd like to hand over to Mads, who will give you an update on research and development.

Mads Krogsgaard Thomsen

Executive VP & Chief Science Officer

Thank you, Lars. Please turn to Slide 11. Let me start with an update on the regulatory process for Degludec and DegludecPlus. As mentioned by Lars, both of the ultra-long-acting insulins Degludec and DegludecPlus have over a 3-month period been submitted for regulatory review in Europe and the U.S., plus Japan in the case of Degludec.

Furthermore, we've now submitted Degludec and DegludecPlus [indiscernible] for regulatory reviews in Switzerland and Canada. In the United States, the PDUFA action date has been set to July 29 this year and the regulatory process is proceeding as expected.

In EU, the DAY 80 drug persistent reports have been received and the European agency process follows the expected schedule. In parallel with the ongoing dialogue with the triad market agencies, Novo Nordisk will continue to submit new product applications for both products in a number of territories during 2012.

We will continuously provide updates on the regulatory progress towards approval of insulin Degludec products as part of the course of the announcements.

Please turn to the next slide for other news from the clinical pipeline. As also mentioned by Lars, Novo Nordisk has now completed both 2-year Phase IIIa Degludec extension studies in subjects with type 2 and type 1 diabetes respectively. In the type 2 diabetes extension trial, around 1,000 patients were initially randomized and 3:1 try the once-daily insulin Degludec in the FlexTouch pen or glargine, both in addition to metformin plus-minus a DPP-4 inhibitor therapy.

The HbA1c after 2 years was similar between the groups being maintained around 7% in both treatment arms with a pre-randomization baseline of around 8.2%. For Degludec, the fasting plasma glucose level stayed close to normal at approximately 6 mmol/l after the 2 years of study, which was statistically significantly lower than in the comparator group.

Furthermore, Degludec also maintained a very low risk of hypoglycaemia. Thus, the risk of nocturnal hypoglycaemic events was 43% lower with Degludec compared to insulin glargine, and the rate of severe hypoglycaemia was likewise statistically significantly lower for Degludec. In the type 1 diabetes phase of basal bonus trial, more than 600 patients were originally randomized 3:1 to either using Degludec or glargine, both given once daily in addition to mealtime insulin [ph].

HbA1c study completion was around 7.4% in both treatment arms. At the end of this extension trial Degludec also maintained a lower risk of confirmed nocturnal hypoglycaemia compared to glargine with a significant 25% risk reduction. In both studies, Degludec demonstrated a good safety and tolerability profile and there were no apparent differences between the treatment groups with respect to adverse events and standard safety parameters.

Turning to progress on the rest of the diabetes portfolio, the European Commission has now approved the use of Levemir during pregnancy following a review of results from a Novo Nordisk Phase IIIb study in 265 pregnant women with type 1 diabetes.

As regards the other [ph] clinical pipeline Novo Nordisk has completed a single-dose Phase I trial with a novel oral long acting insulin, NN1953. We've also completed single and multiple-dose Phase I trials with a novel oral long-acting GLP-1 analogue, NN9924.

For all GLP-1 insulin clinical projects the overall goal for the comprehensive Phase I program is to identify the ideal combination of novel analogue and formulation to allow for one or more one stage tablet preparations to be selected for full development. So far we are witnessing encouraging progress in both programs. Furthermore, the injectable GLP-1 portfolio is on track where the Liraglutide obesity project has completed recruitment in October last year, while the [indiscernible] and the Idegaira compound trials are nearing completion of patient recruitment.

Finally, once-weekly Semaglutide is ready for the Phase III [indiscernible] decision once its profile could be compared up against the clinical Liraglutide clinical data emerging later this half prior to the selection of which once-weekly GLP-1 compound to develop from Phase III.

Moving now on to biopharmaceuticals, 4 important events took place during the fourth quarter. In hemophilia, we finalized the largest registration drug conducted for FVIII product. Thus, Turoctocog alfa was given to 150 hemophilia A patients with 75 exposures each and the safety profile was positive with no patients developing inhibitors and only a very low level of adverse events being reported.

The high success rate of 85% was observed in on-demand treatment of bleeds and a low level of new bleeds occurred. Turoctocog alfa furthermore demonstrated a 100% success rate in preventing surgical bleeds. Equally positive results were found in a paediatric study of 63 patients. Based on these results, Novo Nordisk will work towards submission of the regulatory [indiscernible] to agencies during the second half of this year.

Recently we received a Complete Response Letter from the FDA regarding recombinant FXIII application for congenital deficiency. The U.S. agency asks for additional information prior to considering the FXIII product for approval and we'll work closely with FDA to provide such additional data.

Turning to growth hormone, Novo Nordisk has initiated a Phase I trial with a once-weekly human growth hormone compound with a protraction mechanism that is novel to this field. The aim of the trial is to investigate the safety, tolerability, pharmacokinetics and dynamics of the compound in healthy male subjects.

Lastly in information, Novo Nordisk has completed a Phase IIa trial of anti-IL-20 in 67 patients with rheumatoid arthritis. The trial met its primary endpoint of a statistically significant effect on the efficacy measure DAS28-CRP after 12 weeks of treatment with an acceptable safety and tolerability profile. Based on these positive data, Novo Nordisk expects to progress anti-IL-20 into Phase IIb later this year.

The Phase IIb trial will investigate the following principle elements of relevance to a potential future Phase III program: selection of final dose and patient population, identification of significant clinical differentiators to allow for commercial success and validation of clinical response biomarkers.

With that, over to Jesper for an update on the financial results for 2011.

Jesper Brandgaard

CFO & Executive VP

Thank you, Mads. Please turn to the next slide. In 2011, sales increased by 9% measured in Danish kroner to DKK 66.3 billion and by 11% in local currencies compared to 2010.

The underlying production economy improved by 40 basis points in 2011. The improvement is mainly due to a positive product mix impact driven by the conversion from human to modern insulins.

As a consequence of the negative currency impact of 20 basis points, the reported gross margin improved by 20 basis points to 81.0 in 2011. Total non-production-related cost increased by 5% in local currencies and by 3% reported in Danish currencies.

S&P cost increased by 4% primarily, reflecting increased sale promotion in the U.S and China and the sales force expansion in the U.S. in the fourth quarter of 2010. Moreover, selling and distribution costs in 2011 include cost related to the manufacturer's fee part of the U.S. healthcare reform.

R&D cost in 2011 remained at an absolute level similar to that in 2010. Whereas the cost level in 2010 reflects the execution of the Phase IIIa programs for both Degludec and DegludecPlus, the cost level in 2011 reflects the initiation of pivotal trial activities within diabetes care, obesity and haemophilia.

Operating profit increased by 18% to DKK 22.4 billion. In local currency, the growth was 22%. Net financial show an expense of DKK 449 million in 2011 compared to an expense of DKK 605 million in 2010.

For 2011 the foreign exchange result was an expense of DKK 322 million compared to an expense of DKK 1,341 million in 2010. The foreign exchange loss in 2011 reflect losses on foreign exchange hedging contracts primarily related to the Japanese yen due to the appreciation versus Danish kroner in 2011 compared to the exchange rate level prevailing in 2010 and also in the last quarter of 2009.

The effective tax rate for 2011 was 22%, which is slightly lower than the latest guidance of a tax rate of around 23% for the full year of 2011. The lower-than-expected tax rate primarily relates to a reassessment of tax provisions in the fourth quarter of 2011.

Please turn to the next slide. The 2 graphs illustrate the development of the U.S. dollar and the Japanese yen versus the Danish kroner. The tables on the right show the expected annual impact on operating profit of a 5% movement in each of our key invoicing currencies and the current expense of hedging for the same currencies.

During 2011, the average exchange rate for the U.S. dollar versus the Danish kroner was approximately 5% lower than in 2010. However, at present the value of the U.S. dollar is approximately 6% above the average level of 2011.

Please turn to the next slide. As the Annual General Meeting on 21 of March, 2012, the Board of Directors will propose a 40% increase in dividend to DKK 14 per share of DKK 1, corresponding to a payout ratio of 45.3 percentage point. For 2010, the payout ratio was 39.6, adjusted for the impact from divestment of shares in ZymoGenetics, the payout ratio was 42.8 for 2010.

In addition, the Board of Directors has approved a new DKK 12 billion share repurchase program to be executed during the coming 12 month. Novo Nordisk will initiate this program in accordance with the Safe Harbor regulations. J. P. Morgan will act as the lead manager of the program and will in this capacity repurchase shares on behalf of Novo Nordisk for an amount of up to DKK 2.5 billion during the trading period starting today, and ending on 25 April 2012.

Please turn to the next slide for an update on the financial outlook for 2012.

Novo Nordisk expects sales growth in 2012 of 7% to 11% measured in local currencies. This is based on expectations of continued market penetration for Novo Nordisk's key products, as well as expectations of continued intense competition, generic competition to oral anti-diabetic products, and a continued impact from the implementation of healthcare reforms primarily in the U.S. and Europe.

Given the current level of exchange rate versus Danish kroner, the reported sales growth is expected to be around 4 percentage points higher than the growth measured in local currencies.

For 2012, growth in operating profit is expected to be around 10% measured in local currencies. The outlook for growth in operating profit reflects significant costs related to the expected launch of the ultra-long-acting insulin Degludec. Given the current level of exchange rate versus the Danish kroner, the reported operating profit growth is expected to be 7 percentage points higher than the growth measured in local currencies.

For 2012, Novo Nordisk expects a net financial expense of around DKK 1 billion. The current expectation primarily reflects a net loss on the foreign exchange contracts hedging Novo Nordisk's exposure in U.S. dollar, Japanese yen and Chinese yuan. The accounting effect of the foreign exchange hedging contracts has, in line with Novo Nordisk's accounting policies, been deferred for loss recognition in 2012 when the hedged operating cash flows will be realized. The effective tax rate for 2012 is expected to be in the range from 22% to 23%.

Capital expenditure is expected to be around DKK 3.5 billion, primarily related to investments in filling capacity for biopharmaceuticals in Denmark, filling capacity for insulin in Kaluga, Russia, and new prefilled device production capacity in both Denmark and the U.S.

Expectations for depreciation, amortization and impairment losses are around DKK 2.9 billion and free cash flow is expected to be around DKK 18 billion.

Novo Nordisk operates with 4 long-term financial targets to balance short and long-term considerations, thereby ensuring a focus on shareholder value creation. The target Return on Invested Capital or ROIC has been changed to operating profit after tax to net operating assets to more accurately describe the financial elements included in the ratio.

Further, the target has been increased from 290% from previously 70%. The previous target level assumed that proposed accounting rules regarding treatment of operating leases, the draft International Financial Reporting Standard Leases would have been implemented in the near future.

However, the implementation has now been postponed, and the actual content is currently unclear and as such, this assumption no longer applies.

All of the above expectations in our outlook are based on the assumption that the global economic environment will not significantly change business conditions for Novo Nordisk during the remaining part of 2012 and that currency exchange rate, especially the U.S. dollar, will remain at the current level versus the Danish kroner during the remaining part of 2012.

This concludes the financial update. Now back to you, Lars.

Lars Rebien Sørensen

Former Chief Executive Officer and President

Thank you very much, Jesper. Now ladies and gentlemen, we are moving into the Q&A part. We are ready to take the first question.

Question and Answer

Operator

[Operator Instructions] We'll take our first question today from Luisa Hector of Credit Suisse.

Luisa Caroline Hector

Crédit Suisse AG, Research Division

Could we start with the situations, the marketing situation following the termination of the Lilly, Amylin partnership, maybe just update us in the situation in the GLP market? And also on the insulin side whether, as a consequence you're seeing increased effort from Lilly? That's the first question. And then maybe a couple of others, would you expect an FDA panel for Degludec? And just a quick check on the -- there was a non-recurring adjustment of provisions in the admin line in the fourth quarter, just a quick check on that please?

Lars Rebien Sørensen

Former Chief Executive Officer and President

This is Lars Rebien Sørensen, the CEO. So we have a non-recurring, which Jesper will take care of at the end. We have a question for the panel, FDA potential and FDA panel of Degludec which Mads Krogsgaard will take care of. Then I'll start with the first question, which in a way were linked as I understood it. So the first comment is in relationship to the Lilly, Amylin breakup. This was not entirely surprising to us in that we saw very early on that Lilly had their own ambitions within GLP-1 area. So clearly, this has created some disruption between the two parties, which sort of caused a distraction. With the approval of BYDUREON in the United States, which is the key opportunity for such a product, we are anticipating that it'll have a couple of effects on us. First of all, it's our anticipation that by adding significant a sales force behind BYDUREON in the U.S., the whole GLP-1 market section is getting increased share voice in the diabetes market. Hence, it is going to support an expansion of the GLP-1 market, which is in everybody's interest; it's in the patients' interest, it's Novo Nordisk's interest. And then when you compare the 2 products we have long stated that we believe we have a very competitive product on the market with Victoza against BYDUREON. This has been shown by Amylin themselves in a head-to-head trial with Victoza where we showed that we had better glucose control, we had better weight profile, better antibody profile. And the only advantage that has been claimed as we can see it is the once-weekly injection by BYDUREON up against the once-daily very flexible injection with a very modern convenient device that Victoza is administered in. So in our assessment we have a strong competitive position against BYDUREON, but they're going to help us built the market. So we would anticipate that we will continue to be able to hold on to a capture rate north of 50% thereby remain the leaders in the GLP-1 segment in the United States even after the BYDUREON entry. With regards to Lilly, Lilly has become very focused on their insulin business. I believe their insulin product are now the second-most important in terms of their top line franchises. They have been quite aggressive. As you have noticed we have been speaking about since the last year, 1.5 years, basically gaining business early in 2011 in the United States, gaining business in Europe, in the U.K. in particular, but also gaining business in overseas markets in China, due to reimbursement status of their modern insulins, but also very aggressive pricing on their human insulins in China. So it doesn't really change the matters that much for us. We are seeing Lilly as the short-term most active competitor in the insulin field, but they are active primarily in the area of human insulins. You could say if you are being facetious that they are buying short-term revenues in a segment which are likely to disappear at least as far as the developed markets are concerned. But of course, we anticipate the human insulins be available in China for great many years into the future. So those were the comments on Lilly, Amylin, BYDUREON and insulin and then on to Mads, to have or not to have a pen.

Mads Krogsgaard Thomsen

Executive VP & Chief Science Officer

That is indeed the question. And at this point, I can say Luisa that we have received no information from the FDA in this regard, i.e., as to scheduling an advisory committee. That being said, obviously Nordisk is preparing as if one were to come for this sheer reason that one needs to be prepared for every single

situation. So we are continuously preparing for everything and when that is said, we have a path towards the PDUFA action date on July 29, laid forward by the agency in terms of when, which kind of inspections, et cetera, et cetera are taking place, so we're already a very busy bunch of people in regard to Degludec both busy with the FDA, Europe and even now also other countries.

Lars Rebien Sørensen

Former Chief Executive Officer and President

And then, Jesper, on the administrative line there was a non-recurring in the fourth quarter which is...

Jesper Brandgaard

CFO & Executive VP

Yes, we have increased the provision for employee-related costs like jubilees, et cetera, which was related to the lower, the permanent lower level of interest, we haven't included discounting of those future obligations and that is increasing our provisions in the tune of DKK 50 million. And if you look at the admin cost on a full-year basis there are, let's say, included this year in the growth cost in total those DKK 50 million and additional DKK 50 million which you could relate to one-time relocation cost at the headquarters side, which I wouldn't expect to reoccur next year. So overall probably to the tune of DKK 100 million in non-recurring cost in 2011, 50 of them in Q4 related to employee provisions.

Operator

Thank you. We'll take our next question today from Martin Parkhøi of Danske Bank.

Martin Parkhøi

Danske Bank Markets Equity Research

Martin Parkhøi. I will stick to the 2 question rule. Firstly with respect to China, Lars, you are quoted on some news flash as stating that one of the reasons for the growth, low growth in China is also to some increased competition from local manufacturers. If local manufacturers are aspiring to be a big competitor, how do you draw a parallel to the risk that you're seeing for biosimilar in all other regions because you've always stressed that you were still holding on in China, despite a lot of local producers? And then the second question with respect to Victoza, I guess that in the guidance you have given to the market, you at least have been wrong since it's now already a clear blockbuster in 2011. We're seeing more than DKK 500 million in quarter-on-quarter growth in, from Q3 to Q4. So it's a no-brainer that if that will continue then it will explode also in 2012. Can you give us some kind of guidance on why we should expect quarter-on-quarter growth at that because this has just increased from Q2 to Q3 and then Q3 to Q4?

Lars Rebien Sørensen

Former Chief Executive Officer and President

Thank you, very much Martin and thanks for reminding us, keeping us on it. With regards to China what I've mentioned is that we have seen some market share erosion in human insulins. I would say most is probably Eli Lilly product, but I do believe we've also lost some to some of the local manufacturers. Price levels are getting very low, they can only compete in the local markets. So and they have to have some revenues. So I don't see that necessarily translating into a big risk on the international scene. I don't believe these companies have significant capacity wherewithal to compete at us globally. But it is a factor. We're somewhat disappointed about the fact that the Chinese market did not rebound in the fourth quarter and what I stated I think also to some of the wires today is that it's our anticipation that when we look at 2012 we should have consumed the upheaval in the marketplace due to the health care reform, but also due to the fact that we have gotten the human insulin on these local essential drop lists and tenders in the provincial governments. And therefore we're getting into a situation where we have a more stable market situation and straight bidding. And our anticipation is that we will see growth rates of our business in China of around 15% going forward. We see, as you saw also in 2011, 30% growth of our modern insulins and flat human insulin business. When you look at the IMS market, the IMS market predicts a growth, volume growth at the moment of around 18% in China. Now they are biased in the sense that they're taking their measurements at the hospital level and the government in China is pushing the patients to this at the community clinics. And so this is not really representing the volume and that

growth is actually slower than what has been seen at the hospital level due to simple lack of healthcare capacity to diagnose and to treat diabetic. So we think with 15% we should be able to hold our own in terms of market share in China. Long-term can we remain at 60%, that's probably a stretch. We have an ambition to stay above 50%, so in all our plans we have calculated with some erosion of market share going forward. But that's the nature of things in terms of insulin in China. With regard to blockbuster, that's an interesting one. I think I've been more right than most people on this, because I have been a little bit ahead of ourselves in terms of predicting that it would be a blockbuster in '12 and we did manage to achieve that status in '11 and that is correct. Now of course, anybody's guess. We can make further projections. We now have competition and of course, that means that there will be some of the new patients coming in, rather than going to Byetta, they will be going to BYDUREON. So we're anticipating that we will keep a capture rate of 50% plus, so therefore it may not increase our market share in the GLP-1 segment. Key question for us is market growth and that is a little bit uncertain. When you look at some of the early markets, where we've introduced the product, they have confirmed our original notion, which was that we should see a potential of the GLP-1 segment to be at 10% of the overall value of the diabetes market. This has been arrived at in Denmark, which is the first advanced; other markets are trying to put volume restrictions on the introduction, but, so that's the long-term guidance we can give you. Use 10%, but that will be arrived at, at different point in time in different countries.

Martin Parkhøi

Danske Bank Markets Equity Research

But just a little follow-up on that because as you've seen in the, from the second to the third quarter you almost saw an increase of DKK 300 million. Then in the -- from the third to the fourth quarter you saw almost DKK 550 million increase. If I just add DKK 250 million to each quarter in 2011 then it will be a double blockbuster -- or sorry in '12 of course then it will be a double blockbuster already in '12, is that realistic?

Lars Rebien Sørensen

Former Chief Executive Officer and President

I don't believe that. But we are not giving guidance as you know, Martin, on individual products. I think we hope that you are right. But I don't think it's realistic. Let's move on to the next question.

Operator

And our next question comes from Richard Vosser of JPMorgan.

Richard Vosser

JP Morgan Chase & Co, Research Division

Two please. Just on the U.S. insulin market share, just from the script trends it appears you started off the year with a couple of percentage points share gain for the modern insulin, some local mix, completely different picture to the beginning of 2011. Is this just the Caremark contract? Could you talk us through the dynamics involved in taking the share there? And then the second question is just on Degludec. And just in light of the extension data, which looks good and reiterates the hypoglycaemia benefit for the product but, also in light of the austerity conditions that we see across Europe at least, could you share your comment and thinking in terms of the ability to achieve premium pricing for the product, where you're thinking about it, in terms of that?

Lars Rebien Sørensen

Former Chief Executive Officer and President

Yes, certainly. Well, yes, you're pointing exactly to some of the -- a couple of very interesting issues that dynamics you see in the market. If we take the, and I think we mentioned this last year, when Lilly became extraordinarily aggressive in the pricing, that we were not seeing a long-term future in the human insulin market. But then on the other hand, of course, we don't want to surrender all the patients to our competitors. So that meant that we actually did sharpen our pen so to speak and became more competitive. And you saw a result of this with the Caremark contract, and yes it is correct, that we have seen a pickup of our 2 main modern insulins, Levemir and NovoLog in the U.S. in the beginning of the

year as opposed to the drop that we saw in the beginning of 2011. So there's also different conditions on the Caremark contract and the contract we lost, because the Caremark contract is a looser contract. And so there's more switching and forward switching taking place. So we should stand to gain from that. So a better situation, the medium to short-term in the U.S. market. With regard to Degludec, very interesting point, that you are right, that the economic conditions in Europe doesn't seem very favorable for significant premiums. But when we look at pricing, we look at global pricing and so what you should expect to see is you should expect to see us based on a comparison to Lantus require a modest premium. And this will of course for some economies in Europe be a challenge, there's no doubt about this. Southern European countries are finding it difficult. Now that means that reimbursement and the introduction in perhaps Southern European countries are going to be slower, longer in coming and perhaps in some markets we'll not be able to launch, because we have some considerations for the rub off, the spill off effect of the price in the home market towards markets in the emerging economies. So it'll be an interesting situation that we'll actually end up with having access issues in Europe, which is a new thing, a relatively new thing on these newer modern medicines. Jesper, do you have any...

Jesper Brandgaard

CFO & Executive VP

Yes, just on the capture rate for new scripts in North America, and EMEA also for NovoLog B, some impact in recent months from the shortage that we've seen in the market from glulisine. It's a little bit uncertain how big effect it can have and it seems that, that situation has now more normalized, but I think there is an element in the pickup in our nprx, which may be related to a shortage that we've truly seen in the market.

Lars Rebien Sørensen

Former Chief Executive Officer and President

And Mads, you just had comment on hypos and Degludec.

Mads Krogsgaard Thomsen

Executive VP & Chief Science Officer

Yes, it's just a notion that of course our health economists that have worked on this ever since Phase II, they are walking down 3 roads to make sure that we create the best possible platform, and of course they are as you correctly mentioned, Richard, really supported by the data. So on safety it's about the value of reducing hypoglycaemia, as we've discussed often before. On efficacy, it's about the potential for in a real-life situation actually improving glucodynamic measures, because of the enhanced safety, which we're not able to do in a Phase III treat to target trial. But you can come back to the agencies at later points with the real-world evidence. And then finally because of the both flexibility and also because of the consistency of the molecule that's also something about the cost of glucose drips and so on. So overall, what Lars alluded to as the modest premium is something that is fully justifiable from a health economic perspective, but of course there are these regional differences as described by Lars.

Lars Rebien Sørensen

Former Chief Executive Officer and President

Yes. And you have probably read the recent article in New England Journal of Medicine where they have investigated medicines that cause hospitalization due to side effects, and insulin is actually the second-most commonly causing hospitalization due to hypoglycaemia, which is of course a side effect or an unwanted [ph] effect from the insulin. So it is indeed not a trivial problem. And if Kåre Schultz had been here today, he would have likened the occurrence of severe hypos even though they are relatively rare in type 2 diabetics to the situation of airbags in cars, I would imagine that, it is a very small proportion of the airbags that have been installed in cars around the world that are ever used for this intention. But they are there because when the event occurs, it can be traumatic and it can be damaging. And so I think it's the same notion that we like it in a way to [indiscernible] hypos; these are not trivial. These render the patients unable to fend for themselves, if it's during the night. It can have serious cerebral effects, if it happens to in day, it can cause accidents and other unpleasant things. So we think we've got a good case for building off there. Thank you. Next question please?

Operator

And our next question today comes from Carsten Madsen of Carnegie Bank.

Carsten Lønborg Madsen

Carnegie Investment Bank AB, Research Division

Yes, thank you very much. Just 2 questions here to start off with. One for, first one for Mads, on your long-acting Victoza or Semaglutide, and why you are now starting the Phase I trial with the LA Victoza. Does this mean that you are closer to making a decision about which one of these moleculars you'll work on going forward? And also in that relation, will you skip Phase II and go directly into Phase III, when you have complete Phase I trials? Second question is for Jesper on CapEx, you guide for DKK 3.5 billion for CapEx for 2012. That is actually the same level as you have been spending for last 3 years despite the fact that your franchise has expanded significantly. When will you ever need to spend more money on CapEx? Thank you.

Lars Rebien Sørensen

Former Chief Executive Officer and President

I know that Jesper will be delighted to talk about this, but why don't we start with Mads.

Mads Krogsgaard Thomsen

Executive VP & Chief Science Officer

Right. As regards new molecule, namely Semaglutide, first of all we'll be announcing the long-awaited Phase II data at conferences this year. That being said, of course, we've also kind of shaped up the molecule in preparation of this decision as to whether this one goes into Phase III or the Liraglutide depot formulation receives further development. Semaglutide will be ready for entering Phase III with a highly competitive profile, whereas Liraglutide depot, we simply don't know yet. And that's the whole dilemma, that we're getting to new clinical data later in this first half of the year, and then they will enable management come summertime to make a decision of which one to enter into final development. Can we skip Phase II for the Lira depot? In principal, yes, as we've see other depot preparations such as BYDUREON. But BYDUREON actually did do one Phase II trial, so it is an open-ended question. And I think I'd like to wait until summertime and you'll get very insightful on exactly what we are doing with which of these molecules. But it's a nice position to be in, so happy selection process.

Lars Rebien Sørensen

Former Chief Executive Officer and President

Thank you. And then Jesper, CapEx?

Jesper Brandgaard

CFO & Executive VP

Yes, we've guided to the level of DKK 3.5 billion. And I think the guidance I would give for the range 2012 to '14 would be an investment level in the ballpark of 5% of sales. I think we will spend resources and invest in facilities enable us to roll out a new device that you will see us use with Degludec, DegludecPlus. And longer term replacing the placement device and there will be investment going in that direction. You've seen that included, expanding our facilities in Denmark and U.S. in the first wave. But of course, as we're selling more than \$300 million of FlexPen per year a significant investment is longer term involved in this area, so that would be a key area of investment. And then also longer term, if there's one thing that can make a change to the level of bulk production facilities we need for API production, that would be the success that Mads would be able to demonstrate for the portfolio of all protein projects we have under development both in terms of GLP-1s and also the insulin projects. However it's still early stage, so I think it will probably beyond '14 for those significant investments to materialize if we are successful in that area. So I think you are comfortable in using a 5% guidance for 2012 to '14, that will probably suffice for now.

Operator

And our next question comes from Vincent Ollivier of BNP Paribas.

Vincent Ollivier

The first one is on the FVIII, can you please explain us again, what is the differentiation for this drug versus the existing and well-established competitors, in order for you to grab material market share medium term and long term? And also I have 2 questions with regards to margins. First R&D in 2012, is it fair to expect stabilization around DKK 9.6 billion in absolute terms? And regarding the gross margin is it also possible to assume an improvement of the same magnitude as what we still over '10 to '11?

Lars Rebieen Sørensen

Former Chief Executive Officer and President

I'll start with the first then Mads can pitch in and Jesper can take some of the questions on the margins. FVIII is a biosimilar FVIII basically, to the leading VIII product in the market, FVIII. The trial that we have conducted has demonstrated a very, very stable process and no antibody reactions on the trial participants even though it's the largest trial that's been conducted both in adults and in children. So it's an effective and very safe and so far no antibody eliciting FVIII. See we've developed this, because we want to develop a long-acting FVIII and this is the backbone on which we'll be doing a long-acting FVIII. And so our ideal situation is that we will have this product as a biosimilar FVIII and an improved FVIII in terms of the long-acting FVIII, which will give us a wonderful situation when going to market where we can, especially in emerging markets where there are in a way as you always know 2 segments. There is one segment, which can afford high-end product such as a potential new long-acting VIII and then there are price-sensitive segments, which are public health segments, where a biosimilar of FVIII might be well suited. So that's the whole idea. Of course, the proof of the pudding in the eating and whether we can differentiate the long-acting FVIII, and Mads can perhaps say a few things about this before we go to the margins.

Mads Krogsgaard Thomsen

Executive VP & Chief Science Officer

Yes, Lars, and I think you covered it nicely, so I'll just very briefly, it is indeed a B domain [indiscernible], so of course, it's a different molecule from the others in the industry, but essentially it is a biosimilar approach in terms of having [indiscernible]. Now many people are asking me, "Why didn't you see a single inhibitor patient, even though you had 150 in the trial?" And the short answer is, we cannot know, and nobody knows, which episode [ph] or which protein structure or which contaminant or which immunological phenomena in the individual boys or men that precipitates inhibitors, nobody knows the underlying mechanisms in that regard. All we can relate to is the fact that we have neither in kids or boys, nor in adults, seen any inhibitors at this point. So if you combine a very nice efficacy, very nice effi profile with a formulation into a very decent device that we will take the opportunity to also wrap it into, then I think we are in a situation to grab market share, as Lars alluded to. Of course there are also different markets and more and more tenders going on even in the western markets nowadays. And of course [indiscernible] now will have a very nice offering in that regard and also serving as a backbone for an ATP [ph]. So I think it's a good position

Lars Rebieen Sørensen

Former Chief Executive Officer and President

And Jesper, then on R&D and other improvement to productivity?

Jesper Brandgaard

CFO & Executive VP

Yes, thank God Mads didn't take the long version. In terms of the gross margin, we have guided to this year, we believe we can make an improvement in our gross margin between 50 basis points to 100 basis points where we last year have realized 40-basis-point improvement. We've had a expected bigger impact from healthcare reform last year. And we also see a value in the rollout of the Victoza that will have a recurring effect on our gross margins. So 50 basis points to 100 basis points in local currency improvement and on top of that it's our anticipation with the current currencies that you probably should anticipate some 40-basis-point currency impact in the positive direction. So 2012 at present looks like it will be quite positive on the development in gross margin. In terms of the other cost ratio, we are expecting a selling and distribution ratio in the same ballpark as where we were in 2011. So let's say

around 29%. And the actual amount is going to be very dependent on the precise approval of Degludec, especially in the U.S. In terms of R&D ratio between 14% to 15% to sales, which of course will then imply that we will see a significant growth in absolute terms compared to last year. So I saw the stable absolute level of R&D investment in 2011 as a normal situation. Known orders are continuing to expand our R&D activities and we also expect to do that. We have initiated a portfolio of clinical trials in the second half of 2011 and those costs will impact us on a full-year basis in 2012. So R&D ratio, 14% to 15%. In terms of admin ratio we are moving towards the 4.5 percentage point to sales in admin ratio. So admin should continue to grow significantly less than the top line. So that would be some guidance on the individual cost ratios.

Operator

And our next question comes from Mark Dainty of Citi.

Mark Dainty

Citigroup Inc, Research Division

Just one quick one, probably for Mads on the FVIII. Just wondering what the -- what's required between having the data in hands now and filing in the second half? That seems to be a reasonably lengthy timeframe. Are you waiting for anything else or is that just a little bit of caution?

Lars Rebien Sørensen

Former Chief Executive Officer and President

We are very happy that you asked this question in this call. Because we wonder ourselves, so Mads, maybe you can elaborate on this?

Mads Krogsgaard Thomsen

Executive VP & Chief Science Officer

Well, first of all the latest data, the pediatric data, it just came in very, very recently indeed. So I don't think it's that profound [ph], but at the same time we are also of course cognizant of the fact that if there were an intellectual property out there we'd make sure that we never infringe on any. So it's a question of both technicalities and all other things put together and that gives us the submission in the second half and we'll be more specific about it later on in the year.

Operator

And our next question comes from Mark Purcell of Barclays.

Mark Douglas Purcell

Barclays PLC, Research Division

One question on GLP-1's, one on insulins and Lantus. In terms GLP-1s, can you help us understand what proportion of global value share could the ex-U.S. become in the future, just trying to understand some of the dynamics between the sort of 1.2 and 1.8 mix split? How BYDUREON is doing outside the U.S in markets it's launched? It wasn't in your chart, it was just the Victoza, exenatide comparison? And how successful you think these volume caps could be, so first question ex-U.S. GLP-1 and how large this could be as a proportion of the market in Victoza? And then the second question, you just mentioned that there are going to be some countries going forward that are a little bit more price sensitive when it comes to their insulin choice. And I just wondered if you could hazard a guess in terms of what proportion of the market you believe could stomach a 10%, 20%, 30% premium for Degludec over Levemir and what proportion of the market would be much more attracted to biosimilar glargine formulations from [indiscernible] and Lilly I guess which should be entering the market in 2015?

Lars Rebien Sørensen

Former Chief Executive Officer and President

This is Lars Rebien here. In terms of overseas GLP-1 market, whether we can use the model that we described from our developed markets of a 10% value, I think it's a stretch because the nature of these

markets are that there is a large public sector which is very, very low price and in fact generic, and then generic insulins are also used in those markets. So I find it a stretch to see in the next 5 to 7 years that markets like China, markets like India, markets outside of the developed markets will arrive at 10% of the total value of the diabetes market being GLP-1s. In regards to BYDUREON, BYDUREON has had a reasonable decent launch in Germany; more modest success in the U.K. The real proof of the pudding is United States as you can see also from our numbers, that 65% of the business is coming from the U.S. So it is whether or not they'll make it or break it in the U.S. which is important. And so we could say so far from what we've seen from our perspective, it has been modestly successful and following very much to the trajectory (sic) [trajectory] that we had anticipated. In terms of how one should think about, for instance, European markets in terms of, which are going to be price sensitive going forward, that's a tough call. But I mean if we just look at assuming that markets such as France, Germany, U.K., Scandinavian markets and also some of the Northern Eastern European markets are reasonable to get through with innovation, you could probably take 60-40 as a split whereas the 60% of the market in Europe might be amenable to a premium whereas 40% would be more long-winded discussions and more perhaps accepting biosimilar approach. And so that would be my rough guess, but it's completing guesswork right now.

Jesper Brandgaard

CFO & Executive VP

And Mark, in terms of the distribution of usage of the GLP-1 outside the U.S. it's our assessment that in the reimburse markets you're looking at something like 90% of the patients using the 1.2 microgram version of the product, so that's the most predominant form used. Also the general weight in some of the IO markets is lower. So you probably should anticipate the lower dose version used and then bear in mind that the improved version in Japan is an 0.9 per microgram, so that's some guidance on the amount of drug used.

Lars Rebien Sørensen

Former Chief Executive Officer and President

Yes and then we think the final question. Okay, go ahead, go ahead?

Mark Douglas Purcell

Barclays PLC, Research Division

Sorry, guys. And in terms of cap, how do you think that's going to work out, because obviously, it's pretty difficult to get anything paid for here in the U.K. But as a proportion of the diabetes market with the kind of the gradient you're showing on Slide 10, you're getting close to 9%, talk [ph] to one of the proportion of value of the diabetes market in U.K. and France is already at 10%. So I'm just wondering when and if these caps are actually going to come in, how effective they're going to be? Because in some of these markets Europe, you're already hitting your kind of long-term target, as it were.

Lars Rebien Sørensen

Former Chief Executive Officer and President

Yes, but I do think the whole issue for us is that we get the product into the marketplace, and we get an ability to present the clinical benefits from the product. So yes, I do think it's going to be difficult for the authorities to make those caps effective, because the medical profession and the patient associations, they really see these as a very, very beneficial treatments that effectively deals with their diabetes in a very low risk way and then they have all the other virtues of weight lowering, blood pressure lowering. So it is going to be difficult, but it's going to be temporary measures that will be put in place in many markets.

Jesper Brandgaard

CFO & Executive VP

And you could see, Mark, that the 10% and ambition level we gave for GLP-1 out of the total diabetes care segment was given on a global base. If you think that's a realistic level, we've seen individual markets reaching above that. And I think the key deciding factor here is really how long time can we make patients stay in good control on a product like Victoza, and if the stay time can go beyond 2 or 3 years, of course

then the number of patients on the product will gradually grow. We have seen a steady growth in the number of patient on Victoza, and we estimate currently that we have more than 0.5 million patients on Victoza. And long as we continue to see a steady increase in that, I don't think -- I think it's going to be hard for healthcare regulators to take patients off a drug that keeps them in good control with limited hassle for the physician and limited risk of hypoglycaemia.

Lars Rebien Sørensen

Former Chief Executive Officer and President

So ladies and gentlemen, unfortunately I was soliciting the last question, but we've already run over time and we have an investor call in the city that have to run off to. We thank you all for participating this afternoon. Thank you for your interest in Novo Nordisk. And we will be continuing to come back, hopefully with good results.

Jesper Brandgaard

CFO & Executive VP

Thanks.

Operator

That concludes our conference call for today. Ladies and gentlemen, thank you for your participation. You may disconnect your line.

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