

# Share

Quarterly update for investors from Novo Nordisk **November 2009**



changing diabetes®



**NovoRapid®**  
celebrates 10 years  
on the market



**New data: diabetes**  
increasing globally



**Good results for**  
patients with  
intensified insulin  
treatment

**15%**  
sales increase in the  
first nine months of  
2009

**30%**  
increase in operat-  
ing profit

**15%**  
increase in net  
profit

**28%**  
increase in sales of  
modern insulins

Novo Nordisk continues to increase market shares in the modern insulin market and our portfolio of modern insulins was the key driver of the solid business performance in the first nine months of 2009.

The European launch of Victoza®, the first once-daily human GLP-1 analogue, is progressing well, and we expect to continue the Victoza® launch in more European countries during 2009 and 2010. We expect formal feedback from the United States Food and Drug Administration regarding the regulatory process for liraglutide in the fourth quarter of 2009.

In the area of insulin development, we are very satisfied with the recent progress of the new generation of insulins, SIBA and SIAC. Novo Nordisk is the only company with a new generation of insulins in late-stage clinical development.



Lars Rebien Sørensen  
President and CEO

# Good control with intensified treatment

Three-year results from the 'Treating to Target in Type 2 Diabetes' (4-T) study were presented in October at the International Diabetes Federation Congress in Montreal, Canada.

The study showed that irrespective of the treatment regimen, patients could achieve good blood glucose control with a very low rate of major hypoglycaemia even as they intensified their insulin treatment.

The 4-T trial, sponsored by Novo Nordisk and Diabetes UK, enrolled 708 patients

whose blood glucose levels were too high despite therapy with two oral agents (metformin and sulphonylurea).

## Improved understanding

Initially, patients received either NovoMix® 30 twice-daily, NovoRapid® three times a day or Levemir® once daily. However, if blood glucose levels remained too high after the first year, a second type of insulin was added to the treatment.

"We are proud to have co-sponsored this trial, which I believe in the future will be seen as a significant advancement in our understanding of how to initiate and intensify insulin treatment in patients with type 2 diabetes as their disease progresses," says Mads Krogsgaard Thomsen, chief science officer at Novo Nordisk.

An article about the study has since been published online in the *New England Journal of Medicine*. ■

*At Novo Nordisk's booth at the IDF Congress modern insulins and devices were demonstrated to visitors.*



# New data: diabetes increasing globally

Recent data from the International Diabetes Federation (IDF) reveals that the number of people with diabetes worldwide in 2010 has been upgraded to 285 million. IDF predicts that if the current rate of growth continues unchecked, the total number will exceed 435 million in 2030.

This appears from the 4th edition of the IDF Diabetes Atlas, and is the third time in a row that both the current and future numbers of people with diabetes are raised.

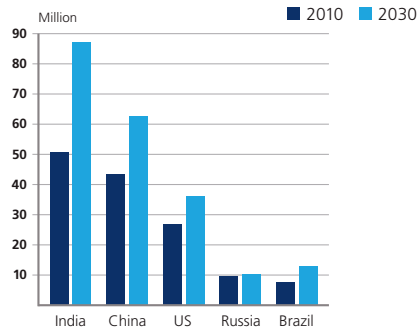
In 1985, the best data available suggested that 30 million people had diabetes worldwide. In 2000, the numbers were revised to just over 150 million. And in less than 10 years this number has almost doubled. Diabetes now affects 7% of the world's adult population.

## Spread and spend loop-sided

The data also shows that people in low- and middle-income countries are bearing the brunt of the epidemic. According to

IDF, more than 70% of all people with diabetes live in the poorer countries of the world, and this trend will continue. The five countries with the greatest number of people with diabetes today, and the projected 20-year trends, are shown in the graph below.

Yet, more than 80% of diabetes spending is in the world's richest countries and not in the poorer countries. In 2010, spending on diabetes as a percentage of total health expenditure worldwide is estimated to be 12%. ■



## First look at Victoza® sales in Europe

Victoza®, the first once-daily human GLP-1 analogue, has been launched in Germany, the United Kingdom and Denmark. Launch activities are progressing well in these markets and in-market penetration is in line with best-in-class launches within diabetes care.

In Germany, Victoza® has now obtained more than 1% of the total diabetes care market and more than 40% of the GLP-1 market, both measured in weekly value market shares.

## New approvals in Japan

In Japan, NovoRapid Mix® 50 and NovoRapid Mix® 70 have recently been approved by the Ministry of Health, Labor and Welfare. Both products have been approved for the treatment of adult type 1 and type 2 diabetes patients. Novo Nordisk expects to launch both NovoRapid Mix® 50 and NovoRapid Mix® 70 in 2010 in Japan when reimbursement discussions are finalised.

# 15%

sales increase in the first nine months of 2009

# 2.5

percentage points improvement in gross margin

# 30%

increase in operating profit

# 15%

increase in net profit

## Performance in the first nine months of 2009

Novo Nordisk increased operating profit by 30% in the first nine months of 2009.

- Sales increased by 15% in Danish kroner and by 11% in local currencies.
  - Sales of modern insulins increased by 28% (24% in local currencies).
  - Sales of NovoSeven® increased by 15% (11% in local currencies).
  - Sales of Norditropin® increased by 15% (9% in local currencies).
  - Sales in North America increased by 29% (17% in local currencies).
  - Sales in International Operations increased by 18% (16% in local currencies).
- Gross margin improved by 2.5 percentage points to 79.5% in the first nine months of 2009, primarily reflecting continued productivity improvements and a positive currency impact of around 1 percentage point.
- Reported operating profit increased by 30% to DKK 11,714 million. Adjusted for the impact from currencies and non-recurring costs in 2008 related to the discontinuation of all pulmonary delivery projects, underlying operating profit increased by around 15%.
- Net profit increased by 15% to DKK 8,445 million. Earnings

per share (diluted) increased by 18% to DKK 13.90.

- Novo Nordisk continues the constructive dialogue with the United States Food and Drug Administration (FDA) regarding the regulatory process for liraglutide. Formal feedback from the FDA regarding liraglutide, a once-daily human GLP-1 analogue, is still expected in the fourth quarter of 2009.
- For 2009, expectations for growth in operating profit measured in local currencies are increased to around 15% and reported operating profit growth is now expected to be around 3 percentage points higher than the operating profit growth in local currencies.

Lars Rebieen Sørensen, president and CEO, said: "The robust sales growth for our portfolio of modern insulins is the key driver of the solid business performance in the first nine months of 2009. The launch of Victoza® in Europe is progressing well and we are seeing strong in-market penetration in the first-wave launch countries, Germany, the United Kingdom and Denmark."

### DIABETES CARE

Sales of diabetes care products increased by 15% measured in Danish kroner to DKK 27,898 million and by 11% in local currencies compared with the first nine months of 2008.

## Modern insulins, human insulins and protein-related products

In the first nine months of 2009, sales of modern insulins, human insulins and protein-related products increased by 16% in Danish kroner to DKK 25,882 million and by 11% measured in local currencies compared with the same period last year, driven by North America and International Operations. Novo Nordisk continues to be the global leader with 51% of the total insulin market and 45% of the modern insulin market, both measured by volume.

The portfolio of modern insulins is the main contributor to growth and sales increased by 28% in Danish kroner to DKK 15,757 million and by 24% in local currencies compared with the first nine months of 2008. All regions realised solid growth rates, with North America accounting for 52% of the growth followed by Europe and International Operations. Sales of modern insulins now constitute 65% of Novo Nordisk's sales of insulin.

## BIOPHARMACEUTICALS

In the first nine months of 2009, sales of biopharmaceutical products increased by 15% measured in Danish kroner to DKK 10,118 million and by 10% measured in local currencies compared with the first nine months of 2008.

### NovoSeven®

Sales of NovoSeven® increased by 15% in Danish kroner to DKK 5,330 million and by 11% in local currencies compared with the first nine months of 2008. Sales growth for NovoSeven®

was primarily realised in Europe and International Operations. The sales growth for NovoSeven® primarily reflected increased sales within the congenital bleeding disorder segments as well as within acquired haemophilia. Treatment of spontaneous bleeds for congenital inhibitor patients remains the largest area of use.

### Norditropin®

Sales of Norditropin® (ie growth hormone in a liquid, ready-to-use formulation) increased by 15% measured in Danish kroner to DKK 3,230 million and by 9% measured in local currencies compared with the first nine months of 2008. North America and Europe were the main contributors to growth measured in local currencies. Novo Nordisk is the second-largest company in the global growth hormone market with 23% market share measured by volume.

### Other products

Sales of other products within biopharmaceuticals, which predominantly consist of hormone replacement therapy (HRT)-related products, increased by 12% in Danish kroner to DKK 1,558 million and by 7% in local currencies. This development primarily reflects continued sales progress for Vagifem®, a topical oestrogen product, countered by generic competition in the US for Activella® (Activelle® outside the US), Novo Nordisk's continuous-combined HRT product. The low-dose version of Activelle® was launched in Europe in April 2009 and has been available in the US since 2007. →

**15%**  
increase in total  
diabetes care sales

**15%**  
increase in  
biopharm sales

**18%**  
Increase in  
International  
Operations sales

**29%**  
increase in North  
American sales

## Quarterly numbers for Novo Nordisk in 2008 and 2009

(Amounts in DKK million, except number of employees, earnings per share and number of shares outstanding)	Q3 2009	Q2 2009	Q1 2009	Q4 2008	Q3 2008	Q2 2008	Q1 2008	% change 2008–2009(Q3)
<b>Sales</b>	<b>12,517</b>	<b>13,001</b>	<b>12,498</b>	<b>12,583</b>	<b>11,246</b>	<b>11,110</b>	<b>10,614</b>	<b>11%</b>
Gross profit	9,832	10,391	9,990	10,047	8,640	8,556	8,201	14%
Sales and distribution costs	3,502	3,837	3,844	3,558	3,155	3,178	2,975	11%
Research and development costs	1,884	1,849	1,744	2,439	1,579	1,980	1,858	19%
– Hereof costs related to AERx®	-	-	-	-	50	(155)	(220)	
Administrative expenses	666	693	679	749	633	626	627	5%
Licence fees and other operating income (net)	34	78	87	73	51	74	88	(33)%
<b>Operating profit</b>	<b>3,814</b>	<b>4,090</b>	<b>3,810</b>	<b>3,374</b>	<b>3,324</b>	<b>2,846</b>	<b>2,829</b>	<b>15%</b>
<b>Operating profit (excl AERx®*)</b>	<b>3,814</b>	<b>4,090</b>	<b>3,810</b>	<b>3,374</b>	<b>3,274</b>	<b>3,001</b>	<b>3,049</b>	<b>16%</b>
Share of profit/(loss) in associated companies	(7)	(11)	(35)	4	(58)	(3)	(67)	(88)%
Financial income	9	166	142	(82)	306	429	474	(97)%
Financial expenses	209	361	412	226	66	21	368	217%
Profit before income taxes	3,607	3,884	3,505	3,070	3,506	3,251	2,868	3%
<b>Net profit</b>	<b>2,755</b>	<b>2,991</b>	<b>2,699</b>	<b>2,330</b>	<b>2,,664</b>	<b>2,471</b>	<b>2,180</b>	<b>3%</b>
Depreciation, amortisation and impairment losses	657	533	607	752	560	567	563	17%
Capital expenditure	726	557	413	764	448	328	214	52%
Cash flow from operating activities	5,039	2,608	4,148	3,204	3,673	2,916	3,070	37%
Free cash flow	4,242	2,062	3,626	2,421	3,210	2,589	2,795	32%
Equity	34,874	34,086	31,345	32,979	32,173	33,046	31,251	8%
Total assets	52,589	51,246	50,205	50,603	48,990	48,478	47,534	7%
Full-time employees at the end of the period	28,497	27,998	27,429	26,575	26,360	26,060	25,765	8%
Basic earnings per share (in DKK)	4.62	4.96	4.44	3.82	4.34	3.99	3.51	6%
Diluted earnings per share (in DKK)	4.58	4.91	4.41	3.80	4.30	3.96	3.48	7%
Average number of shares outstanding (million)	596.4	603.1	607.4	609.3	614.2	618.6	620.9	(3)%
Average number of shares outstanding incl dilutive effect of options 'in the money' (million)	601.4	607.9	612.7	614.4	618.6	623.5	626.3	(3)%

\*) Costs related to the discontinuation of all pulmonary diabetes projects.

→ **OUTLOOK**

Novo Nordisk still expects sales growth in 2009 at the level of 10% measured in local currencies. This is based on expectations of continued market penetration for Novo Nordisk's key strategic products within diabetes care and biopharmaceuticals as well as expectations of continued intense competition. Given the current level of exchange rates versus Danish kroner, the reported sales growth is now expected to be around 1.5 percentage points higher than the growth rate measured in local currencies.

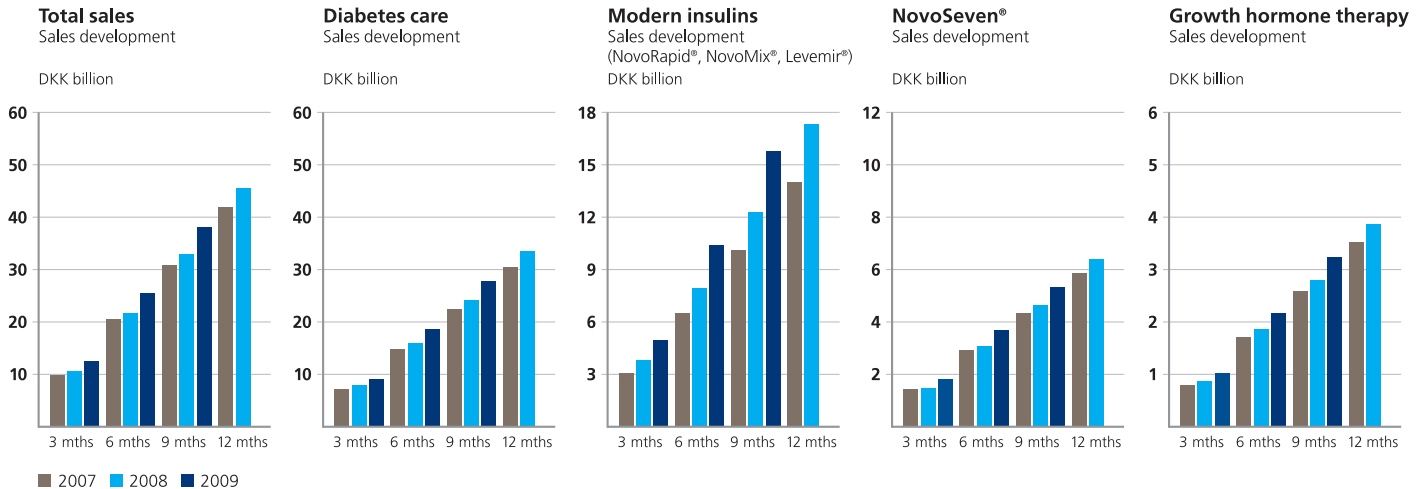
For 2009, growth in operating profit is now expected to be around 15% measured in local currencies. The increased expectations primarily reflect further improvement of the gross margin and slightly lower expected re-

search and development costs for 2009 due to timing of phase 3 clinical trial programmes. Given the current level of exchange rates versus Danish kroner, the reported operating profit growth is now expected to be around 3 percentage points higher than the growth rate measured in local currencies.

For 2009, Novo Nordisk now expects a net financial expense of around DKK 750 million. The current expectation reflects significant foreign exchange hedging losses, primarily related to the US dollar and the Japanese yen.

The effective tax rate for 2009 is still expected to be around 23%.

Capital expenditure is now expected to be around DKK 2.5 billion in 2009, primarily reflecting timing of activities in relation to the new insulin



formulation and filling plant in China. Expectations for depreciations, amortisation and impairment losses of around DKK 2.6 billion are unchanged, whereas free cash flow is expected to be at least DKK 11 billion, primarily reflecting the lower level of capital expenditure.

With regard to the financial outlook for 2010 it is Novo Nordisk's intention to provide detailed guidance on expectations in connection with the full-year release of financial results for 2009 scheduled for 2 February 2010. At present, the preliminary plans for 2010 indicate 5–10% sales growth and more than 5% growth in operating profit, both measured in local currencies. Due to an expected negative currency impact following the recent significant depreciation of Novo Nordisk's main invoicing currencies the reported sales growth for 2010 is expected to be around 3.5 percentage points lower than the growth measured in local currencies, whereas the reported operating profit growth is expected to be around 7 percentage points lower than the growth measured in local currencies. The preliminary plans reflect expectations for continued solid penetration of the portfolio of modern insulins, continued global roll-out of Victoza® and progress for key products within

biopharmaceuticals. The preliminary plans also reflect expected generic competition for oral antidiabetic products, impact from a potential US healthcare reform, and a continued intense competition within both diabetes care and biopharmaceuticals.

All of the above expectations are based on the assumption that the global economic downturn will not significantly change the business environment for Novo Nordisk during the remainder of 2009 and in 2010. In addition, the above expectations are provided that currency exchange rates, especially the US dollar, remain at the current level versus the Danish krone during the remaining part of 2009 and in 2010. Novo Nordisk has hedged expected net cash flows in a number of invoicing currencies and, all other things being equal, movements in key invoicing currencies will impact Novo Nordisk's operating profit. ■

*The full company announcement, including detailed outlook for research and development, can be found at [novonordisk.com](http://novonordisk.com)*

## Forward-looking statement

Novo Nordisk's reports filed with or furnished to the US Securities and Exchange Commission (SEC), including company announcements as well as the company's *Annual Report 2008* and Form 20-F, both filed with the SEC in February 2009, and written information released, or oral statements made, to the public in the future by or on behalf of Novo Nordisk, may contain forward-looking statements. Words such as 'believe', 'expect', 'may', 'will', 'plan', 'strategy', 'prospect', 'foresee', 'estimate', 'project', 'anticipate', 'can', 'intend', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance identify forward-looking statements. Examples of such forward-looking statements include, but are not limited to

- statements of plans, objectives or goals for future operations, including those related to Novo Nordisk's products, product research, product development, product introductions and product approvals as well as cooperations in relation thereto,
- statements containing projections of or targets for revenues, income (or loss), earnings per share, capital expenditures, dividends, capital structure or other net financials,
- statements of future economic performance, future actions and outcome of contingencies such as legal proceedings, and
- statements of the assumptions underlying or relating to such statements.

In the company announcement, examples of forward-looking statements can be found under the headings 'Outlook 2009', 'Research and development update', 'Equity' and 'Legal issues update'.

These statements are based on current plans, estimates and projections. By their very nature, forward-looking statements involve inherent risks and uncertainties, both

general and specific. Novo Nordisk cautions that a number of important factors, including those described in the company announcement, could cause actual results to differ materially from those contemplated in any forward-looking statements.

Factors that may affect future results include, but are not limited to, global as well as local political and economic conditions, including interest rate and currency exchange rate fluctuations, delay or failure of projects related to research and/or development, unplanned loss of patents, interruptions of supplies and production, product recall, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, reliance on information technology, Novo Nordisk's ability to successfully market current and new products, exposure to product liability and legal proceedings and investigations, changes in governmental laws and related interpretation thereof, including on reimbursement, intellectual property protection and regulatory controls on testing, approval, manufacturing and marketing, perceived or actual failure to adhere to ethical marketing practices, investments in and divestitures of domestic and foreign companies, unexpected growth in costs and expenses, failure to recruit and retain the right employees and failure to maintain a culture of compliance.

Please also refer to the overview of risk factors in 'Managing Risks' on pp 24–25 of the *Annual Report 2008* available on the company's website, [novonordisk.com](http://novonordisk.com).

Unless required by law Novo Nordisk is under no duty and undertakes no obligation to update or revise any forward-looking statement after the distribution of the company announcement, whether as a result of new information, future events or otherwise.



## NovoRapid® celebrates 10 years on the market

Ten years ago in October, Novo Nordisk launched its rapid-acting modern insulin: NovoRapid® (NovoLog® in the US).

Since first launched in Switzerland, NovoRapid® is now sold in 127 countries worldwide. It is today the world's most widely used rapid-acting insulin, and it continues to grow.

Over the last decade, NovoRapid® has accumulated a vast quantity of supportive scientific research including the largest

ever study involving pregnant women with type 1 diabetes. It is approved for use in type 1 and type 2 diabetes patients, children from the age of two, adolescents, pregnant and breastfeeding women, the elderly and patients with renal and hepatic impairment.

NovoRapid® achieved blockbuster status (sales totalling 1 billion US dollars in a year) in 2007. ■

## New generation of insulins enter phase 3 clinical development

Ten thousand patients to be enrolled globally.

Under the names BEGIN™ and BOOST™, respectively, the large trial programmes with around 10,000 patients in total are executed in a sequence of four waves.

The first wave for both programmes has been initiated and the first trials have completed recruitment; the second wave is expected to be initiated during the fourth quarter of 2009.

The programmes consist of several trials which will compare SIBA and SIAC with a broad selection of other pharmaceutical products for treatment of diabetes. ■

# BEGIN™

# BOOST™

## Venturing into inflammatory diseases

In September, Novo Nordisk inaugurated its new Inflammation Research Center in Seattle.

The inauguration is an important milestone in the building of a clinical pipeline in inflammatory diseases. With Novo Nordisk's expert knowledge of chronic diseases, proteins and immunology, the company is uniquely positioned to conduct research into inflammatory disorders, because important treatments for these disorders will be protein-based as well.

"The Seattle site will help us build a presence in inflammation. We now have biopharmaceutical experts working together across continents – in Beijing, China; Seattle, US; and Måløv, Denmark – to develop improved treatments for inflammatory diseases, which are critically needed," says Terje Kalland, senior vice president of Novo Nordisk's Biopharmaceuticals Research Unit.

Novo Nordisk decided to build the research centre in Seattle as that is one of the top four US biotech clusters providing a 'centre of excellence' in biopharm research and development.

### Unmet medical needs

Millions of people worldwide are affected by inflammatory diseases, yet it is estimated that pharmacological treatments meet the needs of less than 30% of these patients.

Examples of autoimmune diseases include rheumatoid arthritis, multiple sclerosis, lupus, inflammatory bowel disease and psoriasis.

Novo Nordisk aims to develop protein therapeutics for these diseases and currently has several product candidates in clinical development. ■

*With an inflammatory disorder such as rheumatoid arthritis, even ordinary tasks can be a huge challenge.*





In a packed conference room at EASD, participants listened attentively to the presentation of the meta-analysis.

## Levemir® safety documented in new analysis

At the annual meeting of the European Association for the Study of Diabetes (EASD) held in Vienna, Austria, in September this year, Novo Nordisk presented results from a new meta-analysis on the safety of Novo Nordisk's long-acting modern insulin, Levemir®.

The meta-analysis was performed in response to the June 2009 online publication in *Diabetologia* of four observational studies that, while inconclusive due to methodological limitations, suggested a potential link between another long-acting insulin analogue, Lantus® (insulin glargine), and cancer.

The Levemir® meta-analysis assessed

the relative risk of a cancer diagnosis during clinical treatment with Levemir®. It covered a total of approximately 9,000 patients in 21 randomised, controlled trials and compared the incidence of cancer in patients treated with Levemir® to that of patients treated with either human insulin (NPH insulin) or insulin glargine.

The studies comparing Levemir® to NPH insulin revealed that treatment with Levemir® was associated with a statistically significant lower incidence of cancer than with NPH insulin treatment.

The meta-analysis has since been published online in *Diabetologia*, the journal of the EASD. ■

## AGM and shareholders' meeting 2010

Next year's Annual General Meeting (AGM) will be held on 24 March 2010 at 14.00, followed by the shareholders' meeting at 17.00, both at Bella Center in Copenhagen.

Invitations for both meetings will be distributed in February 2010.

The AGM will be conducted in English with simultaneous interpretation into Danish. Questions asked in Danish will be translated into English. Coffee will be served after the AGM and participants will be able to meet the company's Board of Directors and members of Executive Management.

The shareholders' meeting will be conducted in Danish, and provides an opportunity to meet with the entire Executive Management team. The company's chairman of the Board will present what was approved at the AGM earlier the same day. After the meeting, Novo Nordisk will host a light dinner buffet.

To vote by proxy go to [novonordisk.com](http://novonordisk.com) prior to the 2010 AGM from 26 February to 21 March. Admission cards for the AGM and the shareholders' meeting can also be ordered on [novonordisk.com](http://novonordisk.com) up until 21 March.

# Large study to investigate diabetes in emerging markets

Markets outside Europe, the US and Japan are set to be one of the major future growth engines for Novo Nordisk. And yet, there is limited information about diabetes in these countries.

Novo Nordisk plans to change that with A1chieve™, the largest observational study ever conducted in diabetes.

The study includes 60,000 people with diabetes. They come from 29 countries on four different continents. The participating countries cover two-thirds of the world's population.

## Generating knowledge

The primary purpose of A1chieve™ is to collect data on the safety profile of Levemir®, NovoMix® and NovoRapid®/NovoLog® in populations outside Europe, Japan and the US. So far, the products' safety profiles are primarily based on studies done in people from Europe and the US. The study will also measure efficacy.

Two hundred million people – more

than 70% of all people with diabetes in the world – are found in emerging markets.

“To do our job well, we need to know everything there is to know about these groups of people,” says Patrick Loustau, senior vice president

of Global Marketing in Novo Nordisk.

Patients in A1chieve™ are not like diabetes patients from the Western world. There are differences in diet, culture and genetics. Yet international treatment guidelines in general are based on data from Western countries. ■

*A1chieve™ will affect a huge number of lives. Professor Sekkal Fawiza from Algeria is on the study's Advisory Board.*



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**Product names** Not all products mentioned in *Share* have been introduced worldwide. Trade names may vary from country to country. **Photos:** Thomas Willads, Novo Nordisk, among others.