Business strategy: 'Our focus is our strength'

If Novo Nordisk's business strategy were to be described in one word, it would have to be 'focus'.

ach year, a team of people from different parts of Novo Nordisk's global organisation is tasked by senior management to explore the business environment, analyse trends and come back and challenge Novo Nordisk's strategy based on the findings.

Novo Nordisk's corporate strategy is the result of this process, which ends when the Board of Directors approves the updated strategy in June. In the following months, it is anchored in the annual business and organisation plans, balanced scorecards and performance targets.

The direction and the core elements of the strategy do not change fundamentally from year to year, but are adjusted whenever signals of change occur in Novo Nordisk's business environment. The adjustments ensure that Novo Nordisk is capable of meeting current and emerging challenges and opportunities.

The current business environment has plenty of both. It is characterised by slow economic growth and austerity measures in some parts of the world, and rapid economic growth and urbanisation with alarming implications for public health in others. In high-income countries with ageing populations, governments and private payers are reluctant to pay a premium for new, innovative therapies. Low- and middle-income countries fight a double burden of poverty and poor health, and access to care is inadequate and unevenly distributed. Many countries with largely publicly funded healthcare systems are putting in place market restrictions for new medications and in the US, pharmaceutical companies, including Novo Nordisk, are facing increasingly tough pricing negotiations with managed care organisations and pharmacy benefit managers.

Many pharmaceutical companies are seeing major products going off patent and are unable to bring out innovative products that can make up for the lost revenue. Some have chosen to cut research and development budgets and lay off thousands of employees. Some have added generic and over-the-counter medicines to their offering, while others have created a broader service offering around their core products. And all have realised that new products will only have a chance in the market if they address unmet medical needs and are accompanied by convincing data about their health-economic benefits.

Novo Nordisk has decided to continue making large investments in research and development, strategic products and growth markets. The decision is based on a firm belief that huge unmet medical needs remain to be addressed, not least within diabetes, a disease that is growing at an alarming rate all over the world. Read more on pp 22–23.

To meet the increasing demands for data about its products' health-economic benefits, capabilities are being further strengthened within the company's market access functions. Moreover, Novo Nordisk is expanding its field force in countries where there are significant opportunities for market expansion. It is also exploring new ways of reaching people with unmet health needs. For example, pilot programmes in low-income countries such as Kenya and Bangladesh have helped improve access to products in rural areas.



A focused strategy

The three core elements of Novo Nordisk's strategy have remained unchanged for years:

First, Novo Nordisk has a sharp focus on a few diseases and conditions where it can make a significant difference. As a result of this focus, the company has built strong positions within diabetes care, haemophilia and growth disorders, while creating a platform for entering into treatments for obesity and autoimmune inflammatory diseases.

Second, activities are leveraging the company's five core capabilities:

- Engineering, formulating, developing and delivering protein-based treatments
- Deep disease understanding
- Efficient large-scale production of proteins
- Planning and executing global launches of new products
- Building and maintaining a leading position in emerging markets.

Third, Novo Nordisk has a values-based management system formalised in the Novo Nordisk Way. Read more on p 4. A key element of the Novo Nordisk Way is the Triple Bottom Line business principle, which was written into the company's Articles of Association at the Annual General Meeting in 2004. It states that Novo Nordisk "strives to conduct its activities in a financially, environmentally and socially responsible way".

This is the company that 24.3 million patients rely on for their daily medication, where more than 38,000 employees work and in which more than 130,000 investors have bought shares.

The five strategic focus areas



1. Expand leadership in diabetes

382 million people worldwide are living with diabetes and it is predicted that by 2035 close to 600 million people worldwide will have diabetes. Read more about the diabetes pandemic on pp 22–23.

The global market for diabetes care products amounts to approximately 238 billion Danish kroner, of which Novo Nordisk products account for about 27%. The market has been growing by around 11% annually in the last decade and is expected to experience continued solid growth driven by an increased prevalence of diabetes and the need for better treatments. Of this global market, insulin accounts for 52%, oral diabetes products for 41% and GLP-1 products for 7%.

In 1923 the first patients were treated with insulin from the company that is now Novo Nordisk, and diabetes care remains its largest and fastest-growing business area.

Diabetes care accounts for close to 78% of Novo Nordisk's total sales, most of which comes from insulin and GLP-1 products. In both areas Novo Nordisk is the global market leader in terms of volume.

Novo Nordisk is well positioned to address the unmet medical needs in diabetes.

The insulin portfolio

The insulin portfolio includes:

- Tresiba® (insulin degludec), a once-daily new-generation basal insulin analogue with an ultra-long duration of action and a flat and stable action profile that reduces the rate of low blood sugar (hypoglycaemia). Read more about Tresiba® on pp 24–25.
- Ryzodeg® (insulin degludec/insulin aspart), a soluble insulin combination of Tresiba® and NovoRapid® (insulin aspart) providing both basal and mealtime glucose control.
- NovoRapid® (marketed as NovoLog® in the US), the world's most widely used rapid-acting insulin for use at mealtimes.
- NovoMix® 70/50/30 (NovoLog® Mix 70/30 in the US), dual-release modern insulins that cover both mealtime and basal requirements. These insulins can be used either to initiate or intensify insulin therapy.
- Levemir® (insulin detemir), a soluble, long-acting modern insulin for once-daily use. It provides glucose control with a favourable weight profile.

The primary goal of Novo Nordisk's diabetes research is to discover new therapies that lower blood glucose while reducing the risk of low blood sugar. A recent result of this research is IDegLira, a fixed combination of insulin degludec and liraglutide (the active ingredient in Victoza®). IDegLira is under regulatory review in the EU. Read more about IDegLira on pp 24–25.

Novo Nordisk is also developing a new faster-acting formulation of insulin aspart to be taken at mealtimes and recently initiated an extensive phase 3a programme.

In addition to new and improved injectable insulins, Novo Nordisk is also developing formulations of insulin that can be taken as tablets.

GLP-1 (Glucagon-Like Peptide-1)

With the launch of Victoza® in 2009, Novo Nordisk entered the GLP-1 therapy segment. Victoza® is a human GLP-1 analogue with 97% similarity to the natural gut hormone. Victoza® is taken once daily and, like natural GLP-1, works by stimulating the beta cells in the pancreas to release insulin only when blood sugar levels are high.

GLP-1 therapy is a significant advance in the treatment of type 2 diabetes because it lowers glucose with only a very low risk of triggering low blood sugar.

Victoza® is approved for adults with type 2 diabetes who are unable to achieve blood glucose goals with lifestyle changes and tablet-based treatment (metformin, the most widely used tablet for type 2 diabetes). In less than two years, Victoza® became the leading GLP-1 treatment globally and has steadily expanded the market for GLP-1 treatment. The market is currently valued at around 16.4 billion kroner, of which Victoza® accounts for approximately 70%. Available in more than 80 markets, Victoza® is now used by approximately 800,000 people worldwide according to company estimates.

Based on the expertise Novo Nordisk has gained through the development of Victoza®, the company is now building a GLP-1 portfolio with the intention of providing an even broader range

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Novo Nordisk's strategy Strategic focus areas

Expand leadership in **DIABETES**

Establish presence in OBESITY

Pursue leadership in HAEMOPHILIA

Expand leadership in GROWTH DISORDERS

Establish presence in INFLAMMATION

Core capabilities

Engineering, formulating, developing and delivering proteinbased treatments Deep disease understanding Efficient large-scale production of proteins

Planning and executing global launches of new products Building and maintaining a leading position in emerging markets

Novo Nordisk Way and the Triple Bottom Line business principle

of treatment options. Key projects include a once-weekly GLP-1 analogue, semaglutide, which in 2013 entered phase 3a development. Novo Nordisk is also developing formulations of GLP-1 that can be taken as tablets.

Injection devices

Novo Nordisk invented the market for insulin injection devices with the launch of the world's first insulin pen in 1985. Today, Novo Nordisk offers the world's most widely used durable and disposable devices for insulin and GLP-1, NovoPen® 4 and FlexPen®, and is currently introducing its latest innovations, NovoPen® 5 and FlexTouch®, in many markets. The development of injection devices is based on extensive studies of how patients experience their daily injections and what they want from their device. It is an area where Novo Nordisk can make a difference by developing devices that are simple, safe and user-friendly. Read more about devices



2. Establish a presence in obesity

According to the World Health Organization (WHO), obesity has reached pandemic proportions, with up to 1.4 billion adults (over 20 years old) being overweight. Of these, more than 200 million men and nearly 300 million women are clinically obese (ie BMI ≥ 30). Obesity is known to be a major risk factor in developing serious diseases such as type 2 diabetes and cardiovascular diseases.

Despite the growing prevalence of obesity globally, there are only a few pharmaceutical treatment options currently available and reimbursement for these medications is limited. The market for obesity products currently amounts to 2–3 billion kroner.

Novo Nordisk has been investigating the use of liraglutide in a 3 mg dose as a new once-daily treatment for some people with obesity, namely those with obesity-related medical conditions such as prediabetes, sleep apnoea, high blood pressure and lipid disorders. Liraglutide 3 mg is under regulatory review in the EU and the US. Read more about obesity on pp 28–29.



3. Pursue leadership in haemophilia

Haemophilia is an inherited or acquired bleeding disorder that prevents blood from clotting. An estimated 420,000 people worldwide are living with severe or moderate haemophilia. The global haemophilia drug market is estimated at 53 billion kroner and has grown by more than 4% annually in recent years.

Novo Nordisk entered the haemophilia market in 1996 when it introduced NovoSeven® for the treatment of haemophilia patients who form antibodies against traditional treatments. The company's ambition is to move from this niche into the main segments of the haemophilia A and B market and achieve a leadership position by developing improved treatment options for all patients. Read more about haemophilia on p 30.



4. Expand leadership in growth disorders

Novo Nordisk has been active in the treatment of growth hormone deficiency for almost four decades. Growth hormone therapy is most frequently used in developed countries. Globally it is estimated that more than 2 million people are eligible for growth hormone therapy.

The market for growth disorder treatments is estimated at 16.4 billion kroner and has grown by more than 4% annually since 2009. Novo Nordisk is the leading provider of human growth hormone with a global market share of 30% measured by value.

Novo Nordisk's strategy in growth hormone therapy is to expand leadership by providing innovative and convenient products and devices. Norditropin® (somatropin) is the only liquid growth hormone product with room temperature stability after first use that is available in a prefilled pen device. Novo Nordisk's newest injection device for growth hormone is Norditropin® FlexPro®, which has an easy-touch dosing mechanism.

Novo Nordisk is also developing a long-acting growth hormone formulation, currently in phase 1 trials.



5. Establish presence in inflammation

Autoimmune inflammatory diseases, such as rheumatoid arthritis and Crohn's disease, result from the immune system attacking the body's own tissues and creating a chronic state of inflammation. Many people with autoimmune inflammatory diseases do not respond adequately to current treatments.

Novo Nordisk is using its expertise in designing therapeutic proteins and within chronic disease management care to develop new treatments, particularly for patients who are unresponsive to current treatments. Novo Nordisk has built a portfolio of first-in-class compounds with three projects being investigated in phase 2 clinical studies.

The core capabilities

Engineering, formulating, developing and delivering protein-based treatments

Novo Nordisk has dedicated research and development facilities in Denmark, China, the US and India. More than 7,000 employees are involved in research and development activities throughout the company, working in partnerships with external biotech and academic researchers. Novo Nordisk's researchers have many years' experience with formulation technology, protein engineering, expression and delivery, enabling the company to continuously improve the properties of therapeutic proteins such as insulin and GLP-1. Furthermore, since 1985, when Novo Nordisk launched the world's first insulin injection device – NovoPen® – the company has developed world-class expertise in designing and producing simple and convenient devices for injecting protein therapeutics.

Deep disease understanding

Novo Nordisk has a deep understanding of the unmet medical needs associated with chronic conditions. This, together with strong relationships and numerous collaborations with external researchers and clinicians, provides a solid foundation for the company's research, development and marketing activities. One example is DAWN2™ (Diabetes Attitudes, Wishes and Needs), a study conducted in 17 countries and including more than 15,000 people with diabetes, their family members and healthcare professionals. DAWN2™ highlights opportunities for improving diabetes care, education and community support.

Efficient large-scale production of proteins

A high-quality, cost-effective global manufacturing infrastructure is a prerequisite for competing successfully in an increasingly competitive pharmaceutical market. It also enables Novo Nordisk to make treatments available at very low prices in developing countries. Novo Nordisk has a global production set-up with facilities strategically located in five countries across four continents:

- The production of active pharmaceutical ingredients is a highly specialised process and mainly takes place in Denmark, where Novo Nordisk has nine plants, including the largest insulin factory in the world.
- The production of diabetes finished products takes place in five countries: Denmark, France, the US, Brazil and China, which all have the approval and ability to export to other markets.
- In addition, Novo Nordisk has a number of smaller manufacturing plants that support local demand in selected countries.
- All production facilities operate under one global quality management system with centrally deployed standard operating procedures (SOPs) for all involved employees. This ensures a uniform and high quality standard for all products.

All manufacturing sites are held accountable for meeting ambitious targets for minimising their impact on the environment. Performance measures include energy and water consumption, CO₂ emissions and the amount of waste

generated during production processes. Read more about production on pp 36–37.

Planning and executing global launches of new products

Due to the high and increasing costs associated with developing, obtaining approval for and marketing a new medicine, most pharmaceuticals must be launched globally to optimise the return on investment. And, importantly, such launches must happen over a relatively short time so there is a reasonable period left before the product's patents expire. Through the launches of Victoza® in multiple markets over the past years, Novo Nordisk has refined this capability, which is now being utilised in connection with the launch of, for example, Tresiba®.

Building and maintaining a leading position in emerging markets

Many years of experience have helped Novo Nordisk understand the needs of new markets and forge partnerships with local stakeholders. The company's strategy has always been to establish a local organisation early – as soon as there are signs of a market developing – and to grow organically as the market develops. This has enabled Novo Nordisk to build long-term relations and a sustainable market presence, and is a key reason behind Novo Nordisk's success in rapidly developing markets such as China. Read more about Novo Nordisk's five regions on pp 31–35.

The Triple Bottom Line business principle

Novo Nordisk's strategy is underpinned by the Triple Bottom Line business principle, which ensures that financial, social and environmental impacts are considered when decisions are made. This requires systematic and respectful engagements with key stakeholders to stay attuned to their interests and expectations.

The aim is to ensure long-term profitability by mitigating risks and minimising negative impacts from business activities, and to enhance the positive contributions to society from the company's global operations.

Financially responsible: profitable for the long term

Doing business in a profitable and responsible way is the basis for the long-term viability of the company. Novo Nordisk uses four long-term financial targets to steer the business towards long-term sustainable growth. These targets help Executive Management balance growth in the short term with investments in longer-term growth such as new production facilities and research and development activities.

Socially responsible: promote healthy living – and a healthy and engaging workplace

It is Novo Nordisk's mission to help people with diabetes, haemophilia and other chronic diseases live better lives. This is encapsulated in the company's corporate commitments of Changing Diabetes® and Changing Possibilities in Haemophilia®. As a research-based healthcare company, Novo Nordisk's main contribution is to discover and develop innovative biological medicines and make them accessible to patients throughout the world.

With its deep disease understanding and patient focus, Novo Nordisk plays an active part in the fight against diabetes. The company is engaged in the prevention of diabetes through the promotion of healthy living, and is working to improve awareness, diagnosis and treatment of diabetes. Through these efforts, Novo Nordisk aims to reduce the human and financial burden of diabetes. Read more about Changing Diabetes® on pp 26–27.

Social responsibility is also about ensuring a healthy and engaging workplace for Novo Nordisk's employees. A healthy, inclusive and engaging working environment helps attract, motivate and retain the right people, and this is critical to sustain global growth and make positive contributions to society. Diversity of backgrounds and experience enriches the working environment. A diversity aspiration has been set for senior management teams. It drives strategic efforts to encourage recruitment and promotion of women and people from different nationalities



throughout the organisation. The people strategy offers global standards for equal opportunities, respect for the individual and a safe working environment. As a particular focus, the company promotes healthy lifestyles at work through its NovoHealth programme.

Environmentally responsible: preserve nature's resources

Producing more with less is not just sound household management; it is a way to help preserve scarce natural resources and proactively address sustainability challenges throughout the value chain. As its business grows, Novo Nordisk seeks to reduce the consumption of natural resources and manufactured inputs across the value chain. In addition, there is also a focus on minimising outputs in the form of emissions such as CO₂ and waste. Read more about production on pp 36–37.

Maximising the value of the Triple Bottom Line

The Triple Bottom Line business principle creates value for Novo Nordisk in three ways as it:

- makes the company more adaptive to changes in its business environment.
 This, in turn, mitigates risks and builds trust. Novo Nordisk proactively engages with stakeholders to address global and systemic challenges that could affect the company's success in the long term.
 One example is an active engagement in the development of a new set of global sustainable development goals under the auspices of the United Nations.
- 2. strengthens competitiveness. Changing Diabetes® is an example of how demonstrating social responsibility and systematic stakeholder engagements can effectively complement market strategies to drive revenue growth. Novo Nordisk has developed a method to demonstrate the business case, called the Blueprint for Change programme. Through a series of case studies, the programme documents how the company's approach to doing business in ways that are responsible and profitable creates shared value, ie benefits for both stakeholders and the business.
- 3. is an engine for innovation in collaboration with partners. One example is from the recent Blueprint for Change case study in Indonesia, one of the company's selected growth markets. The study showed how Novo Nordisk, by working with partners, can develop its business by reaching out more effectively to people with diabetes who currently do not have access to insulin treatment. The study has informed the strategy in Indonesia. Read more at novonordisk. com/sustainability.