Valuation of Novo Nordisk A/S 5th February 2015



Cand.merc. Finance & Strategic Management

Master Thesis

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Abstract

This thesis answers the research questions: "What is the fair value of a Novo Nordisk A/S B share (NOVO-B) as of the 5st of February 2015?" and finds it to be DKK337,2.

The valuation and budget is based on an industry and company description in combination with financial and a strategic analysis at the external, industry and internal level.

Key competitive elements within the industry is having efficient operations, in combination with a full product pipeline developed through extensive R&D. Where competitive elements for products is a combination of medical efficiency and patient convenience, relative to product pricing.

I find Novo to be a full-service research-based pharmaceutical firm that operates on a global scale, where the key important denominator for all products is that they are protein related.

Future industry profitability is expected to be high, due low threat of entry and low bargaining power of suppliers. Revenue growth is primarily expected to be driven by volume - through increased global obesity and diabetes prevalence - and not through pricing, as Novo will be facing increasing buyers bargaining power - in particular in the important US market – and increased pressure from biosimilars.

Novo's future market share development within the individual product segments is promising, as a loss of market share is only expected in a single segment, maintaining or increasing in the remaining, while also adding three new products to the portfolio. Combined strengthening Novo's market position.

A strong focus on protein related products, is a long-run competitive advantage relative to Novo peers, as it's a more focused strategy that creates a streamlined operation that translates into higher profitability through greater usage of production of scale and production of learning. Through financial analysis the advantage is evident historically and is considered sustainable, therefore expected to continue. Justifying why Novo's is estimated at a higher multiple than their peers.

My valuation is high relative to the traded price on the valuation day, either suggesting my estimations are to optimistic or that the stock is undervalued, where sensitivity analysis showed that differences in estimated price could be explained in different methodology when selecting risk-free rate, beta and long-term growth rate.

Due to the development in the share price, I consider my valuation as reasonable target price and therefore consider the stock as undervalued at the day of analysis.

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1 Introduction

The current share price of any publicly traded firm can easily be obtained through the stock market. The interesting question is not the current price, but if the share is currently traded at fair value, under- or overvalued. If not traded at fair value, there is a profit to be made by either buying or going short in the particular stock. But how does one analyse if a stock is traded at fair price?

Theoretically, the value of a firm is the present value of all future dividends paid to shareholders - dividends from current equity value and value expected to be gained from future free cash flows. However, as future cash flows are unknown, forecasting is necessary to understand the present value of a firm. Which is where I find my motivation for writing this thesis, as I want to examine and illustrate how an external analyst is able to subjectively estimate if a stock is traded at fair value, using strategic and financial analysis.

When selecting a case firm from a Danish perspective, Novo Nordisk (Novo) is hard to overlook, as it is the largest Danish firm measured by market capitalization. However, I do not only find Novo's size interesting, but also the firms ability to consistently achieve double-digit sales growth over a period of twelve years¹. Equally, I find Novo's primary product insulin to be interesting, as it's the primary drug used to treat diabetes. Where increased standards of living across the globe have given people the possibility to over-consume on their daily food intake. Where a sustained long-run overconsumption of food will lead to obesity, which is the main cause for people to develop type II diabetes. But how does Novo's share price reflect increasing obesity prevalence across the globe?

Through external subjective financial and strategic analysis, I therefore want to examine if Novo will be able to continue to achieve high growth rates. And if the share price as of the 5th of February reflects my expectations of future development. Thereby examining if the share is over- or undervalued, which leads me to my problem statement.

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¹ http://www.ft.com/intl/cms/s/0/a186529e-d103-11e3-9f90-00144feabdc0.html

1.1 Problem statement

The goal of this thesis is to answer the following research question:

What is the fair value of a Novo Nordisk A/S B share (NOVO-B) as of the 5st of February 2015?

Before being able to answer the research question, a number of sub-questions need to be answered:

Introduction

- What are the main areas of competition within the pharmaceutical industry?
- What are Novo's products and markets?

Strategic

- How are factors at internal and external level expected to impact Novo's performance in the future?
- What is Novo's sustainable competitive advantage?

Financial

- How does Novo's financial value drivers historically compare to their peers?
- What trends are evident to explain future development?

Forecasting

- What is the market outlook for the markets Novo participates in?
- How is Novo's market share expected to perform in the future?
- How are Novo's cost ratios expected to develop?

Valuation & Sensitivity

- How sensitive is the estimated base case share price to changes in major underlying value drivers?
- In a best/worst case scenario, what would the share price be?

The sub-questions function as a general guideline throughout the thesis, were the goal of the thesis is to estimate the share price. Implying that the analysis focuses on measurable variables that can be translated into removal or creation of value that will impact the final share price. Consequently, if I, as an external analyst, am not able to translate an analysis into measurable results, they will not contribute to estimating Novo's share price and are thus not relevant to this particular thesis. Which implies that parts of applied models can be excluded, if they are assessed not to contribute with measurable results that will impact estimated share price.

The thesis is written as "desk research" solely based on externally available information. This makes the thesis relevant to equity analysts, as the thesis is similar to what they have available, but also to individual private investors, as the thesis has a dual function that being a concrete valuation of Novo but also a framework of how private investors can make their own valuation.

The date 5st of February 2015 is chosen for the valuation, as this is the release date for Sanofi's 2014 annual report. For later analysis Sanofi will be used as a peer, and to create the best comparison, the date was selected to ensure comparison would be made on 2014 figures, rather than 2013 in the case of Sanofi. Equally, Novo and

Eli Lilly released their annual reports on the 30th of January 2015, so it's believed that the market would have had time to adjust to Novo's earnings announcement.

1.2 Structure

The thesis is structured firstly by explaining the methodology of the overall thesis, where I explain the used models and why I have decided to apply them and overlook others if they are not considered appropriate for my analysis.

The thesis continues with a general explanation of the pharmaceutical industry and how Novo fits into this context, with a description of Novo's share structure, markets and current and potential future portfolio. I have done this because in order to understand what truly drives value in the Novo share, it is deemed necessary to have an understanding of the fundamental function of the firm and its industry. The section is based primarily on (Campbell, John, 2008) and material from Novo.

With a basic understanding of the firm and its industry, I now make a strategic analysis of Novo's sustainable competitive advantages based on their resources and capabilities relative to their peers, analysing at an internal and external level. Throughout the strategic analysis I maintain a strong focus on how the individual strategic elements will affect value drivers in the forecast that follows later. The strategic analysis is primarily based on theory and frameworks from Grant (2010).

Based on the strategic analysis I continue by estimating Novo's future revenue using a top-down approach, using a segmentation of North American and a combined rest of world market. Having estimated future revenues, I estimate future cost and investment ratios. This is done in the financial analysis, firstly by reformulating financial statements making them useful to function as a baseline for future development, where possible trends will be analysed and used for a historical comparison between Novo and their peers, enabling me to estimate future performance useful for forecasting.

Combining forecasted revenues and costs ratios, enables me to prepare Novo's future pro forma accounts that functions as a base case valuation scenario.

Given future financial accounts, I perform a two stage financial valuation based on an enterprise discounted cash flow (E-DCF) model, using the approach and suggestions of Koller, Goedhart and Wessels (2010), resulting in the share price for Novo and thus answering the research question of the thesis.

For reflection, I continue by examining how sensitive the share price is to minor changes in key value drivers, in order to highlight what price range the share could be sold at given different input variables, and explain possible differences between my estimate and actual traded price.

1.3 Delimitations

- The goal is a valuation on the 5th of February. Data and information available after this cut-off date are not to be considered in the analysis as they will not have impacted the share price.
- The thesis is limited to applying the DCF and the EVA valuation approach, with multiples used as sanity check along with a discussion of real options but not its application.
- Real options approach can be very insightful but is beyond the limitation of the thesis, and will therefore not be applied.
- The thesis is written for readers, who are expected to be on cand.merc.FSM level or higher. Meaning a basic introduction to individual models and concepts is considered unnecessary, since it is assumed that the readers are already aware of these. The focus of the thesis is the application and usage of the models and not their theoretical background.
- It is assumed that no "cure" will be found for the underlying diseases Novo aims to treat, so demand for the products will continue to infinity.
- The emphasis of the thesis is limited to the markets of the pharmaceutical industry that Novo competes in.
- Only financial statements dating back five years (2010 2014) are used, based on a semi-efficient interpretation of stock prices, so historical performance does not become indicative of future performance.
- The thesis is delimited from distinguishing between accounting procedures between US GAAP and IFRS.
- Forecasting of revenue growth is limited to a separate North America forecast for key products and a combined Rest of World estimate.

2 Methodology

The following section is used to outline which primary models and theory will be used for analysis. I will explain why they are considered appropriate to answer the research question, along with a discussion of alternative models that could have been used but I have opted out.

2.1 Strategic analysis

I assume that the objective of a firm is to create value for its owners by maximizing economic profits in the long run², and therefore define strategy as: How a firm reaches their objective³ by matching their internal resources and capabilities to the opportunities provided in the external environment⁴.

The definition creates a distinction between the external environment and the internal firm level, which I translate into the strategic analysis, where the strategic analysis becomes a question of "where to compete?" – industry attractiveness – and "how to compete?" in the form of competitive advantage⁵ ⁶.

For the external environment I apply a distinction between external macro factors and industry competitiveness.

2.1.1 External macro environment - (SLEPT)

The macro economical business environment surrounding the firm influences how and where it competes, and does so on a vast amount of variables, making it is necessary to analyse? Wanting to do so, the PEST⁸ (Political, Economical, Social & Technological) framework stands without a clear substitute, but exists in great variety that differs in how finely the original model is subdivided, implying that any additional categories can fit into the original framework.

When choosing which variation of the PEST to use, consideration is towards the research question and the case company i.e. what variation fits best and will provide the best framework for analysis. Where the choice of the most extensive model LONGPESTLE¹⁰ might simply contribute to information overload.

Keeping the case company in mind, the SLEPT (Social, Legal, Economical, Political, Technological) framework has been chosen, with *legal* added as an extra category. One might argue that 'legal' would equally fit well under 'political' as legislation is made and controlled by politicians. But in the case of the pharmaceutical industry, distinguishing 'political' from 'legal' has however been assessed to contribute to the analysis, and will therefore be the applied model for the macro analysis.

Equally, the additional category variations have been opted out, as they have been assessed not to contribute significantly¹¹, and if necessary for analysis they will fit into one of the original PEST categories.

³ Grant, p.16

² Grant, p.36

⁴ Grant, p.122

⁵ Grant, p.18

⁶ Nell, P. C., Session 2, FS58 Strategic Management – Winter Semester 2011 CBS, presentation, slide 7

⁷ Grant, p.64

⁸ http://www.mindtools.com/pages/article/newTMC_09.htm

⁹ SLEPT, PESTEL, PESTLE, STEEPLE, STEEPLED, LONGPESTLE, PESTLIED

¹⁰ Local, National, Political, Economical, Social, Technological, Ethical & Legal.

2.1.2 Industry / ecosystem

Staying in the external environment but moving one stop closer towards the firm, I analyse industry attractiveness, where the firms profitability is influenced by the mix between customers, suppliers and competitors¹². Porter's Five Forces¹³ can arguably be considered as the standard framework for industry analysis - analysing the competitive forces at different levels of the supply chain. The framework has however been criticized for not being able to explain the effects industry has on firms return to assets with most being left unexplained¹⁴.

Alternatively, Cool¹⁵ argues that Five Forces's supply chain approach is too static not being able to explain the dynamic interactions between players in an industry or supply chain. Cool suggests analysing by ecosystem, where emphasis is on analysing profitability dependent on how products compliment each other in their ecosystem, e.g. the amount of gaming consoles sold depends on the amount of successful games developed by third party for the consoles, or the success of a smartphone depends on the applications developed for its system by third party.

Cool's approach of looking at firms products as complimentary and dependent on each other, provides new insight and is a different approach to analysing sources of profitability in industries. The question is, however, if Cool's approach would add value to the analysis above the original Five Forces in the case of Novo. When choosing the framework for macro analysis, the choice is thus based on, what is deemed the best fit for the case firm.

As I shall show later on, due to the nature of the products sold and developed by Novo, they don't have complimentary products equal to the examples of gaming consoles or smartphones, and are therefore traditional in their form. Consequently, with Novo being my case firm, Cool's Eco-system approach is not considered to add value above the Five Forces framework, as Novo's eco-system is more traditional in the sense that pricing, and having the best product are the competitive elements. Porters Five Forces will therefore be used as the framework for industry analysis.

2.1.3 Internal

For the internal analysis I follow the resource-based view¹⁶ (RBV) to identify competitive advantages by analysing firm resources and capabilities – where I define competitive advantage as a firms current or future ability to earn a consistent higher rate of profit than its competitors in the marketplace¹⁷.

¹¹ One could have done a discussion of each individual subcategory that has been opted out, but it has been assessed that it wouldn't contribute to the analytical value of answering the research question. The discussion has therefore been left out. ¹² Grant, p.64

¹³ M. Porter, 1979 – "How Competitive Forces Shape Strategy"

[,] M. E., "The Five Competitive Forces that Shape Strategy," Harvard Business Review 57 (January 2008): 57-71

¹⁴ Nell, P. C., Session 2, FS58 Strategic Management – Winter Semester 2011 CBS, presentation, slide 33

 ¹⁵ Cool, K. Achieving Market Leadership in Eco-Systems, INSEAD & Mile, Madinah Institute, presentation Feb 25, 2013
 ¹⁶ Barney, 1991

The primary limitation of the RBV is that it views firms as independent entities, where the firm is seen as a set of resources and the cooperation of these resources is the firms capabilities¹⁸, and ignores strategic implications of "inter-firm relationships such as alliances, joint ventures etc."¹⁹.

With regards to Novo, the limitation is not viewed as a disadvantage. Because – as I will show later on – due to the nature of Novo's products and their policy towards inter-firm relationships, Novo functions in a way that could be described as being an independent entity – consequently making the RBV suitable for my analysis.

To identify firm resources and capabilities, I build on the industry description by utilizing Porter's value chain²⁰, and evaluate Novo's profit-earning potential based on the extent of which the competitive advantage is established and its sustainability²¹.

2.1.4 SWOT

Within the field of strategic analysis, the SWOT (Strengths, Weaknesses, Opportunities and Threats) is the most widely used and known model, but it is inferior for strategic analysis, as the same identified strategic factors can usually be placed in two boxes dependent on how the situation is analysed²².

Consequently, it will not be used for strategic analysis, but is however useful as a tool to summarize the key elements from the strategic analysis, and will therefore be used for that purpose.

2.2 Valuation model

I follow the approach of Koller et al., (2010), where the valuation process starts by selecting which valuation model to utilize. Equal to the strategic analysis, the goal is to select the model that provides the flexibility needed to analyse the selected case company.

Deciding on valuation model is a choice between the primary models of Discounted Cash Flow (DCF), Relative Multiples and Real Options. DCF is chosen as the primary valuation model, as it's recommended to be the most accurate and flexible method for valuing companies ²³ and remains a favourite among practitioners and academics, as it relies on cash flows rather than accounting based earnings²⁴. Relative multiples²⁵ is used as my secondary model, as a sanity check to test if the DCF results are comparable to traded stocks.

Third option is the Real Options approach based on Merton, Scholes and Blacks method of valuing derivatives²⁶. For valuation purposes the method has been shown to be useful for valuing biotechnology firms²⁷ as individual

¹⁷ Grant, p.211

¹⁸ Nell, P. C., Session 3, FS58 Strategic Management – Winter Semester 2011 CBS, Session 3

¹⁹ Nell, P. C., Session 3, FS58 Strategic Management – Winter Semester 2011 CBS, Session 3, slide 26

²⁰ Porter, 1985 – "Competitive Advantage – Creating and Sustaining Superior Performance"

²¹ Grant, p.135 - 139

²² Grant, p.12 "Strategy Capsule 1.4" – What's Wrong with SWOT?

²³ Koller et al., p.303

²⁴ Koller et al., p.101

²⁵ Multiples for comparison are chosen with basis on Koller et al., recommendations.

²⁶ Koller et al., p.129

drugs being developed can be treated as individual NPV²⁸ projects in a combined portfolio for the entire firm. Valuing Novo through a Real Options approach is definably possible, but it's assumed that with the sources available to the author, it would not deliver a superior estimate to the DCF approach, as estimating the significant amount of probability ratios necessary, would likely be no more than best guess, and I would be unable to compare the estimated probabilities to others, decreasing the level of confidence of the final valuation.

The options approach will however not be completely discarded, but used as inspiration how to add flexibility to the DCF model, through the usage decision trees and assigning probabilities of success to products that are in in-going development. This is further useful in scenario analysis, where probabilities can easily be changed, thus reflecting the potential value of new products not yet marketed.

2.2.1 Discounted cash flow valuation

The DCF framework is available in five different versions – shown in appendix 1 –, varying in what they measure and which discount factor they apply. Both the equity cash flow and capital cash flow have been opted out, because the former has been criticized for being difficult to implement and comes recommended for financial institutions, and the latter is limited in the possibility to compare firms operating performance over time. With basis in Novo's historical capital structure and their current capital structure and dividend policy²⁹, it's assumed that Novo will maintain a fixed target debt to value ratio. The assumption removes the need for the advantages gained by using the adjusted present value model, leaving us with enterprise discounted cash flow (E-DCF) and discounted economic profit³⁰ (EVA).

$$Enterprise\ Discounted\ Cash\ flow_{t=0} = \sum_{t=1}^{n} \frac{FCFF_{t}}{(1+WACC)^{t}} + \frac{FCFF_{n+1}}{(WACC-g)^{t}} \times \frac{1}{(1+WACC)^{n}}$$

$$Discounted \ Economic \ Profit_{t=o} = \sum_{t=1}^{n} \frac{EVA_t}{(1+WACC)^t} + \frac{EVA_{n+1}}{(WACC-g)^t} \times \frac{1}{(1+WACC)^n}$$

Equation 1 - E-DCF & EVA definition - Source: Petersen & Plenborg (2012), p.180 & 217

Following Koller et al.,'s recommendation, both models will be used for the valuation. Since E-DCF and EVA yield the exact same result - if performed correctly - using both will help to ensure the validity of the model, as potential calculation errors should be eliminated.

Having settled on the E-DCF and EVA model, they set the structure for the remaining valuation, by following the structure depicted in figure 1. Showing how the combined revenue forecast and financial analysis arrive at future cash flows, which are discounted at the cost of capital, enabling us to arrive at fair value share price.

²⁷ Kellog D. & Charnes J. M., "Real-Options Valuation for a Biotechnology Company", Financial Analyst Journal Vol. 56, 2000, p.76-84

²⁸ Net Present Value

²⁹ Novo Annual Report 2014, p.44

³⁰ Also known as Economic Value Added



Figure 1 - Relationship between Growth, ROIC & Value - Source: Compiled by author/Koller et al., (2010), p.16

2.2.1.1 Forecasting and financial analysis

Forecasting begins by determining the length of the forecast, where a 10 year two stage growth model is chosen, divided into a 10-year explicit forecast for all line items, and a perpetuity follow the assumption of valuing the firm as a going concern. A 5 year forecast is common, but a 10 year forecast is selected to avoid having the majority of the value captured in the perpetuity and to ensure flexibility when ensuring that the company has reached "steady state" at the end of the forecast period.

Revenue forecast is considered to be the single most important thing to forecast and extra emphasis will be given to it, as almost all line items directly or indirectly depend on revenues³¹. Revenue forecasting is done on a top-down approach, relying on professional forecasts for the aggregated market and using the strategic analysis to focus more on the development of markets share within individual product groups. Top-down is preferred to bottom-up, as analysing on the basis of total markets is assessed to yield a more precise estimate than aggregating across customers, as data is believed to be accessible and precise.

For the remaining parts of the income statement and balance sheet, I forecast them based on an operating profitability analysis following the Du-Pont approach of Petersen & Plenborg (2012), where historical financials are reformulated and analysed in comparison with Novo's peers.

2.3 Data collection, quality & source criticism

The primary source of data in the thesis has been Novo Nordisk's annual report and annual investor presentations. It is in Novo's best interest to provide the best possible image of the firm. But as they are subject to several rules and regulations, including an external audit, the provided data is believed to be unbiased and of high quality. The same holds true for Eli Lilly and Sanofi, so I find the annual reports useful for analysis.

Further, the primary information used from the investor presentation, is provided by external firms that are believed to be unbiased towards Novo, as they are reporting on an aggregated market. Being unbiased is equally believed to be true for the several external new articles and investor reports that have been used in the analysis, as their credibility and reliability have been assessed individually when used. Bloomberg and ThomsonOneBanker have been used as data sources and are believed to be credible, as they are widely used in the financial industry and come recommended by CBS. Equally, the used literature is peer reviewed and therefore considered of high quality.

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³¹ Koller et al., p.189

3 Industry description

The purpose of this section is to provide an introductory overview of the key components in a pharmaceutical (pharma) firm and the life cycle of a pharma product. Enabling us to gain a preliminary understanding of the key areas of competition within the industry. The section is based on Campbell, 2008, and utilizes a framework that is similar to Michael Porter's value chain (M. E. Porter, 1985) but tailored to fit the pharma industry.

3.1 Value chain of a pharmaceutical firm

Pharmaceutical firms are in general divided into either research-based or generic drug manufacturer³² - with Novo being a full-service research-based firm, description is on this type.

The core business relies first and foremost on **research** and **development** (R&D) of drug compounds that after extensive testing and long trial phases - where compounds are tested to be safe for human usage - can obtain approval from authorities, creating a final product ready to be marketed.

Because the R&D period, from initiating research to final product, is very long, pharma firms do R&D on a

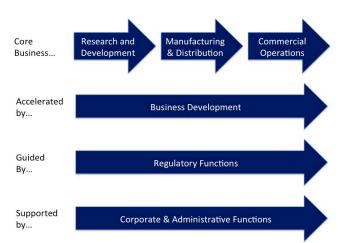


Figure 2 – Overview of a Pharmaceutical firm – Source: Compiled by author / Campbell 2008, p.10

continuing basis on numerous promising compounds. Compounds will typically reach different phases of development at different times, creating a product pipeline for the individual pharma firm.

Key sources of competitive advantage in R&D are: being first to market with a new drug – no competition from substitute products - and having the most efficient drug for the target disease, so practitioners will favour that product. Doing so by having a full pipeline so the firm can continuously release new and improved compounds. Ensuring that the firm has the best product on market.

With a final product ready for market launch, manufacturing is upscaled and packaged for global distribution. Key elements in manufacturing and distribution are developing reliable and cost efficient production facilities. Drug manufacturing is very complex and under high regulatory scrutiny, where drug approvals may be revoked if production doesn't fulfil regulatory requirements. This causes pharma firms to typically have few manufacturing facilities, making reliability a concern, as they are dependent on not having manufacturing breakdowns in order to meet customer demands. Manufacturing is further responsible for forecasting market demands in order to keep production cost at a minimum by controlling supply procurement.

Commercial operations are responsible for sales by creating consumer demand through promotional programs. Traditionally in sales, it's one consumer paying and deciding which product they wish to acquire. Pharma, however, differs from this, as demand typically starts with a physician prescribing the drug, patients

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³² Large scale manufacturing of drugs, which are no longer under patent protection.

using the drug, and then the "payers" (governments, health insurance or employers) paying the largest share of the final cost – dependent on the level of patient reimbursement. Each group of "consumers" has different incentives towards which product is prescribed.

Physicians aim to prescribe the most efficient drug, while being aware of the level of the patient's reimbursement to keep patient cost down. Patients may have drug preferences based on previous experience, impressions from direct-to-consumer promotion or cost consideration if they are not reimbursed 100%. Payers aim to incentivize prescription of the least expensive drug to minimize cost.

The mixture of incentives from all three consumer groups – highly dependent on the level of patient reimbursement – ultimately decides which drug is to be prescribed. If a general guideline has to be made, it is assumed that the chosen product will often be the "best value per dollar" product, but it depends on how the consumer mix is combined.

For commercial operations to create demand, they consequently have to influence all three different consumer groups to favour having their product being prescribed by physicians. They do so by creating a tailored sales strategy that is detailed to each product, region and consumer group, in order to drive product demand. Consequently making each of the former mentioned areas an area of competition for pharma firms. Having to be aware of not one but three consumer groups per sold product, makes it necessary to allocate substantial resources to drive customer demands.

As an example in relation to sales, pharma firms in the US rely on personal interaction with physicians through the usage of a sales force. With each person being a personal representative of the firm. In 2004 there were an estimated 60.000 sales representatives (1 for every 15 licensed physicians), with each representative costing an estimated \$300.000 in recruitment and training (Campbell, John, 2008, p. 180).

Having the core business set, pharma firms use **business development** to accelerate all levels of core business by extending the business beyond their own in-house developed compounds and capabilities. Doing so through acquisition, selling or developing partnerships that add to or enhance the firm's product portfolio and capabilities - E.g. through acquisition of compounds that can be added directly to the pipeline or technology to speed up R&D development.

Business development therefore aims to ensure that corporate goals are still achieved, when in-house capabilities are not sufficient. Keeping the firm competitive by having a stocked pipeline and accelerating R&D as much as possible.

Since drugs have the potential of being a huge health care risk to humans, pharma firms are heavily regulated to ensure public safety. **Regulatory** functions are put in place to ensure that safety is never compromised; so the firm follows its own internal policies, industry guidelines and regulatory requirements, put in place at national level. The regulatory function is therefore highly necessary if the firm wishes to obtain or keep its approval for selling its product in the market.

In the same way as support, **corporate & administrative are** functions put in place to secure the overall infrastructure of the firm, by providing legal, IT, H&R and finance functions. Neither regulatory nor corporate & administrative functions are a focus of competitive areas specific to the industry. The firm cannot function properly without, and it is thus highly necessary for the overall functionality of the firm, where the goal should be to keep the supporting functions as cost efficient as possible without sacrificing functionality that might harm the firm later on.

3.2 Product life cycle

3.2.1 Discovery and development

A final drug (product) starts with preclinical testing, where compounds are checked if they are safe for human trail in order to move on to clinical testing. According to the pharmaceutical research and manufacturers of America only 5 out of every 250 compounds advance to clinical trials.

Having entered clinical trials, compounds are mandated by the Food and Drug Administration (FDA³³)³⁴ and have to follow their rules. Compounds go through

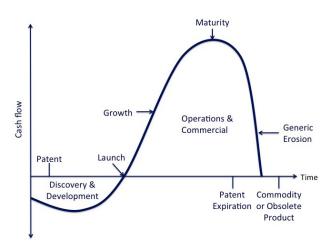


Figure 3 Life Cycle of a Successful Pharmaceutical Product, Source: Compiled by author / Campbell 2008, p.33

three test phases before reaching final approval so the compounds can be launched on the market.

1) Phase I of clinical testing is the first time the compound is tested on humans. Testing is done on a small sample group of healthy individuals. 2) Phase II trials remain on a small sample group, but now on patients with the target disease. 3) Phase III extends the trials to a larger sample group with the target disease, to test the validity of Phase II trials, so the compound works on everybody and not just some.

Standard FDA approval time is listed as ten months³⁵.

³³ Food and Drug Administration

 $^{^{34}}$ Campbell is based on the American regulatory framework (FDA). Similar exists for other countries/regions (Europe, China, etc.). For simplicity and because Novo has $\approx 50\%$ of their revenue in North America, only this region will be described. The reader should be aware that pharma firms have to fulfil the requirements of all FDA equivalents, if they wish to market their product in that individual country.

³⁵ http://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm279676.htm

When compounds have finally undergone all stages of development and reached final approval, the process will typically have taken roughly 10 to 15 years. Of the original 250 compounds – where 5 got to clinical testing – only 1 will be FDA approved to be marketed (Campbell, John, 2008, p.78-80).

Having obtained approval and reached the market, testing continues with Phase IV/post-marketing, to continuously assure the validity of the Phase III results, so the product delivers the expected results. Phase IV is either mandated by the FDA or done voluntarily by the pharma firms. Discovery and development in the pharma industry is thus a very long and expensive process, - since so few compounds make it to market – making it necessary to have a long and continuing pipeline of compounds in on-going development to ensure a steady revenue stream.

3.2.2 Patent

The product life cycle of a pharmaceutical product is closely linked to its patent. Patents are filled when a new promising compound is discovered in order to protect the intellectual property of the firm. Giving the exclusive rights to sell that compound commercially for a typical period of 20 years.

Since patents are filled at discovery and not when the compound is ready for commercial use, the effective patent life is substantially shorter than 20 years, with studies showing that the effective patent protection period is closer to 11 to 12 years. Peak sales years being an even shorter timespan (Campbell, John, 2008, p. 34) – highly incentivizing pharma firms to minimize time from patent filing to product launch, to maximize timespan of commercial use.

At patent expiration the drug formulation becomes publicly available, and sales are eroded by generic substitutes that are essentially a lower-cost copy of the original product, eliminating the profitability of the original product, ending its life cycle. As life cycle is linked to patent expiration, it's important to remember that in the pharmaceutical industry, patents may not be filled at the same time for all countries, or have the same duration, implying that a product may be at a different stage of its life cycle in individual countries.

Beyond the original product, firms attempt to protect their product by developing "isomers" that are updated improved versions of the original product, typically offering fewer side effects. Because isomers differ in structure from the original, they can be filed under a new patent, extending the patent life of their original product.

To an extent, firms can fend of competition by protecting their intellectual property – through patent protection. However, it does not protect them from other research-based firms developing drugs with similar properties, so they may still face fierce competition from substitute products. Monopoly with-in a specific drug segment can only be achieved by being first-in-class. But still then, the average time from market entry of first in class to entry of a follow-on brand has decreased significantly through time, being 10,2 years in the 1970's to 1,2 years in the late 90's (DiMasi & Paquette, 2005). Offering a very short timespan to fully capitalize on the investment, before competition kicks in.

3.2.3 Industry competition characteristics:

Beyond having cost efficient support functions I have narrowed the main areas of competition in the pharmaceutical industry to the following:

Business starts with having a product you can sell in the market place, where continuous development on multiple compounds is necessary to ensure a long continuous product pipeline, due to the high failure rate in R&D, so there is a product to be sold in the first place. Continuous R&D also needs to be done, trying to achieve having the best product on the market, so practitioners will favour the product.

R&D needs to happen as fast as possible – being accelerated by business development – to increase the effective lifetime of product patents, and to make it possible to obtain the advantage of being first-on-market, gaining monopoly on that product, although first-on-market lead times have decreased significantly since the seventies. Development needs to happen without sacrificing on regulatory requirements as it may set back product launch date, if FDA approval is not obtained.

Competition within manufacturing and distribution is to minimize cost through demand forecasting making it possible to have efficient supply procurement. Characterized by having few manufacturing facilities, making production vulnerable to breakdowns and making reliability a concern. In the same way as R&D, operations always need to match to regulatory requirements, and best practice is thus defined as finding the right balance between cost efficient operations that live up to requirements.

Key within commercial operations is that there are three consumer groups for each product sold, thus making it necessary to try to influence each consumer group. The mix of the consumer groups varies on different markets, creating a demand for a tailored sales strategy for each regional market, where sales strategy further needs to be developed at a per product level. Competition is thus characterized as being on multiple levels, with participation in all levels necessary to drive product demand as much as possible.

4 Company description

Novo is a Danish research-based pharmaceutical company dating back to 1925³⁶. The firm, in its current form, is the result of a merger between Novo Industry A/S and Nordisk Gentofte A/S in 1989. Novo was first listed on the Danish stock exchange in 1974 and later on the New York Stock Exchange in 1981³⁷. Today Novo has 41,450 employees in 75 countries and products marketed in 180 countries, making it a truly global firm³⁸. This section is based primarily on material from Novo.

4.1 Share structure

As shown in figure 4, Novo Nordisk A/S has an A/B share structure with unequal voting rights, resulting in the Novo Foundation holding the clear majority vote, with Novo A/S as the controlling company.

The Novo Nordisk Foundation is a self-governing institution that has an overall mission and vision that aims to improve the health and welfare of people, by contributing significantly with R&D in the medical field. At company level as well as university and hospital level³⁹.

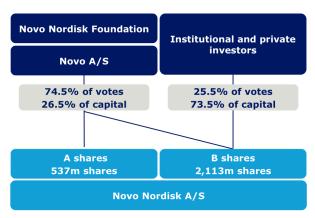


Figure 4 – Novo Share structure – Source: Novo Investor Presentation, Full Year 2014, p. 106

The Novo Nordisk Foundation and Novo Nordisk A/S have overlapping board members to ensure that the two firms have a shared vision and strategy⁴⁰, so that Novo Nordisk A/S maintains its key activities on R&D within the medical field and sales of products yielded from that R&D. Additionally, the foundation has stated that: "In accordance with the foundation's articles of association, Novo A/S is obligated to maintain a controlling interest in Novo Nordisk A/S"⁴¹.

The share structure and commitment protects Novo Nordisk A/S from hostile takeovers, ensuring that the company can continue with stable long-term R&D activities that are aligned with the overall vision and mission of the foundation and their underlying companies. Consequentially, the potential of Novo being a takeover candidate is assumed to be non-existing; therefore any matter related to takeovers are assumed to have zero effect on the Novo Nordisk A/S share price, and will not be analysed later in this thesis.

³⁶ http://novonordisk.com/images/about_us/history/history_uk.pdf

³⁷ http://novonordisk-us.com/documents/content_pages/tab_page/1_2_History.asp#

³⁸ Novo Annual Report 2014, p. 4-5

³⁹ http://www.novonordiskfonden.dk/en/content/vision-and-mission

⁴⁰ Novo Investor Presentation, Full Year 2004, p. 106

⁴¹ http://www.novonordiskfonden.dk/en/content/ownership-and-subsidiaries#info-novoNordisk

4.2 Regions

The diseases that Novo's portfolio targets are not limited geographically. Having patients on a worldwide basis equally makes Novo a global firm, with activities in 180 countries. For simplicity Novo applies a regional grouping of North America, Europe, Japan & Korea, China and International Operations to describe their business⁴². Figure 5 shows the five-year historical sales distribution between regions. Illustrating that North America is the main contributor with half of the revenue and Europe following second, and that distribution between regions is approximately stable in the period. As the main revenue contributor, North America has the primary focus of the thesis.

4.3 Products

Since Novo's establishment, focus has been on insulin that aims to treat diabetes. Later on they have expanded their product portfolio, which now aims at four different focus areas; diabetes, haemophilia, growth disorders and obesity. Being in a market leadership position on the first three and also trying to establish presence within obesity.⁴³.

SALES BY GEOGRAPHIC REGION Japan & Korea Region China International Operations Europe North America DKK billion 100 80 40 20 2010 2011 2012 2013 2014

Figure 5 - Novo Annual Report 2014, p. 14

Until recently Novo was also trying to establish presence in the market for inflammatory disorders. It was, however, decided in September 2014 that all R&D in the area was to be discontinued, to keep a stronger focus on the other key products⁴⁴. A common important denominator for all Novo products is that they are all protein related, and that Novo only deals in prescription drugs and has no OTC⁴⁵ products in their portfolio.

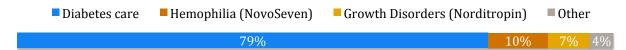


Figure 6 - Sales Distribution by product 2014 - Source: Compiled by author / Novo Annual Report 2014

As seen from figure 6, diabetes is clearly the main revenue source⁴⁶. Given that diabetes care has such a large part of Novo's revenue stream, the thesis has its main analytical focus on diabetes, as it is considered that a focus on key revenue elements will provide the best forecast.

4.3.1 Biosimilar vs. generic erosion⁴⁷

The product life cycle description showed that products in the pharmaceutical industry are subject to generic erosion from competition post patent expiration date. Although this is true, the subject needs to be further described in relation to Novo.

⁴² Novo Nordisk Annual Report 2014

⁴³ Novo Annual Report 2014

⁴⁴ Novo Annual Report 2014, p. 16

⁴⁵ Over the Counter

⁴⁶ Obesity isn't represented in figure 1, because products are still in development and not marketed yet.

⁴⁷ The section is based on: Rotenstein, Ran, Shivers, Yarchoan & Close, 2012. All quotes originate from this article, unless otherwise mentioned. Page number after a quote thus refers to which page of the article the quote is taken.

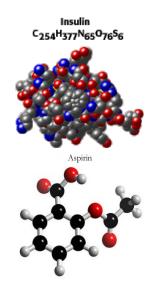


Figure 7 - Molecular structure of Insulin and Aspirin - Source: http://www.healthline.com /diabetesmine/thebiosimilar-promise-of-lessexpensive-insulin#1

When dealing with other pharma companies' ability to replicate current marketed products, it is necessary to make a distinction between biological products and chemical synthesized products, where it's a common denominator for the Novo portfolio that the products are protein-based, thus being biological.

Replicating a chemically synthesized drug is typically not more complicated than mixing the right components together in the appropriate amounts, as they are smallmolecule drugs with uniform and predicable structures - generic erosion is thus expected at patent expiration. Biological drugs, however, differ from this, as they "are produced in living organisms; are larger, more complex, and more difficult to structurally define; and require specific conditions to ensure stability" (p.139) where "minute differences in chemical modifications and higher-order physical structure can significantly alter a final protein product's safety and efficacy" (p.139), and "Small differences in the design and execution of a manufacturing process can have large influence on the clinical profile of a final insulin product" (p.139). Figure 7 illustrating how significantly more complicated the molecular structure of insulin is compared to an everyday drug in the form of Aspirin⁴⁸.

Creating a biosimilar⁴⁹ is thus not simply to replicate the "recipe" but also replicating the manufacturing protocol, as the biosimilar needs to be identical to the original to utilize the existing regulatory approval (FDA / EU)⁵⁰. Manufacturing between original companies is in general similar, but their protocol details will vary, and although the patented information becomes public knowledge: "Patent holders are not required to divulge their protocols; many use techniques and materials that are developed in-house" (p.140), making it very difficult to create a biosimilar that's a copy of the original drug. Biosimilar manufacturers thus have to achieve their own regulatory approval, extending the process significantly.

The threat of erosion from biosimilars is thus far less than with generic drugs and manufacturers of biological drugs may not experience immediate erosion after patent expiration. The differences in generics to biosimilars therefore implies that original drug manufacturers should be equally aware of competition from potential biosimilars, as well as improved originals from other manufacturers – having the best product on the market.

50 http://www.dpc.senate.gov/healthreformbill/healthbill27.pdf

⁴⁸ A common drug, typically used to treat minor aches and pains.

⁴⁹ Generic copy of an origical biological drug.

4.3.2 Diabetes care

Diabetes is mainly treated with insulin, or a GLP-1 agonist⁵¹, to control blood glucose levels.

Treatment is not a one size fits all solution, and patient needs may change over time, so modern ⁵² insulin products are segmented into three categories: fast-acting, long-acting and premix. The primary difference between the products is how it's delivered into the body, affecting how often the patient needs to inject new doses.

Fast-acting products are taken shortly before mealtime, mimicking the body's natural release of insulin. Long-acting products are typically taken once or twice daily, with the aim of achieving a 24 hour insulin coverage and premixed products are a combination of the two⁵³.

What is Diabetes?

"Diabetes affects the way the body uses food for growth and energy. There are two main forms of diabetes: type 1 and type 2. Type 1diabetes is a lifelong autoimmune disease that develops when the body produces an immune response against its own cells, destroying the insulin-producing beta cells in the pancreas. As a result the pancreas stops producing insulin – not always at a young age. Far more common is type 2 diabetes, which accounts for around 90% of all people with diabetes and is caused by a combination of lifestyle and generic factors." - obesity being the main lifestyle disease causing type 2 diabetes – Source: Novo Annual Report 2014, .p28.

Total global market volume has grown steadily at a rate of 13,4% from 2009–2014', with Novo maintaining a market leader position ⁵⁴, where volume is approximately equally distributed between the three segments for the period. With 34% fast-acting products, 28% premix products and 38% long-acting products in 2014⁵⁵.

Novo has four current primary products - shown in figure 8 - contributing with 78% of sales in diabetes care for 2014. As mentioned in the industry description, product life cycle is dependent on patent expiration. Linking this with

Brand name		Туре	Patent expiration
NovoRapid®		Fast-acting insulin	EU: 2017 US: 2017
NovoMix®		Premixed insulin	EU: 2014-2015 US: 2017
Levemir®		Long-acting insulin	EU: 2018 US: 2019
Victoza®	Victora	Long-acting GLP-1 agonist	EU: 2023 US: 2023

Figure 8 - Novo Diabetes Products - Source: Compiled by author / Novo Annual report presentation 30 January 2015, p.41

our chosen 10 year period for the explicit forecast, we see in figure 4, that patent expiration becomes a concern for all four products, making it necessary to look into the R&D pipeline for compounds that can replace the current products. A combined summary of products can be found in appendix 5.

⁵¹ For patients developing diabetes, GLP-1 is used before insulin treatment becomes necessary.

⁵² The portfolio also consists of human insulins, but there is no development of new products within the category, and no growth is expected. The segment is therefore not analysed further in the thesis, but simply included in the later revenue forecast.

⁵³ http://www.novolog.com/insulindiabetes/whatisinsulin.aspx

⁵⁴ Novo Investor presentation full year, 2014, p.25

⁵⁵ Novo Investor presentation full year, 2014, p.39

4.3.2.1 GLP-1:

Current & Expiration Replacement		Comment	
Victoza: 2023	Semaglutide: Phase 3a trails	Replacement expected ready before patent expiration	

Set to replace Victoza is Semaglutide, where dosing frequency is moved from once daily to once weekly, making the product far more convenient to patients. Semaglutide is currently in phase 3a development, with results expected later in 2015⁵⁶. Having Semaglutide this far in development, Novo expects it to be ready long before the patent expiration of Victoza in 2023.

4.3.2.2 Fast acting:

Current & Expiration	Replacement	Comment
NovoRapid: 2017	FIAsp:	Questionable if replacement is ready before patent
	Phase 3a trails	expiration

The fast-acting NovoRapid is set to expire in 2017, creating a demand for a new or updated product as replacement. From the R&D pipeline the next follow on drug is the FIAasp (codename NN1218). The drug is in final stages of testing - Phase 3a trials⁵⁷ - with initial results promising a product that is improved from the current NovoRapid, by being more efficient at lowering glucose levels, but also more convenient since patients are no longer required to take the drug just before mealtime⁵⁸. Being improved from NovoRapid, incentivizes practitioners to favour the new product, but as the product remains to be filed and approved with the FDA and EU, it's questionable if approval will be obtained before patent expiration, which is thus a cause for concern.

4.3.2.3 Long acting:

Current & Expiration	Replacement	Comment
Levemir: 2018/2019	Tresiba:	Received well by market, and approved in all markets but
	Ready for launch	the US

Long acting Levemir has patent expiration in 2018/2019 - within the 10 year forecast. The next in line product is ready in the form of Tresiba, with patent expiration in EU 2028 and US 2030⁵⁹. Tresiba has been approved in EU, Japan and additional markets⁶⁰ for a long time, and has currently been launched in 23 countries⁶¹, with the product contributing with 8% of sales growth in 2014⁶², indicating the product is being received well by the market. Tresiba's initial performance is linked with patient reimbursement, dependent on if countries have reimbursement or not. Tresiba experiences equal growth to insulin substitutes with reimbursement and only modest growth without⁶³. Being a clear illustration of which product is chosen by the market dependent on the consumer mix between practitioner/user/payer, while also highlighting that Novo is dependent on Tresiba gaining reimbursement in all markets, for Tresiba to have the desired success.

⁵⁶ Novo Annual Report 2014, p.4

⁵⁷ http://www.novonordisk.com/rnd/rd-pipeline.html

⁵⁸ Novo Investor Presentation, full year 2014, p.67

⁵⁹ Novo Investor Presentation, full year 2014, p.30

⁶⁰ Novo Investor Presentation, full year 2014, p.65

⁶¹ Novo Investor Presentation, full year 2014, p.9

⁶² Novo Annual Report 2014, p.2

⁶³ Novo Annual Investor Presentation 2014, p.9

With North America being responsible for half of Novo sales, the biggest challenge regarding Tresiba is Novo's missing US approval. Novo has previously filed for approval with the FDA but was declined in February 2013 ⁶⁴, with the FDA requiring more data and studies. Showing the importance of Tresiba to Novo, the share dropped 13% equivalent to a market value of \$14.4 billion the day the FDA announced that they would not approve Tresiba. The additional required studies have been going on since and Novo reports that re-filing for approval could be done "as early as 2015" ⁶⁵ ⁶⁶.

There is no guarantee that the FDA will approve a later refiling. The refiling question thus remains the biggest concern to Novo, when considering their ability to compete in the North American market for long-acting diabetes products.

4.3.2.4 Premix:

Current & Expiration Replacement		Comment	
NovoMix: 2015	Xultophy & Ryzodeg	Approved in all markets but the US, as both replacements	
		are reliable on Tresiba's approval.	

For the premixed market Novo's, current NovoMix is set to expire 2015 in the EU and 2017 in the US. Novo has two substitutes ready in the form of Xultophy and Ryzodeg. The two products have different properties so they target different consumer groups. Ryzodeg is a mixture of Tresiba and NovoRapid targeting type 1 & 2 diabetes, while Xultophy is a mixture of Victoza and Tresiba only useful for type 2 diabetes⁶⁷ - covering 90% of diabetes patients.

Xultophy was approved in Europa as of September 2014⁶⁸ and was launched in January 2015 in Switzerland as the first country with plans to make it available throughout Europe during 2015⁶⁹ - being too early to tell anything significant about market feedback. Equally Ryzodeg was launched by September 2014 in Mexico as the first country⁷⁰, India following with a January 2015 launch⁷¹. Novo states that Ryzodeg has received encouraging early feedback⁷², but it's considered too short a timespan to tell anything significant about the products potential.

⁶⁴ http://www.novonordisk.com/content/Denmark/HQ/www-novonordisk-com/en_gb/home/media/news-details.1676900.html

⁶⁵ Novo Annual Report 2014, p.2

⁶⁶ On March 26th Novo decided to resubmit their drug application for Tresiba to the FDA. Although Novo announced in their annual report that it would happen in 2015, the share rose 10% only on that announcement, firmly showing the importance of Tresiba to Novo's future revenue. As the announcement was made after the cut off valuation date, it will not be included in the valuation, but is still useful when considering the importance of the Tresiba approval.

⁶⁷ Novo Annual Investor Presentation, full year 2014, p.65

⁶⁸ Novo Annual Investor Presentation, full year 2014, p.28

⁶⁹ http://www.novonordisk.com/bin/getPDF.1887730.pdf

⁷⁰ http://www.novonordisk.com/bin/getPDF.1852253.pdf

⁷¹ http://www.firstwordpharma.com/node/1258402#axzz3WiNhSnwB

⁷² Novo Annual Investor Presentation, full year 2014, p.9

Both products suffer from the same primary problem, being that they require independent approval by authorities, where that approval is largely dependent on the approval of the underlying drugs. Victoza and NovoRapid are approved in all markets, but as both mixtures include Tresiba they lack the utterly important US FDA approval. Equally, the patent life of both premix products depend on the underlying drugs⁷³, so they follow that of Tresiba with 2028 – reaching far beyond the forecast period.

Having the premix products also being dependent on the Tresiba's future FDA approval, I find that the lacking FDA approval has an estimated affect on ≈26%⁷⁴ of Novo revenues, – assuming the future keeps 2014 levels - clearly showing its importance.

Conclusive for diabetes care products I find that Novo has a stocked pipeline ready to replace current products within all four segments. Authority approval before patent expiration is a concern for the fast-acting segment. The outlook for both long-acting and premix are good in a global view, but the missing FDA approval of Tresiba in North America remains to be Novo's largest problem, potentially influencing a significant part of Novo revenues.

4.3.2.5 Diabetes - The rule of halves

When explaining the market size for diabetes care, Novo uses the 'Rule of Halves' (Hart, J, 1992), "It illustrates that only half of the many millions of people with diabetes have been diagnosed. Of those who are diagnosed, only half receive treatment from a qualified healthcare professional and, again, just half of these people achieve their treatment targets. Yet it does not end there. Only half of this relatively small group actually achieve the desired outcome and live a life free from diabetes-related complications" (Novo Annual Report, 2014, p. 29.).

The rule thus provides a quick – although rough – understanding of the diabetes market, where only a quarter of people with diabetes are reached by the industry. The rule provides an approach on how to estimate diabetes market size, which can be extended further in the forecasting of future revenues - when applying the top-down approach - by estimating market share. Additionally, the rule also highlights two huge challenges and opportunities to diabetes firms. If they are able to increase the percentage of people who are diagnosed and those who receive care, the total market size for diabetes products should equally increase – potentially increasing revenues.

⁷³ Novo Annual Investor Presentation, full year 2014, p.30

 $^{^{74}}$ Diabetes Care Contributes with 79%, North America being roughly 50% of that and long-acting and premix combined is 66%, giving 0.79*0.5*0.66 = 0.2607 = 26.07%

4.3.3 Obesity, haemophilia & growth disorders

4.3.3.1 Obesity

Current & Expiration Replacement		Comment	
Saxenda: 2023	Novo:	Approved in the EU and have received positive US	
	New product group	feedback	

Treating obesity with weight loss medicine is not yet a revenue source for Novo as it builds on Saxenda, which was approved in the US as of December 2014 and received positive feedback for EU authorities in January 2015⁷⁵. Saxenda was essentially discovered by accident, from patients using the Victoza diabetes product experiencing weight loss as a "side effect". With Saxenda, Novo is exploiting this side effect, as Saxenda and Victoza are identical products with the same formulation and thus patent with expiration in 2023⁷⁶. The difference between the products is that recommended dosis for Victoza is 1.8 mg per day but for Saxenda a higher dose of 3 mg daily - otherwise being identical⁷⁷.

As Saxenda requires injections and has potential side effects, it is not meant as a general weight loss product, but only for individuals who are clinically obese - with a BMI⁷⁸ higher than 30. The global obese population is estimated at 600 million⁷⁹ and Saxenda thus has the potential of becoming a blockbuster⁸⁰ to Novo. It is, however, only a fraction of this population that are on anti-obesity medication. Novo estimates that 0,65%⁸¹ of the US population is on anti-obesity medication were that fraction could increase in the future. As the obesity market is new to Novo its potential remains uncertain.

4.3.3.2 Haemophilia

Current & Expiration	Replacement	Comment	
NovoSeven: 2024 NovoEight		Updated "isomer" version.	
NovoEight: 2028/2039	New product group	Approved in all markets	
N9-GP	New product group	Expected to be filed for approval second half of 2015	

Haemophilia is a rare inherited bleeding disease that prevents the blood from clotting. The disease comes in two forms; type A "to have absent, decreased or defective production of the blood clotting factor VIII" (Novo Annual Report 2014, p.38) with a global population of 350.000 and type B "to have deficiencies in producing clotting factor IX" (Novo Annual Report 2014, p.38), global population of 70.000.

Novo has been represented in the haemophilia market for the past eighteen years with their NovoSeven product⁸². NovoSeven is targeted at both type A and B, but only at those patients who are inhibited to normal

⁷⁵ Novo Annual Investor Presentation, full year 2014, p.28

⁷⁶ Novo Annual Investor Presentation, full year 2014, p. 30.

⁷⁷ http://www.healthcentral.com/diabetes/c/110/173802/victoza-diabetes-saxenda/

 $^{^{78}}$ BMI: Body Mass Index – Defined as a person's weight in kilograms divided by the square of his height in meters (kg/m²)

⁷⁹ World Health Organization – Obesity and overweight. Fact sheet 311, January 2015.

⁸⁰ Pharma products having annual sales above 1 billion dollar

⁸¹ Novo Annual Investor Presentation, full year 2014, p.84

⁸² Novo Annual Report 2014, p.38

haemophilia treatment. Of the combined 420.000⁸³ haemophilia patients, the inhibitor segment only represents a segment of approximately 3.500–4.000 patients⁸⁴. Regarding market size for haemophilia, the disease experiences a tendency equal to that of the diabetes rule of halves, where only an estimated 45% of people with haemophilia are diagnosed, and 15% of the total population are actually treated for the disease⁸⁵, leaving significant growth opportunities for the total market.

The original NovoSeven patent has expired, but Novo has developed an isomer version, which is room temperature stable - the previous version requiring refrigeration. Updating the product has extended the patent until 202486, and is thus not considered problematic for forecasting purposes.

In addition to NovoSeven, Novo has expanded their haemophilia portfolio with NovoEight – patent expiration in 2028/2030⁸⁷ – and NovoThirteen, with the latter treating a rare segment of the haemophilia disease with only an approximate 900⁸⁸ patients worldwide, and will not be analysed further due to the small patient group. NovoEight on the other hand adds a lot more depth to the haemophilia portfolio. Where NovoSeven only targets inhibitors, NovoEight is made for all 350.000 haemophilia A patients⁸⁹ and the product can thus be described as Novo's real entry into the main haemophilia market, with Novo having gained experience of the haemophilia market through NovoSeven. NovoEight has obtained approval in all significant markets, and has so far been launched in eight countries – including Japan and some European countries - with plans for a US launch in 2015⁹⁰.

Looking deeper into the haemophilia pipeline, I see that Novo has two compounds at phase 3 development - N8-GP (haemophilia A) and N9-GP (haemophilia B)⁹¹. Both have received positive test results from phase 3 trials⁹², with plans to submit N8-GP for approval in 2018⁹³ and N9-GP in the second half of 2015⁹⁴. With NovoEight and a potentially soon to be approved N9-GP, Novo will be able to compete in the entire haemophilia market, with an estimated worth of 53 billion DKK⁹⁵, which has been growing at a steady rate of 8,6% from 2008–2013⁹⁶. Novo's strong commitment to enter the market is equally confirmed, as the firm has

83 Hemophilia A: 350.000; Hemophilia B: 70:000

⁸⁴ Novo Annual Investor Presentation, full year 2014, p.87

⁸⁵ World Federation of Hemophilia – Annual Global Survey 2012

⁸⁶ Novo Annual Report, p.100

⁸⁷ Process patents until 2028 in China, Germany and Japan and until 2030 in the US.

⁸⁸ http://ing.dk/artikel/novo-far-blodermedicin-godkendt-132672

⁸⁹ Novo Annual Report 2014, p.18

⁹⁰ Novo Annual Report 2014, p.2

⁹¹ Novo Annual Report 2014, p.27

⁹² Novo Annual Investor Presentation, full year 2014, p.93-94

⁹³ Novo Annual Report 2014, p.38

⁹⁴ Novo Annual Report 2014, p.10

⁹⁵ http://seekingalpha.com/article/2850636-novo-nordisk-curing-the-world-one-dose-at-a-time

⁹⁶ Novo Investor presentation, full year 2014, p.25

acquired additional production facilities as of September 2014 to expand their production capacity for haemophilia products⁹⁷, confirming the firms strategic focus area to pursue leadership in haemophilia⁹⁸.

4.3.3.3 Growth disorders

Current & Expiration	Replacement	Comment		
Norditropin: 2017 NN8640:		Questionable if replacement is ready before patent		
	Phase 3a trails	expiration		

Norditropin is the last marketed product from the Novo pipeline; treating growth hormone deficiency, which is an inherited disease⁹⁹, characterized as: "when the pituitary gland does not make enough growth hormone for the normal development and maintenance of the body" (Novo Annual Report 2014, p.39). Treatment is through a once daily injection, typically administered to children but also adults, but no distinction between children and adults is made in regards to segmentation, so the entire market is treated as one group – an estimated 2 million people live with growth disorders¹⁰⁰. Novo is market leader with Norditropin with a 33% market share that has steadily been growing since 2009. The total growth hormone market has equally been growing at a 2,2% rate in the same period¹⁰¹. Norditropin patent expiration is due in 2017¹⁰², creating a demand for a replacement product, which is found in the form of NN8640, which entered the first phase 3a trials as of November 2014¹⁰³. The primary difference between Norditropin and NN8640 is the time between injections, where Norditropin is daily and NN8640 weekly, the latter thus being a lot more convenient for patients and clearly an "upgrade" from Norditropin.

Having just entered phase 3a trials and Norditropin patent expiration by 2017, it seems possible that NN8640 will be ready by 2017 - assuming everything goes according to plan - ensuring Novo's ability to be competitive in the growth hormone market with a new improved product. A comparison with competitors is, however, necessary to analyse if competitors could potentially be ready with an equally upgraded product before Novo. The comparison will be made in the Five Forces analysis following later.

⁹⁷ Novo Annual Report 2014, p.38

⁹⁸ Novo Annual Report 2014, p.17

⁹⁹ http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency

¹⁰⁰ Novo Annual Report 2014, p.4

¹⁰¹ Novo Annual Report 2014, p.95

¹⁰² Novo Annual Report 2014, p.100

¹⁰³ Novo Annual Report 2014, p.10

4.3.4 Future products – patient convenience

Patient convenience can be a source of competitive advantage

Looking beyond patent expiration issues of biosimilar erosion and remembering the consumer mix learned from the commercial operations it must be remembered that the product chosen by the consumer mix, is not just a question of cheapest but rather "best value per dollar". Novo's main concern regarding competition is thus not only the possible biosimilar erosion at patent expiration but also having an inferior product.

Within pharma, drug efficiency remains first priority, but looking beyond that it's clear that patient convenience is a clear way to gain a competitive advantage. This is visible across all product groups. First by looking at time between required injections, which has already moved from multiple daily to once daily, with R&D trends towards once weekly showing in R&D products within diabetes¹⁰⁴ as well as growth disorders¹⁰⁵.

Convenience is also visible in how products are stored – previously mentioned for haemophilia¹⁰⁶ - and how the drug enters the system, where Novo has a variety of pens and needles¹⁰⁷ ¹⁰⁸ to ensure injections are easy and painless. Further, it's a general assumption that patients prefer oral medication to injection. As a result, Novo is developing several once daily oral compounds, of which the product furthest in development is in Phase 2a¹⁰⁹.

Having included patient convenience, I have now defined three areas of competition for pharmaceutical products that the consumer mix base their decision on, when deciding on the "best value per dollar" product; price, efficiency and patient convenience.

¹⁰⁴ Novo Annual Report 2014, p.26: Semaglutide NN9211 & LAI287

¹⁰⁵ Novo Annual Report 2014, p.27: NN8640

¹⁰⁶ NovoSeven was re-engineered so it could be stored at room temperature rather than refrigerated

¹⁰⁷ Novo Annual Report 2014, p.112

¹⁰⁸ i.e. FlexTouch, FlexPen, NovoPen, NovoFine

¹⁰⁹ Novo Investor Presentation 2014, p.28

5 Strategic Analysis

The strategic analysis builds on the industry and company description and is divided into the external macro environment, industry and internal resources and capabilities.

5.1 External (SLEPT)

The external analysis is divided into five sections: social & demographic, legal, economic, political and technological.

5.1.1 External analysis key takeaways

The key takeaways from the external analysis are:

Potential positive influence on revenues due to

- Global population growth increases population with inherited diseases.
- Increasing global obesity prevalence.
- Increasing global diabetes prevalence, regardless of income level and rural / urban.

Potential negative influence on revenues due to

- Increased governmental price pressure.
- US Diabetes market: Missing Tresiba FDA approval.
- Governmental refusal to recognize or renew patents.
- Delay of product launch to avoid copyright infringement.
- Increased threat of biosimilars due to government stimulation.

Other

- Potential significant fines if convicted of malpractice.
- Novo is independent of business cycles.
- Financial risk is insignificant due to; hedging, risk management and capital structure.
- Missing out on technology opportunities due to M&A policy.
- Stock price unaffected of M&A expectations.

5.1.2 Social & demographic

Key points from the section:

- Increased revenue due to:
 - o Global population growth.
 - o Increasing global obesity.
 - o Increasing global diabetes prevalence, regardless of income level and rural / urban.

The underlying diseases to Novo's products can generally be defined as inherited (diabetes type 1, haemophilia & growth disorders) or lifestyle diseases (diabetes type 2 & obesity), with obesity as the primary cause to type 2 diabetes.

Having assumed that no cure will be found for the underlying diseases, I expect the amount of people with inherited diseases as a minimum will follow the development in world population. Most recent studies suggest that by 2100, the world population will have increased to in between 9,6 to 12,3 billion¹¹⁰ people.

¹¹⁰ http://www.sciencemag.org/content/346/6206/234

Reaching 8 billion people by 2024 from a current 7,3 billon¹¹¹, with population growth rates expected to decline gradually as shown in table 1. Other things being equal, I infer from the population data that population growth rates should have a positive effect on revenues.

Global obesity has doubled since the 1980's with a current global obese population of 600 million¹¹². 2005 projections suggest that the obese population will develop from 392 billion individuals in 2005 to 1,12 billion obese individuals in 2030¹¹³. More recent figures suggest that obesity rates in OECD¹¹⁴ countries have increased in the past five years and will continue to increase, but at a slower pace than previously, mainly due to government programs to prevent obesity prevalence.¹¹⁵.

World Population Growth rates			
Year	Rate		
2015	1,043%		
2020	0,928%		
2025	0,828%		
2030	0,742%		
2050	0,446%		
2070	0,225%		
2090	0,143%		

Table 1 – World Population Growth rates – Source: Own Creation http://www.worldometers.i nfo/worldpopulation/#growthrate

For the major North American market, United States obesity prevalence is expected

to increase 33% from 34,47% in 2015 to 42,19% in 2030¹¹⁶ ¹¹⁷, translating into an increase of 32 million people from 2012 to 2030, increasing health spending related to obesity by \$550 billion¹¹⁸. Equally for Europe, 2014

projections are an increased obese population from 2010 to 2030 in almost all countries, with no sign of a plateau in growth rates - but less steep than the historical data¹¹⁹. Figures equally suggest that obesity prevalence will increase in China from 5,413% in 2015 to 7,534% in 2030, with a linear growth trend¹²⁰. All of the presented obesity data are in line with each other, suggesting that outlook for obesity prevalence is increasing globally and in all major Novo markets, which should affect type 2 diabetes revenues and the potential of Saxenda in a positive direction.

				Diagnostic
				rate –
	2013	2035	CAGR	2013
North	37	50	1,5%	73%
America				
Europe	56	69	0,9%	64%
China	98	143	1,7%	54%
Japan &	10	15	1,7%	54%
Korea				
Rest of	180	315	2,6%	54%
World				
Total	382	592	2,0%	54%

Table 2 - Diabetes Population estimates (millions) & diagnostic rate - Source: Own Creation / IDF Diabetes Atlas 2014

¹¹¹ http://www.worldometers.info/world-population/#growthrate

¹¹² World Health Organization - Obesity and overweight. Fact sheet 311, January 2015

¹¹³ Kelly, Yang, Chen, Reynolds, & He, 2008

¹¹⁴ Organization for Economic Co-operation and Development

¹¹⁵ OECD Obesity update – June 2014

¹¹⁶ Finkelstein et al., p.6

^{117 2015: 34,47%; 2020: 37,40%; 2025: 39,93%; 2030: 42,19%}

¹¹⁸ http://www.huffingtonpost.com/2012/05/07/obesity-america-20-year-forecast-epidemic_n_1496439.html

¹¹⁹ http://www.escardio.org/The-ESC/Press-Office/Press-releases/Last-5-years/The-shape-of-things-to-come-study-predicts-increase-in-adult-obesity-prevalence

¹²⁰ http://www.ifs.du.edu/ifs/frm_TableDisplay.aspx

Looking closer at diabetes development, the International Diabetes Federation (IDF) annually publishes a "Diabetes Atlas" that includes projections of diabetes prevalence. Estimates in table 2¹²¹, shows an expected increase across all Novo segments and confirming Hart's "Rule of halves", where diagnostic rates are significantly higher in the more developed markets of North America / Europe.

IDF highlights that 80% of people with diabetes live in low and middle-income countries¹²², but that prevalence patterns are equal among high to lower middle-income groups with only low-income groups being lower – as shown in figure 9. Additionally, diabetes was typically predominant in urban areas, but statistics show that diabetes is growing in rural areas as well. Generally speaking, IDF estimates diabetes prevalence growing regardless of region, income or rural / urban. Global trends therefore only suggest that other things being equal, Novo's diabetes revenue is expected to increase in all foreseeable future.



Figure 9 - Prevalence (%) of diabetes (20-79 years) by income group and age - Source: IDF Diabetes Atlas 2014, p.16

5.1.3 Legal

Key points from the section:

- US diabetes market: Missing Tresiba FDA approval.
- Government refusal to recognize or renew patents.
- Delay of product launch to avoid copyright infringements.
- Potential significant fines if convicted of malpractice.

As I've shown in the industry description, legal affairs are highly important to pharma firms, with focus on protection of intellectual property, through patents and legal approval to market drugs by the FDA - or their equivalent in other markets.

As previously discussed under long-acting and premix insulin products, the single most important legal issue to Novo is the lacking FDA approval for Tresiba – having an estimated effect of 26%¹²³ of current revenues. As an outside investor, it is speculative to estimate if and when Tresiba will be approved, market consensus is expecting US launch in 2016¹²⁴. With inspiration from real options approach, a simple decision tree will be modelled into the valuation, to be used in scenario analysis, to illustrate the effect of a potential FDA decision.

¹²¹ Japan & Korea are assumed to develop in the same rate as the rest of the Western Pacific region. Diagnostic rates for China, Japan & Korea are set equal to the Western Pacific region. Rest of World diagnostic rate is calculated as an average across the remaining regions.

¹²² IDF Atlas 2014, p. 07

¹²³ Section 4.3.2: Diabetes care - Premix

¹²⁴ J.P. Morgan – European Pharmaceuticals – 05 January 2015

A risk towards intellectual property is if a government will not recognize the validity of new patents or is unable to uphold current patent rights¹²⁵. This has been the case for other corporations two times in India in 2013¹²⁶ and latest in January 2015¹²⁷. Where government refused to "renew" patents for updated "Isomer" products, arguing that the new product wasn't significantly different from the original – the FDA has similar rules for biologics but no precedence of their usage¹²⁸. The two verdicts made it impossible for the firms to extend their patent lifetime, making way for generics that should benefit the low-income population.

From a Novo investor point of view, India's patent practice could be a cause of concern, if other nations with large low-income populations replicate India's policy. However, due to the difference previously explained between generics and biosimilars¹²⁹, it's expected that Novo would stay relatively unaffected by such a policy change, and the risk is not something that will be modelled into the later valuation.

An additional intellectual property consideration is not to conflict with the intellectual property of others. This is clearly illustrated by Novo's decision to delay the launch of NovoEight to April 2015 despite gaining approval in October 2013¹³⁰. Leading to the conclusion that Novo has assessed the potential value loss of delaying NovoEight is less than the potential legal cost of copyright infringement.

Novo is equally at risk of being sued for malpractice, which has previously happened to Novo in the 'oil for food' case, costing Novo a combined 130 million DKK¹³¹ ¹³². The cost of 'oil for food' is, however, only a fraction of the more recent 2014 GlaxoSmithKline case. The firm was found guilty of bribing Chinese doctors and was fined 3,367 billion DKK¹³³ – the largest penalty ever given to a company in China¹³⁴. Such cases are rare, and one would expect analysts to implement major lawsuits into their valuations as they become public. I will follow the same practice and no adjustments will be made towards potential future lawsuits.

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¹²⁵ Novo Annual Report 2014, p.43

¹²⁶ http://articles.latimes.com/2013/apr/01/world/la-fg-wn-indian-court-ruling-generic-drugs-20130401

¹²⁷ http://thinkprogress.org/health/2013/04/01/1804861/india-generic-drug-says-us/

¹²⁸ http://www.biopharma-reporter.com/Markets-Regulations/US-FDA-tweaks-requirements-for-12-year-biologics-exclusivity

¹²⁹ Section 4.3.1: Biosimilar vs. Generic Erosion

¹³⁰ http://www.pmlive.com/pharma_news/novo_nordisk_wins_us_approval_for_haemophilia_treatment_510767

¹³¹ http://investor.borsen.dk/artikel/1/160564/novo_nordisk_betaler_sig_ud_af_irak-skandale.html

¹³² http://investor.borsen.dk/artikel/1/157235/novo_betaler_100_mio_kr_i_irak-forlig.html

^{133 \$488} million

¹³⁴ http://www.ft.com/intl/cms/s/0/dea9811e-3fd5-11e4-936b-00144feabdc0.html#axzz3YEMWIZQT

5.1.4 Economic

Key points from the section:

- Pharma industry is independent of business cycles.
- Financial risk insignificant due to; hedging, risk management and capital structure.

5.1.4.1 Business cycle: Pharma industry is independent of business cycles

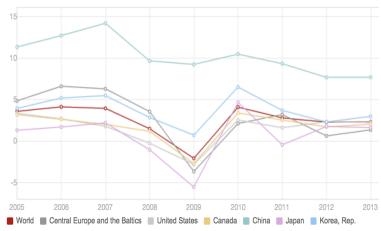


Figure 11 - Health expenditure per capita (current US\$) - Source: World Bank

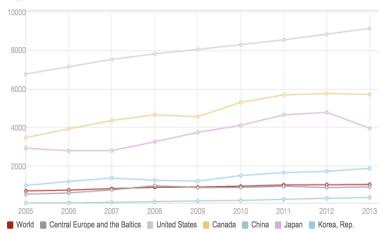


Figure 10 - GDP growth (annual %) - Source: World Bank

Economic analysis is usually constructed around business cycles and development in GDP figures. But since drugs can be described as being part of the bottom of Maslow's Hierarchy of Needs¹³⁵ ¹³⁶, it seems reasonable to make the assumption that the pharmaceutical industry in general is independent of business cycles.

Cleeren et al. have examined this assumption and found mixed results, when differentiating between private / public expenditure between cyclical movements within healthcare – illustrated in appendix 4.

In the private sector 62,5% cut back on spending in economic downturn, but 37,5% increased spending ¹³⁷. Equally within governmental spending, Cleeren et al. found increases and decreases depending on individual government policy, making me unable to draw a clear general pattern from the research.

Examining my initial assumption further, it can be seen from figure 10 that GDP growth rates for all Novo regions – excluding China – follow the same pattern, and clearly show the financial crisis of 2008-2009.

From figure 11 a steady increase in healthcare expenditure can be seen across all regions, where development seems unaffected of the financial crisis. Given that no evident pattern between GDP growth rates and health care expenditure is seen, I assume that my initial assumption holds true, thus the pharma industry in general is unaffected by business cycles. Additionally, by looking at Novo's historical revenues there is no evidence of the

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¹³⁵ http://www.simplypsychology.org/maslow.html

¹³⁶ Physiological needs that the individual's survival depends on, thus necessary regardless of economic conditions.

¹³⁷ Cleeren et al., 2015, p.21

financial crisis, as revenues have only increased annually since 2006, with annual growth between 6% and 19% - 2014 being the worst¹³⁸ - further strengthening my assumption.

It's considered that the assumption of being independent of the general business cycle will benefit the valuation, as forecasts will depend more on the development of the individual drug markets and market shares. Where it is believed that forecasting drug markets can be made with a higher level of confidence than forecasting global economic trends, particularly when the time horizon of a forecast is increased, as GDP forecasts are rarely estimated more than one year forward.

5.1.4.2 Financial risk: Not a concern due to precautions and circumstances

With Novo being a multinational firm, they are naturally exposed to currency risk, and it does have an impact on reported financial results, where risk is placed in the same currencies as the regions where Novo has their majority activities – USD, EUR, CNY, JPY, GBP and CAD¹³⁹. Risk towards the EUR is considered low due to Denmark's fixed-rate policy¹⁴⁰. For the remaining major currencies Novo's foreign exchange risk management, uses currency hedging through foreign exchange forwards and foreign exchange options to minimize risk¹⁴¹. Hedging is not performed for emerging markets as it's deemed unfeasible.¹⁴²

Currency risk can affect results in both directions¹⁴³ and is unpredictable¹⁴⁴. Attempting to forecast currency development for a 10-year time horizon seems unrealistic, and the key take away from currency risk is that Novo has the proper setup risk management to mitigate currency risk. Similar, credit risk is assessed as being low, due to Novo's credit policy¹⁴⁵ of relying on credit ratings¹⁴⁶ for their credit lines with financial counterparties, meaning that out of their current credit risk of 15.935 DKK million, 7.651 DKK million (48%) is placed in the A-range and 8.027 DKK million (50%) in AA-range or higher, with the majority for both being in cash.

The significance of interest rate risk is correlated with a firm's capital structure. During my choice of valuation model, I assumed Novo's capital structure would stay unchanged, and as Novo has no long-term debt their interest rate risk is assessed to be very low. This is reflected by Novo's estimation, where a 1 percentage point increase is expected to decrease the value of Novo's financial instruments by DKK 3 million – an insignificant amount relative to Novo financials.

¹³⁸ Novo Annual Reports 2006 - 2014

¹³⁹ US Dollar, Euro, Chinese Yuan, Japanese Yen, British Pound, Canadian Dollar.

¹⁴⁰ http://www.nationalbanken.dk/da/pengepolitik/fastkursERM2/Sider/default.aspx

¹⁴¹ Novo Annual Report 2014, p.81

¹⁴² Novo Annual Report 2014, p.63

¹⁴³ Novo estimates a +-5% change will impact by +-1.600 million DKK.

¹⁴⁴ Clearly illustrated by Novo's financial results from the past 3 years: 2014: -93 million, 2013: +1.146 million, 2012: -1.207 million

¹⁴⁵ Novo Annual Report 2014, p.82

¹⁴⁶ http://www.standardandpoors.com/ratings/definitions-and-faqs/en/us

5.1.5 Political

Key points from the section:

- Increased governmental price pressure.
- Increased threat of biosimilars due to government stimulation.

The key subjects of political importance to Novo are government-mandated price decreases or changes in legislation that for example might change patient reimbursement or intellectual property protection.

As we learned from the industry description, government is usually a part of the consumer mix; consequently they have an interest in decreasing drug prices to decrease healthcare expenditures. Governments are seeking to decrease expenditures through healthcare reforms, where Novo experiences changes in form of demand for higher rebates and/or restrictions on reimbursements, which Novo expects to continue in the foreseeable future.¹⁴⁷.

As government is only part of the consumer mix, government price pressure will be analyzed in greater detail in the later "bargaining power of customers" in the Five Forces analysis, but increased price pressure is expected to limit revenue growth opportunities.

In addition to demanding lower prices, governments are trying to decrease prices by promoting the development of biosimilars through legislation changes. Biosimilars have been available in the EU since 2006, and in 2010 the US created pathway for biosimilars through the "The Patient Protection and Affordable Care Act"¹⁴⁸ – also known as ObamaCare. The effect on the diabetes markets remains to be seen, as the first diabetes biosimilar was only approved as recently as September 2014 in the EU¹⁴⁹ – Eli Lilly's once daily long-acting Abasaglar¹⁵⁰ - and no biosimilars for any drug category have been approved by the FDA so far¹⁵¹.

As explained previously, the biggest problem with creating a biosimilar is not the formula but the manufacturing process, as firms can keep manufacturing procedures private after patent expiration. Government may change this practice, so manufacturing procedures become public knowledge. US precedent is currently being decided in a patent dispute¹⁵² ¹⁵³, leading the way for the first potential US biosimilar approval. Similar precedence does not exist in Europe, and is therefore not currently considered a risk to Novo. However, if politicians were to change legislation, biosimilar creation would become less difficult and one would expect biosimilars to have equal product life cycles to that of generics, expected to significantly impact revenues.

¹⁴⁷ Novo Annual Report 2014, p.42

¹⁴⁸ http://www.dpc.senate.gov/healthreformbill/healthbill27.pdf

¹⁴⁹ http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe

¹⁵⁰ http://www.ukmi.nhs.uk/applications/ndo/record_view_open.asp?newDrugID=5484

¹⁵¹ http://www.nature.com/news/first-biosimilar-drug-set-to-enter-us-market-1.16709

¹⁵² http://www.nature.com/news/first-biosimilar-drug-set-to-enter-us-market-1.16709

¹⁵³ http://www.mbbp.com/resources/iptech/biosimilar-patents.html

5.1.6 Technological

Key points from the section:

- Missing out on technology opportunities due to M&A policy.
- Stock price unaffected of M&A expectations.

Being a biotechnology firm, Novo is highly dependent on technology for R&D and manufacturing. But as both are highly secretive, performed and developed in-house, I argue that technology in that context is part of their resources and capabilities, and analysis thereof does not belong in external macro analysis but in the later internal analysis.

In an external perspective, Novo is not the only firm developing technology for R&D and manufacturing in the pharma industry. Through the business development department¹⁵⁴ they have the possibility to accelerate development, or decrease cost through new production technology, from joint ventures or acquisition of other firms in the external environment. Novo competitors have the same opportunity, so I expect acquisition prices to be very competitive. Which might explain why Novo has chosen to focus on organic growth, being a "believer in having wholly owned affiliates and expanding them organically as the market develops"¹⁵⁵, having declared that they won't buy anything that can't be financed through their own cash flows¹⁵⁶.

Historically, Novo has followed this M&A policy, as they haven't participated in deals valued more than \$1 billion since 1989¹⁵⁷. Consequently, I don't expect Novo to change their M&A strategy in the future, thus being reliant on in-house developed capabilities. The policy is advantageous because it provides complete control, but equally limits Novo from acquiring new externally developed technologies. Additionally, the M&A policy enables me to exclude the possibility that the stock price is affected by market expectations of future M&A activities.

Equivalent to most modern corporations, Novo is heavily reliant on IT systems for almost all parts of operations. Being heavily reliant on confidential information, a breach of security – i.e. hacking – that leaks information therefore becomes a severe cause of concern - especially with non-patented R&D work. Novo reports that systems are in place to mitigate that risk¹⁵⁸, nevertheless as the recent 2014 Sony hack¹⁵⁹ exemplifies, as long as a firm is "online" it is vulnerable to attacks from third parties.

However, as IT security risk is not exclusive to Novo, I assume the risk is equally shared by competitors, and is not expected to affect the valuation beyond the cost of IT security systems.

¹⁵⁴ Industry Description – Value Chain of A Pharmaceutical Firm

¹⁵⁵ Novo Annual Report 2014, p.22

¹⁵⁶ http://www.wsj.com/articles/novo-nordisk-ceo-has-no-plans-for-big-acquisitions-1409059977

¹⁵⁷ http://www.wsj.com/articles/novo-nordisk-sees-no-strategic-reason-for-big-mergers-1402914416

¹⁵⁸ Novo Annual Report 2014, p.43

¹⁵⁹ http://www.wsj.com/articles/behind-the-scenes-at-sony-as-hacking-crisis-unfolded-1419985719

5.2 Industry (Porter's Five Forces)

Industry definition

Pharma firms that sell prescription drugs that are made and developed equal to Novo products

In this section I follow the Five Forces framework (Porter, M.), to gain a better understanding of Novo's competitive advantage and what drives industry profitability.

To analyse the industry, it's necessary to define the industry I am analysing, where I want to compare with the firms Novo are competing with. Novo is located in the pharma industry, but to analyse the entire pharma industry would be wrong, as Novo isn't competing with all pharma firms.

Rather, Novo's competition is from products that buyers view as substitutes to Novos products, and I use this view of product substitutability to define the industry that's to be analysed.

Within the field of medicine, a lot of different solutions are often viewed as being substitutes – e.g. exercise to treat obesity. I therefore narrow my definition of what is defined as Novo substitutes to; prescription pharmaceutical drugs that are made and developed equally to Novo products.

My industry definition has the implication that I view Novo as being located within four different industries – one for each product group. Analysing each of the five forces for each product group is however not necessary, as characteristics are equal, but separation by product group will be done when necessary.

5.2.1 Industry analysis key takeaways

The key takeaways from the industry analysis are:

Threat of new entrants: Low, suggesting high future industry profit rates

- High capital requirements for: drug development, manufacturing and commercial operations.
- Significant economies of scale, due to global scope.
- No cost advantage on raw materials, as production is based on simple raw materials.
- Significant cost advantage due to economics of learning.
- High governmental & legal barriers through patents and approval procedures.

Threat of substitutes: No increase in overall product prices due to biosimilar pressure

- Substitutes limited to: New drugs from current competitors or biosimilars.
- Biosimilars:
 - Only able to compete on pricing as they are copies.
 - Only considered a direct threat to old gen products.
 - Will indirectly put price pressure on new gen products, due to buyer reluctance to pay a premium for new products.

Bargaining power of suppliers: Low

- Novo has high vertical integration.
- Production is based on simple raw materials.

Bargaining power of buyers: Prices kept at current levels due to increased buyer power

- Bargaining power defined as relative economic power.
- Users and physicians have no bargaining power.
- US Government:
 - ObamaCare has significantly increased bargaining power of buyers.
 - o Novo sales rebates have increased for the past three years.
 - o Future: Uninsured will be registered in ObamaCare as it's being implemented.
- US Insurance companies: Loss of contract suggests equal bargaining power.
- ROW: Majority of buyers are governments that are looking to decreased health care spendings
- ROW: No expectation of price increases due to government bargaining power.

Rivalry between established firms

- Based on the industry definition, Novo is described as being competitive in four industries that follow Novo's product groups: diabetes, obesity, haemophilia and growth disorders.
- See section for summary of individual industries and a combined table in appendix 6.

5.2.2 Threat of new entrants:

Low entry threat, suggesting high future industry profit rates

Key points from the section:

- High capital requirements for: drug development, manufacturing and commercial operations.
- Significant economies of scale, due to global scope.
- No cost advantage on raw materials as production is based on simple raw materials.
- Significant cost advantage due to economics of learning.
- High governmental & legal barriers through patents and approval procedures.

The level of entry and exit barriers affect the level of which firms can earn profits above the required return on capital - high barriers lead to high average rates of profit, with high capital requirements being an effective barrier 160. Where it's the mere threat of entry, and not the actual entry we are analysing, as the threat of entry should force existing firms in the industry maintain competitive pricing to fend of new competitors 161.

Additionally, exit barriers are equally important to avoid "hit n' runs" if firms do not endure sunk cost at entry. 162 I access threat of entry on the following variables: capital requirements, economies of scale, absolute cost advantage, governmental and legal barriers.

5.2.2.1 Capital requirements: High

From the product life cycle in the industry description, I learned that the time period from initiating development to approval is typically between 10 to 15 years. In the process only 5 out of 250 compounds make it to clinical testing and only 1 will make it through development to achieve approval.

Therefore, I assume that a newly established firm would have to operate with negative cash flows for the first 10–15 years.

Additionally, a 2014 study estimates that the cost of developing a single new drug is \$2,5 billion, where costs have only risen historically. ¹⁶³ In addition to development cost, investments within manufacturing, commercial operations and the remaining parts of the value chain are necessary to establish a fully operative pharma firm. Consequently I assess the capital requirements of new entries to be high.

5.2.2.2 Economies of scale: Significant effect on unit cost

As pharmaceutical firms operate on a global scale, where products are sold continuously during the year - patients need daily injections – products are sold in very high volumes. Combining this with the very high capital requirements to entry, I assume that new entrants would have to sell a significant volume to break even.

I thus characterize the pharma industry as having significant economies of scale. Creating difficult conditions for new entrants, as they can't rely on creating new segments in the market – due to the nature of the products. Sold

¹⁶¹ Grant, p.71

¹⁶⁰ Grant, p.73

¹⁶² Investments that cannot be recovered at exit

¹⁶³ http://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/

units need to be captured by obtaining volume from the current market, where existing firms are benefiting significantly from economies of scale.

5.2.2.3 Absolute cost advantage: Not raw materials but significant economics of learning

In respect to raw materials, I do not find any cost advantage, as production is not reliant on any raw materials that are not easily obtained in the market. I do, however, find a cost advantage in relation to economics of learning. Current main competitors have a long history within the industry¹⁶⁴, and should benefit significantly from the experience curve¹⁶⁵, making it difficult for new entries to compete with cost per unit output.

5.2.2.4 Governmental & legal Barriers: High

As the industry & company description showed, patents protect industry intellectual property. With firms trying to prolong patent life through "isomers", indirectly forcing new entrants to develop their own compounds - requiring FDA approval. If new entrants attempt to develop biosimilars, they face the same legal barriers as developing their own new compound. Additionally, compliance cost is expected to be higher for new entrants than established firms 166. I therefore consider the legal barriers to entry as being high.

5.2.2.5 Entry threat summary: Low threat of entry, suggesting high future industry profits

I summarize the entry barriers to the entry as having high capital requirements, with existing firms having a significant cost advantage in unit cost due to significant economies of scale and economies of learning, and high legal barriers exist due to regulatory requirements.

The barriers are considered to be effective against new entries, from firms outside the pharma industry - in line with Novo's own assessment¹⁶⁷. Barriers will however be lower to existing pharma firms, who wish to expand their product portfolio into Novo segments. Conclusively I assess the threat of entry to be low, suggesting high future profit rates in the industry all else being equal.

¹⁶⁴ First commercial Insulin – HUMALIN - was sold by Eli Lilly in 1982. – Source: FDA

¹⁶⁵ "The unit cost per product output declines (typically 20-30%) each time cumulative output doubles. (Anderson, U., Session 6, FS58 Strategic Management – Winter Semester 2011 CBS, slide 11)

¹⁶⁶ Grant, p.73

¹⁶⁷ Novo Annual Report 2014, p.22

5.2.3 Threat of substitutes

Decrease in overall prices due to biosimilar pressure

Key points from the section:

- Substitutes limited to: New drugs from current competitors or biosimilars.
- Biosimilars:
 - Only able to compete on pricing as they are copies.
 - o Only considered a direct threat to old gen products.
- Will indirectly put price pressure on new gen products, due to buyer reluctance to pay a premium for new products.

Given my industry definition, low threat of new entrants, and having previously assumed that no cure will be found for the underlying diseases that Novo's portfolio aim to treat. The possible sources of substitute products are limited to newly developed drugs from current industry rivals and biosimilars – the former will be treated in the following "Intensity of existing rivalry" section.

For insulin, the threat of biosimilars is only recent, with Sanofi's Lantus (long-acting) losing its patent in February 2015, as Eli Lilly and Boehringer¹⁶⁸ have developed biosimilar versions to Lantus. A lawsuit will however keep them off market until mid-2016¹⁶⁹, so the effect on the market remains to be seen. Yet I do know that since the biosimilars are close copies, they will not be better products in pure medical terms, therefore biosimilars will only be able to compete on pricing.

By only being able to compete on pricing, leads me to re-consider the threat of biosimilars, as the main competitive advantage within the industry, is having the best product on the market – for practitioners to favour. Which is what Sanofi has done with their new Toujeo (Tresiba competitor) to replace Lantus¹⁷⁰. Biosimilars will thus not be a substitute to the current generation product but to the "old". Raising the question if users and buyers are willing to select a less efficient drug to save cost, as I would expect practitioners to favour the new generation. Yet Novo reports reluctance within all buyers groups, in both high-income groups and low- and middle-income countries, to pay a premium for new improved products¹⁷¹.

Biosimilars should however indirectly put price pressure on the new generation insulin – based on the argument that if price differences are too high, buyers might be price sensitive enough to choose the old generation. Further, I do not yet know the pricing of biosimilars, but as biosimilars need to be developed and created equally to the original¹⁷², substantially lower prices are not expected¹⁷³.

¹⁶⁸ Both companies are established firms in the biopharma industry, and are therefore not new entries, confirming my conclusion on entry threat.

¹⁶⁹ http://seekingalpha.com/article/2395325-sanofi-confronting-lantus-patent-expiry-with-more-efficient-successor-toujeo

¹⁷⁰ http://www.firstwordpharma.com/node/1207383#axzz3ZAuNuMwG

¹⁷¹ Novo Annual Report 2014, p.16

¹⁷² Section: Biosimilar vs. Generic Erosion

¹⁷³ http://clinical.diabetesjournals.org/content/30/4/138.full#sec-16

Conclusively, biosimilars are not seen as a threat due to the difference between new and old generation drugs, as I expect the most efficient drugs to be favoured. I expect the threat of substitutes to decrease prices in general, due to reluctance to pay a significant premium for new product, creating a negative effect on future revenues.

5.2.4 Bargaining power of suppliers

Suppliers have low bargaining power

Key points from the section:

- Novo has high vertical integration.
- Production is based on simple raw materials.

Given the high level of regulatory scrutiny related to pharmaceutical production, Novo is characterized as being highly vertically integrated – controlling everything from raw to final product while developing manufacturing technologies and procedures in-house. Novo is dependent on supply in the form of two sources; raw materials and work force – the latter will be analysed in the internal analysis.

Novo is not reliant on any specific suppliers for raw materials, as the raw main materials used for insulin production are water, nutrients, sugar and organic or inorganic chemicals¹⁷⁴. Equally no special materials or components are used to achieve the final product. I therefore assume all raw materials can easily be acquired in the market; consequently Novo has a significant bargaining power over its suppliers.

5.2.5 Bargaining power of buyers

Prices kept at current or lower levels due to increased buyer power

Key points from the section:

- Bargaining power defined as relative economic power.
- Users and physicians have no bargaining power.
- US Government:
 - o ObamaCare has significantly increased bargaining power of buyers.
 - o Novo sales rebates have increased for the past three years.
 - o Future: Uninsured will be registered in ObamaCare, as it's being implemented.
- US Insurance companies: Loss of contract suggests equal bargaining power.
- ROW: Majority of buyers are governments that are looking to decrease healthcare spendings
- ROW: No expectation of price increases due to government bargaining power.

Bargaining power of a buyer is dependent on their relative economic power¹⁷⁵, and from the industry description, I know that Novo's customer is not a single buyer, but a mix between users, payers (governments, health insurance or employers) and prescribing physicians.

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 $^{^{174}\,} http://annual report 2008. novon ordisk. com/how-we-perform/responsible-business-practices/bioethics/genetechnology. asp$

¹⁷⁵ Grant, p.76

5.2.5.1 Users and physicians: No bargaining power

In relation to users, I previously described drugs as being at the bottom of Maslow's pyramid of needs. Consequently, the user does not have the choice not to buy a product, but only to choose a substitute – if available. Additionally users are not organized thus relative to the pharma seller, they have no economic power, and their choice will often be based on the prescribing physicians. I therefore don't consider the user to have bargaining power over sellers, i.e. Novo.

Generally speaking, physicians operate independently and product choice is based on the most efficient drug. They are not economically influenced by their choice, so their price sensitivity is only based on the level of patient reimbursement, and thus they have no real incentive to negotiate prices with sellers. Lacking incentive and operating independently, I don't consider physicians as having bargaining power over sellers.

5.2.5.2 US Government as a buyer: Increased bargaining power of government

Within the payer group, the United States is very different from the rest of the world, and since the North American market make up half of Novo revenues, I make a distinction between the two.

50% of the US population is insured by their employers, one-third through governmental programs – Medicare and Medicaid¹⁷⁶ - and the remaining is uninsured¹⁷⁷. The governmental programs are relatively new being part of the 2010 ObamaCare that provides public health insurance to over 44 million previously uninsured Americans¹⁷⁸. Expectancy for the future is that the uninsured group will move into the Medicare and Medicaid, as ObamaCare is currently being implemented¹⁷⁹. The programs have effectively combined the bargaining power of uninsured individuals, as they are governmental programs their relative economic power is high. Novo reports an only

increasing demand for higher rebates, which is not expected to change in the future¹⁸⁰, and historically table 3 shows that rebates have only increased for the past three years.

Combining the price pressure with the move from uninsured into ObamaCare, the bargaining power of the US government will only increase, resulting in a negative effect on net US revenue.

Sales rebates relative to gross sales											
	2014	2013	2012								
Gross sales	100%	100%	100%								
US managed care and Medicare	13%	11%	9%								
US wholesaler charge-backs	10%	9%	8%								
US Medicaid rebates	4%	3%	3%								
Non-US rebates, discounts	3%	3%	3%								
and sales return											
Total gross-to-net sales	33%	28%	25%								
adjustments											
Net sales	67%	72%	75%								

Table 3 – Novo sales rebates relative to gross sales – Source: Compiled by author – Novo Annual Report 2014, p.64

¹⁷⁶ Both a part of the previously mentioned ObamaCare

¹⁷⁷ Novo Annual Report 2014, p.42

¹⁷⁸ http://obamacarefacts.com/

¹⁷⁹ Novo Annual Report 2014, p.23

¹⁸⁰ Novo Annual Report 2014, p.42

5.2.5.3 US insurance buyers: Equal bargaining power

The same trend is found within the private insurance sector, most noticeably in 2013, when Novo lost two contracts with Express Scripts that accounted for between 15–20% of the Victoza prescription sales in the US¹⁸¹. The contract was lost to an inferior product¹⁸², illustrating that price had become more important than best product.

The loss of contract was not Novo being unable to meet the price demands, but the result of a pricing strategy, where Novo believes that Victoza as a superior product is able to demand a price premium¹⁸³.

Table 3 shows that Novo is willing to deliver rebates to significant buyers, but they are not willing to compete under any circumstance, demonstrating that the industry has product differentiation. Being unable to agree on terms, I assess that Novo and private insurance companies are equal in bargaining power. Being a single case, it's challenging to valuate if the loss of contract was a single event, but for Novo it's worrying that they lost to an inferior product.

Novo is positioned as selling the best product on the market¹⁸⁴ but at a premium price. If buyers are unwilling to meet that price and will settle with the cheaper but worse product, Novo might see a loss of market share – if they stick to their pricing policy – as competitors are willing to sell at a discount. Novo equally states that they will not enter a market, if they don't find the conditions reasonable¹⁸⁵.

5.2.5.4 ROW buyers: Price pressure from governments

For the rest of the world, the largest payers are usually governments, who are seeking to decrease healthcare cost, and do so by demanding lower prices 186 187, using price protection mechanisms that ensure rebates and restrictions on reimbursements 188. Consequently for all major regions, there are no expectations of growth due to price increases 189. As governments buy in bulk, they are therefore considered to have substantial economic power, thus equally bargaining power.

Additionally for the poorest countries¹⁹⁰, Novo has a differential pricing policy where they are obliged to sell insulin at a price that must not exceed 20% of the average insulin price of the Western world¹⁹¹ ¹⁹². Revenues will therefore follow that of the major regions.

¹⁸¹ http://www.reuters.com/article/2013/09/03/us-novonordisk-contracts-idUSBRE9820IZ20130903

¹⁸² http://www.firstwordpharma.com/node/1136091#axzz3ZAuNuMwG

¹⁸³ http://www.reuters.com/article/2013/11/05/us-novonordisk-ceo-idUSBRE9A40I220131105

¹⁸⁴ http://www.firstwordpharma.com/node/1136091#axzz3ZAuNuMwG

¹⁸⁵ Novo Annual Report 2014, p.42

¹⁸⁶ Novo Annual Report 2014, p.63

¹⁸⁷ Novo Annual Report 2014, p.22

¹⁸⁸ Novo Annual Report 2014, p.23

¹⁸⁹ Novo Annual Report 2014, p.23-24

¹⁹⁰ 32 of the world's 47 poorest countries.

¹⁹¹ Novo Annual Report 2014, p.11

¹⁹² EU, Norway, Switzerland, US, Canada & Japan.

5.2.5.5 Summary on buyers bargaining power: No increase in price

Novo is experiencing a demand for decreased prices in all regions, with the major buyers having significant bargaining power due to their relative economic power. Novo shows that they are willing to offer discounts, but only within what they find reasonable. For future development, prices are expected to be kept at current levels or decrease¹⁹³, and does therefore not offer a revenue growth potential in the long run.

5.2.6 Rivalry between established competitors

As described in the beginning of the Five Forces analysis, Novo can be described as a competitor within four different industries – one for each product group. I will apply this segmentation to analyse rivalry, where my primary measurements of rivalry are on product differentiation or price, to analyse future development in market share. A table of key points is provided at the beginning of each segment, with a combined table listed in appendix 6.

5.2.6.1 Diabetes care

I follow the same segmentation from the description, so I divide the market into: GLP-1, fast-acting, long-acting and premix.

5.2.6.1.1 GLP-1:

Key points from the section:

- Bydureon to gain market share from Victoza, due to new 2014 easy-to-use pen.
- Future competition is between once weekly, Bydureon, Trulicity and Semaglutide.
- Future market will be shared between the three, with Novo as market leader, due to being the best product on market, and by maintaining a large part of current market share.

Historically, competition within GLP-1 can be described as a duopoly as competition is primarily split between Novo and AstraZeneca¹⁹⁴ (AZN), divided between three products; Victoza (Novo), Byetta (AZN) and Bydureon (AZN).

The market is relatively new, with Byetta being the first GLP-1 product to gain FDA approval in

2005¹⁹⁵. Novo followed with a EU/US launch in 2009/2010¹⁹⁶ and as figure 12 illustrates, Novo has since established a significant position as market leader.

Bydureon was launched in 2012, and is to be viewed as AZN's new improved product over Byetta as it's injected only once weekly¹⁹⁷ compared to the previous once daily.

¹⁹³ Most likely in the US, as ObamaCare is still being implemented.

¹⁹⁴ Both products were previously owned by Amylin, but were acquired by AstraZenaca and Bristol-Myers in a split deal in 2012. - http://www.forbes.com/sites/matthewherper/2012/06/30/why-bristol-and-astra-teamed-up-to-buy-amylin-in-unique-7-billion-deal/

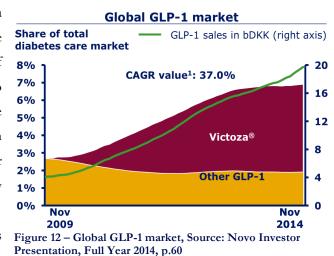
¹⁹⁵ http://www.drugs.com/history/byetta.html

¹⁹⁶ http://www.fiercepharma.com/special-reports/victoza-top-15-drug-launch-superstars

 $^{^{197}\} http://www.astrazeneca.com/Media/Press-releases/Article/03032014-us-fda-approves-bydureon-pender of the control of t$

Victoza is once daily¹⁹⁸, so Bydureon should have a clear competitive advantage to Victoza, but as can be seen from figure 12 that advantage hasn't shown itself in market share. The lack of success might be down to the Bydureon's lack of easy-to-use pen¹⁹⁹, as it must be injected with traditional needles that are thicker than what Novo provides. It would seem patients prefer more frequent – but easier – injections to once weekly but more difficult.

This apparent competitive advantage for Novo is expected to disappear, as AZN achieved FDA



approval for an easy-to-use pen for Bydureon as of March 2014²⁰⁰. As an inferior product, I expect Victoza to lose market share - for all forecasting years - to Bydureon following launch of their easy-to-use pen in September 2014²⁰¹.

With regards to future competition, I expect the entire market to move towards the once weekly products. In the

future, AZN is not going to be the only once weekly manufacturer, as I expect competition is going to be between Bydureon, Trulicity (Eli Lilly) and Novo's Semaglutide²⁰²

Trulicity was launched the US in November 2014²⁰³, and a wide EU launch is expected soon, following a November 2014 EU approval²⁰⁴ and UK launch in January 2015²⁰⁵.

In June 2014, Trulicity was clinically proven to be non-inferior to Victoza²⁰⁶, which Bydureon hasn't previously been able to achieve ²⁰⁷.

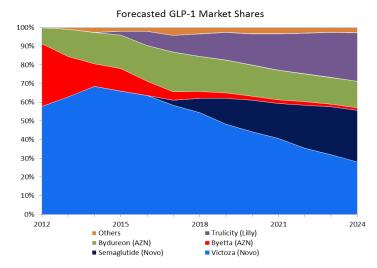


Figure 13 - Forecasted GLP-1 Market shares - Author creation

¹⁹⁸ https://www.victozapro.com/

¹⁹⁹ http://www.forbes.com/sites/edsilverman/2012/04/17/the-amylin-mystery-and-bydureon-sales/

²⁰⁰ http://www.astrazeneca.com/Media/Press-releases/Article/03032014-us-fda-approves-bydureon-pen

²⁰¹ http://www.astrazeneca-us.com/media/press-releases/Article/bydureon-pen-now-available-in-pharmacies

²⁰² Previously described in the company description.

²⁰³ http://lilly.mediaroom.com/index.php?s=9042&item=137370

²⁰⁴ http://www.nytimes.com/2014/11/26/business/international/eli-lilly-gets-european-approval-to-sell-trulicity-a-type-2-diabetes-drug.html

²⁰⁵ http://www.pharmaceutical-journal.com/news-and-analysis/news-in-brief/dulaglutide-launched-in-the-uk-as-once-weekly-diabetes-treatment/20067568.article

²⁰⁶ https://investor.lilly.com/releasedetail.cfm?releaseid=854680

Consequently, Trulicity is the best current GLP-1 product on market – as Semaglutide is still in development – so I expect Trulicity to capture market share from Victoza as well as Bydureon, with Victoza being the last choice of the three.

With Victoza considered the last choice of the three, Novo's future within GLP-1 then falls on Semaglutide. Clinical trials for Semaglutide are expected to finish in the beginning of 2016²⁰⁸, so submission for approval is expected in 2016 and launch in 2017²⁰⁹. Accordingly, I expect a loss of total Novo GLP-1 market share until 2017.

Phase III results for Semaglutide have not yet been announced, but Phase II results suggest that Semaglutide is at least comparable to current GLP-1 products or better²¹⁰, as Semaglutide has shown to provide a significant higher weight loss and better haemoglobin level compared with Victoza²¹¹.

Based on the Phase II trials; when launched I expect Semaglutide to be the best product on market, with Trulicity second, Bydureon third - given it's inferiority to Victoza.

Trulicity and Bydureon have a significant first mover advantage, which they will gain market share on, but after the 2017 launch, I expect Semaglutide to gradually recapture the market share lost by Victoza. So Novo will achieve a long-run market share slightly below current – due to being last on market, as depicted by figure 13.

5.2.6.1.1.1 Oral:

Within the GLP-1 segment, Novo is also developing several oral long-acting once daily pills. Current available data is from Phase I trials, and the pill furthest in development has moved to Phase II²¹². Being the first to launch an oral product could prove to be a major blockbuster for Novo. They are however not the only company developing an oral GLP-1 product²¹³, and only starting Phase II trials, I don't consider the product to be far enough in development to include it in a later forecast.

5.2.6.1.2 Fast-acting:

Key points from the section:

- Patent expiration eminent for all current products.
- Future competition is on new FIAsp, Afrezza and current gen products.
- Afrezza is best product on market as inhalable, but is not expected to become market leader due to historic failure of previous inhalable products.
- FIAsp to gain market share from current competition and cannibalize on NovoRapid to increase total Novo market share within the segment.

²⁰⁷ https://investor.lilly.com/releasedetail.cfm?releaseid=554248

²⁰⁸ Novo Annual Investor Presentation, full year 2014, p.71

²⁰⁹ Based on a 10 month FDA approval period as described in industry description.

²¹⁰ J.P. Morgan, Equity Report on Novo Nordisk – 24. February 2014, p.12-16

²¹¹ Novo Annual Investor Presentation, full year 2014, p.70

²¹² Novo Annual Investor Presentation, full year 2014, p.65 & 77

²¹³ http://www.bloomberg.com/news/articles/2014-09-17/sanofi-wants-to-add-oral-glp-1-to-diabetes-offer-chancel-says

Current competition within the segment is distributed between NovoLog/NovoRapid (Novo) and Humalog (Eli Lilly) and Apidra (Sanofi), with a market share distribution of 54%, 38% and 8%²¹⁴.

All three products are set to have patent expiration within the next three years²¹⁵ ²¹⁶, so I expect future competition will rely more on next generation products.

With Novo FIAsp's in phase 3a trials, I expect launch in 2016. Neither Eli Lilly nor Sanofi has developed their own new fast-acting replacement; instead they have entered into partner agreements – Sanofi with Mannkind and

their drug Afrezza²¹⁷. Eli Lilly with Adocia, where the drug is only in the Phase Ib development, thus being very far from filing for approval, so I don't consider it as a competitor. Consequently, I expect competition to be between FIAsp, Afrezza and current products.

As a competitor, Afrezza distinguishes itself by being an inhalable drug to FIAsp's injection – giving Afrezza a clear advantage within patient convenience. Further, Afrezza was FDA approved as of June 2014²¹⁸, with an expected launch in Q1 2015²¹⁹ - providing a significant head start over FIAsp.

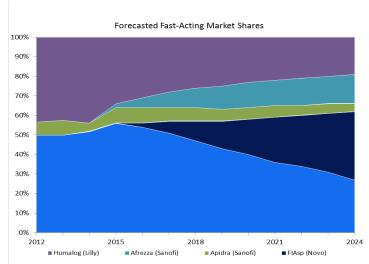


Figure 14 – Forecasted Fast-Acting Market Shares – Author Creation

Afrezza, however, faces a challenge, as they are not the first company trying to market inhalable fast-acting insulin. Pfizer has previously attempted with an equal product (Exubera), but failed massively due to its inconvenience, and not reacting fast enough compared to injectable insulins. Studies and design of Afrezza's inhaler suggest both hurdles have been overcome, but Afrezza still has to prove it can succeed where Pfizer failed²²⁰, making it hard to make the case that Afrezza will be an instant blockbuster at launch. Afrezza does, however, provide enough benefits so it should capture market share.

²¹⁴ J.P. Morgan, Equity Report on Novo Nordisk – 24. February 2014, p.28

²¹⁵ http://www.drugs.com/availability/generic-humalog.html

²¹⁶ http://www.drugpatentwatch.com/ultimate/tradename/APIDRA

²¹⁷ http://www.news.mannkindcorp.com/phoenix.zhtml?c=147953&p=irol-newsArticle&ID=1957210

²¹⁸ http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm403122.htm

²¹⁹ http://www.smarteranalyst.com/2015/01/15/mannkind-analyst-cory-kasimov-provides-update-j-p-morgan-healthcare-conference/

²²⁰ http://www.nasdaq.com/article/will-mannkinds-afrezza-succeed-where-pfizers-exubera-failed-cm29932

I expect Afrezza and FIAsp to be the products that will capture market share in the future. I expect Afrezza to capture market share from all current products. But as an improved product, I equally expect FIAsp to capture market share from Humalog and Apidra, while also cannibalizing on NovoRapid. As a combined effect, I expect Novo's market share within the fast-acting segment to increase, as depicted by figure 14.

5.2.6.1.3 Long-acting

Key points from the section:

- Current products under severe threat from Lilly biosimilar expected in 2016.
- Levemir market share will decline gradually from 2016 and forwards.
- Future competition is between new "ultra-long-acting" Tresiba and Toujeo (Sanofi).
- US Tresiba launch expected in 2017.
- Disregarding Lilly's biosimilar: Novo and Sanofi will approximately maintain their total market share.

The segment is currently being dominated by Sanofi's Lantus with a market share of 77%²²¹ and Novo's Levemir capturing the remaining 23%²²². But as described in threat of substitutes, Sanofi is facing immense pressure from Eli Lilly's biosimilar, which is expected to enter the market in 2016.

Increasing competition led Sanofi to predict that their diabetes sales growth will be flat to slightly growing through 2018²²³ - including the current Lantus product and future products.

When Eli Lilly's biosimilar enters the market, it is expected to be at lower price than Lantus²²⁴, enabling them to capture market share. I equally expect this will hurt Levemir sales growth, and expect that Levemir sales will decline gradually from 2016 and forward. With sales being most affected in the first two years, as Eli Lilly attempts to capture market share.

Growth opportunities within the segment are expected from the new generation of "ultra-long-acting" products – Novo's Tresiba and Sanofi's Toujeo. For future competition, the major question is the lacking US FDA approval for Tresiba, where the decision to file for resubmission will be taken in the first half of 2015²²⁵. In the case of a resubmission, I expect Novo has corrected the mistakes from the previous submission, and I am confident that approval will be obtained. Given the FDA's standard approval of 10 months, I expect a 2017 launch for Tresiba in the US.

²²³ http://www.bloomberg.com/apps/news?pid=conewsstory&tkr=SAN:FP&sid=alcSLZ7w1HSk

²²¹ http://seekingalpha.com/article/2395325-sanofi-confronting-lantus-patent-expiry-with-more-efficient-successor-toujeo

²²² Novo Annual Investor Presentation, full year 2014, p.52

From previously it is known that biosimilars have to be created equally to it's original, so it's not possible for a biosimilar manufacturer to immediately undercut prices. Consequently, the biosimilar manufacturers' ability to produce on equal unit cost to the originals depends on their production of scale. Given Eli Lilly is one of Novo's main competitors – Sanofi being the other – I predict that they can produce at equal pricing to Sanofi and Novo.

²²⁵ Novo Annual Investor Presentation, full year 2014, p.15

Meanwhile, Toujeo is currently undergoing FDA review²²⁶ that started in July 2014, so an FDA decision is expected as soon as February 2015, enabling a 2015 launch if approved - providing Sanofi with a two year first mover advantage.

There are currently no studies available that suggest that either Toujeo or Tresiba is superior to each other – Sanofi saying they are not worried about Tresiba²²⁷, but the opinion is obviously biased.

Given that the current products Levemir and Lantus don't have superiority over one

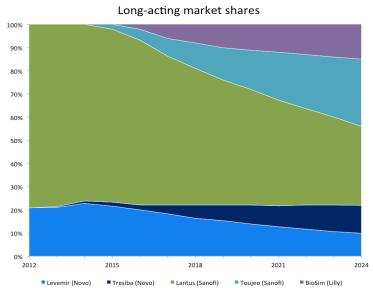


Figure 15 - Forecasted Long-Acting Market Shares - Author Creation

another²²⁸, I assume the same will hold true for Toujeo and Tresiba, so their pharmaceutical capabilities will be indistinguishable.

Having similar capabilities, I expect market share development to be dependent on the commercial operations of each individual company. I expect both companies to maintain their current market share – with a small loss to Novo due to the two-year first mover advantage in the US, as depicted by figure 15. With each firm utilizing their current sales force to convince physicians, and with the argument of brand loyalty and switching cost for patients and physicians, as there is no real clear benefit from competing products²²⁹.

5.2.6.1.4 Premix:

Key points from the section:

- Premix equal to long-acting, as products are dependent on them.
- Future competition is between Novo and Sanofi's LixiLan.
- Novo's market share to increase to market leader, due to product superiority.

Within the premix segment, I find that competition is equal to the long-acting segment, as the premix products are based on the long-acting products. Novo's competition is thus equal to Sanofi with their LixiLan, which they are developing in a partner agreement with Zealand Pharma²³⁰.

LixiLan is a direct competitor to Xultophy – being an insulin/GLP-1 mix. Novo currently has an estimated 37% market share in the segment²³¹. I expect Novo's market share to increase, with Novo becoming market leader in

²²⁶ http://www.drugs.com/nda/toujeo_140708.html

²²⁷ http://medwatch.dk/Medicinal Biotek/article7130635.ece

²²⁸ http://www.diabeteshealth.com/blog/lantus-and-levemir-whats-the-difference/

²²⁹ Coscelli A. The Importance of Doctor's and Patients Preferences in the Prescription Decision "Journal of industrial Economics 2000", Vol. 48, Issue 3.

²³⁰ http://www.zealandpharma.com/annualreport2014/Lyxumia-and-Lixilan.pdf

the long run. The expectation builds on Xultophy's position of being superior to LixiLan ²³² and that Xultophy is being launched in all non-US countries throughout 2015 - with expected US launch in 2017, following a Tresiba approval.

Meanwhile, LixiLan filing is expected in early 2016²³³ - suggesting a 2017 launch – providing Novo with a significant head start in all non-US markets.

5.2.6.2 Obesity

Key points from the section:

- Novo's Saxenda only injectable product substitutes are oral.
- Significant price premium expected for Saxenda.
- Expected sales to be in lower ranges of market consensus, due to price premium and failures of current available oral substitutes.

With Saxenda, Novo is entering into a market where the competitive products are Qsymia²³⁴ (Vivus), Belviq²³⁵ (Eisai) and Contrave²³⁶ (Takada/Orexigen). All have been FDA approved and differ from Saxenda by being Oral instead of injection. As oral is highly preferable to injection, Saxenda's success requires it to be significantly more efficient and have competitive pricing.

Saxenda's price is not yet known, but as Saxenda is identical to Victoza – just administered at a higher dose – I expect the same price per mg, given an estimated Saxenda price of \$873²³⁷ a month²³⁸. All three competitors sell at around \$210 per month²³⁹ ²⁴⁰ ²⁴¹, so I expect Novo to demand a significant premium. With regards to effectiveness, studies show Victoza to be more efficient than Belviq and Contrave, but Qsymia is superior to Saxenda²⁴².

Studies clearly show that Saxenda works²⁴³, but as current marketed products are being described as failures²⁴⁴, I have difficulties seeing the success of Saxenda. Users have to overcome the boundary of moving from pill to injection – and then at a premium cost.

However, there is a general market consensus that Saxenda will reach sales of DKK11,1 billion, with minimum expectation at DKK 3,8 billion and max at 18,3 billion.²⁴⁵

²³¹ Novo Annual Investor Presentation, full year 2014, p.47

²³² http://www.euroinvestor.dk/nyheder/2014/06/17/novo-sydbank-ideglira-mere-potent-end-lixilan/12853803

²³³ http://diatribe.org/issues/65/conference-pearls/2

²³⁴ http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312468.htm

²³⁵ http://www.eisai.com/news/news201238.html

²³⁶ http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm413896.htm

²³⁷ Victoza cost is \$524 according to truemedcost.com, with Victoza at 1,8mg and Saxenda 3mg.

²³⁸ Novo has later released a price of \$1000.

²³⁹ http://www.drugs.com/price-guide/qsymia

²⁴⁰ http://www.drugs.com/price-guide/belviq

²⁴¹ http://www.goodrx.com/contrave

²⁴² J.P. Morgan, Equity Report on Novo Nordisk – 24. February 2014, p.20

²⁴³ Novo Annual Investor Presentation 2014, p.83

²⁴⁴ http://medwatch.dk/Top_picks_in_english/article7088233.ece

Given the above comparison of product differences and pricing, I expect future Saxenda revenue in the lower end of market consensus.

5.2.6.3 Haemophilia

As I learned from the company description, the haemophilia market is segmented into three diseases – A, B & Inhibitors, with Novo only currently competing within Inhibitors.

5.2.6.3.1 Inhibitors:

Key points from the section:

- Loss of market share to AryoGen biosimilar based on expired Novo patent.

Since NovoSeven's approval in 1999²⁴⁶ the product has had monopoly through its patent protection. The original patent has now expired, where Novo renewed the patent through an isomer update that made NovoSeven room temperate stable. This did not, however, protect the original patent, leaving it open for biosimilar competition. Iranian AryoGen has developed AryoSeven²⁴⁷ as a biosimilar to the original NovoSeven patent, with a December 2014 study showing they have identical capabilities²⁴⁸.

The updated isomer NovoSeven RT has the advantage of being room temperature stable, but as the product is typically used in hospitals – critical bleeding episodes and surgical procedures²⁴⁹. I don't consider this being a significant competitive advantage. Instead, I expect AryoSeven to be able to offer competitive pricing, so Novo will gradually experience biosimilar erosion on NovoSeven. Conclusively, I expect NovoSeven sales to decrease gradually in the later forecast, by losing market share to AryoSeven.

5.2.6.3.2 Haemophilia A

Key points from the section:

- Limited success of NovoEight: Viewed as Novo's entry to the market.
- Future market based on new long-acting products from: Biogen, Bayer, Baxter and Novo (N8-GP expected launch in 2019).
- Bayer has best product and N8-GP is non-superior.
- Novo to gain modest 10% long run market share in a competitive market.

NovoEight is Novo's first attempt into the greater Haemophilia A (factor VIII) market. NovoEight is a biosimilar of Baxter's Advate²⁵⁰ - both being short acting. NovoEight has only been launched as of 2014, with

 $^{^{245}\} http://investor.borsen.dk/artikel/1/296695/sydbank_saxendas_succes_kommer_til_at_tage_tid.html$

http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm056916.htm

²⁴⁷ http://www.aryoseven.com/

²⁴⁸ https://ash.confex.com/ash/2014/webprogram/Paper75864.html

²⁴⁹ Novo Annual Report 2014, p.7

²⁵⁰ J.P. Morgan, Equity Report on Novo Nordisk – 24. February 2014, p.29

US launch in 2015²⁵¹ so sales information is scarce. As a biosimilar I only consider pricing as the competitive element, and with long acting products (N8-GP) in development, NovoEight is expected to have limited success. Only gaining a small market share, and is seen as Novo's entry product to the haemophilia A market.

Looking forward, patient convenience is improved, as products move from short acting to long acting. The future long acting market consist of four players; Biogen, Bayer, Baxter and Novo²⁵². Biogen has a significant head start, as the FDA as of June 2014 approved their Elocate product²⁵³, where Bayer, Baxter is still in Phase 3 trials. With Novo only hoping to file for approval by 2018²⁵⁴ sales are not expected before 2019.

In regards to patient convenience, N8-GP and Elocate require injection every 3 days, but Bayer's only require injection every 5 days, thus having a competitive advantage, but equally to Novo, launch is not expected before 2019, with the product being in phase 3 trials. As N8-GP is non-superior, I expect Novo to compete on pricing – unable to demand a premium.

Novo is entering into a highly competitive haemophilia A market, where they don't have first mover advantage, and their product is currently not superior to competitors. I therefore consider Novo's N8-GP to gain a modest market share from 2019 that will grow gradually to 10% looking forward.

5.2.6.3.3 Haemophilia B:

Key points from the section:

- Competition on long-acting between: Biogen, CSL and Novo (N9-GP).
- Novo expected to be last on market (Launch in 2016).
- As last and new to the market, without having the best product, I expect Novo to gain a long-run 20% market share.

For the market Novo is set to enter, competition consists of four players; Baxter, Biogen, CSL and Novo²⁵⁵. Equivalent to the Haemophilia A market, products vary by being short or long acting, where all but Baxter are long acting. I therefore don't consider Baxter as being able to compete with the three others.

Biogen has a significant head start, as their drug Alprolix was FDA approved as of March 2014²⁵⁶, and CSL is first to follow as they filed for approval in December 2014²⁵⁷, putting Novo at a disadvantage as they are not expected to file for approval before the second half of 2015²⁵⁸.

²⁵¹ Company Description, Products

²⁵² J.P. Morgen Equity Report on Novo Nordisk – 24. February 2014, p.29

²⁵³ http://www.reuters.com/article/2014/06/06/us-biogen-idec-fda-approval-idUSKBN0EH2AW20140606

²⁵⁴ Company Description, Products

²⁵⁵ J.P. Morgan Equity report on Novo

²⁵⁶ http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm391037.htm

²⁵⁷ http://www.cslbehring.com/newsroom/rIX-FP-for-Hemophilia-B-BLA-Submited-to-FDA

²⁵⁸ Company Description, Products

With regards to product differentiation in patent convenience, Novo's N9-GP and CSL's CSL-654 are once weekly, were Alprolix is once every ten days²⁵⁹. Given the head start and a competitive advantage, I expect Alprolix to become market leader, with CSL to follow second – as they have already filed.

Given the expected 2015 filing of N9-GP, I expect launch in 2016. Alprolix's advantage is not considered to be significant enough to capture the entire market, so I expect Novo to gain a long run market share of 20%.

5.2.6.4 Growth Disorders

Key points from the section:

- Oligopoly market with six players Novo as market leader.
- Competition is not product efficiency, but patient convenience.
- Future once weekly products are expected to arrive on market at the same time.
- Novo will expand market leadership due to a superior product.

The market can be described as being oligopoly with 6 significant players. Novo being market leader, where sales represent 7% of 2014 revenues.

As illustrated in appendix 4, competition within the growth hormone market is not on product efficiency, but on product differentiation through patient convenience - as described in the company description. Novo's main competitive advantage in regards to patient convenience is that Norditropin is the only product that can be stored at room temperature. The FDA approved

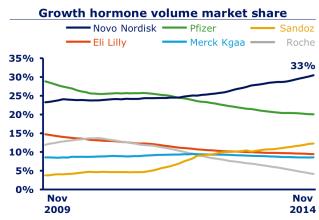


Figure 16: Growth disorder volume market share – Source: Novo Annual Report Presentation, p.95

the new room temperature formulation in 2010 for the US market²⁶⁰ and it was approved in the EU in 2013²⁶¹. It's believed that the patent years correspond well with figure 16, as Novo starts to gain market share by 2010 and is accelerated following the EU patent, but it's questionable if the growth in market share can be sustained with patent expiration in 2017.

From the company description, I know that future development is equally within patent convenience, with the NN8640 being once weekly versus the current once daily. I find that competitors are developing drugs with equal once weekly capabilities, most noticeable Pfizer²⁶² and Merck²⁶³. Pfizer is currently in phase 3 trials and Merck is preparing for phase 3 trials. With Novo equally having begun Phase 3a trials in November 2014, I

²⁵⁹

 $http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBL\ As/FractionatedPlasmaProducts/UCM391049.pdf$

²⁶⁰ http://press.novonordisk-us.com/index.php?s=20295&item=122594

²⁶¹ http://www.pharmiweb.com/pressreleases/pressrel.asp?ROW_ID=71429#.VUjB7NOeDGd

²⁶² http://www.pfizer.com/news/press-release/press-release-

detail/opko_and_pfizer_enter_into_global_agreement_for_opko_s_long_acting_human_growth_hormone_hgh_ctp

²⁶³ http://ambrx.com/pipeline/arx201-hgh-growth-deficiency/

estimate Pfizer and Novo to market their once weekly products at the same time. The Pfizer product does, however, not have the same room temperature capabilities as Novos.

Conclusively, I notice a significant rivalry between established competitors, all trying to have the best product on market based on patient convenience. Novo's market leadership is explained by having the most superior product, and the firm is ready to meet the new requirements for "best product" by developing the once weekly NN8640. While maintaining the advantage of being the only product that's room temperature stable. I therefore expect Novo to increase its market share to a long run 40% within the growth disorder segment.

5.3 Internal – Resources and capabilities

For the internal analysis, I distinguish between resources and capabilities, where resources are the productive assets of the firm, and capabilities are what the firm can do with its resources²⁶⁴.

The Five Forces analysis showed that Novo is competing in four different industries, thus having multiple competitors. Based on Novo's revenue distribution between the industries, two competitors stand out as Novo's primary competition; Eli Lilly and Sanofi. For the internal analysis, these firms will be used to analyse if Novo's internal resources and capabilities are eligible as competitive advantages.

5.3.1 Resources

Key points from the section:

- Novo has fewer plants than competitors.
- Equal between competitors:
 - O Distribution resources, due to same global strategic positioning of plants.
 - Credit ratings.
 - o Financial strength.
- Patents, regulatory and administrative functions are not a competitive advantage, as they are "needed to play".
- Novo has a strong corporate culture, enabling them to sustain key employees.
- Novo is able to attract necessary human resources for additional growth through strong reputation.

5.3.1.1 Plants & distribution: Novo has fewer plants but equal distribution resources

Novo's production of the active pharmaceutical ingredients (API) in all products is highly centralized, as manufacturing only takes place in Denmark. Where the final production and assembly takes place in five countries; Denmark, France, US, Brazil and China, and additionally smaller plants in selected countries to supply local demand²⁶⁵.

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²⁶⁴ Grant, p.127

²⁶⁵ Novo Annual Report 2014, p.18

Sanofi follows a similar strategy, but has a much wider spread of production facilities with no single global site. Sanofi has production in Brazil, Mexico, India, China and Russia²⁶⁶, but where Novo limits themselves to single plants in individual countries, Sanofi has several plants²⁶⁷.

Eli Lilly has manufacturing spread out over 13 countries²⁶⁸, where manufacturing of API's is done in US and Puerto Rico, with manufacturing of insulin cartridges in France and China²⁶⁹.

For distribution, I see no apparent competitive advantage as all three have strategically spread out their production facilities. Equally I find that the three companies have locations in many of the same countries, so there should be no advantage to be gained, from having facilities in lower-cost countries than competitors.

5.3.1.2 Finance: Equal credit rating and financial strength

All three companies have close to identical credit ratings²⁷⁰ ²⁷¹ and positive free cash flows per share, and are returning cash to shareholders through dividend payments²⁷².

I believe that all three firms either have sufficient capital, or are able to borrow to invest in new and on-going projects. As such, I consider the three companies to have equal financial strength, thus not a competitive advantage to Novo.

5.3.1.3 Intellectual property & support functions: Not a competitive advantage

As discussed previously, pharmaceutical companies are heavily dependent on their intellectual property, and this can arguably be said to be the most valuable asset they possess. Equally the protection thereof through patents secures them from being replicated, but I argue that patents are not a competitive advantage.

Patents ensure long-term profitability by avoiding replicability, but that profitability is only sustained as long as the product is best on market. Thus, the competitive advantage is the underlying product, where the patent is merely a protection mechanism necessary to all pharma companies, and thereby not unique to the specific firm. It's simply necessary if a firm wishes to compete in the industry, and doesn't explain long-term profitability, e.g. if a far superior and cheaper product becomes available in the market, I assume users will switch to that product, regardless that the current product is still patent protected.

Equally, I find the regulatory and corporate and administrative support functions are not a source of competitive advantage. A pharmaceutical company will not function without, but I believe that as a resource they are easily transferable between companies and can be categorised as needed to play and not needed to win.

²⁶⁶ http://en.sanofi.com/products/manufacturing_distribution/manufacturing_distribution.aspx#para_1

²⁶⁷ http://en.sanofi.com/our_company/worldwide/worldwide.aspx

²⁶⁸ http://www.lilly.com/about/key-facts/Pages/key-facts.aspx

²⁶⁹ https://investor.lilly.com/releasedetail.cfm?ReleaseID=807331

²⁷⁰ Based on S&P Long-term Issuer Rating (Foreing) and Short Term Issuer Rating (Foreing) – Thomson ONE Banker

²⁷¹ S&P Long-term: AA-, S&P Short-term: A-1+

²⁷² Thomson ONE Banker

5.3.1.4 Human: Strong corporate culture and external image

Pharmaceutical firms are dependent on human resources for ingenuity and know-how to utilize and further develop their intellectual property. Additionally, firms invest substantial funds into the education of employees, to further develop their capabilities. But as firms cannot own human resources, the mobility of key employees is a threat to the competitive advantage of firms²⁷³.

Establishing a culture that ensures the satisfaction among current staff and attracts new talents can then become a competitive advantage.

Novo uses the concept of "The Novo Nordisk way"²⁷⁴ to establish a culture where employees values are aligned. Novo performs an annual compliance survey that measures, to which extent employees are aligned with "The Novo Nordisk way" on a scale from 1–5. Similar compliance rating method is not found with Eli Lilly and Sanofi. Novo believes it is a statement of being able to "walk the talk" as they put an actual measure on employees' alignment and satisfaction.²⁷⁵

For 2014 the company reported a score of 4,3 – which according to Novo signals a strong corporate culture.

From an external perspective, Novo was ranked as the globally #72 best place to work by Fortune Magazine²⁷⁶ ²⁷⁷ - Eli Lilly & Sanofi were not ranked – and Novo was ranked as the worlds 2nd best employer for scientist in 2014²⁷⁸. Consequently, I consider Novo as having a strong corporate culture that's able to maintain current key employees. And by having a good external reputation, I am confident Novo will be able to acquire the necessary human resources for continued growth.

Additionally, Novo distinguishes themselves from Eli Lilly and Sanofi through their M&A policy²⁷⁹ - limited use of a business development. By being limited to organic growth, Novo has full control of recruitment and education of employees. Thus avoiding the potential corporate culture issues that can develop when businesses merge - ensuring alignment between employees' values and goals.

²⁷³ Grant, p.138

²⁷⁴ http://novonordisk-us.com/documents/content_pages/tab_page/2_2_Our_Culture.asp#

²⁷⁵ Source: Interview with Ingrid Korff – Manager at Novo Nordisk A/S.

²⁷⁶ http://archive.fortune.com/magazines/fortune/best-companies/2014/list/?iid=BC14_sp_full

²⁷⁷ The ranking is created based on employee surveys

²⁷⁸ http://www.business.dk/medico/novo-nordisk-verdens-naestbedste-arbejdsplads-for-forskere

²⁷⁹ Covered in External Analysis - Technological

5.3.2 Capabilities

Key points from the section:

- R&D: Competitive advantage due to more narrow strategic focus.
- Manufacturing: Greater production of scale advantages.
- Commercial operations: Not an advantage as Sanofi has superior capabilities.

Research and development: Advantage from strategic focus 5.3.2.1

As a knowledge intensive firm, Novo's core capability is R&D. Combining their human resources with the intellectual property in the form of technology, techniques and procedures that the firm has developed through years of operation.

	R&D Cost / Total Revenue											
	2010	2010 2011 2012 2013 2014										
Novo	15,0%	13,5%	13,4%	13,5%	14,5%							
Eli Lilly	30,6%	20,7%	23,4%	23,9%	24,1%							
Sanofi	13,4%	13,7%	13,6%	14,3%	14,1%							

Table 4 - R&D Cost relative to Total Revenue - Source: Author Creation

Unfortunately, the same holds true for Eli Lilly and Sanofi, and previous analysis of rivalry between the three, did not suggest that Novo has a capability to consistently create superior profits, by consistently creating superior products. Additionally, table 4 illustrates that all three have maintained the same R&D cost relative to revenue, thus not suggesting Novo is making an additional effort within R&D.

The above would suggest the three to be equally competitive within R&D. However, I will argue that Novo has a competitive advantage, due to the differences in the three companies' portfolios. Both Eli Lilly²⁸⁰ and Sanofi²⁸¹ have a range of products that are all related by being pharma products. The same holds true for Novo, but their strategic focus is even narrower by only operating with protein-based treatments. The focus creates a more streamlined organisation, making the company experts within a specific area rather than several, achieving a "deep disease understanding"282, which is equally showed as they are the only company to have a full diabetes portfolio, and by their 2014 choice of abandoning a new segment within inflammatory disorders.

The competitive advantage is considered established, by Novo being the only company with an only protein related focus, and sustainable as it's considered unlikely that Eli Lilly or Sanofi would pursue the same strategy, and entry from external competition was previously analysed as being low.

5.3.2.2 Manufacturing: Greater production of scale advantages

The competitive advantage achieved from Novo's strategic focus is equally translated into Novo's manufacturing capabilities.

By being limited to protein products, Novo is able to achieve greater production of scale Source: Author Creation

	COS / Total Revenue										
	2010	2010 2011 2012 2013 201									
Novo	16,2%	16,1%	14,7%	14,4%	13,9%						
Eli Lilly	18,9%	20,9%	21,2%	21,2%	25,1%						
Sanofi	27,3%	29,6%	30,8%	33,0%	32,3%						

Table 5 – Cost of sales / Total Revenue

²⁸⁰ http://www.lilly.com/products/human/Pages/Our-Current-Products.aspx

²⁸¹ http://en.sanofi.com/products/products.aspx

²⁸² Novo Annual Report 2014, p.17

advantages, as they are able to limit their production to fever plants & facilities – as described in the resource section. As can be seen from table 5 this assumption seems to hold true, as Novo is able to achieve the lowest production cost of the three, and therefore is considered a competitive advantage. Equally to R&D, the advantage is established, transparent, and replicable but considered unlikely, as I don't expect Eli Lilly or Sanofi to adapt similar strategy.

5.3.2.3 Commercial operations: Sanofi has superior capabilities

I don't consider the strategic advantage gained from the strategic focus to be translated into Novo's commercial operations. I will not directly compare sales cost, as they are reported in combination with distribution cost. But from the rivalry between established competitors section, I learned that within the long-acting segment, Novo's Levemir and Sanofi's Lantus had equal capabilities, yet Sanofi has a 77% market share to Novo's 23%.

Sanofi's significantly larger market share is partly explained by being first to market, but it's believed that their ability to maintain their market share is caused by having a superior commercial operation to Novo²⁸³. Consequently, I don't consider Novo as having a competitive advantage through their commercial operations.

5.3.3 Sustainable competitive advantage

Key points from the section:

- Long-run competitive advantage from strategic focus only on protein related diseases.

For the internal analysis I conclude that Novo's long-term sustainable competitive advantage is caused by their strategic focus of only focusing on protein related products. The advantage is established and sustainable, creating a streamlined firm, which becomes expert within a particular field, rather than good in many, achieving greater economies of learning and economies of scale than competitors.

²⁸³ Source: Interview with Ingrid Korff – Manager at Novo Nordisk A/S

5.4 SWOT

To summarize the strategic analysis the SWOT framework is applied to identify Novo's strengths, weaknesses, opportunities and threats:

Strengths

- Competitive advantage from strategic focus on protein related diseases.
- Greater production of scale advantages than competitors through strategic focus.
- Only firm with full pipeline.
- Independent of business cycles.
- Strong corporate culture and good external image.
- Sufficient financial strength to fund new R&D and projects.
- Low threat of entry from external competition.
- High bargaining power over suppliers from vertical integration and simple raw materials.

Weaknesses

- Missing US Tresiba approval, affecting 26% of current revenue.
- Non-superior commercial operation.
- No increase in overall product prices due to biosimilar pressure and increased buyer power.

Opportunities

- Increasing global population.
- Increasing global obesity and diabetes prevalence.
- Large potential upside from new product categories; obesity, haemophilia A & B.
- Improve diagnostic rates to overcome "the rule of halves".

Threats

- Increasing global price pressure through healthcare reforms.
- Biosimilars entering the market, stimulated by governments.

6 Budget

6.1 Revenue forecast

I continue the separation of individual product groups from the company and strategic analysis. I forecast the global and or US market and combine the forecast with the rivalry between established competitors analysis, to return a total franchise revenue forecast.

Key points from the section:

- Combined revenue forecast is below but within the limits of market expectations.

6.1.1 Diabetes

As I have shown previously, the diabetes market is segmented dependent on the underlying product. It is, however, not necessary to forecast the individual market, as the volume distribution between the segments have historically been roughly equal²⁸⁴. I assume the distribution will continue in the future, thus only needing to forecast the overall diabetes market.

Historically, the market value has grown by a 16% CAGR between 2004-2014 and an even higher 17,2% from 2009-2014. Growth has however primarily been driven by price increases as volume growth was a significant smaller 5,8% for the same period²⁸⁵. Based on the strategic analysis, I expect lower future CAGR value growth rates, as growth is expected from volume and not price increase due to political pressure.

Estimates project the US market to grow from a 8,99% CAGR from 2012 to 2022 with ROW projected at a 9,46% CAGR ²⁸⁶. Equally, a market consensus estimates a global 11,4% CAGR from 2014-2018²⁸⁷, suggesting the market is to grow the most in the first forecasting years with gradually declining growth rates here after.

For a long-run growth rate, I follow the social and demographic analysis and set it according to the IDF 2035 estimates with 3% for the US market and 2% for ROW.

	Diabetes market growth forecast											
	2015 2016 2017 2018 2019 2020 2021 2022 2023 2024											
US	15%	14%	13%	12%	8%	7%	6%	5%	4%	3%		
ROW	15%	15%	14%	12%	10%	8%	7%	4%	3%	2%		

 $Table\ 6-Diabetes\ market\ growth\ rate\ forecast-Author\ creation$

Before combining market growth rates with predicted market share development from the competitor analysis, I draw inspiration from the options based valuation approach, to adjust for the probability that drugs currently in development will obtain marketed approval for the predicted year.

For all future products but Tresiba, I apply an 80% risk adjustment. For Tresiba I apply a 95% risk adjustment for the US market, as I am highly confident Tresiba will obtain US approval, as Tresiba has obtained EU

²⁸⁴ Novo Annual Investor Presentation, full year 2014, p.39

²⁸⁵ Novo Annual Investor Presentation, full year 2014, p.27

²⁸⁶ GlobalData – Projection of global type 2 diabetes pharmaceutical market revenues by region in 2012 and 2022 (in billion U.S. dollars).

²⁸⁷ http://www.reuters.com/article/2014/01/30/us-oramed-trial-idUSBREA0T0LR20140130

approval and is a refiling, where criticism towards the original filing should have been corrected. Including the risk adjustment I am now able to predict the future diabetes revenue, with the major parts of the model represented in appendix 8. In addition to the modern insulins described above, Novo has annual sales of 10-11 billion from human insulins. Sales have been stable for the past five years²⁸⁸, so I predict this will hold true for all future years, with 0% growth rate.

6.1.2 Hemophilia

The combined hemophilia A & B market is estimated at \$10 billion and is estimated to grow to \$13B by 2020²⁸⁹. Based on the product description, I derive the Hemophilia A to \$8,33 billion and Hemophilia B as \$1,66 billion, expected to grow to \$10,83 and \$2,16 billion respectively.

As an inherited disease, I expect a long-run growth rate equal to the global population growth rate of 0,225%, described in the external analysis. Again, I combine the expected growth from the total market with the market share development from the competitor analysis to derive a forecast for Novo.

6.1.3 Growth disorders

The value of the global market has grown by a CAGR of 2,2% for 2009-2014²⁹⁰. I find no evidence suggesting the market should develop differently in the future. Given the growth rate is relatively modest and not significantly different from the population growth rate, I forecast the market to continue with a 2,2% growth rate for all forecasting periods. I combine the growth rate with Novo's long run 40% market share from the competitor analysis, to return the total forecast for Novo's growth disorder segment.

6.1.4 Market consensus comparison

Market consensus is based on the average from several analysts. A combined table of estimates can be found in appendix 9. As analysts have individual assumptions for their estimate, these will not be examined. The comparison is only performed for the first five

Revenues					
DKK mm	2015	2016	2017	2018	2019
Forecast	97.934	106.511	116.599	124.760	134.336
Consensus	107.776	117.070	127.394	134.669	141.583
Difference	9.842	10.559	10.795	9.909	7.247
Market min.	97.570	106.292	115.067	120.189	122.543
Market max.	112.463	122.099	137.433	157.840	166.259

Table 7 - Revenue consensus comparison - Author creation

years, as consensus isn't available for further periods.

Table 7 shows that the combined franchise forecast is bullish, as the forecast is below consensus for all 5 years. But I notice that the forecast is within the minimum estimate for all five periods, so the forecast is considered realistic in relation to market expectations. Other things being equal, the revenue forecast should return a stock price below trading level.

²⁸⁸ Novo Annual Investor Presentation, full year 2014, p.45

²⁸⁹ Baxter 2015 Investor Conference – Hematology, p. 4

²⁹⁰ Novo Annual Investor Presentation, full year 2014, p.95

6.2 Financial statement forecast

I continue to use Eli Lilly and Sanofi as the basis for my comparison. As previously described, they are not identical in operation to Novo, with the main difference being a broader portfolio for Eli Lilly and Sanofi. They are however Novo's main competitors and assessed as being the best companies to use for comparison.

6.2.1 Restatement of financial accounts

I have restated the financial accounts in order to obtain the necessary measures for the later comparison of key ratios. Restatement of the individual accounts is done following the approach of Petersen & Plenborg 2012, p.70-79.

I find Sanofi to have the most comparable financial statements, as they report under the IFRS procedure – equal to Novo - where Lilly uses US GAAP. Additionally, Sanofi reports in Euro making the figures comparable to Novo - given Denmark's fixed rate exchange policy towards the Euro²⁹¹. Lilly Reports in US dollars creating noise within the comparison, due to exchange rate fluctuations.

For Novo and Sanofi's income statement, the individual depreciation and amortization have been subtracted from the related expenses. The same has not been possible for Eli Lilly, as the necessary information is unavailable. To create a better comparison, I considered to apply the same depreciation pattern from Novo onto Eli Lilly's accounts. The returned result was, however, considered unrealistic. Therefore, I decided to rely on Lilly's statement of operations for the best comparison. It should be noted that higher cost ratios for Lilly might relate to un-subtracted depreciation and amortization.

In restating Novo's balance sheet, I have classified other non-current financial assets as interest-bearing assets, as they are measured at fair-value and available for sale²⁹², and retirement benefit obligations as part of finance according to Petersen & Plenborg²⁹³.

In relation to Lilly; in 2012 and 2013 Lilly gained income from a terminated partnership agreement with Amylin²⁹⁴. The filing is considered non-recurrent and therefore listed as extraordinary and unrelated to operations, where it was previously classified as: Other (income) expense. Restated financial accounts for all three companies are available in appendix 8.

I have selected to calculate Novo's tax shield based on the statutory Danish tax rate, as I will apply the same approach for the later valuation. For Eli Lilly and Sanofi I have selected their effective tax rate. Differences in tax rate selected, will not affect the later comparison of key ratios, as ratios have been calculated on a before tax basis, to avoid differences in tax rates.

²⁹³ Petersen & Plenborg (2012), p.78

²⁹¹ http://www.nationalbanken.dk/da/pengepolitik/fastkursERM2/Sider/Default.aspx

²⁹² Novo annual report 2014, p.85

²⁹⁴ https://investor.lilly.com/releasedetail2.cfm?ReleaseID=621647

6.2.2 Operating profitability

Key points from the section:

- Novo has superior profitability explained by their competitive advantage of maintaining a strategic focus on protein related diseases.

I follow the Du-Pont approach to measure operating profitability, benchmarking against competitors. As Novo currently has no long-term debt, and it has previously been assumed that this will be continued in the forecast, focus is on operating profitability and effects of financial gearing have been omitted.

6.2.2.1 ROIC²⁹⁵ before tax:

For comparison ROIC is either calculated before or after tax. To create the best comparison, I have selected ROIC before tax, as the firms operate in different countries and are therefore subject to

ROIC before tax	2010	2011	2012	2013	2014
Novo	85%	100%	119%	117%	124%
Eli Lilly	61%	57%	56%	55%	35%
Sanofi	14%	8%	10%	8%	10%

Table 8 - Historical ROIC before tax - Author creations

different effective tax rates, and this should therefore eliminate noise from tax rate differences.

A significant difference can be noticed across the three firms, with Novo showing clear superiority. Equally, it can be noticed that only Novo has been able to increase their ROIC while Lilly has almost cut profitability in half, with Sanofi having relative stable yet decreasing ROIC. To explain Novo's superior ROIC, further decomposing of the ROIC is necessary

6.2.2.2 Turnover rate²⁹⁶

As shown Novo is superior in utilizing their invested capital - with improvements for the first three years and a relatively stable level hereafter.

Turnover rate	2010	2011	2012	2013	2014
Novo	2,59	2,96	3,16	3,10	3,19
Eli Lilly	2,13	2,53	2,72	2,35	2,27
Sanofi	0,71	0,52	0,55	0,53	0,54

Table 9 - Historical Turnover rate - Author creation

For Eli Lilly a relatively stable turnover

rate is noticed for the period, with a combined increase from 2010-2014. I therefore don't find turnover rates are able to explain Lilly's significant decrease in ROIC.

For Sanofi, I find turnover rates far more explanatory, as they are significantly lower than Novo and Lilly, and decreasing, indicating they have inferior ability to utilize their invested capital.

Looking more closely at Sanofi's balance sheet, I notice a considerable commitment in intangible assets that is not found with Novo and Sanofi. The assets are related to three acquisitions from 2004-2011²⁹⁷. Given Novo's

²⁹⁶ Revenue / Invested Capital

²⁹⁵ EBIT / Invested Capital

²⁹⁷ Sanofi Annual Report 2014, p.F44 – F45

strategy of only using organic growth, I therefore consider the large differences in ROIC and turnover rate between Novo and Sanofi, to be largely related to M&A strategy.

Profit margin²⁹⁸ (EBIT) 6.2.2.3

Given the previously mentioned differences in ability to deduct depreciation and amortization (D&A), I have selected to compare profit margins at the EBIT level, in Table 10 - Historical EBIT profit margin - Author creation

Profit margin (EBIT)	2010	2011	2012	2013	2014
Novo	33%	34%	38%	38%	39%
Eli Lilly	29%	22%	21%	24%	15%
Sanofi	19%	16%	18%	15%	18%

order to eliminate D&A differences. Equally, I avoid comparing at NOPAT level to eliminate differences in effective tax rates.

For profit margins the same pattern as the ROIC analysis can be noticed, with Novo being the only firm able to increase margins for the five year period - with Lilly cutting their margin in half. Suggesting Novo has been superior in managing their cost. Profit margins are therefore considered the primary explanation for Lilly's decreasing ROIC.

Sanofi's margins are somewhat comparable to Lilly and Novo, and I therefore conclude their ROIC differences to partially be explained by lower profit margins, but more significantly from different M&A strategy.

Common-size comparison²⁹⁹

To further compare profit margins, I perform a common-size comparison of major cost items.

Between Novo and Lilly equal S&A cost but superior cost of sales with opposite trends and relatively stable R&D levels can be noticed. I therefore account the large differences in ROIC between Novo and Lilly to be caused by Novo being able to manage their cost better and improve it over time.

% of revenue	2010	2011	2012	2013	2014					
	Cost of sales									
Novo	16,2%	16,1%	14,7%	14,4%	13,9%					
Eli Lilly	18,9%	20,9%	21,2%	21,2%	25,1%					
Sanofi	27,3%	29,6%	30,8%	33,0%	32,3%					
		Sales &	& Adminis	trative						
Novo	34,8%	33,3%	31,7%	32,0%	30%					
Eli Lilly	30,6%	32,4%	33,2%	30,8%	33,8%					
Sanofi	24,0%	24,3%	24,8%	25,8%	26,4%					
		Research	and deve	lopment						
Novo	15%	13,6%	13,4%	13,5%	14,5%					
Eli Lilly	21,2%	20,7%	23,4%	23,9%	24,1%					
Sanofi	13,4%	13,7%	13,6%	14,3%	14,1%					

Table 11 - Historical common-size comparison - Author creation

I believe that this corresponds well with the strategic analysis, and I account the differences to be caused by Novo's competitive advantage of strategic focus on protein related disease, giving them greater production of

²⁹⁸ EBIT / Revenue

²⁹⁹ Cost of sales and R&D table is equal to tables in the internal analysis.

scale advantages. Equally, this corresponds well with Novo having similar S&A levels, as I don't consider the advantage to translate into the S&A cost item.

For Sanofi I concluded in the internal analysis that they have superior commercial operations capabilities. This is confirmed in the cost item, as they have the lowest level of the three companies. Within R&D I find Sanofi has equal levels to Novo. This is surprising, because I learned from the turnover rate that they follow a different growth strategy by using acquisition. I would therefore expect Sanofi to have lower levels compared with Novo.

It is considered that the similar levels are a sign of Novo's competitive advantage, as they are required to allocate fewer resources to maintain a full pipeline, due to their strategic protein focus. Equally, Novo has roughly half of the cost of sales level to Sanofi, showing greater production of scale advantages, which is also believed to be caused from Novo's competitive advantage.

6.2.4 Profitability summary

Based on ROIC levels, I find Novo to be highly competitive, as the company shows substantial superior profitability levels. I find differences to be caused by Novo having better cost levels, and an ability to improve them over time, where competitors have increased theirs. Between Novo and Sanofi the most significant difference in ROIC levels is caused by the firms following different acquisition strategies, with Novo having the same R&D levels as Sanofi.

Overall, I account Novo's superior profitability to be caused by the competitive advantage of maintaining a strategic focus on protein related diseases. The advantage does, however, not translate into superior sales and administrative cost levels.

6.2.5 Operating expenses forecast

I forecast all operating as percentage of revenues³⁰⁰ to arrive at the EBITDA margin.

Key points from the section:

- Cost of sales decreases to a long-run level of 11% through production of scale.
- Sales and distribution kept at current levels due to opposite effects from ObamaCare and new markets with Obesity and Haemophilia A and B.
- R&D is kept at the five-year average, as research will continue within existing areas.
- Administrative cost decreases slightly in the period to 3,1% due to economies of learning and historical data.
- Other operating income kept at the five year average.
- EBITDA margin starting below but converging towards market consensus.

6.2.5.1 Cost of sales

Historically, I find cost of sales has dropped between 0,1%-1,4% annually relative to revenues. Based on the strategic analysis, I don't find new products in the pipeline that suggest Novo will deviate from their strategic focus. Equally, because Novo only focuses on organic growth, I believe Novo will be able to continue to gradually increase their gross profit margin, due to production of scale and economics of learning. Additionally,

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³⁰⁰ Koller et al., p.194

due to the nature of the raw components used for production, I don't find increasing consider raw material prices, as being able to increase cost levels significantly.

Because production of scale advantages are considered to follow an exponential pattern³⁰¹, cost levels will reach a long-run steady state for the terminal period, which I estimate to 11%.

6.2.5.2 Sales and distribution

Based on the previous common size and internal analysis, I don't consider Novo's competitive advantage to translate into lower long-run cost levels. I expect Novo to require additional resources due to their entry into the new obesity and hemophilia A & B market. But at the same time, I expect fewer resources to be required for the major US market. As uninsured consumers transition into ObamaCare, so fewer resources are needed for individual practitioners, as Novo will increasingly have to deal with the US government as the major buyer. With new markets and ObamaCare having opposite effects, I expect sales and distribution costs to be equal to the 2014 levels for all forecast periods.

6.2.5.3 Research and development

From the company description, I know that due to the ownership of the Novo Nordisk Foundation, Novo Nordisk A/S is required to continue to significantly contribute with R&D in the medical field. Additionally, due to the strategic focus I don't expect Novo to try to add completely new product groups to the portfolio, so large increases in R&D are not expected. Rather, I expect that current R&D levels will stay relative stable for all forecasting periods, as research will continue within existing research areas. Maintaining current levels equally seem true from the common size comparison, as Eli Lilly and Sanofi have roughly maintained their R&D levels for the five year period.

For forecasting purposes, I select the five-year average of 14% as my long-run forecast margin.

6.2.5.4 Administrative cost

Novo has been able to decrease its administrative cost by 1,1% in a five year period. For the budget period revenues are estimated to multiply by 1,95. I expect Novo to achieve some level of economies of learning through improved organizational routines, so I don't expect administrative cost to grow at a 1:1 level. Rather, I expect administrative cost to be at 80% of current levels, translating into a cost of margin relative to revenues of 3,1% with current levels at 3,9%.

6.2.5.5 Other operating income

The income is related to income of a secondary nature, in relation to main activities of Novo such as license income and other subsidiaries in the form of NNIT and NNE Pharmaplan³⁰². The income has been relatively stable for the five year period, and I have no reason to believe the income will increase significantly relative to revenue. I therefor select the five-year average of 1% as our long-run estimate for all forecasting periods.

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³⁰¹ Nell, P. C., Session 6, FS58 Strategic Management – Winter Semester 2011 CBS, slide 15

³⁰² Novo Annual Report 2014, p.69

6.2.5.6 Market consensus EBITDA comparison

Having the individual cost margins set, I am now able to calculate the estimated EBITDA margin and compare with market consensus.

EBITDA margin	2015	2016	2017	2018	2019
Estimate	43,6%	44,1%	44,5%	44,9%	45,3%
Consensus	46,8%	45,5%	46,2%	44,6%	45,8%

Table $1\,2$ – Comparison of forecasted and market consensus EBITDA margin - Author creation

I notice that the estimated margin is

below consensus, but gradually converging. Other things held equal, it suggests a final stock valuation below trading level. However, as only the first five years are available, it's hard to conclude on the long run estimate. Especially since I don't know the market consensus on the terminal EBITDA margin.

6.2.6 Other value drivers

To complete the income statement, I need to forecast future depreciation. I do so by forecasting the balance sheet:

- Balance sheet: The balance sheet is forecasted in relation to revenues as it provides the most stable forecast³⁰³. Exemptions are made for inventories and trade payables that are set to follow cost of sales³⁰⁴.
- Depreciation: Depreciation is calculated as percentage of PP&E³⁰⁵, where I have used the five-year historical average for the budget.
- Tax rate: I continue the approach from the financial restatement and select the Danish statutory tax rate for forecasting, with 23,5% in 2015 and 22% from 2016 and forward³⁰⁶
- Net borrowing rate: The rate is calculated net financial expenses after tax / net interest-bearing debt³⁰⁷. There is no pattern in Novo's historical interest rate, as financial expenses are primarily related to gains/losses from forward contracts and future options used for hedging purposes due to Novo's capital structure. I have therefore selected the 2014 rate for all future periods.
- Net interest-bearing debt: Estimated as a percentage of invested capital, based on the average from the fiveyear period³⁰⁸.

A combined table of budget value drivers is available in appendix 11.

³⁰³ Koller et al., p.199

³⁰⁴ Koller et al., p.200

³⁰⁵ Koller et al., p.201

³⁰⁶ http://www.skm.dk/media/139059/aftale-om-en-v_kstplan.pdf

³⁰⁷ Petersen & Plenborg, 2012, p. 117

³⁰⁸ Petersen & Plenborg, 2012, p. 176

6.2.7 Pro forma financial statements

Combining revenue, operating expense forecast and other value drivers, I calculate the combined pro forma income, balance and cash flow statement, available in appendix 12, 13 and 14 respectively. They form the basis for the valuation, as the free cash flow to the firm (FCFF) is available from the cash flow statement to use in the E-DCF, and NOPAT from income statement along with invested capital from the balance sheet, to form the basis for the EVA valuation.

6.2.7.1 Profitability development

From the pro forma financial statements, I see that aligned with the operating expense forecast, Novo's profitability will continue to increase due to improved profit margins and better utilization of invested capital. Equally I notice that Novo reaches a steady state level in 2023 as the forecasted ratios are maintained for 2024 and the terminal period.

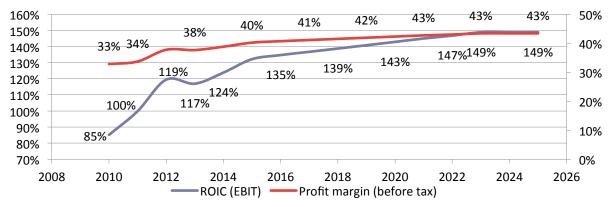


Figure 17 – Forecasted ROIC (EBIT) and profit margin (before tax) – Author creation

Turnover	2011	2013	2015	2017	2019	2021	2023	Terminal
rate	2,96	3,10	3,28	3,32	3,36	3,39	3,43	3,43

Table 13 - Forecasted turnover rate - Author creation

7 Valuation

Using the pro forma financial statements, I valuate Novo's stock price using the DCF-model as primary, EVA as control and multiple for comparison. Finally I test the DCF results using a sensitivity analysis, where I analyse how the stock price reacts by changing some of the key variables.

7.1 Weighted average cost of capital

To arrive at a present value of the estimated future cash flows, I discount at the opportunity cost of capital using the weighted average cost of capital (WACC)³⁰⁹.

$$WACC = \frac{NIBD}{(NIBD + E)} r_d (1 - T_m) + \frac{E}{(NIBD + E)} r_e$$

Equation 2 - WACC Definition - Source: Petersen & Plenborg (2012), p.246

To arrive at the final WACC discount rate I estimate each of the individual subcomponents of the WACC formula.

7.1.1 Capital Structure

As the WACC name suggests, the formula is based on the weighted sum of required return to shareholders and debt holders. Making it necessary to estimate the future capital structure to determine the weighting. The capital structure is to be calculated based on market values - not book values. This, however, forms a problem, as the purpose of the thesis is to estimate the market value of debt and equity³¹⁰.

To overcome this issue, one possibility is to estimate long-term capital structure based on comparable firms. This can, however, be challenging as firms are rarely completely comparable. Eli Lilly and Sanofi would be first choice for comparison. But as I noticed in the profitability analysis, due to differences in M&A policy, the two firms have very different ROIC rates, as M&A is funded by long-term debt, which Novo does not have. A comparable firm should also be one, which follows the same growth strategy as Novo, which I am unlikely to find. I therefore do not consider comparison as an appropriate estimate for Novo's capital structure.

Alternatively, it is suggested to estimate the capital structure by estimating the market values of debt and equity. But looking at Novo's balance sheet in appendix 9, I notice that Novo has no non-current debt and negative net-interest bearing debt. The major debt components are hedging instruments, which are reported at fair market value, on the basis of quoted market prices³¹¹ - suggesting that Novo is 100% equity financed. The observation is equally supported when measured at market values, where Novo is reported as being 100% equity financed for the five year historical period³¹².

Additionally, based on Novo's M&A strategy of only relying on organic growth and keeping focus on protein related diseases. I don't find evidence to suggest that Novo will require external funding. Maintaining a capital

³⁰⁹ Koller et. Al., p.231

³¹⁰ Petersen & Plenborg, 2012, p.246

³¹¹ Novo Annual Report 2014, p.82

³¹² Thomson One Banker

structure reliant on equity equally seems supported from the overall industry, as it's normal to have low Debt/Equity levels with an 11,43% industry average³¹³. I therefore conclude that Novo's long-term capital structure is 100% equity.

Mathematically, in relation to the WACC formula, being 100% equity financed means that the WACC is only based on the cost of equity as the cost of debt is eliminated.

7.1.2 Cost of equity

I estimate the cost of equity based on the capital asset pricing model (CAPM):

$$r_e = r_f + \beta_i [E(r_m) - r_f]^{314}$$

Equation 3 – SML – Source: Petersen & Plenborg (2012), p.249

7.1.2.1 Risk-free interest rate: 3,47%

Following the approach of Petersen & Plenborg, the risk-free interest rate is estimated based on a 10 year nominal government bond, where Danish is selected to ensure inflation is modelled consistently between cash flow and the estimated risk-free rate³¹⁵. On the 5th of February 2015, the yield to maturity on a Danish government bond was 0,393%³¹⁶. The observed current rate is however extremely low, due to the current economic situation in Denmark and Europe – where Denmark is used as safe harbour -, as the five year average effective rate has been 2,02% and the 25 year average rate has been 4,92%³¹⁷.

As the selected rate should reflect the rate that is expected to be applied for each future period³¹⁸, it's questionable if the quoted rate is a good proxy for the risk-free interest rate.

For valuation purposes Ernst & Young suggests³¹⁹ four different approaches:

- 1) using an average yield as proxy for the risk-free rate
- 2) assessing the risk-free rate by reference to government bond yields in another country where there has been less volatility in yields
- 3) adjusting the ERP to compensate for movements in spot government yields
- 4) considering a specific risk premium or discount in addition to the spot Government bond yield. (EY, p.12).

Out of the four suggested approaches, I have selected to use the average historical yield for the risk-free rate. However, there is no guideline regarding, which time period to use for the average, but it's suggested that the overall declining European yields need to be factored into the analysis³²⁰.

³¹³ Damodoran A. - http://pages.stern.nyu.edu/~adamodar/

 $^{^{314}}$ r_f = risk free interest rate, B_i = Systematic risk on equity (levered beta), r_m = return on market portfolio

³¹⁵ Petersen & Plenborg, 2012, p.251

³¹⁶ http://www.investing.com/rates-bonds/denmark-10-year-bond-yield-historical-data

³¹⁷ http://www.statistikbanken.dk/

³¹⁸ Petersen & Plenborg, 2012, p.249

³¹⁹ Earnest & Young, Estimating risk-free rates for valuations, Dec. 31, 2014, p.12

³²⁰ Earnest & Young, Estimating risk-free rates for valuations, Dec. 31, 2014, p.10

I do so by selecting an average of the 5 and 25 yields on the 10-year Danish government bond, resulting in a risk-free rate of 3,47%. The rate is assessed as realistic, compared to the historical 10 year yields of UK, US, Japan, Germany and Euro upper bound yields³²¹.

7.1.2.2 Liquidity premium: None

Investors require a liquidity premium for stock with limited or no liquidity³²². However, I do not find this being the case for Novo as a high 90 day average volume is reported for the stock³²³. So I assign a liquidity premium of 0% for Novo.

7.1.2.3 Systematic risk on equity (levered beta): 0,8133

Beta represents the extra required return from investor, based on the systematic risk of the underlying stock relative to the market portfolio³²⁴. As beta is dependent on the market portfolio, I measure beta as a linear regression based on historical stock and market returns. Doing so raises three fundamental questions; 1)What is used as the market portfolio? 2)Frequency of return measurements and 3)How long the measurement period should be.

Market portfolio: In a Danish perspective, using the C20 CAP would seem like the obvious choice. This would, however, be incorrect, as Novo's weighting within the index is too high. Alternatively, I follow the suggestion of Koller et al. and select the MSCI World Index as the market portfolio³²⁵.

Frequency of measurements: Merton R. argued that estimates would improve with more frequent measurements³²⁶. Using very frequent data can, however, be problematic if the stock is illiquid, as stock returns might be zero if the stock isn't traded. To overcome this issue, Koller et al. suggest using monthly returns³²⁷. Based on my decision not to apply a liquidity premium to Novo, I do believe it's possible to estimate Novo's beta based on more frequent observations than monthly. To create a secondary estimate, I will therefore use both monthly and weekly observations to estimate beta and compare the results. Additionally, I find that Bloomberg uses weekly observations to calculate beta, suggesting the approach is applicable³²⁸.

Measurement period: Again I follow the approach of Koller et al. and select a measurement period of five years³²⁹, for both weekly and monthly observations as they have been shown to perform the best³³⁰.

³²¹ Earnest & Young, Estimating risk-free rates for valuations, Dec. 31, 2014, p.2

³²² Petersen & Plenborg, 2012, p.265

³²³ http://www.nasdaq.com/symbol/nvo

³²⁴ Petersen & Plenborg, 2012, p.249

³²⁵ Koller et. al., p.249

³²⁶ R. Merton, "On estimating the Expected Return on the Market", Journal of Financial Economics 8 (1980): 323 - 361

³²⁷ Koller et al, p.248

³²⁸ Koller et al., p.247

³²⁹ Koller et al., p.247

³³⁰ G. Alexander and N. Chervany, "On the Estimation and Stability of Beta," *Journal of Financial and Quantative Analysis* 15 (1989): 123-137.

Regression results are available in appendix 15, where I select the adjusted beta to improve the estimate through smoothing to dampen extreme observations³³¹. For monthly observations I notice a beta of 0,615, but also noticing a standard error of beta of 0,186 suggesting a beta range of 0,429-0,801 – following a two error standard approach. In the weekly observation beta is 0,678 with a standard error of 0,086, providing a range of 0,592-0,764. The tighter range for weekly observations seems to confirm Merton's argument, and as I believe Novo's stock to be liquid enough to provide weekly returns, the weekly estimate of 0,678 is assessed being more accurate, as it equally has a higher squared correlation.

Other beta estimates

An alternative approach to measuring beta is estimating beta from industry comparable firms. In a January 2015 dataset Damodaran calculated the unlevered pharma industry beta as 0,95³³². Beta usually needs to be re-levered to accommodate for the capital structure of the target firm. However, based on the capital structure section, this is unnecessary as Novo is - and has historically for the five year period been - 100% equity financed. The reported unlevered industry beta should therefore be equal to Novo's beta.

In addition to the reported industry beta, for comparison purposes I have collected various reported beta estimates from different databases. As can be seen in table 14, results vary significantly as there is no standard procedure on how to calculate beta.

A third option is to apply a "quality assessment" based on operating and financial risk³³³. With basis in the strategic and financial analysis I believe

FT.com 1,15 0,94 Google Finance MSN MoneyCentral 0,92 1,15 Reuters Yahoo 0,69 0,75 Nasdaq Bloomberg 0,67 0,9 Average:

Table 14 – Beta estimates collected by author – Author creation

Novo's financial risk to be low and their operating risk to be neutral, suggesting an equity beta of 0,6-0,85, which is within the range of the regression analysis.

Conclusive on beta

For a combined estimate I have chosen to select the average of the weekly regression (0,678), Damodarans industry beta (0,95), collected betas from databases (0,9) and the middle value of Petersens & Plenborg's "quality assessment" (0,725) for a combined estimated beta of 0,8133.

7.1.2.4 Return on market portfolio: 5,5%

The return on market portfolio is typically calculated using an ex post approach - calculating the difference between historic returns on a risk-free investment and the stock market – or an ex ante approach based on analyst consensus earnings forecast³³⁴.

³³¹ Koller et. al., p.253

³³² http://pages.stern.nyu.edu/~adamodar/

³³³ Petersen & Plenborg 2012, p.261-262

³³⁴ Petersen & Plenborg, 2012, p.263

Damodoran follows the ex post approach and monthly updates the implied returns based on the S&P 500, where he suggested a rate of 6,21% on the 1st of January 2015³³⁵. Koller et al. suggest 4,5-5,5% as an appropriate range, equally stating that a rate of 8%, which is often reported, is too high, as it's based on short-term bonds. From an ex ante approach Fernandez P. conducted a 2012 survey with results from 7.192 people in 82 countries suggesting a Danish market return of 5,5%³³⁶. Based on the stated figures, I believe 5,5% is a reasonable estimate for the market portfolio return.

Using the CAPM model with the estimated inputs, I can now calculate Novo's WACC to: $WACC = 3,47\% + 0,8133 \times 5,5\% \approx 7,94\%$

7.2 Present value valuation

7.2.1 Terminal growth

With basis in the two stage DCF and EVA models shown in equation 1, it is necessary to estimate the terminal growth rate in order to arrive at the enterprise discounted cash flow and discounted economic profit.

When determining the terminal growth rate it is important to remember the underlying implication of the selected growth rate. As the terminal value is calculated as perpetual, using a growth rate higher than the economy growth rate, implies that at some point, the firm will grow so large that it will make up the entire economy. Equally, a growth rate lower than the economy implies the firm will gradually make up less and less of the combined economy, where a negative growth rate implies that the firm will disappear at some point³³⁷.

Given the mentioned implication of the chosen growth rate, I choose to use a growth rate equal to the combined growth in the economy, thus assuming Novo will maintain its current "portion" of the economy.

As Novo operates on a global scope, a global growth needs to be selected, however, forecasted GPD rates vary significantly for high-income and developing countries. To make the growth rate a better fit to Novo, I calculate a combined rate for Novo based on their market segmentation and apply a weighting equal to their current revenue distribution, as best estimate for

	Growth rate	Weight	G*W
North America	2,75%	0,49	1,34%
Euro	1,28%	0,23	0,29%
Japan & Korea	1,60%	0,06	0,09%
China	7,10%	0,09	0,65%
International	4,98%	0,14	0,70%
		Growth rate	3.06%

Table 15 – Estimated terminal growth rate, Source: http://www.worldbank.org/en/publication/globaleconomic-prospects/data – Author Creation

future development, resulting in a terminal growth rate of 3,06%.

³³⁶ Fernandez et al., 2012, Market Risk Premium used in 82 countries in 2012.

³³⁵ http://pages.stern.nyu.edu/~adamodar/

³³⁷ http://people.stern.nyu.edu/adamodar/pdfiles/ovhds/dam2ed/growthandtermvalue.pdf

7.2.2 DCF & EVA valuation

With basis in my methodology, I calculate Novo's share price using the DCF and EVA model that are available in appendix 16 and 17. To arrive at share price from market value of equity, I divide by undiluted shares outstanding, which is estimated as gross number of shared issued minus shares held in treasury³³⁸. For Novo I estimate number of shares outstanding to be 2,650-57 = 2593 million shares³³⁹.

From the calculated share price of the models, two corrections have been made in order to derive the fair value share price on the 5th of February 2015. Theoretically, in order to get the DCF and EVA valuation to return the same results, it's necessary to discount in full periods. By discounting in full periods, one makes the assumption that cash flows arrive in lump sumps at the end of the year on the balance date, where in reality cash flows arrive continuously during the year. Thus, as discounting in full periods will understate the final share price, I adjust by using a mid-year factor³⁴⁰ to correct for the difference, thereby "assuming cash flow is generated symmetrically around the midyear point" ³⁴¹.

Additionally, I adjust the value to match the actual date of valuation³⁴². Novo's annual report is based on the balance date of 31 December 2014, so adjustment is made forward to the 5th of February 2015. As Novo has negative NIBD, adjustment is made directly to the share prices using WACC, as it isn't necessary to differentiate between return to equity holders and return to debt holders.

Having adjusted for midyear discounting and actual valuation date, using the EVA and DCF model, I arrive at an estimate base case share price of DKK 337,2 on the 5th of February 2015.

Comparing the present value of the individual years and terminal period, between EVA and DCF, I notice that cash received is almost equal to value created. I primarily account the similarity to Novo's organic growth strategy, as Novo isn't required to make significant cash investments into new assets, as current assets and organic growth is sufficient to generate future cash flows.

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Terminal
DCF PV	26.115	26.992	27.464	28.106	28.170	28.360	28.231	27.823	27.231	26.090	548.310
EVA PV	25.877	27.014	27.731	27.721	27.962	27.844	27.542	26.914	26.211	24.871	525.363
Diff.	238	-21	-249	385	209	516	689	909	1.019	1.219	22.947

Table 16 – Present value in DKK of DCF and EVA calculations for individual forecasted years and terminal – Author creation

³³⁹ Novo annual report 2014, p.15

³³⁸ Koller et al., p.285

³⁴⁰ Share price $\times (1 + wacc)^{0,5}$

³⁴¹ Koller et al., p.104

³⁴² Share after midyear adjustment× $(1 + wacc)^{36/365}$

7.2.3 Sensitivity analysis

To test the sensitivity of the base case valuation, I analyse how changes in WACC and long-term growth rate effect the estimated share price. I do so by first estimating how the WACC could change, by changing the underlying values of the WACC. From the WACC estimation, I noticed that the risk-free rate and beta had the highest ranges of possible inputs. So I test alternative outputs of WACC based on changes in the risk-free rate and beta, using the ranges found in the WACC section. From appendix 18, I select the 25% and 75% quartile of 6,4% and 9,03% as input to test price sensitivity to WACC. Equally, I test using the terminal growth rates found for individual regions, where I have excluded China as an outlier.

Based on appendix 18, keeping the growth rate constant and changing the WACC results in a share price in the range of 276-494 keeping the growth rate constant - with a base price of DKK 337,2. The estimated share price is thus very sensitive to the selected methodology used when selecting the risk-free rate and calculating beta. Equally, share price changes by 278-480 for changes in growth rate. This illustrates that the calculated share price, will highly depend on how one chooses to interpret the "economy" in which Novo operates in and how one chooses to calculate the long-term growth rate.

From the previous comparison of revenue forecast, and EBITDA margin to market consensus, I concluded that my revenue estimates were below market consensus. And the EBITDA margin was converging towards consensus – in combination suggesting a share price below trading level. The comparison of revenue and EBITDA development, was, however, limited to data not being available after 2019. So I am unable to analyse if my revenue and EBITDA margin, will stay below market consensus for the entire forecast. But as the quoted trading price on the valuation date was DKK 282,5, I notice that all else being equal, the calculated sensitivity ranges are wide enough to explain differences, between my estimate and trading price. I therefore conclude that, all else being equal, the price difference may be due to different methodology, when estimating beta, risk-free rate and long-term growth rate.

7.2.4 Scenario analysis

When forecasting future revenues, I risk adjusted future revenues from products that are still in development, to reflect the possibility that authorities would not approve the products. Drawing inspiration from the option-based valuation approach, I use the risk-adjustment as a decision tree to create a best and worse case scenario for Novo Nordisk

7.2.4.1 Best case

In relation to approval of future products, the best case scenario for Novo Nordisk is that all future products are approved, thus assigning 100% risk adjustment in future revenues. Doing so increases the share price by 3,7% to DKK 350. The increase is modest, but it should be noted that risk adjustments in the base case scenario are set relatively high at 80% and 95%, so limited upside is expected. E-DCF results for the scenario are available in appendix 19.

7.2.4.2 Worst case

From the strategic analysis, I concluded that Novo has a significant weakness as it is dependant on the US Tresiba approval, as 26% of current revenues are dependant on the approval. I assigned a high risk adjustment of 95% for the possible future Tresiba approval. For Novo's worst case scenario, I analysed the effects on the share price, if Tresiba will never receive US approval. Where not achieving approval will affect long-acting and the premix segments, as future premix products are dependant on Tresiba. Additionally, I assumed the market share lost by the missing Tresiba approval, will be gained by competitors and not by substitute Novo products.

For the worst case scenario, I find a decrease in valuation of 20,7% to a share price of DKK 279,3 with DCF results available in appendix 20. The decrease isn't as significant as the current 26% of revenues, which is believed to be caused by Novo adding more products to the portfolio in the form of obesity and haemophilia a and b, which dilutes the future impact of Tresiba to the total concern revenue. DCF results for the scenario is available in appendix 20.

7.2.5 Conclusive on present value valuation

By applying the DCF and EVA models, I have calculated Novo's fair share price on the 5th of February 2015 as DKK 337,2. I believe my valuation model is robust as the DCF and EVA models return the same results. Where I account the similarities between present value cash flows and economic value added to Novo's growth strategy.

My valuation is high – suggesting a buy recommendation - compared with the actual traded price on the valuation date of DKK 282,5. But through my sensitivity analysis, I noticed differences in methodology. When estimating the risk-free rate, beta and long-term growth rate are sufficient to explain differences in price, as my previous comparison of revenues and EBITDA margin to market consensus, suggested a price below trading level.

Additionally, based on my risk adjustment to new products, I find the stock has more potential downside than upside, as a best case scenario on new products increases share price by 3,7%. Where a worst case scenario of never obtaining Tresiba approval in the US market would decrease the fair share value by 20,7%.

7.3 Relative valuation

As a sanity check to the present value valuation, I perform a relative valuation using multiples. Multiples are not the main focus of this thesis, so I limit my choice of multiples to the recommendations of Koller et al., (p.305-322). Recommendation is to use EBITA, but at the same time it's recommended to use forward-looking figures³⁴³. Applying both creates an issue, as analysts do not report at EBITA level. Instead of potentially obscuring forecasted figures, by estimating my own amortization, I have opted to compare at EBIT level. EBIT has been chosen over EBITDA, as I find from the analytical income sheets that the compared companies do not share depreciation rates³⁴⁴.

Additionally, Eli Lilly and Sanofi are again chosen as peer group, as I believe they are the best comparable companies available.

The comparison shows that I have predicted Novo to be either overvalued, suggesting the cash flow valuation is to optimistic. Or that Novo should be traded higher than its peers, as it has better growth prospects. As Novo is not estimated at a significant higher EBIT multiple than Eli Lilly - I believe the latter to be true. I do so with basis in the strategic analysis, where I found Novo to have a more focused strategy, as there should be more synergy between products in Novo's portfolio than Eli Lilly's. That should show as a loss of value³⁴⁵ in the Lilly stock that could justify the differences in EBIT

	EV /	EBIT
	2018	2019
Eli Lilly	14,6	13,2
Sanofi	10,3	9,7
Average	12,4	11,5
Novo PV estimate	16,0	14,7

Table 17 – Multiples, Source: Compiled by author / Thomson One Banker

multiple. With basis in the EBIT multiple, I therefore consider my present value valuation to be reasonable.

³⁴³ Koller et al., p.311

³⁴⁴ Petersen & Plenborg, p.229

³⁴⁵ Berger, P. G. & Ofek E. (1995) Diversification's effect on firm value, Journal of Financial Economics 37, 39-65

8 Conclusion

I will now conclude on my findings to answer my research question for this thesis: What is the fair value of a Novo Nordisk A/S B share (Novo-B) as of the 5th of February 2015?

Through strategic and financial analysis, budgeting and present value calculations using DCF and EVA, I have estimated a base case fair share value of DKK 337,2.

Competition within the industry is found to rely on having the medically best and most convenient product on market, relative to its price. Pharma firms try to achieve this by having a full pipeline, ensuring a steady stream of new products. And by relying on production of scale advantages to achieve low cost levels, where Novo – equal to its peers - tries to maximize scale advantages, by operating on a global scale. Additionally, Novo is able to achieve greater scale advantages relative to its peers, through the company's competitive advantage of having a more focused product strategy; as all Novo products are protein related. Historically, the competitive advantage has provided Novo with higher gross profit margins than its peers. The competitive advantage is believed to be sustainable, so the trend will continue, translating into future higher gross profit margins, in the forecasted budget that equally translates into lower higher margins (EBIT) compared to peers, as other cost levels are kept constant.

Novo is found to be independent of business cycles, where the revenue value drivers are found to be a growing volume demand, through a growing population and increased diabetes and obesity prevalence across the globe. Equally, revenue growth is not expected from prices being increased, as Novo is facing increased bargaining power from buyers. Most significantly from the important US market with ObamaCare and an increased pressure from biosimilars, as patents within the industry have or are set to expire.

For a combined view on Novo's future market share, the outlook is promising, as loss of market share is only expected within haemophilia inhibitors. Novo is expected to maintain current market share within GLP-1, long-acting and premix, while increasing their market share within fast-acting and growth disorders. Additionally, Novo is looking to add new products to the portfolio in the form of obesity and haemophilia A + B that will help support future revenue growth.

The used DCF and EVA models are considered robust as they return the same results. The models were shown to be very sensitive to changes in the risk-free rate, beta and long-term growth rates. But as there is no industry standard practice, the sensitivity analysis showed that the returned price ranges were significant enough to explain the deviation between my base case fair share value and the traded market price of DKK 282,5. I am, however, confident in my estimates, so I believe my valuation to be valid. Additionally, using the best/worst case scenario, I found the Novo stock to have more down- than upside, as Novo is highly dependant on a future FDA approval of Tresiba.

Conclusively, as my fair value estimate builds on thorough and subjective strategic and financial analysis, I believe my estimate to have validity, and with an estimated share price of DKK 337,2 relative to a traded price of DKK 282,5, I find the stock to be undervalued.

9 Perspective

My estimated share price lies significantly above the traded price on the day of comparison, indicating that my underlying value drivers are to optimistic in relation to market consensus. From the day of valuation the share price has increased and my estimated price was reached only 36 days later - on 13th of March 2015, with further price increases hereafter.

The stock will have been affected by the news flow after the valuation date. I do, however, not believe there was any significant news to justify a 16,2% increase, between the day of valuation and the 13th of March of 2015. Based on the share price development after the valuation date, I therefore consider my valuation of Novo's share to be correct, as the stock is believed to be undervalued at DKK 282,5.

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Appendix 1 – DCF Valuation Models

Frameworks for DCF-Based Valuation

Model	Measure	Discount factor	Assessment
			Works best for projects,
Enterprise discounted cash	Free cash flow	Weighted average cost of	business units, and companies
flow	Free cash flow	capital	that manage their capital
			structure to a target level.
Discounted on nomin nuclit	Economic profit	Weighted average cost of	Explicitly highlights when a
Discounted economic profit	Economic pront	capital	company creates value.
			Highlights changing capital
Adjusted present value	Free cash flow	Unlevered cost of equity	structure more easily than
			WACC-based models.
			Compresses free cash flow and
			the interest tax shield in one
C : 1 1 0	6 1 1 1 0	TT 1 1	number, making it difficult to
Capital cash flow	Capital cash flow	Unlevered cost of equity	compare operating
			performance among companies
			and over time.
			Difficult to implement correctly
			because capital structure is
Equity cash flow	Cash flow to equity	Levered cost of equity	embedded within the cash flow.
			Best used when valuing
			financial institutions.

Source: (Koller, Goedhart, & Wessels, 2010), p.102

Appendix 2 – Word list and abbreviations

- API: Active Pharmaceutical Ingredient
- DCF: Discounted Cash Flow
- EBIT: Earnings before interest and taxes
- EBITA: Earnings before interest tax and amortization
- EBITDA: Earnings before interest, taxes, depreciation and amortization
- E-DCF: Enterprise Discounted Cash Flow
- NIBD: Net Interest Bering Debt
- NPV: Net Present Value
- OTC: Over the counter
- PV: Present value
- R&D: Research and Development
- RBV: Resource Based View
- ROW: Rest Of the World
- WACC: Weighted Average Cost of Capital

Appendix 3 – Healthcare elasticities

Distribution of co-movement elasticities:

Private Expenditures

		Procyclical	Countercyclical
enditures	Procyclical	Czech Republic, Hungary, Iceland, Greece, Israel, Italy, Korea (south), Luxembourg, Mexico, Portugal, Slovakia, Turkey	Australia, Austria, Japan, Poland
Public Expenditures	Countercyclical	Belgium, Chile, Denmark, Finland, the Netherlands, Norway, U.K., U.S.	Canada, France, Germany, Ireland, New Zealand, Spain, Sweden, Switzerland

Source: Cleeren, Lamey, Meyer, & De Ruyer, "How business cycles affect the healthcare sector: A cross-country investigation", p.25

Appendix 4 – Growth hormone products on market Available primary growth hormone on the market:

Tength of Annual Page	Norditropin® FlexPro® Pen	Nutropin AQ [®] NuSpin [™]	Genotropin Pen®	HumatroPen [®]	Omnitrope® Per
Residence Residence Strong 1 & Reliance Strong 1 & Reliance Strong 1 & Reliance Strong 1 & Reliance	5 mg, 10 mg, and 15 mg	5 mg, 10 mg, and 20 mg	5 mg and 12 mg	6 mg, 12 mg, and 24 mg	5 mg and 10 mg
	(somatropin [rDNA origin] injection)	(somatropin [rDNA origin] injection)	(somatropin [rDNA origin] injection)	(somatropin [rDNA origin] injection)	(somatropin [rDNA origin] injection)
s there an option available to hide the needle?a	•	•	•	•	
s mixing required?			•	•	
Do cartridges need to be loaded or changed?			•	•	•
s the device disposable?	•	•			
s there room temperature storage after first use?	● b				
Are batteries required?			•		
What is the greatest dose delivered?	8 mg	7 mg	4 mg	6 mg	5.4 mg
Can you set a dose greater than the amount of medicine left in the pen?		•	•	•	•
Are you able to dial backwards?	•	•	•	•	
is there an audible "click" or "beep" when the dose has left the pen?	•		•		

Source: https://www.norditropin.com/how-to-take-it/devices-on-the-market

Appendix 5 – Pipeline summary of major products

The table below provides a summary of Novo's current and pipeline products:

		Current & expiration	Replacement	Comment		
	GLP-1	Victoza: 2023	Semaglutide: Phase 3a trials	Replacement expected ready before patent expirations.		
Diabetes	Fast acting	NovoRapid: 2017	FIAasp: Phase 3a trials	Questionable if replacement is ready before patent expiration		
	Long acting	Levemir: 2018/2019	Tresiba: Ready for launch	Received well by market, and approved in all markets but US.		
	Premix	NovoMix: 2015	Xultophy & Ryzodeg	Approved in all markets but the US, as both replacements are reliable on Tresiba's approval.		
Obesity		Saxenda: Equal to Victoza	None New product group	Approved in the EU and have received positive US feedback.		
lia	Inhibitors	NovoSeven: 2024	NovoEight	Updated "Isomer" version.		
Hemophilia	A	NovoEight: 2028/2039	New product group	Approved in all markets.		
Hem	В	N9-GP	New product group	Expected to be filed for approval in second half of 2015.		
Growth Disorders		Norditropin: 2017	NN8640: Phase 3a trials	Questionable if replacement is ready before patent expiration		

Appendix 6 – Summary of rivalry between established competitors

The table below summarizes the key current and future competition takeaways from rivalry between established

compet	itors:	
	GLP-1	 Bydureon to gain market share from Victoza, due to new 2014 easy-to-use pen. Future competition is between once weekly, Bydureon, Trulicity and Semaglutide. Future market will be shared between the three, with Novo as market leader, due to being the best product on market, and by maintaining a large part of current market share.
Diabetes	Fast- Acting	 Patent expiration eminent for all current products. Future competition is on new FIAsp, Afrezza and current gen products. Afrezza is best product on market as inhalable, but is not expected to become market leader due to historic failure of previous inhalable products. FIAsp to gain market share from current competition and cannibalize on NovoRapid to increase total Novo market share within the segment.
I	Long- Acting	 Current products under severe threat from Lilly biosimilar that's expected in 2016. Levemir market share will decline gradually from 2016 and forwards. Future competition is between new "ultra-long-acting" Tresiba and Toujeo (Sanofi). US Tresiba launch expected in 2017. Disregarding Lilly's biosimilar: Novo and Sanofi will approximately maintain their total market share.
	Premix	 Premix equal to Long-acting, as products are dependent on them. Future competition is between Novo and Sanofi's LixiLan Novo's market share to increase to market leader, due to product superiority
Obesity		 Novo's Saxenda only injectable product, others are oral Significant price premium expected for Saxenda Expected sales to be in lower ranges of market consensus due to price premium and failures of current oral substitues.
	Inhibitors	- Loss of market share to AryoGen biosimilar that's based on expired patent.
Haemophilia	A	 Limited success of NovoEight: Viewed as Novo's entry to the market Future market based on new long-acting products from: Biogen, Bayer, Baxter and Novo (N8-GP expected launch in 2019). Bayer has best product and N8-GP is non-superior Novo to gain modest 10% long-run market share in competitive market.
Ha	В	 Competition on long-acting between: Biogen, CSL and Novo (N9-GP) Novo expected to be last on market (Launch in 2016). As last and new to the market, without having the best product, we expect Novo to gain a long-run 20% market share.
Growth Disorders		 Oligopoly market with six players, Novo as market leader. Competition is not product efficiency but patient convenience. Future once-weekly products expected to arrive on market at the same time. Novo will maintain and expand market leadership due to superior product.

Appendix 7 – Total franchise forecast

_	Km	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
	GLP-1	9.495	11.633	13.426	14.705	16.227	17.452	19.582	20.832	21.755	22.264	22.577	22.777	22.449
	y/y growth		22,5%	15,4%	9,5%	10,3%	7,6%	12,2%	6,4%	4,4%	2,3%	1,4%	0,9%	-1,4%
	Fast-acting	15.693	16.848	17.449	20.810	23.639	26.908	29.705	31.860	34.352	36.560	38.512	40.034	41.065
	y/y growth		7,4%	3,6%	19,3%	13,6%	13,8%	10,4%	7,3%	7,8%	6,4%	5,3%	4,0%	2,6%
	Long-acting	9.786	11.689	14.875	16.785	18.122	20.490	22.881	24.862	26.666	27.877	29.590	30.604	31.347
	y/y growth		19,4%	27,3%	12,8%	8,0%	13,1%	11,7%	8,7%	7,3%	4,5%	6,1%	3,4%	2,4%
	Premix	9.342	9.759	9.871	11.735	13.906	16.318	16.560	18.673	20.701	22.719	24.332	25.791	27.055
Diabetes	y/y growth		4,5%	1,1%	18,9%	18,5%	17,3%	1,5%	12,8%	10,9%	9,7%	7,1%	6,0%	4,9%
abe	Obesity				771	1.488	2.005	2.345	2.599	2.780	2.962	3.147	3.335	3.375
Ö						93,0%	34,7%	17,0%	10,8%	7,0%	6,5%	6,2%	6,0%	1,2%
	Human insulins	11.302	10.869	10.298	10.298	10.298	10.298	10.298	10.298	10.298	10.298	10.298	10.298	10.298
	y/y growth		-3,8%	-5,3%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%
	Oral ,	2.758	2.246	1.728	1.434	1.190	988	820	681	565	469	389	323	268
	y/y growth	2 544	-18,6%	-23,1%	-17,0%	-17,0%	-17,0%	-17,0%	-17,0%	-17,0%	-17,0%	-17,0%	-17,0%	-17,0%
	Related sales	2.511	2.412	2.333	2.256	2.182	2.110	2.040	1.973	1.908	1.845	1.784	1.725	1.668
	y/y growth	CO 007	-3,9%	-3,3%	-3,3%	-3,3%	-3,3%	-3,3%	-3,3%	-3,3%	-3,3%	-3,3%	-3,3%	-3,3%
	Total	60.887	65.456	69.980	78.794	87.052	96.569	104.230	111.777	119.025	124.993	130.628	134.887	137.525
	Inhibitors	8.933	9.256	9.142 -1,2%	9.138	9.131	9.119 -0,1%	9.104	9.084	9.060	9.031	8.998 -0,4%	8.959 -0,4%	8.915 -0,5%
S	ind A		3,0%	-1,270	0,0%	-0,170	-0,1%	-0,5%	1.402	2.166	3.700	4.529	6.099	6.896
ica	eil oo y/y growth A y/y growth B								1.402	54,5%	70,8%	22,4%	34,7%	13,1%
eut	B B						246	645	944	1.262	1.588	1.924	2.265	2.592
Biopharmaceuticals	y/y growth							162,5%	46,3%	33,7%	25,9%	21,1%	17,7%	14,5%
ırm	Growth Disorders	5.698	6.114	6.506	6.760	7.022	7.292	7.408	7.689	7.979	8.278	8.587	8.905	9.232
pha	y/y growth	6,4%	3,9%	3,9%	3,8%	3,7%	3,7%	1,6%	3,7%	3,6%	3,6%	3,6%	3,6%	3,6%
Bio	Other	2.508	2.746	3.178	3.242	3.306	3.373	3.373	3.440	3.509	3.579	3.651	3.724	3.798
	y/y growth		9,5%	15,7%	2,0%	2,0%	2,0%	2,0%	2,0%	2,0%	2,0%	2,0%	2,0%	2,0%
	Total	17.139	18.116	18.826	19.140	19.459	20.030	20.529	22.559	23.976	26.177	27.688	29.951	31.434
То	tal franchise	78.026	83.572	88.806	97.934	106.511	116.599	124.760	134.336	143.001	151.171	158.317	164.838	168.959
	y/y growth		6,6%	5,9%	9,3%	8,1%	8,7%	6,5%	7,1%	6,1%	5,4%	4,5%	4,0%	2,4%

Appendix 8 – Underlying revenue forecast model of major products

US GLP-1 market:

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
US Market DKK million	10.224	11.777	13.706	15.762	17.969	20.305	22.741	24.560	26.280	27.856	29.249	30.419	31.332
Growth %		15,2%	16,4%	15%	14%	13%	12%	8%	7%	6%	5%	4%	3%
Market Share													
Victoza (Novo)	58%	64%	66%	63%	61%	55%	52%	46%	42%	38%	33%	30%	26%
Byetta (AZN)	34%	20%	17%	13%	8%	5%	4%	3%	2%	2%	2%	1%	1%
Bydureon (AZN)	8%	16%	14%	20%	21%	23%	20%	19%	18%	17%	16%	15%	15%
Trulicity (Lilly)				2%	8%	9%	12%	15%	17%	20%	23%	25%	27%
Semaglutide (Novo)						3%	8%	14%	17%	19%	23%	26%	28%
Others			3%	2%	2%	5%	4%	3%	4%	4%	4%	3%	3%
Novo total share	58%	64%	66%	63%	61%	58%	60%	60%	59%	57%	56%	56%	54%
Sales DKK m													
Victoza (Novo)	5.930	7.537	9.046	9.930	10.961	11.168	11.825	11.298	11.037	10.655	9.652	9.126	8.146
Byetta (AZN)	3.476	2.355	2.376	2.049	1.437	1.015	910	737	526	487	439	304	235
Bydureon (AZN)	818	1.884	1.925	3.152	3.773	4.670	4.548	4.666	4.730	4.736	4.680	4.563	4.700
Trulicity (Lilly)	0	0	0	315	1.437	1.827	2.729	3.684	4.468	5.571	6.727	7.605	8.460
Semaglutide (Novo)	0	0	0	0	0	609	1.819	3.438	4.468	5.293	6.727	7.909	8.773
Others	0	0	359	315	359	1.015	910	737	1.051	1.114	1.024	913	1.018

Rest of the world GLP-1 market:

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
ROW Market	4.818	5.319	5.688	6.542	7.523	8.576	9.605	10.566	11.411	12.210	12.698	13.079	13.341
Growth %		10%	7%	15%	15%	14%	12%	10%	8%	7%	4%	3%	2%
Market Share	Market Share 0,993												
Victoza (Novo)	74%	77%	77%	73%	70%	66%	60%	53%	49%	46%	41%	36%	33%
Byetta (AZN)	20%	14%	12%	10%	7%	4%	4%	3%	3%	3%	3%	3%	3%
Bydureon (AZN)	6%	7%	10%	13%	14%	17%	16%	14%	14%	13%	12%	12%	12%
Trulicity (Lilly)				2%	7%	9%	12%	14%	16%	18%	19%	22%	23%
Semaglutide (Novo)						2%	7%	14%	17%	18%	23%	25%	27%
Others		1%	1%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Novo total share	74,0%	77,0%	77,0%	73,0%	70,0%	68,0%	67,0%	67,0%	66,0%	64,0%	64,0%	61,0%	60,0%
Sales DKK million													
Victoza (Novo)	3.565	4.096	4.380	4.775	5.266	5.660	5.763	5.600	5.591	5.616	5.206	4.708	4.402
Byetta (AZN)	2.045	1.649		654	527	343	336	317	285	366	381	392	400
Bydureon (AZN)	613	824	1.371	850	1.053	1.458	1.489	1.479	1.540	1.587	1.524	1.569	1.601
Trulicity (Lilly)	0	0	0	131	527	772	1.153	1.479	1.826	2.198	2.413	2.877	3.068
Semaglutide (Novo)	0	0	0	0	0	172	672	1.479	1.940	2.198	2.921	3.270	3.602
Others	0	153	137	131	150	172	192	211	228	244	254	262	267

GLP-1 market: Global sales and total Novo franchise

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Global Sales DKK mill.													
Victoza (Novo)	9.495	11.633	13.426	14.705	16.227	16.828	17.588	16.898	16.629	16.272	14.858	13.834	12.549
Byetta (AZN)	5.521	4.004	2.376	2.703	1.964	1.358	1.246	1.054	811	854	820	697	635
Bydureon (AZN)	1.431	2.709	3.296	4.003	4.827	6.128	6.037	6.146	6.271	6.323	6.204	6.132	6.301
Trulicity (Lilly)	0	0	0	446	1.964	2.599	3.882	5.163	6.293	7.769	9.140	10.482	11.528
Semaglutide (Novo)	0	0	0	0	0	781	2.492	4.918	6.407	7.490	9.648	11.179	12.375
Others	0	153	496	446	510	1.187	1.102	948	1.279	1.358	1.278	1.174	1.285
Total	16.447	18.499	19.594	22.304	25.491	28.881	32.346	35.126	37.690	40.066	41.947	43.498	44.672
Global Market Share													
Year	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Victoza (Novo)	58%	63%	69%	66%	64%	58%	54%	48%	44%	41%	35%	32%	28%
Byetta (AZN)	34%	22%	12%	12%	8%	5%	4%	3%	2%	2%	2%	2%	1%
Bydureon (AZN)	9%	15%	17%	18%	19%	21%	19%	17%	17%	16%	15%	14%	14%
Trulicity (Lilly)	0%	0%	0%	2%	8%	9%	12%	15%	17%	19%	22%	24%	26%
Semaglutide (Novo)	0%	0%	0%	0%	0%	3%	8%	14%	17%	19%	23%	26%	28%
Others	0%	1%	3%	2%	2%	4%	3%	3%	3%	3%	3%	3%	3%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
•													
Novo Forecast in DKK													
Victoza	9.495	11.633	13.426	14.705	16.227	16.828	17.588	16.898	16.629	16.272	14.858	13.834	12.549
Growth %		23%	15%	10%	10%	4%	5%	-4%	-2%	-2%	-9%	-7%	-9%
Semaglutide	0	0	0	0	0	781	2.492	4.918	6.407	7.490	9.648	11.179	12.375
Growth %							219%	97%	30%	17%	29%	16%	119
Semaglutide 80% risk a	djusted					625	1.993	3.934	5.126	5.992	7.718	8.943	9.900
Total Novo Franchise	9.495	11.633	13.426	14.705	16.227	17.452	19.582	20.832	21.755	22.264	22.577	22.777	22.449

US fast acting market:

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
US Market DKK million	17.043	18.431	18.872	21.703	24.741	27.958	31.313	33.818	36.185	38.356	40.274	41.885	43.142
Growth %		8,1%	2,4%	15%	14%	13%	12%	8%	7%	6%	5%	4%	3%
Market Share													
NovoRapid (Novo)	53%	54%	54%	56%	54%	51%	47%	43%	40%	36%	34%	31%	27%
Humalog (Lilly)	40%	39%	38%	34%	31%	28%	26%	25%	23%	22%	21%	20%	19%
Apidra (Sanofi)	6%	7%	8%	8%	8%	7%	7%	6%	6%	6%	5%	5%	4%
FIAsp (Novo)	0%	0%	0%	0%	2%	6%	10%	14%	18%	23%	26%	30%	35%
Afrezza (Sanofi)	0%	0%	0%	2%	5%	8%	10%	12%	13%	13%	14%	14%	15%
Others	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	5 0%
Novo total share	53%	54%	54%	56%	56%	57%	57%	57%	58%	59%	60%	61%	62%
Sales DKK m													
NovoRapid (Novo)	9033	9953	10191	12154	13360	14259	14717	14542	14474	13808	13693	12984	11648
Humalog (Lilly)	6817	7188	7626	7379	7670	7828	8141	8454	8323	8438	8458	8377	8197
Apidra (Sanofi)	1023	1290		1736	1979	1957	2192	2029	2171	2301	2014	2094	1726
FIAsp (Novo)	0	0	0	0	495	1677	3131	4734	6513	8822	10471	12565	15100
Afrezza (Sanofi)	0	0	0	434	1237	2237	3131	4058	4704	4986	5638	5864	6471
Others	0	0	0	0	0	0	0	0	0	0	0	0	0

Rest of world fast acting market:

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
ROW Market	12.566	12.769	13.441	15.457	17.775	20.264	22.696	24.965	26.962	28.850	30.004	30.904	31.522
Growth %		2%	5%	15%	15%	14%	12%	10%	8%	7%	4%	3%	2%
Market Share													
NovoRapid (Novo)	53%	54%	54%	56%	54%	51%	47%	43%	40%	36%	34%	31%	27%
Humalog (Lilly)	40%	39%	38%	34%	31%	28%	26%	25%	23%	22%	21%	20%	19%
Apidra (Sanofi)	6%	7%	8%	8%	8%	7%	7%	6%	6%	6%	5%	5%	4%
FIAsp (Novo)	0%	0%	0%	0%	2%	6%	10%	14%	18%	23%	26%	30%	35%
Afrezza (Sanofi)	0%	0%	0%	2%	5%	8%	10%	12%	13%	13%	14%	14%	15%
Others	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Novo total share	53,0%	54,0%	54,0%	56,0%	56,0%	57,0%	57,0%	57,0%	58,0%	59,0%	60,0%	61,0%	62,0%
Sales DKK million													
NovoRapid (Novo)	6.660	6.895	7.258	8.656	9.599	10.335	10.667	10.735	10.785	10.386	10.201	9.580	8.511
Humalog (Lilly)	6.817	7.188	7.171	5.255	5.510	5.674	5.901	6.241	6.201	6.347	6.301	6.181	5.989
Apidra (Sanofi)	1.023	1.290	1.510	1.237	1.422	1.418	1.589	1.498	1.618	1.731	1.500	1.545	1.261
FIAsp (Novo)	0	0	0	0	356	1.216	2.270	3.495	4.853	6.635	7.801	9.271	11.033
Afrezza (Sanofi)	0	0	0	309	889	1.621	2.270	2.996	3.505	3.750	4.201	4.327	4.728
Others	0	0	0	0	0	0	0	0	0	0	0	0	0

Fast acting market: Global sales and total franchise:

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Global Sales DKK million													
NovoRapid (Novo)	15.693	16.848	17.449	20.810	22.959	24.593	25.384	25.277	25.259	24.194	23.894	22.565	20.159
Humalog (Lilly)	13.635	14.377	14.798	12.634	13.180	13.502	14.042	14.696	14.524	14.785	14.758	14.558	14.186
Apidra (Sanofi)	2.045	2.580	1.510	2.973	3.401	3.376	3.781	3.527	3.789	4.032	3.514	3.639	2.987
FIAsp (Novo)	0	0	0	0	850	2.893	5.401	8.230	11.367	15.457	18.272	21.837	26.132
Afrezza (Sanofi)	0	0	0	743	2.126	3.858	5.401	7.054	8.209	8.737	9.839	10.190	11.200
Others	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	31.373	33.805	33.757	37.160	42.517	48.222	54.008	58.783	63.147	67.206	70.278	72.789	74.663
Global Market Share													
Year	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
NovoRapid (Novo)	50%	50%	52%	56%	54%	51%	47%	43%	40%	36%	34%	31%	27%
Humalog (Lilly)	43%	43%	44%	34%	31%	28%	26%	25%	23%	22%	21%	20%	19%
Apidra (Sanofi)	7%	8%	4%	8%	8%	7%	7%	6%	6%	6%	5%	5%	4%
FIAsp (Novo)	0%	0%	0%	0%	2%	6%	10%	14%	18%	23%	26%	30%	35%
Afrezza (Sanofi)	0%	0%	0%	2%	5%	8%	10%	12%	13%	13%	14%	14%	15%
Others	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Novo Forecast in DKK													
NovoRapid	15.693	16.848	17.449	20.810	22.959	24.593	25.384	25.277	25.259	24.194	23.894	22.565	20.159
Growth %		7%	4%	19%	10%	7%	3%	0%	0%	-4%	-1%	-6%	-11%
FIAsp	0	0	0	0	850	2.893	5.401	8.230	11.367	15.457	18.272	21.837	26.132
Growth %							87%	52%	38%	36%	18%	20%	20%
FIAsp 80% risk adjustmer	nt			0	680	2.315	4.321	6.584	9.093	12.366	14.618	17.469	20.906
Total Novo Franchise	15.693	16.848	17.449	20.810	23.639	26.908	29.705	31.860	34.352	36.560	38.512	40.034	41.065

US long acting market:

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
US Market DKK million	28.443	34.926	41.074	47.235	53.847	60.848	68.149	73.601	78.753	83.478	87.652	91.158	93.893
Growth %		22,8%	17,6%	15%	14%	13%	12%	8%	7%	6%	5%	4%	3%
Market Share													101%
Levemir (Novo)	19%	20%	23%	22%	20%	18%	16%	15%	14%	13%	12%	11%	10%
Lantus (Sanofi)	81%	80%	77%	76%	73%	66%	60%	55%	51%	46%	42%	38%	34%
BioSim (Lilly)	0%	0%	0%	0%	2%	6%	8%	10%	11%	12%	13%	14%	15%
Tresiba (Novo)	0%	0%	0%	0%	0%	2%	4%	5%	6%	7%	8%	9%	10%
Toujeo (Sanofi)				2%	5%	8%	12%	15%	18%	22%	25%	28%	32%
Others	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Novo total share	19%	20%	23%	22%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Sales DKK m													
Levemir (Novo)	5.290	6.823	9.386	10.392	10.769	10.953	10.904	11.040	11.025	10.852	10.518	10.027	9.389
Lantus (Sanofi)	23.153	28.103	31.688	35.898	39.309	40.159	40.890	40.481	40.164	38.400	36.814	34.640	31.924
BioSim (Lilly)	0	0	0	0	1.077	3.651	5.452	7.360	8.663	10.017	11.395	12.762	14.084
Tresiba (Novo)	0	0	0	0	0	1.217	2.726	3.680	4.725	5.843	7.012	8.204	9.389
Toujeo (Sanofi)	0	0	0	945	2.692	4.868	8.178	11.040	14.176	18.365	21.913	25.524	30.046
Others	0	0	0	0	0	0	0	0	0	0	0	0	0

Rest of world long acting market:

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
ROW Market	18.544	19.626	21.382	24.589	28.277	32.236	36.104	39.715	42.892	45.894	47.730	49.162	50.145
Growth %		6%	9%	15%	15%	14%	12%	10%	8%	7%	4%	3%	2%
Market Share													
Levemir (Novo)	24%	24%	23%	21%	20%	19%	17%	16%	14%	12%	11%	10%	10%
Lantus (Sanofi)	76%	75%	74%	72%	68%	61%	57%	52%	48%	45%	41%	38%	35%
BioSim (Lilly)	0%	0%	0%	0%	2%	6%	8%	10%	11%	12%	13%	14%	15%
Tresiba (Novo)	0%	1%	3%	5%	6%	7 %	9%	10%	12 %	13%	15%	16%	16%
Toujeo (Sanofi)	0%	0%	0%	2%	4%	7%	9%	12%	15%	18%	20%	22%	24%
Others	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Novo total share	24,2%	24,8%	25,7%	26,0%	26,0%	26,0%	26,0%	26,0%	26,0%	25,0%	26,0%	26,0%	26,0%
Sales DKK million													
Levemir (Novo)	4.496	4.723	4.831	5.164	5.655	6.125	6.138	6.354	6.005	5.507	5.250	4.916	5.015
Lantus (Sanofi)	14.048	14.760	15.893	17.704	19.228	19.664	20.579	20.652	20.588	20.652	19.569	18.681	17.551
BioSim (Lilly)	0	0	0	0	566	1.934	2.888	3.971	4.718	5.507	6.205	6.883	7.522
Tresiba (Novo)	0	143	658	1.229	1.697	2.257	3.249	3.971	5.147	5.966	7.159	7.866	8.023
Toujeo (Sanofi)	0	0	0	492	1.131	2.257	3.249	4.766	6.434	8.261	9.546	10.816	12.035
Others	0	0	0	0	0	0	0	0	0	0	0	0	0

Long acting market: Global sales and total franchise:

	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Global Sales DKK millio	n												
Levemir (Novo)	9.786	11.546	14.217	15.555	16.425	17.077	17.042	17.394	17.030	16.359	15.769	14.944	14.404
Lantus (Sanofi)	37.200	42.863	47.580	53.602	58.537	59.823	61.469	61.132	60.752	59.052	56.383	53.322	49.474
BioSim (Lilly)	0	0	0	0	1.642	5.585	8.340	11.332	13.381	15.525	17.600	19.645	21.606
Tresiba (Novo)	0	143	658	1.229	1.697	3.473	5.975	7.652	9.872	11.810	14.172	16.070	17.413
Toujeo (Sanofi)	0	0	0	1.436	3.823	7.124	11.427	15.806	20.609	26.626	31.459	36.340	42.081
Others	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	46.986	54.552	62.455	71.823	82.124	93.083	104.253	113.316	121.645	129.373	135.382	140.320	144.977
Global Market Share													
Levemir (Novo)	21%	21%	23%	22%	20%	18%	16%	15%	14%	13%	12%	11%	10%
Lantus (Sanofi)	79%	79%	76%	75%	71%	64%	59%	54%	50%	46%	42%	38%	34%
BioSim (Lilly)	0%	0%	0%	0%	2%	6%	8%	10%	11%	12%	13%	14%	15%
Tresiba (Novo)	0%	0%	1%	2%	2%	4%	6%	7 %	8%	9%	10%	11%	12%
Toujeo (Sanofi)	0%	0%	0%	2%	5%	8%	11%	14%	17%	21%	23%	26%	29%
Others	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Novo Forecast in DKK													
Levemir	9.786	11.546	14.217	15.555	16.425	17.077	17.042	17.394	17.030	16.359	15.769	14.944	14.404
Growth %		18%	23%	9%	6%	4%	0%	2%	-2%	-4%	-4%	-5%	-4%
Tresiba		143	658	1.229	1.697	3.473	5.975	7.652	9.872	11.810	14.172	16.070	17.413
Growth %			360%	87%	38%	105%	72%	28%	29%	20%	20%	13%	8%
Tresiba US						1.217	2.726	3.680	4.725	5.843	7.012	8.204	9.389
Tresiba US 95% Risk adj	usted					1.156	2.590	3.496	4.489	5.551	6.662	7.794	8.920
Total Novo Franchise	9.786	11.689	14.875	16.785	18.122	20.490	22.881	24.862	26.666	27.877	29.590	30.604	31.347

Appendix 9 – Restated financial accounts

Novo Nordisk - Analytical Income Statement

DKK millions	2010	2011	2012	2013	2014
Net Sales	60.776	66.346	78.026	83.572	88.806
Cost of good sold	9.848	10.709	11.475	12.059	12.316
Gross profit	50.928	55.637	66.551	71.513	76.490
Sales and distribution cost	18.135	18.909	21.448	23.302	23.159
Research and development cost	9.142	8.995	10.434	11.267	12.846
Administrative costs	3.009	3.187	3.259	3.449	3.454
Other operating income, net	716	565	<i>757</i>	797	896
Share of profit of associated companies	1.070	0	0	0	0
EBITDA	22.428	25.111	32.167	34.292	37.927
Depriciation & amortisation	2.467	2.737	2.693	2.799	3.435
EBIT	19.961	22.374	29.474	31.493	34.492
Тах	4.302	4.940	6.795	7.094	7.712
NOPAT	15.659	17.434	22.679	24.400	26.780
Financial income	382	514	125	1.702	167
Financial expenses	2.057	963	1.788	656	563
Net financial income before tax	-1.675	-449	-1.663	1.046	-396
Tax shield	419	112	416	-262	97
Net financial income after tax	-1.256	-337	-1.247	785	-299
Group profit after tax	14.403	17.097	21.432	25.184	26.481
Income taxes	3883	4828	6379	7355	7615
Tax on operating profit	4302	4940	6795	7094	7712
Tax on financial income	419	112	416	-262	97
Statutory tax rate	25,0%	25,0%	25,0%	25,0%	24,5%

Novo Nordisk - Analytical Balance Sheet					
DKK million	2010	2011	2012	2013	2014
Intangible Assets	1.458	1.489	1.495	1.615	1.378
Property, plant and equipment	20.507	20.931	21.539	21.882	23.136
Investments in associated companies	43	0	0	0	0
Deferred income tax assets	1.847	2.414	2.244	4.231	5.399
Total non-current assets	23.855	24.834	25.278	27.728	29.913
Inventories	9.689	9.433	9.543	9.552	11.357
Trade receivables	8.500	9.349	9.639	10.907	13.041
Tax receivables	650	883	1.240	3.155	3.210
Other receivables and prepayments	2.403	2.376	2.705	2.454	2.750
Total current assets	21.242	22.041	23.127	26.068	30.358
Deferred income tax liabilities	2.865	3.206	732	672	7
Trade payables	2.906	3.291	3.859	4.092	4.950
Tax payables	1.252	1.171	593	2.222	2.771
Other current liabilities	7.954	8.534	8.982	9.386	11.051
Provisions for other liabilities	2.023	2.324	1.907	2.183	2.041
Provisions for other liabilities	4.644	5.940	7.656	8.310	11.590
Total non-interest bearing debt	21.644	24.466	23.729	26.865	32.410
Invested capital (net operating assets)	23.453	22.409	24.676	26.931	27.861
Equity and liabilities					
Share capital	600	580	560	550	530
Treasury shares	-28	-24	-17	-21	-11
Retained earnings	36.097	37.111	39.001	41.137	41.277
Other reserves	296	-219	1.088	903	-1.502
Total Equity	36.965	37.448	40.632	42.569	40.294
Net interest-bearing debt					
Non-current debt	504	502	0	0	0
Current debt	562	351	500	215	720
Derivative financial instrument	1.158	1.492	48	0	2.607
Retirement benefit obligations	569	439	760	688	1.031
Interest-bearing debt	2.793	2.784	1.308	903	4.358
Marketable securities	3.926	4.094	4.552	3.741	1.509
Derivative financial instruments	108	48	931	1.521	30
Cash	12.017	13.408	11.553	10.728	14.396
Other non-current financial assets	254	273	228	551	856
Interest-bearing assets	16.305	17.823	17.264	16.541	16.791
Net-interest-bearing debt	-13.512	-15.039	-15.956	-15.638	-12.433
Invested Capital	23.453	22.409	24.676	26.931	27.861

Sanofi - Analytical Income Statement					
€ millions	2010	2011	2012	2013	2014
Net sales	34.036	35.058	35.957	33.306	34.109
Cost of sales	9.302	10.389	11.075	10.983	11.029
Gross Profit	24.734	24.669	24.882	22.323	23.080
Research and development	4.556	4.788	4.905	4.770	4.824
Selling and general expenses	8.171	8.508	8.931	8.602	8.991
Other operating income/expenses	77	46	148	450	164
Share of profit/(loss) of asssociates	1.036	1.102	424	85	147
Net income attributable to non-					
controlling interest	-257	-247	-172	-162	-127
EBITDA	12.863	12.274	11.446	9.324	9.449
Depreciation & Amortization	3.962	3.456	3.408	4.301	2.456
Non-operating expenses	2.366	3.087	1.608	-82	850
EBIT	6.535	5.731	6.430	5.105	6.143
Tax	1.513	595	1.332	934	1.311
NOPAT	5.022	5.136	5.098	4.171	4.832
Financial income	105	140	93	109	193
Financial expenses	467	552	751	612	605
Net financial obligations (before tax)	-362	-412	-658	-503	-412
Tax shield	83	140	224	171	140
Net financial obligations (after tax)	-279	-272	-434	-332	-272
Group profit after tax	4.743	4.864	4.664	3.839	4.560
Equity In Earnings	978	1.070	393	35	-51
Minority Interest	254	241	169	158	119
Net Income to shareholders	5.467	5.693	4.888	3.716	4.390
Income taxes	1.430	455	1.108	763	1.171
Tax on operating profit	1.513	595	1.332	934	1.311
Tax on financial income	83	140	224	171	140
Statutory tax rate	23,0%	9,0%	19,2%	16,6%	20,4%

Sanofi Analytical Balance sheet					
€ million	2010	2011	2012	2013	2014
Property, plant and equipment	8.155	10.750	10.578	10.182	10.396
Intangible assets	44.411	62.221	58.265	52.529	53.740
Investments in associates and joint ventures	924	807	487	448	2.384
Non-current financial assets	1.644	2.399	3.799	4.826	2.575
Deferred tax Assets	3.051	3.633	4.369	4.144	4.860
Total non-current assets	58.185	79.810	77.498	72.129	73.955
Inventories	5.020	6.051	6.379	6.352	6.562
Accounts receivable	6.507	8.042	7.507	6.831	7.149
Other current assets	2.000	2.401	2.355	2.287	2.157
Total current assets	13.527	16.494	16.241	15.470	15.868
Non-interest bearing debt					
Deffered tax liabilities	3.808	6.530	5.932	5.060	4.105
Provisions and other non-current liabilities	9.326	10.346	11.043	8.735	9.578
Non-current liabilities related to business combinations	3.020	20.0.0	11.0.0	0.700	3.070
and to non-controlling interest	388	1.336	1.350	884	1.133
Accounts payable	2.800	3.183	3.190	3.003	3.651
Other current liabilities	5.624	7.221	6.728	6.725	7.712
Current liabilities related to business combinations and to					
non-controlling interest	98	220	100	24	131
Liabilities related to assets hold for sale or exchange	1.672	20	39	1	0
Total non-interest bearing debt	23.716	28.856	28.382	24.432	26.310
Invested conited (not expecting exects)	47.006	C7 440	CE 257	62.167	62 512
Invested capital (net operating assets)	47.996	67.448	65.357	63.167	63.513
Equity and Liabilities					
Equity attributable to equity holders of Sanofi	53.097	56.203	57.352	56.904	56.120
Equity attributable to non-controlling interest	191	170	134	129	148
Total Equity	53.288	56.373	57.486	57.033	56.268
Net interest-bearing debt					
Short-term debt and current portion of long-term debt	1.565	2.940	3.812	4.176	1.538
Long-term debt	6.695	12.499	10.719	10.414	13.276
Interest-bearing debt	8.260	15.439	14.531	14.590	14.814
Assets held for sale or exchange	7.036	67	101	14	10
Current financial assets	51	173	178	185	218
Cash and cash equivalents	6.465	4.124	6.381	8.257	7.341
Interest-bearing assets	13.552	4.364	6.660	8.456	7.569
Net-interest-bearing debt	-5.292	11.075	7.871	6.134	7.245
Invested Capital	47.996	67.448	65.357	63.167	63.513

Eli l	Lilly - Analytical Income statement					
\$ m	illion	2010	2011	2012	2013	2014
Net	sales	23.076	24.287	22.603	23.113	19.616
	Cost of good sold	4.366	5.068	4.797	4.908	4.933
Gro	ss profit	18.710	19.219	17.807	18.205	14.683
	Marketing, Selling and administration	7.053	7.880	7.514	7.126	6.621
	Research and development cost	4.884	5.021	5.278	5.531	4.734
	Acquired in-process R&D	50	388	0	57,1	200,2
	Other (income) expense	-128,6	72,9	41	-63,9	-368,3
EBI	ΓDA	6.851	5.857	4.974	5.555	3.497
	Depriciation & amortisation	192	401	281	121	469
EBI	Г	6.659	5.456	4.693	5.434	3.028
	Tax	1.485	1.022	1.337	1.213	615
NO	PAT	5.173	4.434	3.356	4.222	2.413
	Extra ordinary	0	0	-787,8	-495,4	0
Fina	ancial income / expenses					
	Financial income	52	80	105	120	121
	Financial expenses	186	186	178	160	149
Net	financial expenses before tax	-134	-106	-73	-40	-28
	Tax shield	30	20	18	8	6
Net	financial expenses after tax	-104	-86	-55	-32	-22
Gro	up profit after tax	5.070	4.348	4.089	4.685	2.391
Inco	me taxes	1.456	1.002	1.320	1.205	610
Tax	on operating profit	1.485	1.022	1.337	1.213	615
Tax	on financial income	30	20	18	8	6
Effec	tive tax rate	22,3%	18,7%	24,4%	20,5%	20,3%

Eli Lilly Balance sheet					
\$ million	2010	2011	2012	2013	2014
Cash and cash equivalents	5.993	5.923	4.019	3.830	3.872
Short-term investments	734	975	1.666	1.567	955
Accounts receivable	3.494	3.598	3.336	3.434	3.235
Other receivables	664	640	<i>552</i>	588	567
Inventories	2.518	2.300	2.644	2.929	2.740
Prepaid expenses and other	1.437	813	822	756	812
Total current assets	14.840	14.248	13.039	13.105	12.180
Other Assets					
Restricted cash	0	0	0	0	5.406
Investments	1.780	4.030	6.313	7.625	4.569
Goodwill	4.819	5.128	4.753	1.517	1.758
Other intangibles, net	0	0	0	2.814	2.884
Sundry	1.622	2.493	2.534	2.213	2.418
Total other assets	8.221	11.651	13.600	14.169	17.035
Property and equipment, net	7.941	7.760	7.760	7.976	7.964
Total assets	31.001	33.660	34.399	35.249	37.178
Liabilities and Equity					
Current Liabilities					
Short-team borrowing and current maturities of long-					
term debt	156	1.522	12	1.013	2.689
Accounts payable	1.072	1.125	1.188	1.119	1.128
Employee compensation	852	805	940	944	759
Sales rebates and discounts	1.373	1.771	1.777	1.942	2.069
Dividends payable	540	542	541	524	530
Income taxes payable	458	262	144	254	94
Deferred income taxes	0	422	1.048	793	1.467
Other current liabilities	2.477	2.481	2.739	2.328	2.473
Total current liabilities	6.927	8.931	8.390	8.917	11.208
Other Liabilities					
Long-term debt	6.771	5.465	5.519	4.200	5.368
Accured retirement benefits	1.887	3.069	3.012	1.549	2.563
Long-term income taxes payable	1.235	1.086	1.334	1.079	999
Other noncurrent liabilities	1.769	1.574	1.369	1.863	1.654
Total other liabilities	11.662	11.193	11.236	8.691	10.583
Commitments and contingencies					
Common stock	721	724	717	699	695
Additional paid-in capital	4.799	4.887	4.963	5.050	5.292
Retained earnings	12.733	14.898	16.088	16.992	16.483
Deferred costs - ESOP	-52,4				
Employee benefit trust	-3.013	-3.013	-3.013	-3.013	-3.013
Accumulated other comprehensive	-2.670	-3.859	-3.797	-2.003	-3.992
Cost of common stock in treasury	-96	-95	-192	-94	-91
Total Eli Lilly and Company shareholders equity	12.420	13.542	14.765	17.631	15.373
Noncontrolling interest	-8	-6	9	9	15
Total equity	12.413	13.536	14.774	17.641	15.388
Total liabilities and equity	31.001	33.660	34.399	35.249	37.178
Total habilities and equity	51.501	33.000	J-4.333	33.273	37.170

Appendix 10 – Market consensus revenue forecast Market consensus revenue forecast

Revenues DKK MM	2015	2016	2017	2018	2019
Baader Helvea Equity R.	106,126.90	115,426.00	125,972.50	136,394.90	142,013.00
Berenberg	104,591.00	112,314.00	120,221.00	128,149.00	
Bernstein	108,231.00	117,148.00	127,349.00	134,914.00	141,780.00
Bryan Garnier	108,276.00	114,768.00			
Commerzbank	97,570.00	106,292.00	115,644.00	124,536.00	122,543.00
Credit Suisse	112,463.00	114,993.00	120,838.00		
Danske Markets	106,529.00	120,456.00	137,433.00	157,840.00	
DNB Markets	106,478.00	120,138.00	136,667.00		
Handelsbanken	110,870.00	120,313.00	130,754.00	140,961.00	152,040.00
Jefferies	106,766.00	116,735.00	125,499.00	134,621.00	144,312.00
Jyske Bank	109,091.00	116,885.00	126,661.00		
Kepler cheuvreus	108,297.00	118,690.00	128,865.00		
Mirabaud Securities	110,004.00	117,576.00	119,980.00	123,088.00	128,167.00
Morningstar	107,716.00	115,556.00			
Natixis	105,890.00	113,846.00	123,403.00	136,046.00	146,263.00
Nordea Markets	110,720.00	125,916.00	141,128.00		
SEB Equities	110,871.00	122,099.00	134,070.00	150,402.00	166,259.00
Seciete Generale	103,484.00	108,700.00	115,067.00	120,189.00	126,634.00
Swedbank Markets	110,642.00	120,547.00	132,035.00		
Consensus	107.775,65	117,069.79	127,393.95	134,660.31	141,582.93

Source: Thomson One Banker

Appendix 11 – Budget value drivers

	<u> </u>	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Term.
int	Revenue y/y growth		8,4%	15,0%	6,6%	5,9%	9,3%	8,1%	8,7%	6,5%	7,1%	6,1%	5,4%	4,5%	4,0%	2,4%	3,1%
statement	Cost of sales	16,2%	16,1%	14,7%	14,4%	13,9%	13,5%	13,1%	12,8%	12,5%	12,2%	11,9%	11,6%	11,3%	11,0%	11,0%	11,0%
tate	Sales and dist.	29,8%	28,5%	27,5%	27,9%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%
s ət	R&D	15,0%	13,6%	13,4%	13,5%	14,5%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%
Income	Administrative	5,0%	4,8%	4,2%	4,1%	3,9%	3,8%	3,7%	3,6%	3,5%	3,4%	3,3%	3,2%	3,2%	3,1%	3,1%	3,1%
=	Other operating income	1,2%	0,9%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%
	Intangible Assets	2,4%	2,2%	1,9%	1,9%	1,6%	1,6%	1,6%	1,6%	1,6%	1,6%	1,6%	1,6%	1,6%	1,6%	1,6%	1,6%
	Property, plant and equipment	33,7%	31,5%	27,6%	26,2%	26,1%	26,0%	26,0%	26,0%	26,0%	26,0%	26,0%	26,0%	26,0%	26,0%	26,0%	26,0%
٩	Investments in associated companie	0,1%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%
Van V	Deferred income tax assets	3,0%	3,6%	2,9%	5,1%	6,1%	6,1%	6,1%	6,1%	6,1%	6,1%	6,1%	6,1%	6,1%	6,1%	6,1%	6,1%
פֿ	Other non-current financial assets	0,4%	0,4%	0,3%	0,7%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%
7	Trade receivables	14,0%	14,1%	12,4%	13,1%	14,7%	13,6%	13,6%	13,6%	13,6%	13,6%	13,6%	13,6%	13,6%	13,6%	13,6%	13,6%
et	Tax receivables	1,1%	1,3%	1,6%	3,8%	3,6%	3,6%	3,6%	3,6%	3,6%	3,6%	3,6%	3,6%	3,6%	3,6%	3,6%	3,6%
Balance sheet	Other receivables and prepayments	4,0%	3,6%	3,5%	2,9%	3,1%	3,0%	3,0%	3,0%	3,0%	3,0%	3,0%	3,0%	3,0%	3,0%	3,0%	3,0%
Se	Deferred income tax liabilities	4,7%	4,8%	0,9%	0,8%	0,0%	0,6%	0,6%	0,6%	0,6%	0,6%	0,6%	0,6%	0,6%	0,6%	0,6%	0,6%
lan	Retirement benefit obligations	0,9%	0,7%	1,0%	0,8%	1,2%	0,9%	0,9%	0,9%	0,9%	0,9%	0,9%	0,9%	0,9%	0,9%	0,9%	0,9%
Ba	Provisions for other liabilities	3,3%	3,5%	2,4%	2,6%	2,3%	2,5%	2,5%	2,5%	2,5%	2,5%	2,5%	2,5%	2,5%	2,5%	2,5%	2,5%
	Tax payables	2,1%	1,8%	0,8%	2,7%	3,1%	2,1%	2,1%	2,1%	2,1%	2,1%	2,1%	2,1%	2,1%	2,1%	2,1%	2,1%
	Other current liabilities	13,1%	12,9%	11,5%	11,2%	12,4%	12,2%	12,2%	12,2%	12,2%	12,2%	12,2%	12,2%	12,2%	12,2%	12,2%	12,2%
	Provisions for other liabilities	7,6%	9,0%	9,8%	9,9%	13,1%	13,1%	13,1%	13,1%	13,1%	13,1%	13,1%	13,1%	13,1%	13,1%	13,1%	13,1%
		98,4%	88,1%	83,2%	79,2%	92,2%	88,2%	88,2%	88,2%	88,2%	88,2%	88,2%	88,2%	88,2%	88,2%	88,2%	88,2%
à	Trade payables	29,5%	30,7%	33,6%	33,9%	40,2%	37,1%	37,1%	37,1%	37,1%	37,1%	37,1%	37,1%	37,1%	37,1%	37,1%	37,1%
	Depriciation % of PP&E	12,0%	13,1%	12,5%	12,8%	14,8%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%
2	Tax rate	25,0%	25,0%	25,0%	25,0%	24,5%	23,5%	22,0%	22,0%	22,0%	22,0%	22,0%	22,0%	22,0%	22,0%	22,0%	22,0%
Others	Net borrowing rate	12,1%	3,0%	10,1%	-6,6%	3,1%	3,1%	3,1%	3,1%	3,1%	3,1%	3,1%	3,1%	3,1%	3,1%	3,1%	3,1%
	Net interest-bearing debt as % of invested cap.	-59,8%	-68,4%	-68,3%	-58,9%	-45,5%	-60,2%	-60,2%	-60,2%	-60,2%	-60,2%	-60,2%	-60,2%	-60,2%	-60,2%	-60,2%	-60,2%

Appendix 12 - Pro forma income statement

DKK millions	2010R	2011R	2012R	2013R	2014R	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	Terminal
Revenue	60.776	66.346	78.026	83.572	88.806	97.934	106.511	116.599	124.760	134.336	143.001	151.171	158.317	164.838	168.959	174.132
y/y growth		8,4%	15,0%	6,6%	5,9%	9,3%	8,1%	8,7%	6,5%	7,1%	6,1%	5,4%	4,5%	4,0%	2,4%	3,0%
Cost of good sold	9.848	10.709	11.475	12.059	12.316	13.221	13.953	14.925	15.595	16.389	17.017	17.536	17.890	18.132	18.585	19.155
% of revenue	16,2%	16,1%	14,7%	14,4%	13,9%	13,5%	13,1%	12,8%	12,5%	12,2%	11,9%	11,6%	11,3%	11,0%	11,0%	11,0%
Gross profit	50.928	55.637	66.551	71.513	76.490	84.713	92.558	101.674	109.165	117.947	125.984	133.635	140.427	146.706	150.373	154.978
Sales and dist.	18.135	18.909	21.448	23.302	23.159	25.539	27.776	30.407	32.535	35.032	37.292	39.422	41.286	42.987	44.061	45.411
% of revenue	29,8%	28,5%	27,5%	27,9%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%	26,1%
R&D	9.142	8.995	10.434	11.267	12.846	13.695	14.894	16.305	17.446	18.785	19.997	21.139	22.139	23.051	23.627	24.350
% of revenue	15,0%	13,6%	13,4%	13,5%	14,5%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%	14,0%
Administrative costs	3.009	3.187	3.259	3.449	3.454	3.721	3.941	4.198	4.367	4.567	4.719	4.837	5.066	5.126	5.255	5.416
% of revenue	5,0%	4,8%	4,2%	4,1%	3,9%	3,8%	3,7%	3,6%	3,5%	3,4%	3,3%	3,2%	3,2%	3,1%	3,1%	3,1%
Other operating income	716	565	757	797	896	972	1.057	1.157	1.238	1.333	1.419	1.500	1.571	1.636	1.677	1.728
% of revenue	1,18%	0,85%	0,97%	0,95%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%	1,0%
Share of profit of ass. firms	1.070															
EBITDA	22.428	25.111	32.167	34.292	37.927	42.729	47.004	51.922	56.055	60.895	65.395	69.736	73.507	77.178	79.107	81.530
% of revenue			41,2%	41,0%	42,7%	43,6%	44,1%	44,5%	44,9%	45,3%	45,7%	46,1%	46,4%	46,8%	46,8%	46,8%
Depriciation & amortisation	2.467	2.737	2.693	2.799	3.435	3.323	3.614	3.956	4.233	4.558	4.852	5.129	5.371	5.593	5.733	5.908
% of PP&E	12,0%	13,1%	12,5%	12,8%	14,8%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%	13,0%
EBIT	19.961	22.374	29.474	31.493	34.492	39.406	43.390	47.966	51.822	56.337	60.543	64.607	68.136	71.585	73.375	75.622
Tax	4.302	4.940	6.795	7.094	7.712	9.260	9.546	10.553	11.401	12.394	13.319	14.213	14.990	15.749	16.142	16.637
NOPAT	15.659	17.434	22.679	24.400	26.780	30.146	33.844	37.413	40.421	43.943	47.224	50.393	53.146	55.836	57.232	58.985
Net financial	-1.675	-449	-1.663	1.046	-396	555	599	653	695	744	788	829	864	895	917	945
Tax shield	419	112	416	-262	97	-130	-132	-144	-153	-164	-173	-182	-190	-197	-202	-208
Net financial after tax	-1.256	-337	-1.247	785	-299	424	467	509	542	581	615	647	674	698	715	737
Group profit after tax	14.403	17.097	21.432	25.184	26.481	30.570	34.312	37.923	40.963	44.524	47.838	51.040	53.820	56.534	57.947	59.722

Appendix 13 – Pro forma balance sheet

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Terminal
Intangible Assets	1.378	1.567	1.704	1.866	1.996	2.149	2.288	2.419	2.533	2.637	2.703	2.786
Property, plant and equipment	23.136	25.463	27.693	30.316	32.438	34.927	37.180	39.304	41.162	42.858	43.929	45.274
Investments in associated companies	0	0	0	0	0	0	0	0	0	0	0	0
Deferred income tax assets	5.399	5.954	6.475	7.089	7.585	8.167	8.694	9.190	9.625	10.021	10.272	10.586
Total non-current assets	29.913	32.984	35.872	39.270	42.019	45.244	48.162	50.914	53.320	55.517	56.904	58.647
Inventories	11.357	11.663	12.308	13.165	13.757	14.457	15.011	15.469	15.781	15.995	16.395	16.897
Trade receivables	13.041	13.352	14.521	15.896	17.009	18.314	19.496	20.610	21.584	22.473	23.035	23.740
Tax receivables	3.210	3.540	3.850	4.215	4.510	4.856	5.169	5.464	5.723	5.958	6.107	6.294
Other receivables and prepayments	2.750	2.938	3.195	3.498	3.743	4.030	4.290	4.535	4.749	4.945	5.069	5.224
Total current assets	30.358	31.492	33.874	36.774	39.018	41.657	43.966	46.077	47.837	49.371	50.605	52.155
Non-interest bearing debt												
Deferred income tax liabilities	7	571	621	680	728	784	834	882	924	962	986	1.016
Provisions for other liabilities	2.041	2.401	2.611	2.858	3.058	3.293	3.506	3.706	3.881	4.041	4.142	4.269
Trade payables	4.950	4.900	5.171	5.531	5.780	6.074	6.307	6.499	6.630	6.720	6.888	7.099
Tax payables	2.771	2.030	2.208	2.417	2.586	2.785	2.964	3.133	3.282	3.417	3.502	3.609
Other current liabilities	11.051	11.975	13.023	14.257	15.255	16.426	17.485	18.484	19.358	20.155	20.659	21.292
Provisions for other liabilities	11.590	12.781	13.901	15.217	16.282	17.532	18.663	19.729	20.662	21.513	22.051	22.726
Total non-interest bearing debt	32.410	34.658	37.536	40.961	43.689	46.893	49.759	52.434	54.736	56.808	58.228	60.011
Invested capital												
(net operating assets)	27.861	29.818	32.211	35.083	37.347	40.008	42.369	44.557	46.421	48.080	49.282	50.791
Equity and liabilities												
Equity beginning of period		40.294	47.236	51.027	55.577	59.164	63.378	67.118	70.586	73.537	76.166	78.070
Net earnings		30.570	34.312	37.923	40.963	44.524	47.838	51.040	53.820	56.534	57.947	59.722
Dividends		-23.628	-30.520	-33.373	-37.377	-40.309	-44.098	-47.573	-50.868	-53.906	-56.043	-57.331
Total Equity	40.294	47.236	51.027	55.577	59.164	63.378	67.118	70.586	73.537	76.166	78.070	80.461
Net-interest-bearing debt	-12.433	-17.418	-18.816	-20.494	-21.817	-23.371	-24.750	-26.028	-27.117	-28.086	-28.788	-29.670
Invested Capital	27.861	29.818	32.211	35.083	37.347	40.008	42.369	44.557	46.421	48.080	49.282	50.791

Appendix 14 – Pro forma Cash flow statement

Cash flow statement	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Terminal
NOPAT	26.780	30.146	33.844	37.413	40.421	43.943	47.224	50.393	53.146	55.836	57.232	58.985
+ depriciation & amortization		3.323	3.614	3.956	4.233	4.558	4.852	5.129	5.371	5.593	5.733	5.908
- Delta NWC		-1.114	-495	-526	-485	-565	-557	-563	-543	-537	-186	-233
- Net investments (non-current	assets)	6.393	6.502	7.354	6.982	7.783	7.770	7.881	7.778	7.789	7.120	7.651
Free cash flow to the firm (FCFF)		28.189	31.451	34.542	38.157	41.283	44.863	48.205	51.283	54.177	56.030	57.476
Net new financial liabilities		-4.985	-1.398	-1.678	-1.323	-1.554	-1.379	-1.279	-1.088	-969	-702	-882
Net financial after tax		424	467	509	542	581	615	647	674	698	715	737
Free cash flow to equity holders	(FCFE)	23.628	30.520	33.373	37.377	40.309	44.098	47.573	50.868	53.906	56.043	57.331
Dividends		-23.628	-30.520	-33.373	-37.377	-40.309	-44.098	-47.573	-50.868	-53.906	-56.043	-57.331
Cash surplus		0	0	0	0	0	0	0	0	0	0	0



Appendix 16 - Enterprise discounted cash flow valuation 2016 2017 2018 2019 2020 2021 2022 2023

**											
E-DCF valuation millions DKK	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Terminal
Free cash flow to the firm	28.189	31.451	34.542	38.157	41.283	44.863	48.205	51.283	54.177	56.030	57.476
t	1	2	3	4	5	6	7	8	9	10	
Discount factor	0,93	0,86	0,80	0,74	0,68	0,63	0,59	0,54	0,50	0,47	
Present value, FCFF	26.115	26.992	27.464	28.106	28.170	28.360	28.231	27.823	27.231	26.090	
PV of FCFF in forecast horizon	274.582	-									
Present value of FCFF in terminal period	548.310										
Enterprise value	822.893		g	3,06%							
NIBD	-12.433		rf	3,47%							
Market value of equity	835.326	-	rm	5,50%							
Shares outstanding millions	2593		Beta	0,8133							
Share price 31 December 2014	322		WACC	7,94%							
Mid-year discounting factor	1,039	-									
Factor adjustment to valuation date (36 days)	1,008	_									
Share price 5th of February 2015	337,2	-									

g	3,06%
rf	3,47%
rm	5,50%
Beta	0,8133
WACC	7,94%

Appendix 17 – Economic value added valuation

EVA valuation millions DKK	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Terminal
NOPAT	30.146	33.844	37.413	40.421	43.943	47.224	50.393	53.146	55.836	57.232	58.985
Invested capital, beginning of period	27.861	29.818	32.211	35.083	37.347	40.008	42.369	44.557	46.421	48.080	49.282
Cost of capital	2.213	2.368	2.559	2.787	2.967	3.178	3.365	3.539	3.687	3.819	3.915
EVA	27.933	31.476	34.855	37.635	40.977	44.046	47.028	49.607	52.149	53.413	55.070
t	1	2	3	4	5	6	7	8	9	10	
Discount factor	0,926	0,858	0,795	0,737	0,682	0,632	0,586	0,543	0,503	0,466	
Present value, EVA	25.877	27.014	27.713	27.721	27.962	27.844	27.542	26.914	26.211	24.871	
Invested capital beginning of period	27.861										
PV of EVA in forecast horizon	269.669										
PV of Terminal	525.363										
Enterprise Value	822.893		g	3,06%							
NIDB	-12.433		rf	3,47%							
Market value of equity	835.326		rm	5,50%							
Shares outstanding millions	2593		Beta	0,8133							
Share price 31 December 2014	322		WACC	7,94%							
Mid-year discounting factor	1,039	•			•						
Factor adjustment to valuation date (36 days)	1,008										
Share price 5th of February 2015	337,2										

Appendix 18 - Sensitivity analysis

Changes in WACC by changes in Beta (H) and Risk-free rate (V)

	0,39%	1,16%	1,93%	2,70%	3,47%	3,83%	4,20%	4,56%	4,92%
0,59	3,6%	4,4%	5,2%	6,0%	6,7%	7,1%	7,5%	7,8%	8,2%
0,65	4,0%	4,7%	5,5%	6,3%	7,0%	7,4%	7,8%	8,1%	8,5%
0,70	4,3%	5,0%	5,8%	6,6%	7,3%	7,7%	8,1%	8,4%	8,8%
0,76	4,6%	5,3%	6,1%	6,9%	7,6%	8,0%	8,4%	8,7%	9,1%
0,81	4,9%	5,6%	6,4%	7,2%	7,9%	8,3%	8,7%	9,0%	9,4%
0,90	5,3%	6,1%	6,9%	7,6%	8,4%	8,8%	9,1%	9,5%	9,9%
0,98	5,8%	6,6%	7,3%	8,1%	8,9%	9,2%	9,6%	10,0%	10,3%
1,07	6,3%	7,0%	7,8%	8,6%	9,3%	9,7%	10,1%	10,4%	10,8%
1,15	6,7%	7,5%	8,3%	9,0%	9,8%	10,2%	10,5%	10,9%	11,2%
	М	IN	25% Q	uartile	Average	75% Q	uartile	М	ax
	3,6	5%	6,4	0%	7,67%	9,0	3%	11,	2%

Share price changes by changes in Terminal Growth (H) and WACC (V) 1 28% 1 73% 2 17% 2 62% 3 06% 3 54% 4 02% 4 50% 4 98%

	1,28%	1,/3%	2,1/%	2,62%	3,06%	3,54%	4,02%	4,50%	4,98%
6,4%	365	388	416	450	494	556	643	773	992
6,8%	339	358	381	408	442	490	554	644	783
7,2%	316	332	351	373	401	438	486	552	647
7,6%	296	309	325	344	366	396	434	483	551
7,9%	278	290	303	319	337	361	391	430	480
8,2%	267	277	289	303	319	340	366	399	441
8,5%	256	266	276	289	303	322	344	372	407
8,8%	247	255	265	276	289	305	325	349	379
9,0%	238	245	254	264	276	290	307	328	354
	М	IN	25% Q	uartile	Average	75% Q	uartile	M	ax
	23	8	29	96	385	43	30	99)2

Appendix 19 – Best case scenario

E-DCF valuation millions DKK	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Terminal
Free cash flow to the firm	28.189	31.453	34.609	38.439	41.878	45.829	49.516	52.973	56.247	58.460	60.255
t	1	2	3	4	5	6	7	8	9	10	
Discount factor	0,93	0,86	0,80	0,74	0,68	0,63	0,59	0,54	0,50	0,47	
Present value, FCFF	26.115	26.995	27.517	28.313	28.577	28.972	28.999	28.741	28.271	27.221	
PV of FCFF in forecast horizon	279.721	-									
Present value of FCFF in terminal period	574.827										
Enterprise value	854.547	=	g	3,06%							
NIBD	-12.433	_	rf	3,47%							
Market value of equity	866.980	_	rm	5,50%							
Shares outstanding millions	2593		Beta	0,8133							
Share price 31 December 2014	334		WACC	7,94%							
Mid-year discounting factor	1,039	-			-						
Factor adjustment to valuation date (36 days)	1,008										
Share price 5th of February 2015	350,0	-									

g	3,06%
rf	3,47%
rm	5,50%
Beta	0,8133
WACC	7,94%

2016 2017 2018 2019 2020 2021 2022 2023 2024 Terminal

2016 2017 2018 2019 2020 2021 2022 2023 2024 Terminal

Appendix 20 – Worst case scenario

E-DCF valuation millions DKK	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024 1
Free cash flow to the firm	28.189	31.451	34.448	36.521	38.007	39.741	40.998	41.926	43.509	44.541
t	1	2	3	4	5	6	7	8	9	10
Discount factor	0,93	0,86	0,80	0,74	0,68	0,63	0,59	0,54	0,50	0,47
Present value, FCFF	26.115	26.992	27.390	26.901	25.935	25.123	24.010	22.747	21.869	20.740
PV of FCFF in forecast horizon	247.822	•								
Present value of FCFF in terminal period	431.563	_								
Enterprise value	679.384	_	g	3,06%						
NIBD	-12.433		rf	3,47%						
Market value of equity	691.817	_	rm	5,50%						
Shares outstanding millions	2593		Beta	0,8133						
Share price 31 December 2014	267		WACC	7,94%]					
Mid-year discounting factor	1,039	•			•					
Factor adjustment to valuation date (36 days)	1,008									
Share price 5th of February 2015	279,3	-								

g	3,06%
rf	3,47%
rm	5,50%
Beta	0,8133
WACC	7,94%