# IN DEPTH VALUATION INDICATES STOCK IS FAIRLY PRICED

Investment rating: Hold Downside Potential: 4.8%

#### Friday 9th May 2016

- Our DCF analysis implies a downside potential of 4.8%.
- We forecast revenue to grow at a CAGR of 7.3% over the next 5 years.
- EBITDA CAGR expected to grow at 8.2% over next 5 years.
- We conduct a deep dive market share oriented valuation of over 90% of Novo's portfolio.
- The main diabetes franchise is expected to grow at a CAGR of 9%, achieving market share of 40% by the end of 2020 despite added competition from the new drugs Trulicity and Toujeo.
- Academic insights were obtained through conversations with Dr. David Brayden, Professor of Advanced Drug Delivery at the School of Veterinary Medicine UCD.
- Novo's pivot into the obesity market rests on the shoulders of Semaglutide and further down the line on whether they will be able to deliver the drug orally. For now, the first hurdle is receiving FDA approval. This market has the potential to be very lucrative and our projections estimate possible annual revenue of DKK 11.404mn by 2020 in a Bayes model forecast.
- Novo has the second most productive R&D in Europe with 17.5% of economic returns to R&D expenses vs average of 2.59% of the whole market.
- Management recently revised the long-term operating profit growth target to 5-9%, down from 10-15%.
   This was likely viewed with pessimism by investors and led a market rout. In our analysis we forecast operating profit to grow at a CAGR of 6.5%.





# Novo Nordisk [NOVOB DC]

**Company Initiation Report** 



# CAPITALIZATION AS OF 22/04/2016 IN DKK MN

Share Price	357.8
Shares Out.	2,012.6
<b>Market Capitalization</b>	720,094
- Cash & Short Term	20,465.0
Investments	
+ Total Debt	1,073.0
+ Pref. Equity	0.0
+ Total Minority Interest	0.0
= Total Enterprise Value	827.770.3

# DCF ANALYSIS

Est. Enterprise Value	663,313.5
Est. Equity Value	685,705.6
Implied Share Price	340.71

**Downside Potential 4.8%** 

**Target Price DKK 340** 

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# IMPORTANT DISCLOSURE

Before reading, please see the disclaimer at the end of this report for important information.





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#### RECENT PERFORMANCE AND COMPANY OVERVIEW



Figure 1: Historic share price performance. Source: Bloomberg.

#### INVESTMENT THESIS

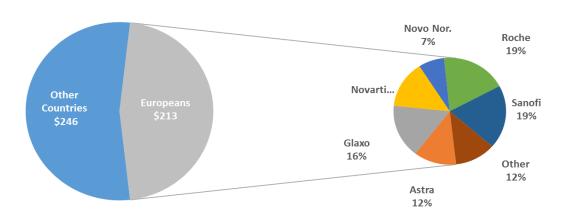


Figure 2: Large pharma market share by company. Source: Bloomberg and our own analysis.

Novo Nordisk has continuously met or exceeded expectations over the past 5+ years and has maintained a clear focus around diabetes. Sales over the past 3 years are quite remarkable at a CAGR of 13.6%. Novo is not subject to the same risks from patent expirations as its peers for reasons outlined in the section 'a note on why diabetes patients can't buy insulin'. The specialist focus that Novo enjoys brings with it greater success in bringing new drugs through the pipeline (17.5% of economic returns to R&D expenses vs an average of 2.59% for the whole market [Appendix B2]) – indicating that management is skilled at abandoning doomed projects early and thus saving billions down the line. Management recently revised the long-term operating profit growth target to 5-9%, down from 10-15% which was likely viewed with pessimism by investors and led to a market rout. The companies operating profit has grown at CAGR of 21% of the last five years. In our analysis we forecast operating profit to grow at a CAGR of 6.5%. Incorporating these factors into our valuation we generate an enterprise value of DKK 663,313mn suggesting that the stock is fairly priced, with potential downside of 4.8% at current prices. The great unknown for Novo is how the largely untapped market for treating obesity will develop with Novo well placed to capitalize given the weight loss properties of its GLP-1 franchise; of course this is contingent on the all-important relabeling FDA approval and subsequent success in marketing the drug to obese patients without diabetes as well as prescribers.



# UCD DUBLIN

#### 2015 REVENUE BREAKDOWN

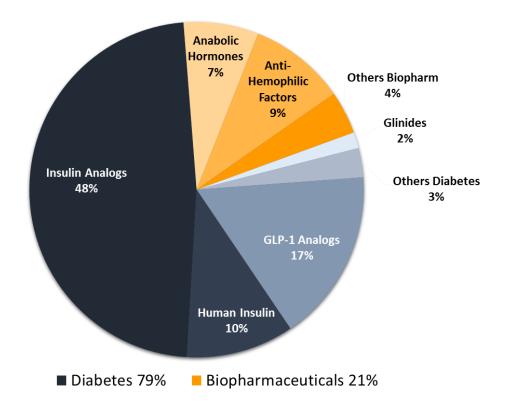


Figure 3: 2015 Novo revenue by segment. Source: Annual Report 2015 and our own analysis.

#### DIABATES FRANCHISE

As evidenced by the chart above, the diabetes franchise accounts for 79% of 2015 revenue. 73% of this diabetes revenue is derived from the manufacture of Insulin, both Human Insulin and the more modern Insulin analogues. Insulin is largely catered towards the type I diabetics whose bodies do not have the capacity to produce Insulin for genetic reasons, however Insulin is used to treat late stage type II diabetics whose ability to produce Insulin themselves has regressed considerably. 21% of the remaining 27% of the revenue in this franchise is derived from the successful GLP-1 type II drug 'Victoza'. GLP-1s are small proteins which work to increase the production of insulin from the pancreas; the drug has a strong efficacy, safety and weight loss profile with the disadvantage being the method of administration via a pen injection. Novo has another GLP-1 drug in Phase III called 'Semaglutide' which promises weekly administration over Victoza's current daily injection.

#### **OBESITY**

Victoza the company's best seller in the GLP-1 category for type 2 diabetes, along with Novo's star pipeline product Semaglutide (an improved Victoza with weekly dosage as opposed to daily) have the best profile for weight reduction among the entire portfolio of diabetes drugs on the market (see appendix C.1. for Semaglutide Phase III clinical trials). The key here is that diabetes patients are sensitive to weight loss and will prize any drug that will help them achieve a healthy profile. If Novo can win a relabeling of Victoza or a labelling of Semaglutide to reflect its benefits to treating obesity it has the potential to generate sales that could easily surpass its sales in the diabetes drug market. Clinical results indicate they have a strong case and appear to be on track to achieving this.

#### A NOTE ON WHY PATIENTS WITH DIABETES CAN'T BUY GENERIC INSULIN:

On the outset of researching this industry we were curious as to the potential impact of patent expirations. We found an academic journal in which 2 researchers from John Hopkins University conducted a study to

NOVOB DC IN DEPTH VALUATION INDICATES STOCK IS FAIRLY PRICED examine why there is no generic insulin available to diabetics (Jeremy Greene M.D. Ph. D., 2015). Their findings were as follows:

- Drug companies have made incremental improvements that kept insulin under patent for more than 90 years
- This keeps older versions off the generic market, the authors say, because generic manufacturers have less incentive to make a version of insulin that doctors perceived as obsolete.

A University of Toronto medical team discovered insulin in 1921, and in 1923, the university, which held the first patent, gave drug companies the right to manufacture it and patent any improvements. In the 1930s and 1940s, pharmaceutical companies developed long-acting forms that allowed most patients to take a single daily injection. In the 1970s and 1980s, manufacturers improved the purity of cow- and pig-extracted insulin. Since then, several companies have developed synthetic analogues.

Biotech insulin is now the standard in the U.S., the authors say. Patents on the first synthetic insulin expired in 2014, but these newer forms are harder to copy, so the unpatented versions will go through a lengthy Food and Drug Administration approval process and cost more to make. When these insulin come on the market, they may cost just 20 to 40 percent less than the patented versions, Riggs and Greene write.

#### BIOPHARMACEUTICALS

Novo Nordisk is also the market leader in both the Haematology market and the market for Human Growth Hormones.

#### MANAGEMENT STRATEGY

Management strategy is to maintain a focused portfolio and dominant position with specialist knowledge around the following four areas:<sup>1</sup>

- 1. Diabetes
- 2. Obesity
- 3. Haematology
- 4. Growth Disorders

Novo is unique among the sector of large pharmaceuticals with its narrow focus around a few interrelated areas. The result has been the creation of an institution with specialist knowledge, a position of market dominance and a clear strategy to address the needs of modern sedentary life.

#### REVENUE FORECASTS

We forecasted the company revenue over the next 5 years by first forecasting the market value via a regression and then proceeding on a drug-by-drug basis accounting for the market share of its main competitors. This analysis includes forecasting the late stage pipeline drugs. Our general approach was to examine historic trends within the various markets and identify an analogous drug which to see how quickly it captured market share after achieving FDA approval, similarly we captured the rate at which the old generation revenues decline as a new generation succeeds it. Drugs in the pipeline are also calculated with the probability of failure at each stage of the FDA process using Novo's track record at bringing drugs through each stage of the process. We regressed the value of the segments separately and multiplied our forecasted market share for each drug in each year to obtain the drug revenues.

<sup>&</sup>lt;sup>1</sup> 2015 Annual Report



#### DIABETES FRANCHISE

In order to forecast the market size we first split the diabetes market in two segments: the market for insulin which mainly caters to type I diabetics and the diabetes drugs market which only caters to type II diabetics. We then conducted a regression on both of these markets to forecast the market size over the next 5 years. Finally we forecast the change in market share for each drug individually by using historical trends and analogous drugs from previous generations which faced the same market conditions upon entry from the pipeline or had to deal with competition from the next generation of drugs. We felt that this approach was the best way to capture physician prescriber habits and also changes in market share which takes account for inflation.

#### **INSULIN**

We conducted a regression of the market value over the past 9 years to forecast the next 5 years market value. Our time series decomposition is as follows. Regression statistics can be found in Appendix C.1.:

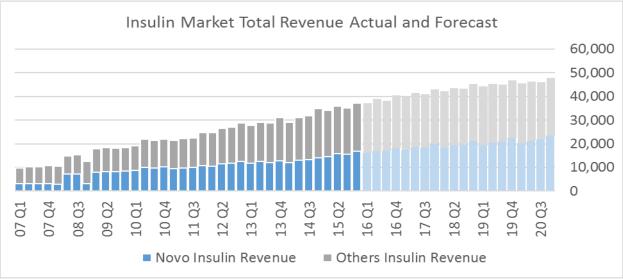


Figure 4: Insulin market value over the past 9 years and forecast. Source: Symphony Health Solutions with our projections

Our model predicts the insulin market to grow at a CAGR of 5.46% until 2020 vs 10.97% over the past 5 years. The total insulin market is expected to generate revenue of DKK 185,588mn in 2020 vs DKK 142.263mn in 2015. Historical data showed that the insulin market revenue on average grew most during the second and fourth quarters of each year and less during the first and third quarters. We took account of this seasonality when forecasting the revenue of each segment.



**HUMAN INSULIN** 

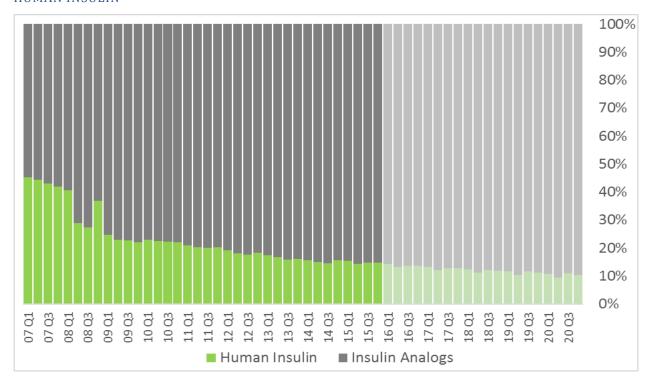


Figure 5: Insulin market share by class with projections to 2020. Source: Symphony Health Solutions with our projections

Human Insulin is losing market fast to Insulin Analogues, especially due to its limitation when injected under the skin. In high concentrations, such as in a vial or cartridge, human (and also animal insulin) it clumps together. This clumping causes slow and unpredictable absorption from the subcutaneous tissue and a dose-dependent duration of action (i.e. the larger dose, the longer the effect or duration). Insulin Analogues on-the-other-hand have a more predictable duration of action.

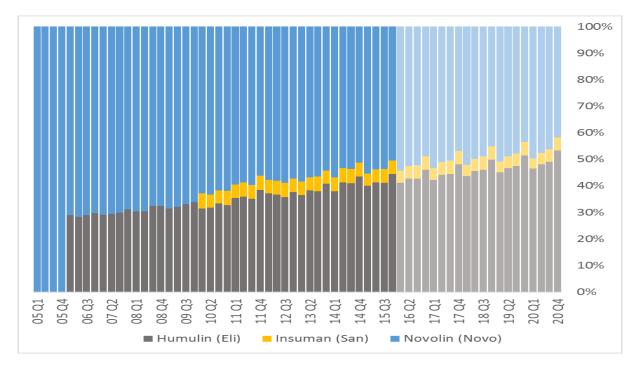


Figure 6: Human Insulin market share by product with projections to 2020. Source: Symphony Health Solutions with our projections

# NOVOR DC

#### OVOB DC IN DEPTH VALUATION INDICATES STOCK IS FAIRLY PRICED



We forecasted the size of the Human Insulin market for each quarter until December 2020 using a rolling window EWMA model. To predict the market share of each quarter the model uses observations from corresponding quarters over the last five years. This accounts for seasonality. This period was chosen to reflect a smoother decrease in the market share to insulin analogues, since insulin analogues were first introduced in 2004. Our model predicts the market to contract at a CAGR -1.71% towards annual revenues of DKK 19,340 in 2020 vs CAGR 2.16% last five years and DKK 21,077 in 2015.

We forecasted the market share of Novolin, Humulin and Insuman using the same approach described above in order to reflect the latest trends. Our model predicts that Insuman and the old Novolin to lose market share to Humulin at a CAGR of -3.67% and -4.45% respectively. Humulin is to grow at a CAGR of 1.6%.

#### **INSULIN ANALOGUES**

We forecasted the size of the insulin analogues market for each quarter until December 2020 using a EWMA model. To predict the market share of each quarter the model uses observations from corresponding quarters over the last five years. This accounts for seasonality. This period was chosen to reflect a smoother increase in market share over human insulin. Our model predicts the market to grow at a CAGR of 6.53% reaching annual revenue of DKK 166,248mn in 2020 vs DKK 121,186mn in 2015.

#### SHORT-ACTING INSULING

Short acting insulin is mainly used at meal-times when typically glucose levels are at their peak for diabetics who require micro management of their Insulin levels or opt for a customised insulin schedule. Many of these are also mixed with longer lasting insulin's to tailor fit the patient, this is a recent trend and manufacturers have been releasing combination therapies to facilitate this.

We forecasted the market share of the insulin analogues using the same procedure of mentioned before. Our model predicts the market to grow at a CAGR of 7.15% until 2020 generating revenue of DKK 75,964mn vs DKK 53,786mn in 2015.

In our forecast, Novo Rapid and Novomix lose market share to the newer Apidra that grows at a CAGR of 13.35%, against 2.91% of NovoMix/NovoLog, 7.38% NovoRapid/Novolog and 8.14% Humalog.

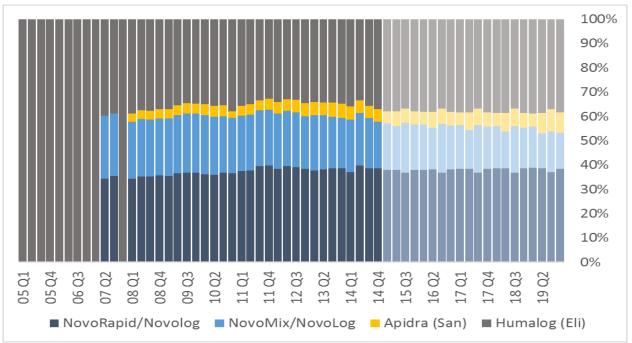


Figure 7: Short Acting Insulin Analogues market share by product with projections to 2020. Source: Symphony Health Solutions with our projections



The long acting insulin market is expected to grow at a CAGR of 6.02%, reaching annual revenues of DKK 90,284mn by 2020 vs DKK 67,4mn in 2015.

Sanofi's Lantus was the first modern long acting Insulin analogue to hit the market and has been dominant since. Lantus did lose market share upon the arrival of Novo's Levimir in 2007, which boasts greater efficacy. Lantus has been losing market share to Levemir and we expect this to continue alongside the ramp up of the new generation which will eventually gradually replace them. As the first in class new generation long acting Insulin Novo's Tresiba is in a position to grow, it will face competition from Sanofi's Toujeo, it's new Lantus. Recently launched Xultophy is a combination of Tresiba and Victoza, a GLP-1.

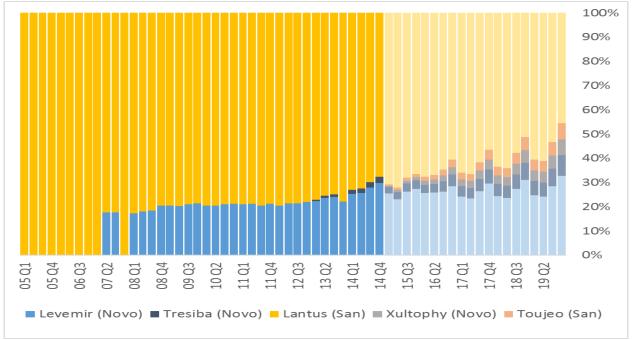


Figure 8: Long Acting Insulin Analogue market share by product with projections to 2020. Source: Symphony Health Solutions with our projections

To model the ramp up of Tresiba we used as a proxy the quarterly growth rate of Lantus, the first Insulin analogue available in the market. Our first observation starts with the growth rate in sales of Lantus in the ninth quarter. This starting point was chosen to reflect the fact that Tresiba has been in the market for 8 quarters as of December 2015. According to this model, Tresiba's revenue is expected to grow at a CAGR of 33.58% until 2020.

Xultophy and Toujeo were modelled using a EWMA based on Tresiba, since this drug is part of the new generation insulin and the most recent launch available in the segment. Both insulins are expected to capture together 10.3% of the long acting insulin market.

Lantus and Levemir were modelled using rolling windows EWMA of the respective last three quarters. Lantus is expected to lose market share to the newest competitors, with revenue Increasing at a CAGR of 1.08% vs 12.76% over the last five years. Levemir is expected to maintain its market share of 27.2% in 2020 with revenue growing at a CAGR of 6.09% vs 21.61% over the last five years.





#### DIABETES TYPE II MEDICATION

We conducted a time series decomposition of the first difference of the market value over the past 9 years to forecast the next 5 years market value. Regression Statistics can be found in the Appendix C.2.:

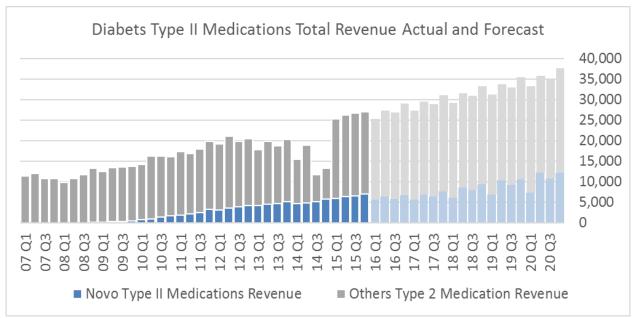


Figure 9: Type II diabetes medications market value over the past 9 years and forecast. Source: Symphony Health Solutions with our projections

Our model predicts the type II diabetes medication to grow at a CAGR of 6.14% until 2020 vs 10.89% in the last 5 years. The total type II diabetes medication is expected to generate revenues of DKK 141.350 in 2020.



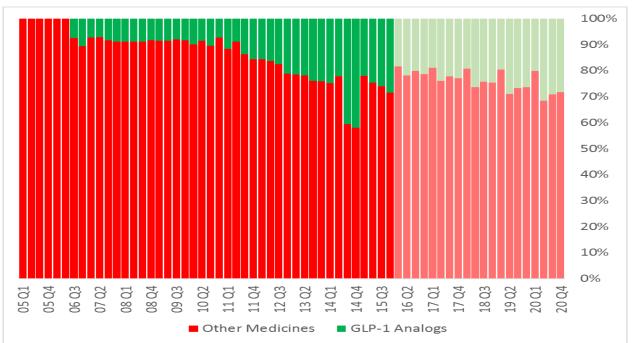


Figure 10: Type II diabetes medications market share by class (GLP-1 vs Others) with projections to 2020. Source: Symphony Health Solutions with our projections





Novo's main drug for diabetes type II, Victoza is the leader among the GLP-1 class. When it first came to the market (ca 2009/2010) it quickly took market share from the back then leader Byetta. Since then, Victoza has driven the popularity of the GLP-1 class. Victoza's now faces competition from Eli Lilly's Trulicity, a pen injection taken only once a week and also other classes of drugs like DPP-4 and PPARs that works towards the goal of boosting insulin and/or reducing glucose. SGLT-2 Inhibitors is a new class that can match the GLP market by 2020, the same year that Victoza will lose patent protection.

According to market data, breakthrough drugs reach sales peak between 7 to 9 years after coming to market. Since Victoza had its first sales in 2010 and is now facing stronger, we expect its compound annual growth rate to slow down to an average of 5.45% until 2020, reaching sales of DKK 23,508 vs 18,027 in 2015.

#### **SEMAGLUTIDE**

Semaglutide is currently in Phase III trials and is one of the most highly anticipated in the GLP-1 analogue segment. Just like Trulicity, it promises to be a once a week injection to treat type II diabetes. Phase III data suggests a reduction in HbA1c levels by 1.5% – 1.6% from the current industry standard 8.1% bringing patients into the 'sweet spot' of 6.5% - 7% needed to maintain their health and weight. Data also suggests considerable weight loss (about 4kgs for the average weight of 92kgs). The primary side effect is nausea which fits the same profile as best seller Victoza. Novo is also working on delivering Semaglutide by oral tablet, this would be preferential to injection and could be lucrative, but it's not expected until 2020 earliest.

We expect Semaglutide to surpass Trulicitys sales if the drug makes its way to the market. Accounting for a joint probability of 70% of passing phase III and approval, we forecast Semaglutide to generate annual revenue of DKK 1.314 in 2017 and to grow at a CAGR of 105.46% until 2020.

#### OTHER MEDICATIONS WHICH COMPETE WITH GLP-1

#### SGLP-2 INHIBITORS

A new class which could match the GLP-1 class by 2020 (48% CAGR over 2016-2020). Novo has no drugs in this class so will miss out and is betting that its GLP-1 franchise will be able to compete. SGLP-2 Inhibitors work by increasing the uptake of glucose in the kidneys to take care of hyperglycaemia. Crucially they are administered orally, have a good efficacy and safety profile but with an inferior weight loss profile to GLP-1.

#### **BIGUENIDES**

Metformin is the industry standard first type 2 medication prescribed when exercise fails to stop the decline of naturally produced insulin. It is also used in combination with other treatments as diabetes deteriorates. Metformin has been available since 1980 and is now a generic, due to this it is not very lucrative with annual revenue of \$502m in 2015. It is produced by Merck.

#### **PPARS**

Formerly the leading class for type 2 diabetes treatment but recalled by the FDA due to high levels of toxicity. Small amounts are still produced by Eli Lilly and Tekeda in markets where they have not fully been phased out.

# **DPP-4 INHIBITORS**

This class of drug has been around for over 10 years and is expected to more or less stick around with (CAGR 2%). The reason for its longevity is that it was the first diabetes drug to be administered orally. This is crucial as about 10% of patients are trypanophobic but there is also a mental barrier to diabetics moving from drugs to

 $<sup>^{2}</sup>$  See Appendix C.1 for Semaglutide Clinical Trials

NOVOB DC IN DEPTH VALUATION INDICATES STOCK IS FAIRLY PRICED daily injections. Having said all that DPP-4 Inhibitors are essentially an inferior product with less efficacy, less weight loss profile and have been recently relabelled by the FDA with a warning of 'severe joint pain', In fact the DPP-4 market leader – Januvia of Merck was recalled in 2013.

A 2013 recall in Junuvia of Merck resulted in DPP-4 sales wobble:

2013	2014	2015
50,744.67	32,903.75	59,312.01

• It is unclear which class gained as a result especially considering the strong bounce back of dpp4 in 2015, however GLP1 analogues over the same period:

2013	2014	2015
17,551.90	18,329.34	26,611.00

#### **BIOPHARMACEUTICALS**

#### HAEMATOLOGY

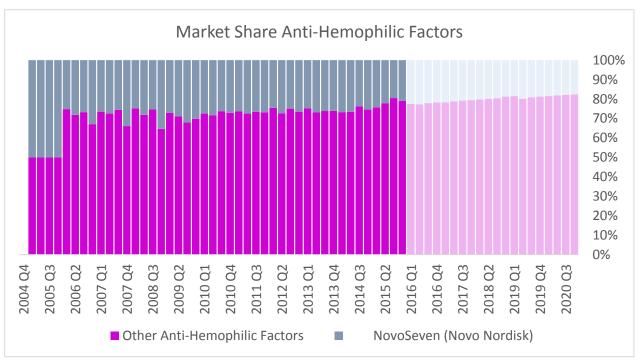


Figure 11: Haematology market share by product with projections to 2020. Source: Symphony Health Solutions with our projections

Our model predicts that the anti-haemophilic factors market will grow at a CAGR OF 6.07% vs 11.17% 2010/ 2015, generating annual revenue of DKK 48,797 vs 36,342 in 2015. The market Share of NovoSeven is expected to decrease to 21% vs 26% in 2015.



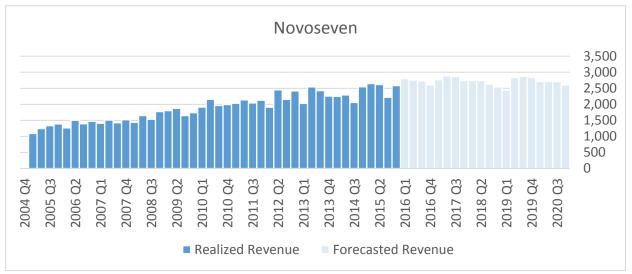


Figure 12: NovoSeven Revenue with our projections to 2020. Source: Symphony Health Solutions with our projections

To model Novoseven annual revenue we used the market share of the drug according to analysts' projections and found the corresponding revenue according to our model. This generated an expected growth of 1.3% at annual compounding rate, vs 4.62% growth in 2010/2015, generating DKK 10,736 in sales by the end of 2020 vs 10,064 in 2015.

#### HUMAN GROWTH HORMONE

Our model predicts that the anabolic hormones market will grow at a CAGR OF 6.07% vs 11.17% in 2015, generating annual revenue of DKK 21,839 vs 16,475 in 2015. The market share of Norditropin is expected to decrease to 36% in 2020 vs 43% in 2015.

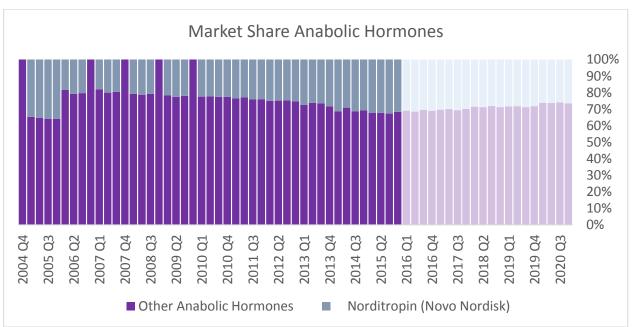


Figure 13: Haematology market share by product with projections to 2020. Source: Symphony Health Solutions with our projections



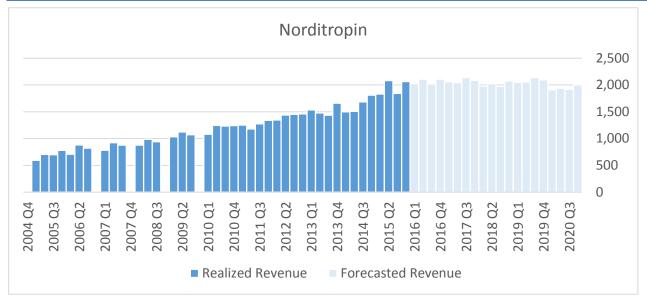


Figure 14: NovoSeven revenue with our projections to 2020. Source: Symphony Health Solutions with our projections

Nordtropin revenue was forecasted using the market consensus of its future revenue as percentage of the total market value for the segment. We then applied that weight into our model to predict its future revenue. We expect annual revenue to decrease by a CAGR of -.13%, generating DKK 7,770 in sales by the end of 2020 vs 7,820 in 2015.

#### MARGIN ANALYSIS

Management has been focused on driving costs down as a % of sales over the past 5 years.

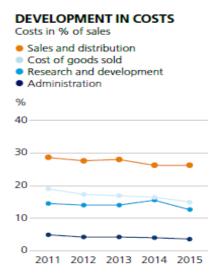


Figure 15: Costs in % of sales 2011-2015. Source: 2015 Annual Report

#### COSTS OF GOODS SOLD

The company does not provide specific commitments to COGS expenditure so we took an exponentially weighted moving average of the past 3 years, first in the pharmaceutical (Appendix A.1.) and then in the biopharmaceutical segment in (Appendix A.2.) before totalling these two (Appendix A.3.). We used the EWMA to take account of managements drive to reduce costs as a % of sales.

#### **R&D INVESTMENT**



The company does not provide specific commitments to R&D expenditure so we took an exponentially weighted moving average of the past 3 years, first in the pharmaceutical segment in (Appendix A.1.) and then in the biopharmaceutical segment in (Appendix A.2.) before totalling these two (Appendix A.3.). We used the EWMA to take account of managements drive to reduce costs as a % of sales.

#### SG&A EXPENSES

The company does not provide specific commitments to SG&A expenditure so we took an exponentially weighted moving average of the past 3 years, first in the pharmaceutical segment (Appendix A.1.) and then in the biopharmaceutical segment in (Appendix A.2.) before totalling these two (Appendix A.3.). We used the EWMA to take account of managements drive to reduce costs as a % of sales.

#### ADMINISTRATIVE EXPENSES

The company does not provide specific commitments to administrative expenditure so we took an exponentially weighted of the past 3 years, first in the pharmaceutical segment (Appendix A.1.) and then in the biopharmaceutical segment in (Appendix A.2.) before totalling these two (Appendix A.3.). We used the EWMA to take account of managements drive to reduce costs as a % of sales.

#### VALUATION ASSUMPTIONS

#### MARKET BENCHMARK

We use the STOXX Europe 600 as our benchmark. We choose this Index given that Novo is a European company and the STOXX Europe 600 is commonly used to represent the European broad market. We examined a 5-year period from 31/05/2011 to 30/04/2016 of 12 monthly compound returns, we chose this duration as we are forecasting the next 5 years in our DCF valuation.

#### WACC

We calculated the WACC as follows:

WACC = 
$$\frac{E}{V}$$
 \* Re +  $\frac{D}{V}$  \* Rd \* (1 - Tc)

This resulted in a WACC of 10.0% (Please see Appendix A.4. for the full disclosure of WACC Calculations)

#### COST OF EQUITY (RE)

We calculated the cost of equity as the average of the last annualized 60 months returns as follows:

$$Rf + \beta(Rm - Rf)$$

This resulted in a cost of equity of 10.0%.

#### RISK FREE RATE (RF)

We estimated the risk free rate (Rf) based on the historical returns of the Danish 1-Month T-Bill given its low credit risk and also to avoid inflation or currency risk. The period used to estimate the annual Risk-Free Rate was the past 5 years using rolling windows of 1 year and then taking an arithmetic average of the entire period, given that in the past two years the interest rate has been in a historically low.

This resulted in Risk Free rate of 0.16%.

MARKET RATE OF RETURN (RM)

To calculate the market rate of return (Rm) we obtained the historical monthly total returns of the STOXX Europe 600 Index over the past 5 years<sup>3</sup> and calculated the annual return based on a rolling window of 1 year and then took an average of the 5 periods.

This resulted in a Market Risk Premium of 10.77%.

#### **BETA**

We calculated the Beta as follows: First we regressed the STOXX Europe  $600^4$  total monthly returns minus the risk free rate against the NOVOB total monthly returns minus the risk free rate over a 60 months' period from 30/04/2011 to 30/04/2016.

This produced the following results:

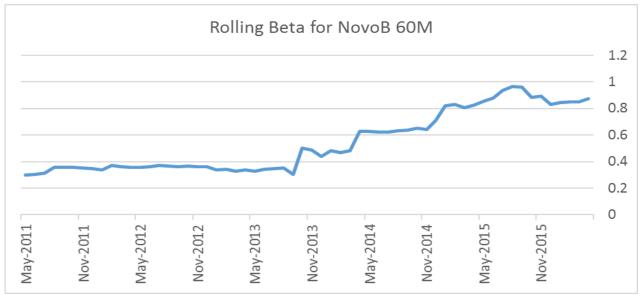


Figure 16: Rolling Beta NovoB vs STOXX Europe 600. Source: Bloomberg and own Analysis.

We then used this beta to calculate the adjusted beta to take account of the mean reversion property using the following formula:

$$\alpha + (1 - \alpha) * \beta$$

Where alpha is equal to 1/3. The end result is an adjusted levered beta:  $\beta = 0.92$ .

#### COST OF DEBT (RD)

We calculated the cost of debt as follows:5

 $\frac{\textit{Total interest paid in 2015}}{\textit{Average of Total Debt in 2015 and 2014}}$ 

This resulted in a value of 7.47%

#### CORPORATE TAX RATE

We calculated our corporate tax rate as:

<sup>4</sup> Bloomberg

<sup>5</sup> 2015 Annual Accounts

<sup>&</sup>lt;sup>3</sup> Bloomberg



# IN DEPTH VALUATION INDICATES STOCK IS FAIRLY PRICED Total tax paid in 2015 profit before tax 2015



This resulted in a value of 19.8%

#### **DEBT RATIO & EQUITY RATIO**

The company's debt ratio is 0.1%, calculated as Total Debt/Total Capitalization. The equity ratio is 99.9%, calculated as 1 - debt ratio.

#### PERPETUITY GROWTH RATE

We estimate that the perpetuity growth rate of the company is in line with the today's market, and the historical growth in GDP of 4%.

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# IMPORTANT DISCLOSURE

Please read this document before reading this report.

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# APPENDIX A FINANCIAL ANALYSIS

# A.1. DIABETES FINANCIAL ANALYSIS

Year	2013	2014	2015	2016	2017	2018	2019	2020
TOTAL	83,572	88,806	107,927	114,226	123,170	133,429	145,133	153,751
DIABETES NET SALES	65,456	69,980	85,590	90,611	99,368	110,413	121,295	131,556
Glinides	2,246	1,728	1,687	1,254	748	691	651	617
NovoNorm/Prandin (Repaglinide)	2,246	1,728	1,687	1,254	748	691	651	617
GLP-1 Analogs	11,633	13,426	18,027	18,007	20,645	27,099	33,196	39,456
Victoza (Liraglutide)	11,633	13,426	18,027	16,822	17,620	18,415	20,130	23,509
Semaglutide (Phase III)	-	-	-	0	1,315	6,110	9,374	11,404
Human Insulin	10,869	10,298	11,231	10,975	10,602	10,154	9,665	8,945
Novolin (R and N)	10869	10298	11,231	10,975	10,602	10,154	9,665	8,945
Insulin Analogs	38,153	41,933	51,602	56,938	63,651	68,383	73,356	77,794
Levemir (Insulin Detemir)	11,546	14,217	18,300	18,746	21,083	21,544	22,937	24,592
Tresiba	-	396	1,438	2,304	3,194	4,104	4,967	6,115
NovoMix/NovoLog Mix (Insulin Aspart Mix)	9,759	9,871	11,144	11,920	12,424	12,861	13,043	12,860
NovoRapid/Novolog (Insulin Aspart)	16,848	17,449	20,720	23,227	25,168	27,138	28,765	29,579
Xultophy	0	0	0	742	1,783	2,736	3,644	4,647
Others	2,555	2,595	3,043	3,437	3,722	4,087	4,426	4,744
% Margin	78.3%	78.8%	79.3%	79.3%	80.7%	82.8%	83.6%	85.6%
COGS	11,909	12,482	13,725	15,685	16,943	18,571	20,681	22,330
% Margin	18.2%	17.8%	16.0%	17.3%	17.1%	16.8%	17.1%	17.0%
Gross Profit	53,547	57,498	71,865	74,926	82,425	91,842	100,614	109,226
% Margin	81.8%	82.2%	84.0%	82.7%	82.9%	83.2%	82.9%	83.0%
Sales and Dist. Costs	20,584	20,373	24,926	27,044	29,190	32,520	35,843	38,761
% Margin	31.4%	29.1%	29.1%	29.8%	29.4%	29.5%	29.6%	29.5%
R&D	7,786	9,318	10,475	11,317	12,584	13,772	15,213	16,520
% Margin	11.9%	13.3%	12.2%	12.5%	12.7%	12.5%	12.5%	12.6%
Administrative costs	2,767	2,790	3,051	3,545	3,796	4,164	4,648	5,009
% Margin	4.2%	4.0%	3.6%	3.9%	3.8%	3.8%	3.8%	3.8%
Other operating income, net	510	516	488	517	567	630	692	750
EBITDA	25,129	27,971	36,415	36,486	40,622	45,487	49,489	53,882
% Margin	38.4%	40.0%	42.5%	40.3%	40.9%	41.2%	40.8%	41.0%
Depreciation, amortisation and impairment	2,209	2,438	2,514	2,950	3,201	3,471	3,887	4,196
% Margin	3.4%	3.5%	2.9%	3.3%	3.2%	3.1%	3.2%	3.2%
Operating profit	22,920	25,533	33,901	33,536	37,421	42,016	45,602	49,686
Operating margin	35.0%	36.5%	39.6%	37.0%	37.7%	38.1%	37.6%	37.8%





# A.2. BIOPHARMACEUTICALS FINANCIAL ANALYSIS

Year	2013	2014	2015	2016	2017	2018	2019	2020
TOTAL	83,572	88,806	107,927	114,226	123,170	133,429	145,133	153,751
IOPHARMACEUTICALS	18,116	18,826	22,337	23,615	23,802	23,016	23,838	22,195
Anabolic Hormones	6,114	6,506	7,820	8,267	8,333	8,058	8,345	7,770
Norditropin	6,114	6,506	7,820	8,267	8,333	8,058	8,345	7,770
Anti-Hemophilic Factors	9,256	9,142	10,064	10,889	11,263	10,655	10,997	10,736
NovoSeven	9,256	9,142	10,064	10,889	11,263	10,655	10,997	10,736
Others	2,746	3,178	4,453	4,458	4,206	4,303	4,495	3,688
% Margin	21.7%	21.2%	20.7%	20.7%	19.3%	17.2%	16.4%	14.4%
COGS	2,231	2,080	2,463	2,701	2,661	2,582	2,687	2,491
% Margin	12.3%	11.0%	11.0%	11.4%	11.2%	11.2%	11.3%	11.2%
Gross Profit	15,885	16,746	19,874	20,914	21,141	20,434	21,150	19,703
% Margin	87.7%	89.0%	89.0%	88.6%	88.8%	88.8%	88.7%	88.8%
Sales and Dist. Costs	2,796	2,850	3,386	3,598	3,613	2,556	1,621	529
% Margin	15.4%	15.1%	15.2%	15.2%	3.6%	2.3%	1.3%	0.4%
R&D	3,947	4,444	3,133	4,639	4,526	4,065	4,465	4,098
% Margin	21.8%	23.6%	14.0%	19.6%	19.0%	17.7%	18.7%	18.5%
Administrative costs	741	747	806	916	908	868	911	844
% Margin	4.1%	4.0%	3.6%	3.9%	3.8%	3.8%	3.8%	3.8%
Other operating income, net	172	254	618	653	659	637	660	614
EBITDA	9,163	9,956	13,612	13,238	13,599	14,282	15,613	15,582
% Margin	50.6%	52.9%	60.9%	56.1%	57.1%	62.1%	65.5%	70.2%
Depreciation, amortisation and impairment	590	997	445	824	846	701	799	735
% Margin	3.3%	5.3%	2.0%	3.5%	3.6%	3.0%	3.4%	3.3%
EBIT or Operating Profit	8,573	8,959	13,167	12,414	12,752	13,582	14,813	14,847
Operating margin	47.3%	47.6%	58.9%	52.6%	53.6%	59.0%	62.1%	66.9%





# A.3. TOTAL FINANCIAL ANALYSIS

OTALS	2013	2014	2015	2016	2017	2018	2019	2020
Revenue	83,572	88,806	107,927	114,226	123,170	133,429	145,133	153,751
COGS	14,140	14,562	16,188	18,386	19,604	21,153	23,368	24,821
% Margin	16.9%	16.4%	15.0%	16.1%	15.9%	15.9%	16.1%	16.1%
Gross Profit	69,432	74,244	91,739	95,840	103,566	112,276	121,764	128,929
% Margin	83.1%	83.6%	85.0%	83.9%	84.1%	84.1%	83.9%	83.9%
Sales and Dist. Costs	23,380	23,223	28,312	30,643	32,804	35,076	37,464	39,290
% Margin	28.0%	26.2%	26.2%	26.8%	26.6%	26.3%	25.8%	25.6%
R&D	11,733	13,762	13,608	15,956	17,110	17,837	19,678	20,618
% Margin	14.0%	15.5%	12.6%	14.0%	13.9%	13.4%	13.6%	13.4%
Administrative costs	3,508	3,537	3,857	4,461	4,704	5,032	5,558	5,853
% Margin	4.2%	4.0%	3.6%	3.9%	3.8%	3.8%	3.8%	3.8%
Other operating income, net	682	770	1,106	1,170	1,225	1,266	1,351	1,364
EBITDA	34,292	37,927	50,027	49,724	54,221	59,769	65,102	69,464
% Margin	41.0%	42.7%	46.4%	43.5%	44.0%	44.8%	44.9%	45.2%
Depreciation, amortisation and impairment	2,799	3,435	2,959	3,774	4,047	4,172	4,687	4,932
% Margin	3.3%	3.9%	2.7%	3.3%	3.3%	3.1%	3.2%	3.2%
Income from partial divestment of NNIT A/S (not								
allocated to segments)			2,376.00					
EBIT or Operating Profit	31,493	34,492	49,444	45,950	50,174	55,598	60,415	64,533
Operating margin	37.7%	38.8%	45.8%	40.2%	40.7%	41.7%	41.6%	42.0%
Adjusted EBIT	31,493	34,492	47,068	45,950	50,174	55,598	60,415	64,533
Operating margin	37.7%	38.8%	43.6%	40.2%	40.7%	41.7%	41.6%	42.0%
Net Financial (Income)/Expenses	-1,046	396	5,961					
Profit before income taxes	32,539	34,096	43,483	45,950	50,174	55,598	60,415	64,533
Income Taxes	7,355	7,615	8,623	9,894	10,645	11,613	12,807	13,617
% Margin	22.6%	22.3%	19.8%	21.5%	21.2%	20.9%	21.2%	21.1%
Net profit for the year	25,184	26,481	34,860	36,056	39,528	43,984	47,608	50,916
% Margin	30.1%	29.8%	32.3%	31.6%	32.1%	33.0%	32.8%	33.1%
Capital Expenditures	3,207	3,986	5,209	6,105	7,000	7,583	8,248	8,738
% Margin	3.8%	4.5%	4.8%	5.3%	5.7%	5.7%	5.7%	5.7%





# A.4. WACC

WACC Calculation	
Capital Structure	
Debt-to-Total Capitalization	0.1%
Equity-to-Total Capitalization	99.9%
Cost of Debt	7.470/
Cost of Debt Tax Rate	7.47%
After-tax Cost of Debt	19.8% <b>6.0%</b>
Cost of Equity	
Risk-free Rate <sup>(1)</sup>	0.16%
Market Risk Premium <sup>(2)</sup>	10.77%
Adjusted Lev. Beta alpha =0.87	0.92
Size Premium <sup>(3)</sup>	- %
Cost of Equity	10.0%
WACC	10.0%

WACC	<u>FY 2011</u> 31/12/2011	<u>FY 2012</u> 31/12/2012	<u>FY 2013</u> 31/12/2013	<u>FY 2014</u> 31/12/2014
Equity				
Cost of Equity	10.1%	14.5%	12.6%	13.2%
Weight of Equity	99.8%	99.9%	100.0%	99.9%
+ Debt				
Cost of Debt	1.0%	0.0%	0.0%	0.0%
Weight of Debt	0.2%	0.1%	0.0%	0.1%
+ Preferred Equity				
Cost of Pref Equity				
Weight of Pref Equity	0.0%	0.0%	0.0%	0.0%
WACC Source: Bloomberg	10.0%	14.5%	12.6%	13.2%





# A.5. DISCOUNTED CASH FLOW

DKK in millions, fiscal year endin	ng December 31)							0	perating Scenari	0	Base
Operating Scenario	1										
Mid-Year Convention	Y		orical Period		CAGR		_	ojection Period			CAGR
		<u>2013</u>	<u>2014</u>	<u>2015</u>	('13 - '15)	2016	2017	2018	2019	2020	('15- '20)
Sales		83,572.0	88,806.0	107,927.0	13.6%	114,226.0	123,170.0	133,428.9	145,132.6	153,750.6	7.3%
% growth		3.8%	6.3%	21.5%		5.8%	7.8%	8.3%	8.8%	5.9%	
COGS		14,140.0	14,562.0	16,188.0		18,386.2	19,603.8	21,152.8	23,368.3	24,821.2	
Gross Profit		69,432.0	74,244.0	91,739.0	14.9%	95,839.8	103,566.2	112,276.1	121,764.2	128,929.4	7.0%
% margin		83.1%	83.6%	85.0%		83.9%	84.1%	84.1%	83.9%	83.9%	
SG&A and R&D		35,140.0	36,317.0	41,712.0		46,115.8	49,345.5	52,506.6	56,662.6	59,465.2	
EBITDA		34,292.0	37,927.0	50,027.0	20.8%	49,724.0	54,220.7	59,769.5	65,101.7	69,464.3	6.8%
% margin		41.0%	42.7%	46.4%		43.5%	44.0%	44.8%	44.9%	45.2%	
Depreciation & Amortization		2,799.0	3,435.0	2,959.0		3,774.1	4,047.2	4,171.9	4,686.6	4,931.7	
EBIT		31,493.0	34,492.0	47,068.0	22.3%	45,949.9	50,173.5	55,597.6	60,415.1	64,532.6	6.5%
% margin		37.7%	38.8%	43.6%		40.2%	40.7%	41.7%	41.6%	42.0%	
Taxes		7,118.6	7,703.4	9,333.9		9,893.9	10,645.1	11,613.1	12,807.3	13,616.9	
EBIAT		24,374.4	26,788.6	37,734.1	24.4%	36,056.1	39,528.4	43,984.4	47,607.8	50,915.7	6.2%
Plus: Depreciation & Amortization	1	2,799.00	3,435.00	2,959.00		3,774.1	4,047.2	4,171.9	4,686.6	4,931.7	
Less: Capital Expenditures		3,207	3,986	5,209		(6,104.5)	(7,000.0)	(7,583.0)	(8,248.2)	(8,738.0)	
Less: Increase in Net Working Ca	apital			(1,663.0)		(4,308.2)	(1,367.2)	(1,628.1)	(2,033.6)	(1,427.3)	
Unlevered Free Cash Flow						29,417.4	35,208.4	38,945.3	42,012.7	45,682.2	
WACC		10.0%				•					
Discount Period						0.5	1.5	2.5	3.5	4.5	
Discount Factor	_					0.95	0.87	0.79	0.72	0.65	
Present Value of Free Cash F	-IOW					28,046.6	30,512.4	30,678.8	30,082.7	29,732.8	
A											
Assumptions Sales (% growth)		N	Λ 6	3%	21.5%		8.3%	10.6%	11.4%	11.6%	9.1%
COGS (% sales)		16.99			15.0%		16.1%	16.0%	15.9%	16.2%	16.2%
SG&A (% sales)		42.0%			38.6%		40.4%	40.2%	39.5%	39.3%	39.1%
Depreciation & Amortization (%	6 sales)	3.39		9%	2.7%		3.3%	3.3%	3.1%	3.2%	3.2%
Capital Expenditures (% sales)	,	(3.8%			(4.8%)		5.2%	5.4%	5.4%	5.4%	5.4%
Tax Rate		22.69	, , , , , , , , , , , , , , , , , , , ,		19.8%		21.5%	21.2%	20.9%	21.2%	21.1%
Working Capital (% sales)		219	% 1	4%	13%		16.3%	16.2%	16.2%	16.3%	16.3%



# NOVOB DC

# IN DEPTH VALUATION INDICATES STOCK IS FAIRLY PRICED



Enterprise Value		
Cumulative Present Value of FCF	149,053.33	Implied Equity
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Enterprise Value
Terminal Value		Less: Total Debt Less: Preferred Sec
Terminal Year EBITDA (2020E)	69,464.29	
Exit Multiple	12.0x	Less: Noncontrolling Plus: Cash and Cash
Terminal Value	833,571.44	
Discount Factor	0.62	Implied Equity Va
Present Value of Terminal Value	517,260.25	
% of Enterprise Value	77.6%	Shares Out.
Enterprise Value	666,313.58	Implied Share Pri

Implied Equity Value and S	hare Price	Implied Perpetuity Growth R	Rate
Enterprise Value	666,313.58	Terminal Year Free Cash Flow (2020E)	45,682.15
Less: Total Debt	(1,073.0)	WACC	10.0%
Less: Preferred Securities	-	Terminal Value	833,571.44
Less: Noncontrolling Interest	-		
Plus: Cash and Cash Equivalents	20,465.0	Implied Perpetuity Growth Rate	4.0%
Implied Equity Value	685,705.58	Implied EV/EBITDA	
Shares Out.	2,012.6	Enterprise Value	666,313.58
chares out.	2,012.0	Terminal Year EBITDA (2020E)	69,464.3
Implied Share Price	340.71		
Overpriced by	-4.8%	Implied EV/EBITDA	9.6x

			Enterpr	ise Value			Implied Equity Value						
•	_			Exit Multiple			_			Exit Multiple			
		10.0x	11.0x	12.0x	13.0x	14.0x		10.0x	11.0x	12.0x	13.0x	14.0x	
	8%	628,620	675,866	723,112	770,359	817,605	8%	648,012	695,258	742,504	789,751	836,997	
ပ္ပ	9%	603,722	648,840	693,959	739,078	784,196	9%	623,114	668,232	713,351	758,470	803,588	
WACC	10.0%	580,104	623,209	\$666,314	709,419	752,524	10.0%	599,496	642,601	\$685,706	728,811	771,916	
>	11%	557,688	598,886	640,084	681,282	722,481	11%	577,080	618,278	659,476	700,674	741,873	
	12%	536,402	575,793	615,185	654,577	693,969	12%	555,794	595,185	634,577	673,969	713,361	

			Implied S	hare Price		PV of Terminal Value as % of Enterprise Value						
				Exit Multiple						Exit Multiple		
		10.0x	11.0x	12.0x	13.0x	14.0x		10.0x	11.0x	12.0x	13.0x	14.0x
	8%	321.98	345.46	368.94	392.41	415.89	8%	75.2%	76.9%	78.4%	79.7%	80.9%
ပ္ပ	9%	309.61	332.03	354.45	376.87	399.29	9%	74.7%	76.5%	78.0%	79.4%	80.5%
ACC	10.0%	297.88	319.30	\$340.71	362.13	383.55	10.0%	74.3%	76.1%	77.6%	79.0%	80.2%
≥	11%	286.74	307.21	327.68	348.15	368.62	11%	73.9%	75.7%	77.2%	78.6%	79.8%
	12%	276.16	295.74	315.31	334.88	354.45	12%	73.4%	75.3%	76.8%	78.2%	79.5%





# A.6. RATIO ANALYSIS

Ratios	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
	31/12/2005	31/12/2006	31/12/2007	31/12/2008	31/12/2009	31/12/2010	31/12/2011	31/12/2012	31/12/2013	31/12/2014	31/12/2015
Profitability	14.00/	14.00/	10 40/	10.62/	20.40/	24.00/	27.40/	22.00/	27.00/	25.00/	44.20
Return on Assets	14.8%	14.9%	18.4%	19.6%	20.4%	24.8%	27.1%	32.9%	37.0%	35.9%	41.3%
Return on Capital	20.7%	21.5%	26.9%	28.6%	30.6%	39.5%	45.4%	54.1%	60.1%	63.3%	78.4%
Return on Equity	21.7%	22.3%	27.4%	29.6%	31.3%	39.6%	46.0%	54.9%	60.5%	63.9%	79.9%
Margin Analysis											
Gross Margin	72.8%	75.3%	76.6%	77.8%	79.6%	80.8%	81.0%	82.7%	83.1%	83.6%	85.0%
SG&A Margin											-
EBITDA Margin	29.2%	29.1%	28.6%	32.5%	34.2%	35.1%	37.5%	41.2%	41.0%	42.7%	48.6%
EBIT Margin	24.0%	23.5%	21.4%	27.2%	29.2%	31.1%	33.7%	37.8%	37.7%	38.8%	45.8%
Earnings from Cont. Ops Margin	24.0%	23.5%	21.4%	27.2%	29.2%	31.1%	33.7%	37.8%	37.7%	38.8%	45.8%
Net Income Margin	17.4%	16.7%	20.4%	21.2%	21.1%	23.7%	25.8%	27.5%	30.1%	29.8%	32.3%
Normalized Net Income Margin	17.4%	16.7%	20.4%	21.2%	21.4%	22.0%	26.1%	27.7%	30.3%	30.4%	30.5%
Free Cash Flow Margin	14.3%	12.5%	21.9%	24.7%	25.0%	26.8%	27.6%	24.1%	27.2%	31.2%	30.6%
Asset Turnover											
Total Asset Turnover	0.9x	0.9x	0.9x	0.9x	1.0x	1.0x	1.1x	1.2x	1.2x	1.2x	1.3>
Fixed Asset Turnover	1.8x	1.9x	2.1x	2.4x	2.7x	3.1x	3.2x	3.7x	3.8x	3.9x	4.4)
Accounts Receivable Turnover	7.6x	7.8x	7.4x	7.2x	7.4x	7.7x	7.3x	8.1x	8.1x	7.4x	7.6
Inventory Turnover	1.2x	1.2x	1.1x	1.1x	1.1x	1.2x	1.3x	1.4x	1.5x	1.4x	1.3>
Short Term Liquidity											
Current Ratio	1.8x	2.1x	2.3x	2.2x	2.4x	2.0x	1.9x	1.9x	1.7x	1.4x	1.3x
Quick Ratio	0.9x	1.0x	1.3x	1.3x	1.5x	1.3x	1.3x	1.2x	1.1x	0.9x	0.9
Cash from Ops. To Curr Liab	0.5x	0.5x	0.7x	0.8x	0.9x	0.9x	0.8x	0.7x	0.6x	0.5x	0.5
Avg. Days Sales Out.	47.9x	46.9x	49.1x	50.9x	49.0x	47.3x	49.7x	45.0x	45.2x	49.4x	48.3
· .											
Avg. Days Inventory Out.	297.2x	308.1x	324.6x	337.3x	343.2x	307.9x	277.2x	257.9x	246.5x	262.0x	271.9
Avg. Days Payable Out.  Avg. Cash Conversion Cycle	47.7x 297.4x	57.5x 297.6x	64.1x 309.6x	72.3x 315.9x	76.1x 316.1x	82.8x 272.4x	91.7x 235.2x	96.4x 206.5x	102.6x 189.1x	100.8x 210.6x	102.5> 217.7>
wg. cash comersion cycle	237.1%	237.0%	303.0%	313.3%	310.12	272.1.	233.24	200.5%	103.11	210.0%	
Long Term Solvency	0.70/	= 00/		<b>=</b> 00/	2 =2/	2.00/	2.20/	4.00/	0.50/	4.00/	
Total Debt/Equity	9.7%	5.0%	4.2%	7.0%	3.5%	2.9%	2.3%	1.2%	0.5%	1.8%	2.3%
Total Debt/Capital	8.9%	4.8%	4.1%	6.6%	3.3%	2.8%	2.2%	1.2%	0.5%	1.8%	2.2%
LT Debt/Equity	4.5%	3.9%	3.0%	3.0%	2.7%	1.4%	1.3%	0.0%	0.0%	0.0%	0.0%
LT Debt/Capital	4.1%	3.7%	2.9%	2.8%	2.6%	1.3%	1.3%	0.0%	0.0%	0.0%	0.0%
Total Liabilities/Total Assets	8.9%	9.9%	10.3%	9.2%	10.2%	9.7%	10.0%	5.2%	5.0%	4.0%	4.3%
EBIT / Interest Exp.	31.84x	30.81x	27.60x	50.30x	38.89x	37.78x	81.36x	508.17x	572.60x	884.41x	737.97x
EBITDA / Interest Exp.	38.77x	38.04x	36.88x	60.22x	45.53x	42.72x	90.59x	553.93x	622.64x	972.49x	782.13>
(EBITDA-CAPEX) / Interest Exp.	23.42x	28.25x	29.76x	53.02x	38.68x	35.96x	79.41x	495.79x	563.76x	870.18x	704.16
Total Debt/EBITDA	0.27x	0.13x	0.11x	0.16x	0.07x	0.05x	0.03x	0.02x	0.01x	0.02x	0.02
Net Debt/EBITDA	-0.24x	-0.32x	-0.50x	-0.53x	-0.64x	-0.71x	-0.68x	-0.49x	-0.42x	-0.41x	-0.37
Altman Z Score	7.43	8.94	10.83	8.64	9.17	11.8	11.46	15.87	15.25	14.63	17.58



# APPENDIX B RESEARCH & DEVELOPMENT

# B.1. SEMAGLUTIDE PHASE III CLINICAL TRIALS

Study	Study Design	N	Diabetes Duration (Yrs)	Baseline A1c (%)	% A1c < 7%	A1c Change from Baseline (%)	Change in Body Weight (kg)	Nausea (%)	Vomiting (%)	Diarrhoea (%)	GI disorders (incl. Nausea) (%)
DURATION-6 (13)	Liraglutide 1.8.mg qd	450	-	8.5	60.2	-1.48	-3.58	20.4	10.7	13.1	-
with lifestyle changes + OADs Length = 24 wks	Exenatide 2.0mg qw	461	-		52.3	-1.28	-2.68	9.3	3.7	6.1	-
AWARD-6 Trial (43)	Dulaglutide 1.5mg	299	7	8.1	68.3	-1.42	-2.9	20.4	7	12	35.8
Length = 26 weeks	Liraglutide 1.8mg	300	7	8.1	67.9	-1.36	-3.61	18	8.3	12	35.7
SUSTAIN-3 Length = 56 Weeks	Semaglutide 1.0 mg(qw) Bydureon 2.0 mg (qw)	813		8.4 8.4	66% 40%	-1.5 -0.9	-5.6 -1.8	22% 11%			

Source: Bloomberg

Bydureon and Exenatide are Byetta (GLP-1) Pre-Victoza generation

Liraglutide is Victoza (GLP-1) Novo

Semaglutide is Novo

Dulaglutide is Trulicity (GLP-1) Eli Lilly





# B.2. R&D PRODUCTIVITY RANKING

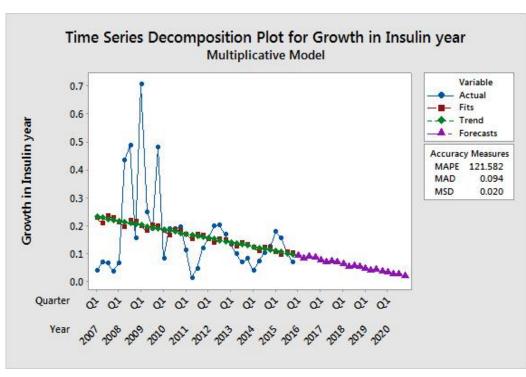
Rank	Company	Economic Returns to R&D Spending*	Patents / \$IM R&D spend*	Average Relative Quality of Innovation*	Average Rank (by share of innovation) in Target Research Areas	Internal Bias Index
1	Bristol-Myers Squibb	1.50%	0.22	1.2	1.9	23
2	Celgene	32.30%	0.23	1.5	8.4	98
3	Vertex	-125.40%	0.81	2.4	4.2	53
4	Gilead	20.80%	0.16	1.1	6.4	185
5	Allergan	8.00%	0.46	1.4	8.1	96
5	Roche	7.70%	0.09	0.9	2	24
7	Amgen	9.40%	0.09	1.1	5.3	58
8	Johnson & Johnson	8.20%	0.07	I	4.8	34
9	Novo Nordisk	17.50%	0.11	1.7	10.8	439
9	AbbVie	11.10%	0.12	I	9.4	54
9	Pfizer	-3.20%	0.11	0.9	2.5	24
12	AstraZeneca	3.90%	0.1	I	7.1	43
12	Biogen Idec	9.10%	0.13	1.1	13.1	155
12	Shire	18.60%	0.11	1.4	15.4	338
15	Sanofi	1.50%	0.09	0.9	4.2	28
16	Merck	3.00%	0.08	0.9	5.4	35
17	GlaxoSmithKline	1.00%	0.09	I	6	36
18	Novartis	8.40%	0.05	0.7	5.3	37
19	Regeneron	8.30%	0.16	0.7	13.7	638
20	Bayer	-2.10%	0.07	0.9	10.3	82
21	Eli Lilly	4.50%	0.05	0.8	11.7	131
22	Alexion	12.80%	0.03	0.4	21.4	8,012
	Sources: Bloomberg; AcclaimIP; SSR H	Health Hidden Pipeline Analysis and ass	umptions. *Rolling 5-year average.			
	MARKET AVERAGE	2.59%	0.16	1.09	8.06	482.86

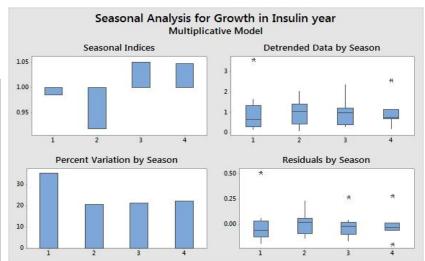


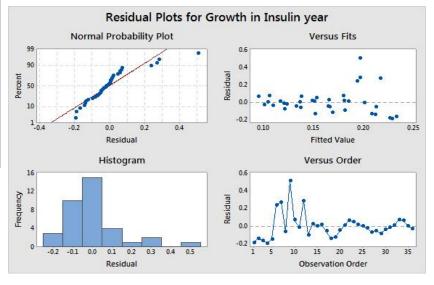


#### APPENDIX C REGRESSIONS

#### C.1. INSULIN MARKET REGRESSION





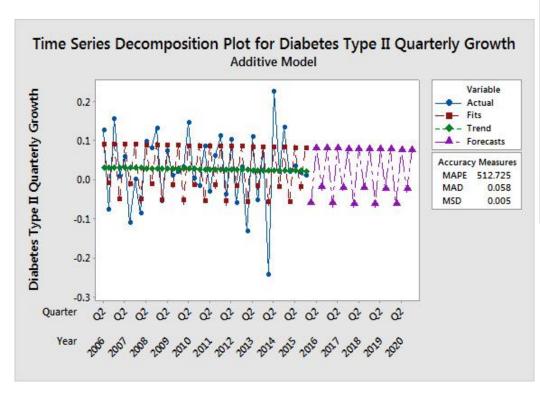


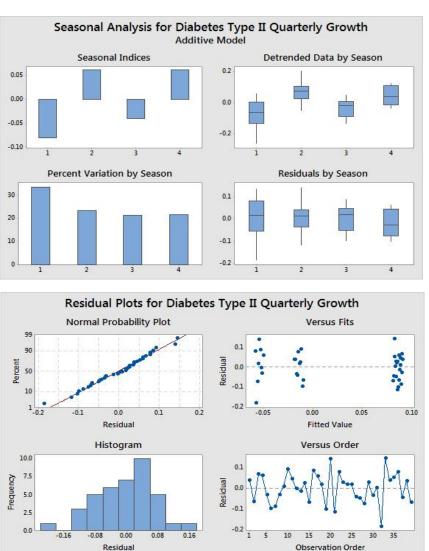
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#### C.2. DIABETES TYPE 2 TREATMENTS REGRESSION





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# APPENDIX D NEWSFLOW

		pired are awaiting updates by the company**	Last updated				
Company	Product Name	Event	Expected Date	Broad Indication	Category	Event Type	Phase
		**Events with expired Expected Dates are awaiting updates**					
Dance Biopharm	Dance 501 (inhaled insulin)	Initiate global Phase III trial in type II diabeteswill pursue 505(b)(2) NDA in US and similar pathways in EU and China	Early 2015	diabetes	Clinical Data Milestones	Trial Initiation	Phase I
Johnson & Johnson/ Mitsubishi Tanabe Pharma	Invokana (canagliflozin, Canaglu)	Complete Phase III trial on ambulatory blood pressure in type II diabetes	2Q 2015	diabetes	Clinical Data Milestones	Trial Completion	Phase I
Johnson & Johnson/ Mitsubishi Tanabe Pharma	Invokana (canagliflozin, Canaglu)	Complete Phase III trial in type I diabetes	2Q 2015	diabetes	Clinical Data Milestones	Trial Completion	Phase I
Johnson & Johnson/ Mitsubishi Tanabe Pharma	Invokana (canagliflozin, Canaglu)	Complete Phase III trials as add-on to DPP-4 or to basal insulin in type II diabetes	3Q 2015	diabetes	Clinical Data Milestones	Trial Completion	Phase II
lonis Pharma (Isis Pharma)		Present data from Phase II trial in type II diabetesdid not reach significant reductions in primary endpoint in Aug 2015	2H 2015/2016	diabetes	Clinical Data Milestones	Data Release	Phase I
AstraZeneca/ Bristol- Myers Squibb/ Otsuka/ Kyowa Kakko Kirin	Onglyza (saxagliptin)	Potential FDA approval (company-expected timeline) of label update based on data from Phase IV long-term outcomes study SAVOR-TIMI 53 in adult type 2 diabetes patients with cardiovascular risk factors	2H 2015	diabetes	Regulatory Milestones	PDUFA	
Merck	omarigliptin (Marizev, MK-3102)	US regulatory filing in once-weekly dosing in type II diabetes	End of 2015	diabetes	Regulatory Milestones	Regulatory Filing	
Diamyd Medical AB (Mertiva)	Diamyd	Present first data (three-year) from researcher-initiated Phase II trial DiAPREV- IT in prevention of type I diabetes in children at high risk of developing the disease	2015	diabetes	Clinical Data Milestones	Data Release	Phase I
Eli Lilly	dulaglutide (Trulicity)	Complete Phase III AWARD 7 trial in type II diabetes patients with chronic kidney disease	2015	diabetes	Clinical Data Milestones	Trial Completion	Phase II
Novo Nordisk	FIAsp (NN1218, faster-acting formulation of insulin aspart)	Present data from Phase III ONSET 1 and 2 trials in type I and type II diabetes	2015	diabetes	Clinical Data Milestones	Data Release	Phase II
onis Pharma (Isis Pharma)		Present data from Phase II trial in type II diabetes	2015	diabetes	Clinical Data Milestones	Data Release	Phase I
lovo Nordisk	FIAsp (NN1218, faster-acting formulation of insulin aspart)	Update on FDA acceptance of NDA in type I and type II diabetes	Feb, 2016	diabetes	Regulatory Milestones	Regulatory Action	
ohnson & Johnson/ /litsubishi Tanabe <sup>p</sup> harma	Invokamet XR (Invokana [canagliflozin]/metform in XR fixed-dose combo)	Update on FDA acceptance of NDA for type II diabetes, including initial therapy	Feb, 2016	diabetes	Regulatory Milestones	Regulatory Action	
Sanofi	SAR425899	Initiate Phase II trial in type II diabetes, with focus in overweight and obese patients	Early 2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase





		pired are awaiting updates by the company**	Last updated				
Company	Product Name	Event	Expected Date	Broad Indication	Category	Event Type	Phase
		**Events with expired Expected Dates are awaiting updates**					
Transition Therapeutics/ Eli Lilly		Eli Lilly decision whether to continue development post Phase II data of once- weekly dose in type II diabetes in Feb 2016	Mar-May 2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase II
Sanofi/ Zealand Pharma	LixiLan (lixisenatide [Lyxumia]/ Lantus combo)	EU regulatory filing of lixisenatide/Lantus fixed-ratio combo for type 2 diabetes	March, 2016	diabetes	Regulatory Milestones	Regulatory Filing	
Merck/ Samsung	MK-1293 (biosimilar to Lantus)	US and EU regulatory filing in type I and type II diabetes	1Q 2016	diabetes	Regulatory Milestones	Regulatory Filing	
Novo Nordisk/ Emisphere	,	Initiate first Phase III efficacy PIONEER trial in type II diabetes	1Q 2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase III
AstraZeneca/ Bristol- Myers Squibb/ Otsuka/ Kyowa Kakko Kirin		Potential CHMP opinion (BI-estimated timeline) in type II diabetes	Apr-Jul 2016	diabetes	Regulatory Milestones	Regulatory Action	
Novo Nordisk	semaglutide	Data from Phase III CV outcomes trial SUSTAIN 6 in type II diabetes	April, 2016	diabetes	Clinical Data Milestones	Data Release	Phase III
Novo Nordisk	IDegLira (Xultophy, NN9068, Victoza and Degludec fixed ratio combo)	FDA release of briefing documents for May 25 Endocrinologic and Metabolic Drugs Advisory Committee meeting	May 20 2016	diabetes	FDA Advisory Committee Meetings	FDA Briefing Documents	
Sanofi/ Zealand Pharma	,	FDA release of briefing documents for May 24 Endocrinologic and Metabolic Drugs Advisory Committee meeting	May 23 2016	diabetes	FDA Advisory Committee Meetings	FDA Briefing Documents	
Novo Nordisk	IDegLira (Xultophy,	FDA Endocrinologic and Metabolic Drugs Advisory Committee meeting to discuss the safety and efficacy of new drug application (NDA) 208583 for insulin degludec and liraglutide injection, submitted by Novo Nordisk Inc., for the proposed indication: adjunct to diet and exercise to improve glycemic control in the treatment of adults with type 2 diabetes mellitus.  FDA White Oak Campus, Building 31 Conference Center, the Great Room (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD	May 24 2016	diabetes	FDA Advisory Committee Meetings	FDA Panel	
Sanofi/ Zealand Pharma	LixiLan (lixisenatide [Lyxumia]/ Lantus combo)/lixisenatide (Lyxumia)	FDA Endocrinologic and Metabolic Drugs Advisory Committee meeting to discuss the safety and efficacy of new drug applications (NDAs) 208673 for insulin glargine and lixisenatide injection, a fixed ratio drug product consisting of insulin and a GLP-1 receptor agonist, and 208471 for lixisenatide injection, a GLP-1 receptor agonist, submitted by Sanofi Aventis c/o Sanofi U.S. Services Inc., proposed for the treatment of adults with type 2 diabetes mellitus. FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD	May 25 2016	diabetes	FDA Advisory Committee Meetings	FDA Panel	





		oired are awaiting updates by the company**	Last updated				
Company	Product Name	Event	Expected Date	Broad Indication	Category	Event Type	Phase
		**Events with expired Expected Dates are awaiting updates**					
Johnson & Johnson/ Mitsubishi Tanabe Pharma	Invokamet (Vokanamet, canagliflozin [Invokana]/metformin IR fixed-dose combo)	BI-estimated PDUFA date for initial therapy in type II diabetes	May, 2016	diabetes	Regulatory Milestones	PDUFA	
Boehringer Ingelheim/ Eli Lilly	linagliptin/metformin XR fixed-dose combo (Jentadueto XR)	BI-estimated PDUFA date of once-daily treatment of type II diabetes	May-Aug 2016	diabetes	Regulatory Milestones	PDUFA	
Adocia		Present data from Phase Ib trial vs Humalog Mix75/25 and separate and simultaneous injections of Humalog and Lantus in type II diabetes at ADA	Jun 10-14 2016	diabetes	Clinical Data Milestones	Data Release	Phase I
Sanofi/ Zealand Pharma	LixiLan (lixisenatide [Lyxumia]/ Lantus combo)	Present data from Phase III trials LixiLan-O and LixiLan-L of lixisenatide/Lantus fixed-ratio combo for type 2 diabetes at ADA	Jun 10-14 2016	diabetes	Clinical Data Milestones	Data Release	Phase II
Novo Nordisk	Tresiba (degludec)	Present data from Phase III trials BEGIN-SWITCH 1 and 2 on switching from Lantus in type I and type II diabetesto support sNDA filing for label claim on hypoglycemia, at ADA	Jun 10-14 2016	diabetes	Clinical Data Milestones	Data Release	Phase II
Novo Nordisk	Victoza (liraglutide)	Present data from Phase III LEADER trial on cardiovascular outcomes at ADA	Jun 10-14 2016	diabetes	Clinical Data Milestones	Data Release	Phase II
Mylan/ Biocon	biosimilar to Lantus	Complete Phase III trials INSTRIDE 1 and INSTRIDE 2 for non-inferiority to Lantus in type I and type II diabetes	June, 2016	diabetes	Clinical Data Milestones	Trial Completion	Phase II
GW Pharma	GWP42004 (THCV)	Data from Phase II trial in type II diabetes	2Q 2016	diabetes	Clinical Data Milestones	Data Release	Phase I
Sanofi	new insulin lispro (Humalog biosimilar, SAR342434)	Data from Phase III SORELLA trials in type I and type II diabetes vs Humalog	2Q 2016	diabetes	Clinical Data Milestones	Data Release	Phase II
Merck/ Pfizer	ertugliflozin (PF- 04971729)	Data from Phase III trials of monotherapy and fixed-dose combinations with metformin and Januvia in type II diabetes	1H 2016	diabetes	Clinical Data Milestones	Data Release	Phase II
Novo Nordisk/ Merrion Pharma	OI338GT (NN1953, oral basal insulin)	Data from Phase IIa trial in oral administration of basal insulin in type II diabetes patients	1H 2016	diabetes	Clinical Data Milestones	Data Release	Phase I
AstraZeneca/ Bristol- Myers Squibb/ Otsuka/ Kyowa Kakko Kirin	SaxaDapa (saxagliptin [Onglyza]/dapagliflozin [Forxiga] fixed dose combo)	Resubmit NDA in type II diabetes, following complete response letter in Oct 2015	1H 2016	diabetes	Regulatory Milestones	Regulatory Filing	
Novo Nordisk	Tresiba (degludec)/ Ryzodeg (insulin degludec/insulin aspart, DegludecPlus)	Complete cardiovascular outcomes trial DEVOTE vs Lantus, as requested by the complete response letter in Feb 2013	Mid 2016	diabetes	Clinical Data Milestones	Trial Completion	Phase I
Novo Nordisk	IDegLira (Xultophy, NN9068, Victoza and Degludec fixed ratio combo)	BI-estimated PDUFA date of NDA in type II diabetes	Jul 25 2016	diabetes	Regulatory Milestones	PDUFA	





Company	Product Name	Event	Expected Date	Broad Indication	Category	Event Type	Phase
Company	1 Todact Hame	Event	Expedica Bate	Droad malcution	Cutegory	Lvent Type	i nasc
		**Events with expired Expected Dates are awaiting updates**					
Sanofi/ Zealand Pharma	lixisenatide (Lyxumia, AVE 0010)	BI-estimated PDUFA date of NDA for once-daily treatment in combination with oral anti-diabetics and/or basal insulin in type II diabetes	Late July 2016	diabetes	Regulatory Milestones	PDUFA	
Sanofi/ Zealand Pharma		BI-estimated PDUFA date of NDA of lixisenatide/Lantus fixed-ratio combo for type 2 diabetes, with use of priority review voucher	Aug 23 2016	diabetes	Regulatory Milestones	PDUFA	
Boehringer Ingelheim/ Eli Lilly	empagliflozin (Jardiance, BI10773)	BI-estimated PDUFA date of sNDA to update label with data from cardiovascular outcome study EMPA-REG OUTCOME	Mid Sept 2016	diabetes	Regulatory Milestones	PDUFA	
Johnson & Johnson/ Mitsubishi Tanabe Pharma	Invokamet XR (Invokana [canagliflozin]/metform in XR fixed-dose combo)	BI-estimated PDUFA date of NDA for type II diabetes, including initial therapy	Sept 20 2016	diabetes	Regulatory Milestones	PDUFA	
Novo Nordisk		File sNDA for label claim on hypoglycemia, with data from BEGIN-SWITCH 1 and 2 trials	3Q 2016	diabetes	Regulatory Milestones	Regulatory Filing	
Novo Nordisk	FIAsp (NN1218, faster-acting formulation of insulin aspart)	BI-estimated PDUFA date of NDA in type I and type II diabetes	Oct 9 2016	diabetes	Regulatory Milestones	PDUFA	
Boehringer Ingelheim/ Eli Lilly		US launch in type I and type II diabetesSanofi and Lilly settled patent litigation in Sept 2015; FDA granted tentative approval in Aug 2014 and full approval in Dec 2015	Dec 15 2016	diabetes	Commercial Milestones	Drug Launch	
Eli Lilly		Interim analysis of cardiovascular outcomes trial REWIND	4Q 2016/1Q 2017	diabetes	Clinical Data Milestones	Data Release	Phase II
Sanofi/ Hanmi Pharma	efpeglenatide (SAR439977)	Initiate Phase III trials for weekly or monthly dosing in diabetes	4Q 2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase II
Ionis Pharma (Isis Pharma)	IONIS-GCGR (ISIS- GCGR)	Data from additional Phase II trials to optimize dose and dosing schedule in type II diabetes	4Q 2016	diabetes	Clinical Data Milestones	Data Release	Phase II
Lexicon Pharma/ Sanofi		Initiate Phase III trials in type II diabetes	4Q 2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase II
Novo Nordisk		Data from cardiovascular outcomes trial DEVOTE vs Lantus, as requested by the complete response letter in Feb 2013	4Q 2016	diabetes	Clinical Data Milestones	Data Release	Phase II
Mylan/ Biocon	biosimilar to Lantus	Submit one biosimilar application in US and EU for type I and type II diabetes	2H 2016	diabetes	Regulatory Milestones	Regulatory Filing	
Ligand Pharma		Initiate Phase II trial in type II diabetes with solid dosage form, after completing study comparing it with oral liquid formulation used in Phase I	2H 2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase II
AstraZeneca/ Bristol- Myers Squibb/ Otsuka/ Kyowa Kakko Kirin		Potential EU approval (company-expected timeline) in type II diabetes	2H 2016	diabetes	Regulatory Milestones	Regulatory Action	





**Events with Expect	ed Dates that have ex	pired are awaiting updates by the company**	Last updated	l: 4/1/2016			
Company	Product Name	Event	Expected Date	Broad Indication	Category	Event Type	Phase
		**Events with expired Expected Dates are awaiting updates**					
Novo Nordisk	semaglutide	US and EU regulatory filing in type II diabeteswill include data from CV outcomes trial SUSTAIN 6	2H 2016	diabetes	Regulatory Milestones	Regulatory Filing	
Lexicon Pharma/ Sanofi	sotagliflozin (LX4211, SAR439954)	Data from two pivotal efficacy Phase III trials in type I diabetes	2H 2016	diabetes	Clinical Data Milestones	Data Release	Phase III
Novo Nordisk	Victoza (liraglutide)	US and EU regulatory filing for label update with data from Phase III LEADER trial on cardiovascular outcomes	2H 2016	diabetes	Regulatory Milestones	Regulatory Filing	
Merck/ Pfizer	ertugliflozin (PF- 04971729)	US regulatory filing of monotherapy and fixed-dose combinations with metformin and Januvia in type II diabetes	End of 2016	diabetes	Regulatory Milestones	Regulatory Filing	
Adocia	BioChaperone combo (insulin glargine/insulin lispro formulated at 75/25 ratio)	Initiate Phase II trials vs both basal insulin only and premixed insulin therapies in type II diabetes	2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase II
Eli Lilly/ Adocia	BioChaperone lispro ultra-rapid insulin	Initiate Phase III trials in type I and type II diabetes	2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase III
Boehringer Ingelheim/ Eli Lilly	empagliflozin (Jardiance)/metformin XR fixed-dose combo	US regulatory filing for type II diabetes	2016	diabetes	Regulatory Milestones	Regulatory Filing	
Boehringer Ingelheim/ Eli Lilly	empagliflozin	Potential EU approval (company-expected timeline) to update label with data from cardiovascular outcome study EMPA-REG OUTCOME	2016	diabetes	Regulatory Milestones	Regulatory Action	
Boehringer Ingelheim/ Eli Lilly	Glyxambi (empagliflozin [Jardiance]/ linagliptin fixed-dose combo)	Potential EU approval (company-expected timeline) for type II diabetes	2016	diabetes	Regulatory Milestones	Regulatory Action	
Johnson & Johnson/ Hanmi Pharma	HM12525A	Initiate Phase II trial for diabetes and obesity	2016	diabetes and obesity	Clinical Data Milestones	Trial Initiation	Phase II
Novo Nordisk	IDegLira (Xultophy, NN9068, Victoza and Degludec fixed ratio combo)	Present data from Phase IIIb trial DUAL III on switching from GLP-1 in type II diabetes	2016	diabetes	Clinical Data Milestones	Data Release	Phase III
Merck	Januvia (sitagliptin)	Potential FDA approval (company-expected timeline) of label update with Phase III cardiovascular outcomes trial TECOS in type II diabetes	2016	diabetes	Regulatory Milestones	PDUFA	
Novo Nordisk/ Emisphere	semaglutide tablets (OG217SC, NN9924, oral GLP-1)	Initiate majority of remaining nine efficacy and safety Phase III PIONEER trials in type II diabetes, including cardiovascular outcomes trial PIONEER 6	2016	diabetes	Clinical Data Milestones	Trial Initiation	Phase III
Johnson & Johnson/ Mitsubishi Tanabe Pharma	Invokana (canagliflozin, Canaglu)	US and EU regulatory filing in type I diabetes	2016-2019	diabetes	Regulatory Milestones	Regulatory Filing	
Novo Nordisk	IDegLira (Xultophy, NN9068, Victoza and Degludec fixed ratio combo)	Potential US launch (company-expected timeline) in type II diabetes	Jan, 2017	diabetes	Commercial Milestones	Drug Launch	
Sanofi	Toujeo (U300, Lantus [insulin glargine] new formulation)	Initial data from US real life study ACHIEVE CONTROL in insulin-naive type II diabetes	Early 2017	diabetes	Clinical Data Milestones	Data Release	
Sanofi	Toujeo (U300, Lantus [insulin glargine] new formulation)	Initial data from EU real life study REACH CONTROL in insulin-naive type II diabetes	Early 2017	diabetes	Clinical Data Milestones	Data Release	
Sanofi		Initial data from EU real life study REGAIN CONTROL in type II diabetes uncontrolled on basal insulin	Early 2017	diabetes	Clinical Data Milestones	Data Release	
Novo Nordisk	FIAsp (NN1218, faster-acting formulation of insulin aspart)	Potential EU approval (BI-estimated timeline) in type I and type II diabetes	1Q 2017	diabetes	Regulatory Milestones	Regulatory Action	





		d Pharma Catalyst Calendar		1 4/4/0040			
		pired are awaiting updates by the company**	Last updated				
Company	Product Name	Event	Expected Date	Broad Indication	Category	Event Type	Phase
		**Events with expired Expected Dates are awaiting updates**					
Novo Nordisk	Tresiba (degludec)	Potential FDA approval (company-expected timeline) of sNDA for label claim on hypoglycemia, with data from BEGIN-SWITCH 1 and 2 trials	May-Jul 2017	diabetes	Regulatory Milestones	PDUFA	
Kamada	Glassia (IV alpha-1 antitrypsin [AAT])	Unblind trial and report data from planned interim analysis based 60 patients with one year of therapy of Phase II/III trial in type I diabetes	1H 2017	diabetes	Clinical Data Milestones	Data Release	Phase II/
Johnson & Johnson/ Mitsubishi Tanabe Pharma	Invokana (canagliflozin, Canaglu)	Complete cardiovascular outcomes studies CANVAS/CANVAS-R	3Q 2017	diabetes	Clinical Data Milestones	Trial Completion	
Merck	omarigliptin (Marizev, MK-3102)	Primary completion of CV outcomes trial in type II diabetes	Late 2017	diabetes	Clinical Data Milestones	Trial Completion	Phase II
AstraZeneca/ Bristol- Myers Squibb/ Alkermes/ Eli Lilly	Bydureon (exenatide once-weekly) suspension	US and EU regulatory filing for once-weekly suspension formulation autoinjector (no reconstitution required) in type II diabetes	2017	diabetes	Regulatory Milestones	Regulatory Filing	
AstraZeneca/ Bristol- Myers Squibb/ Ono	Forxiga (dapagliflozin, Farxiga)	Data from Phase III trials DEPICT 1 and 2 in type I diabetes	2017	diabetes	Clinical Data Milestones	Data Release	Phase II
AstraZeneca/ Bristol- Myers Squibb/ Ono	Forxiga (dapagliflozin, Farxiga)	EU regulatory filing in type I diabetes	2017	diabetes	Regulatory Milestones	Regulatory Filing	
AstraZeneca/ Bristol- Myers Squibb/ Ono	Forxiga (dapagliflozin, Farxiga)	Data from Phase III trial DERIVE in type II diabetes patients with moderate renal impairment	2017	diabetes	Clinical Data Milestones	Data Release	Phase II
Novo Nordisk	LAI287 (ultra long- acting insulin, NN1436)	Initiate Phase II trial for once-weekly dosing in type I diabetes	2017	diabetes	Clinical Data Milestones	Trial Initiation	Phase II
Ligand Pharma	LGD-6972 (glucagon)	Data from Phase II trial in type II diabetes	2017	diabetes	Clinical Data Milestones	Data Release	Phase II
Novo Nordisk	semaglutide	Data from Phase II trial of once daily dosing vs Victoza in type II diabetes	2017	diabetes	Clinical Data Milestones	Data Release	Phase II
Merck/ Pfizer	ertugliflozin (PF- 04971729)	Potential launch (company-expected timeline) of monotherapy and fixed-dose combinations with metformin and Januvia in type II diabetes	>=2017	diabetes	Commercial Milestones	Drug Launch	
Novo Nordisk/ Emisphere	semaglutide tablets (OG217SC, NN9924, oral GLP-1)	Data from Phase III cardiovascular outcomes trial PIONEER 6 for type II	4Q 2018	diabetes	Clinical Data Milestones	Data Release	Phase II
AstraZeneca/ Bristol- Myers Squibb/ Alkermes/ Eli Lilly	,	Data from EXSCEL trial on cardiovascular event lowering	2018	diabetes	Clinical Data Milestones	Data Release	Phase II
AstraZeneca/ Bristol- Myers Squibb/ Alkermes/ Eli Lilly	Bydureon (exenatide once weekly)	US, EU and Japan regulatory filing with data from EXSCEL trial on cardiovascular event lowering	2018	diabetes	Clinical Data Milestones	Data Release	Phase II





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Eli Lilly	dulaglutide (Trulicity)	Data from cardiovascular outcomes trial REWIND	2018	diabetes	Clinical Data Milestones	Data Release	Phase III
AstraZeneca/ Bristol- Myers Squibb/ Ono	Forxiga (dapagliflozin, Farxiga)	US and Japan regulatory filing in type I diabetes	2018	diabetes	Regulatory Milestones	Regulatory Filing	
Novo Nordisk/ Emisphere	semaglutide tablets (OG217SC, NN9924, oral GLP-1)	Data from nine Phase III PIONEER trials in type II diabetes	2018	diabetes	Clinical Data Milestones	Data Release	Phase III
Boehringer Ingelheim/ Eli Lilly	Tradjenta (Trajenta, Trazenta, linagliptin)	Data from cardiovascular outcomes trial CAROLINA vs glimepiride	2018	diabetes	Clinical Data Milestones	Data Release	
Boehringer Ingelheim/ Eli Lilly	Tradjenta (Trajenta, Trazenta, linagliptin)	Data from cardiovascular and renal outcomes trial CARMELINA vs placebo	2018	diabetes	Clinical Data Milestones	Data Release	
Merck/ Pfizer	ertugliflozin (PF- 04971729)	Data from CV outcomes trial in type II diabetes	2019	diabetes	Clinical Data Milestones	Data Release	Phase III
AstraZeneca/ Bristol- Myers Squibb/ Ono	Forxiga (dapagliflozin, Farxiga)	Data from cardiovascular outcome trial DECLARE-TIMI58	2019	diabetes	Clinical Data Milestones	Data Release	Phase III
AstraZeneca/ Bristol- Myers Squibb/ Ono	Forxiga (dapagliflozin, Farxiga)	US, EU and Japan regulatory filing with data from cardiovascular outcome trial DECLARE-TIMI58	2020	diabetes	Regulatory Milestones	Regulatory Filing	
Ligand Pharma	LGD-6972 (glucagon)	Potential launch (company-expected timeline) in type II diabetes	<=2020	diabetes	Commercial Milestones	Drug Launch	
Sanofi	new insulin lispro (Humalog biosimilar, SAR342434)	Potential launch (company-expected timeline) in type I and type II diabetes	<=2020	diabetes	Commercial Milestones	Drug Launch	
Bristol-Myers Squibb/ Biocon	AC165198	Phase I trial for diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase I
Eli Lilly/ Adocia	BioChaperone lispro ultra-rapid insulin	Phase Ib trials in type I and type II diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase I
Novo Nordisk	IDegLira (Xultophy, NN9068, Victoza and Degludec fixed ratio combo)	104-week Phase IIIb trial DUAL VIII vs Lantus on long-term glycemic control in type II diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase III
Sanofi/ Hanmi Pharma	long-acting insulin 115 (HM12470, SAR440067)	Phase I development for weekly dosed insulin in type II diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase I
Sanofi/ Hanmi Pharma	long-acting insulin/efpeglenatide fixed-dose combo	Preclinical development for weekly dosing in diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Preclinical





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Company	Product Name	Event	Expected Date	Broad Indication	Category	Event Type	Phase
		**Events with expired Expected Dates are awaiting updates**					
Lexicon Pharma	LX2761	Preclinical development for diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Preclinical
Merck	MK-8521	Phase IIa trial in type II diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase II
OPKO Health	MOD-6031 (long- acting oxyntomodulin)	Phase I trial for long acting subcutaneous formulation in overweight or obese healthy volunteers	Ongoing	diabetes and obesity	Clinical Data Milestones	Data Release	Phase I
Novo Nordisk	NN1406 (liver- preferential mealtime insulin)	Phase I trial of physiologically distributed short-acting insulin in type I diabetes males	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase I
Novo Nordisk	NN9828 (anti-IL- 21/Victoza [liraglutide])	Phase II trial of anti-IL-21 and liraglutide 1.8mg, alone or in combination, in preserving insulin-producing beta cells in newly diagnosed type I diabetes patients	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase II
Novo Nordisk	OI320GT (NN1957, oral insulin)	Phase Ia trial of oral insulin in healthy volunteers	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase I
Merck	sitagliptin/atorvastatin (MK-0431E)	Phase III trials in type II diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase III
Lexicon Pharma/ Sanofi	sotagliflozin (LX4211, SAR439954)	Phase II trial in type I diabetes patients younger than 30 years of age and an A1c of greater than 9	Ongoing	diabetes	Clinical Data Milestones	Data Release	Phase II
Novo Nordisk/ XOMA	XMetA	Preclinical development for type I and II diabetes	Ongoing	diabetes	Clinical Data Milestones	Data Release	Preclinical
Halozyme	Hylenex	Update on US regulatory pathway on updating labeling to include CONSISTENT 1 data as a pre-treatment in patients with diabetes using insulin pumpsFDA will likely require additional clinical data; will seek partners, reported Nov 2014	Pending	diabetes	Regulatory Milestones	Regulatory Filing	
Generex	Oral-lyn buccal insulin spray	Amend IND for Phase I trial of enhanced formulation for diabetes	Pending	diabetes	Clinical Data Milestones	Trial Initiation	Phase I
RedHill Biopharma	RHB-104 (clarithromycin/clofazi mine/rifabutin fixed dose combination)	Potentially initiate Phase IIa proof-of-concept trial in type I diabetes, pending final data and independent report for pre-clinical study in 3Q14	Pending	diabetes	Clinical Data Milestones	Trial Initiation	Phase II
Novo Nordisk	Ryzodeg (insulin degludec/insulin aspart, DegludecPlus)	Data from Phase IIIb trial of twice daily dosing in insulin naïve type II diabetes	Pending	diabetes	Clinical Data Milestones	Data Release	Phase III
Novo Nordisk	Ryzodeg (insulin degludec/insulin aspart, DegludecPlus)	Launch in EU for in type I and II diabetes	Pending	diabetes	Commercial Milestones	Drug Launch	
Chugai/ Kowa/ Sanofi	tofogliflozin (Apleway, RG7201, CSG452)	EU regulatory filing in Type II diabetes after securing partners	Pending	diabetes	Regulatory Milestones	Regulatory Filing	
Novo Nordisk	Tresiba (degludec)/ Ryzodeg (insulin degludec/insulin aspart, DegludecPlus)	Potential Canadian approval for type I and II diabetes, after providing additional data requested by Health Canada	Pending	diabetes	Regulatory Milestones	Regulatory Action	
Zealand Pharma	ZP2929	Decision on next step, after discussion with FDA, for Phase I trial for a once-daily subcutaneous administration to improve glycemic control and induce weight loss in patients with Type 2 diabetes and patients with obesity—Boehringer returned rights in Jan 2014	Pending	obesity and diabetes	Clinical Data Milestones	Trial Initiation	Phase I



# **IMPORTANT DISCLOSURE**

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