CARL LYONS
Carl lives in Denmark and has haemophilia A

US biopharmaceutical market

Eddie Williams
SVP, US Biopharmaceuticals
Forward-looking statements

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Important drug information

- Victoza® (liraglutide 1.2 mg & 1.8 mg) is approved for the management of type 2 diabetes only
- Saxenda® (liraglutide 3 mg) is approved in the US and EU for the treatment of obesity only
Novo Nordisk US biopharmaceutical history started with the launch of Norditropin® in 1997

- 1997: Norditropin® launch
- 2000: Norditropin® cartridge and NordiPen® delivery system introduction
- 2003: Vagifem® and Activella® re-acquisition
- 2005: Norditropin® NordiFlex™ launch
- 2007: Norditropin® Noonan Syndrome indication
- 2010: Norditropin® FlexPro® launch
- 2013: Norditropin® Storage Flexibility launch
- 2015: Norditropin® FlexPro® 30mg launch

**Key Milestones:**

- 1999: NovoSeven® launch
- 2005: NovoSeven® FVII Deficiency indication
- 2008: NovoSeven® Room Temperature stable (RT) launch
- 2010: NovoSeven® RT 8mg vial launch
- 2013: NovoSeven® RT MixPro™ Launch
- 2014: NovoSeven® RT Glanzmann Thrombasthenia indication Tretten® launch
- 2015: Novoeight® launch

1 Tretten® is the brand name in the US and Canada. The European brand name is NovoThirteen®
US biopharmaceutical franchise

**NovoSeven® RT**
- Coagulation Factor VIIa (Recombinant)
- Launched 1999
- Market leader in bypassing agent segment
- Treats patients across several rare bleeding disorders

**Novoeight®**
- Antihaemophilic Factor (Recombinant)
- Launched Q2 2015
- Competitive label, including portability
- Direct patient and health care professional engagement

**tretten®**
- Coagulation Factor XIII A-Subunit (Recombinant)
- Launched Q2 2014
- Opportunity to demonstrate leadership in recombinant factor replacement therapy

**norditropin®**
- Somatropin (mDNA origin) injection
- Launched 1997
- Value and volume leader in a clinically undifferentiated market

**VAGIFEM®**
- Estradiol vaginal tablets
- Launched 2003
- Lower dose version launched 2010
- Growth challenged due to competition
US biopharmaceutical sales are growing high single digit

**US biopharmaceutical reported sales**

<table>
<thead>
<tr>
<th>DKK billion</th>
<th>Q3 2010</th>
<th>Q3 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
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</tr>
<tr>
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<tr>
<td>0.5</td>
<td></td>
<td></td>
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<tr>
<td>0.0</td>
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<td></td>
</tr>
</tbody>
</table>

CAGR$^1$ +8.6%

**Key market dynamics**

- **Biopharmaceuticals** sales growth driven by **Norditropin®** and **Vagifem®**
- **Haemophilia** sales historically driven by **NovoSeven® RT**
- **Norditropin®** strong growth driven by successful market access execution and preference for FlexPro® device
- **Vagifem®** performance driven by positive price development; generic Vagifem® expected in Q4 2016

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$^1$ CAGR for 5-year period
Note: Other biopharmaceuticals include Vagifem®, Activella® and Glucagen®
Maintaining NovoSeven® RT market leadership through continued label expansion

**NovoSeven® RT US sales across indications**

- Congenital Factor VII Deficiency
- Acquired Haemophilia (AH)
- Surgery in CHwI
- Congenital Haemophilia with Inhibitors (CHwI)
- Glanzmann’s Thrombasthenia

**US indications and key dynamics**

**NovoSeven® RT US indications**
- Congenital Haemophilia with Inhibitors (CHwI)
- Surgery in CHwI
- Acquired Haemophilia (AH)
- Congenital Factor VII Deficiency
- Glanzmann’s Thrombasthenia

**NovoSeven® RT key dynamics**
- First and only recombinant bypassing agent
- Market value share leader, ~75%
- Small CHwI patient population, impacted by Immune Tolerance Induction (ITI) and clinical trial enrollment

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1 Based on internal Novo Nordisk estimate
Note: NovoSeven® RT is not approved for prophylactic use in the US
Novoeight® launch is progressing as prophylaxis patients switch, primarily due to portability

Patients are primarily switching from prophylaxis regimen and due to portability

- **Prophylaxis**: 67%
- **On Demand**: 13%
- **Unknown**: 19%

<table>
<thead>
<tr>
<th>Portability</th>
<th>Reliability</th>
<th>Company</th>
<th>Purity</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>13%</td>
<td>64%</td>
<td>19%</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

US indications and key dynamics

**Novoeight® US indications**
- Adults and children with haemophilia A for:
  - Control and prevention of bleeding
  - Perioperative management
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

**Novoeight® key dynamics**
- Effective patient engagement
- Product benefits resonating with patients and prescribers as patients shift to Novoeight® due to portability and reliability

Source: Novo Nordisk data on file, 30 September 2015
Novo Nordisk continues to expand leadership within the growth hormone market in the US

**US growth hormone volume market share**

- Novo Nordisk
- Pfizer
- Sandoz
- Eli Lilly
- Roche
- Serono
- Teva/Ferring

**US indications and key dynamics**

**Norditropin® US indications**
- Growth Hormone Deficiency (adult and paediatric)
- Noonan Syndrome
- Turner Syndrome
- Small for Gestational Age (SGA)

**Norditropin® key dynamics**
- Clinically undifferentiated market with seven players
- Key Norditropin® differentiators are temperature stability, FlexPro® device and support programmes
- Value market share of approximately 45%¹
- Highly managed market by payors
- Submitted for potential expansion of indications: Idiopathic Short Stature and Prader Willi Syndrome

Source: Novo Nordisk internal estimate based on specialty pharmacy data, weekly retail and weekly institutional data

¹ Novo Nordisk internal estimate based on Company financial reports, Specialty pharmacy data, weekly retail and weekly institutional data
Concluding remarks

- Maintain NovoSeven® RT market leadership
- Drive continued solid uptake of Novoeight®
- Continue expansion of Norditropin® market leadership
Scott has haemophilia A
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Significant unmet medical needs still exist in haemophilia

Need to reduce disease and treatment burden

Raise the bar on treatment outcomes
- Control bleeding and minimise pain
- Reduction and elimination of bleeds
- Protect joints: maintain joint function

Reduce the burden of treatment
- Less cumbersome administration
  - Reduce dosing frequency
  - Pursue less invasive administration
- Minimise risk of inhibitors
- Ensure portability of products

Potential advances in treatment outcomes and reduction of treatment burden
Novo Nordisk has a comprehensive biopharm portfolio

<table>
<thead>
<tr>
<th>Research/preclinical(^1)</th>
<th>Phase 1 and 2</th>
<th>Phase 3</th>
<th>Launched(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Replacement factor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bypassing agent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Growth Hormone</td>
</tr>
<tr>
<td>Concizumab (NN7415)</td>
<td>N8-GP (NN7088)</td>
<td>N9-GP (NN7999)</td>
<td>NovoSeven(^\circledR)</td>
</tr>
<tr>
<td>Monoclonal anti-TFPI</td>
<td>Long-acting rFVIII</td>
<td>Long-acting rFIX</td>
<td>NovoEight(^\circledR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Somapacitan (NN8640)</td>
<td>NovoThirteen(^\circledR) TRETTE(^\circledR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Once-weekly GH</td>
<td>Norditropin(^\circledR)</td>
</tr>
</tbody>
</table>

\(^1\) Illustrative, not representative for exact number of research projects. \(^2\) HRT products excluded
N9-GP administered once weekly reduces median bleeding rate to 1.0 episode per year in phase 3 trial

**N9-GP phase 1 pharmacokinetics**

<table>
<thead>
<tr>
<th>Time (h)</th>
<th>rFIX</th>
<th>pdFIX</th>
<th>N9-GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.2</td>
<td>1.0</td>
<td>0.8</td>
</tr>
<tr>
<td>24</td>
<td>1.0</td>
<td>0.8</td>
<td>0.6</td>
</tr>
<tr>
<td>48</td>
<td>0.8</td>
<td>0.6</td>
<td>0.4</td>
</tr>
<tr>
<td>72</td>
<td>0.6</td>
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</tr>
<tr>
<td>96</td>
<td>0.4</td>
<td>0.2</td>
<td>0.0</td>
</tr>
<tr>
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<tr>
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<td></td>
</tr>
<tr>
<td>168</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
</tbody>
</table>

- Dose normalised 50 IU/kg (N=15)
- One stage clot assay

**Paradigm 2 headline results (phase 3)**

- Steady-state half-life of 110 hours
- Median bleeding rate for patients treated on demand was 15.6 episodes per year
- Patients on once-weekly prophylactic treatment had a median bleeding rate of 1.0 episode per year when treated with 40 IU/kg
- Among patients receiving 40 IU/kg:
  - 99% of bleeding episodes treated with only one infusion
  - Two thirds of patients experienced complete resolution of bleeding into target joints
- N9-GP appeared to have a safe and well tolerated profile with no patients developing inhibitors

**Next steps**

- Submission of N9-GP in the US and Europe expected before end H1 2016


Source: Novo Nordisk Company Announcement, 17 May 2013
N8-GP administered every fourth day reduces median bleeding rate to 1.3 episode per year in phase 3 trial

**N8-GP phase 1 pharmacokinetics**

- FVIII activity (IU/mL)
- Dose 50 IU/kg (n=8)
- One stage clot assay

**Pathfinder 2 headline results (phase 3)**

- PK documented single dose half-life of 18.4 hours and mean trough level before next dose of 8%
- Patients on every fourth day prophylaxis (50 IU/kg) had a median ABR of 1.3
- 95% of mild to moderate bleeds managed with 1-2 doses
- N8-GP appeared to have a safe and well tolerated profile
- One patient developed inhibitors, as expected in a population of previously treated haemophilia A patients

**Pathfinder 2 extension trial results**

- 55 patients with ≤2 bleeds during 6 months in the main phase were randomised 2:1 to either once-weekly (75 IU/kg) or every fourth day (50 IU/kg) treatment for 180 days
- Patients in both treatment arms had a median ABR of 0

**Next steps**

- Expansion of production capacity; US/EU submission 2018

**Source:** Tiede et al. J Thromb Haemot. 2013;11:670-675
Concizumab has the potential to introduce a new paradigm in the treatment of haemophilia

**Concizumab (NN7415) has a promising pharmacokinetic profile**

<table>
<thead>
<tr>
<th>Concizumab ELISA (ng/mL)</th>
<th>Healthy subjects 50 µg/kg</th>
<th>Healthy subjects 250 µg/kg</th>
<th>Healthy subjects 1000 µg/kg</th>
<th>Patients 1000 µg/kg</th>
<th>Patients 3000 µg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELISA</td>
<td></td>
<td></td>
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</table>

**Key characteristics of concizumab (NN7415) and phase 1b clinical trial**

- Anti-Tissue-Factor-Pathway-Inhibitor (anti-TFPI) is a new mechanism restoring thrombin generation in factor VIII and factor IX deficient patients, as well as inhibitor patients
- Mechanism without the risk of inhibitors
- Mechanism with potential for prophylaxis for all patients and convenient subcutaneous administration in a ready-to-use liquid formulation in a device
- Explorer 3 clinical trial initiated in Q3 2015:
  - Phase 1b multiple dose, dose escalation trial in around 45 people with haemophilia A
  - Investigates safety and PK/PD of concizumab administered subcutaneously
  - Top line data expected in 2017

ELISA: Enzyme-linked immunosorbent assay. Explorer 1 trial; Source: Chowdary P, et al. XXIV congress of the ISTH 2013, Amsterdam. Abstract #2990

PK: pharmacokinetic; PD: pharmacodynamic
NN7077, a new factor VII analogue, shows prolonged activity in animal studies

**Pharmacokinetics in nonhuman primates (clot activity)**

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>FVIIa level (IU/ml)</th>
<th>NN7077 (mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.8 ± 0.2 h</td>
<td>34.0 ± 2.0 h</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
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<tr>
<td>10</td>
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</tbody>
</table>

Note: Pharmacokinetics in animals may vary significantly from pharmacokinetics in man

**New factor VII analogue in preclinical development**

- NN7077 is a new potent factor VII analogue, currently in preclinical development as a prophylactic treatment for patients with inhibitors
- NN7077 has a 18-fold prolonged half-life in nonhuman primates
- In vivo pharmacokinetic and duration-of-effect data support a target product profile of every-other-day IV dosing
- Clinical development planned to be initiated in 2017

Source: Novo Nordisk data on file
Somapacitan (NN8640) is a potent hGH derivative designed for once weekly dosing with an auto-injection pen

**NN8640 pharmacodynamic profile in adults with growth hormone deficiency (AGHD)**

<table>
<thead>
<tr>
<th>IGF-1 (ng/mL)</th>
<th>0.02 mg/kg/week</th>
<th>0.04 mg/kg/week</th>
<th>0.08 mg/kg/week</th>
<th>0.12 mg/kg/week</th>
</tr>
</thead>
</table>

Note: Mean IGF-1 after four weekly doses of long-acting growth hormone in AGHD. Dashed lines indicate IGF-1 reference range (83 to 168 ng/mL); IGF-1: insulin-like growth factor 1. Source: Højby Rasmussen M et al, Poster presented at the 96th ENDO/16th ICE meeting 2014, LBSU-0377

**Key characteristics of somapacitan (NN8640)**

- Somapacitan is a growth hormone derivative in development for treatment of GHD in children and adults via once weekly administration
- Potential for increased adherence to therapy
- Convenient subcutaneous administration of ‘ready-to-use’ liquid formulation in a device
- Low injection volume and small needle
- Phase 3 clinical trial initiated in Q4 2014:
  - 280 drug naïve people with AGHD
  - To investigate efficacy and safety of somapacitan administered once weekly
  - Top line data expected in 2016
- A phase 2 trial in children with GHD is expected to be initiated in H1 2016

hGH: human growth hormone; AGHD: adult growth hormone deficiency; GHD: growth hormone deficiency
Concluding remarks

- Regulatory submission of N9-GP in the US and Europe before end H1 2016
- Regulatory submission of N8-GP by 2018
- Concizumab represents a potential new paradigm in the treatment of haemophilia
- Development of NN7077, a new factor VII analogue with potential for prophylaxis
- Somapacitan represents a more convenient treatment option for people with growth disorders