# Q4-2014 Conference Call 27 February 2015 Presenting team

Niklas Prager, President and CEO Henrik Krook, EVP Commercial Rein Piir, EVP Corporate Affairs & IR



A research-based pharmaceutical company focused on infectious diseases and oncology





Highlights from Q4 Niklas Prager, CEO





Summary of the Group's figures, continuing operations (SEK m)	Q4		Q1-Q4	
	2014	2013	2014	2013
Net turnover	377,0	147,1	1 767,0	446,1
Gross profit	324,5	126,5	1 593,0	374,3
Operating profit before depreciation and amortisation (EBITDA)	214,9	32,0	1 221,9	76,4
Operating profit (EBIT)	206,5	20,6	1 188,7	25,2
Profit/loss before tax	204,3	22,8	1 192,7	27,7
Profit/loss after tax	147,3	19,3	1 132,7	16,0

### **Royalties dominate but strong contribution from Nordic sales**

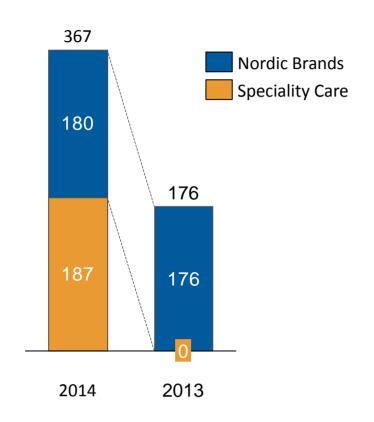


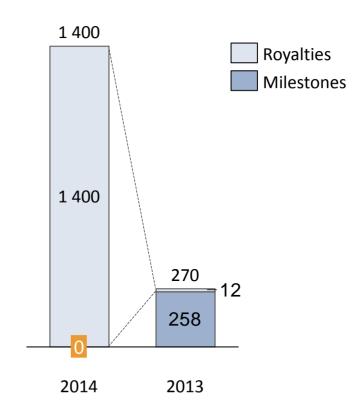
Breakdown of net turnover (SEK m)	Q4		Q1-Q4		
	2014	2013	2014	2013	
Outlicensing and partnership agreements					
Non-recurrent payments		-	88,0	_	258,5
Pharmaceutical sales		156,6	47,6	366,8	176,1
Royalties		220,4	11,5	1 400,2	11,5
Total		377,0	147,1	1 767,0	446,1

- o In the fourth quarter, our Speciality Care sales reached 103,2 (0) MSEK with continued strong OLYSIO® sales in the Nordics.
- Nordic Brands grew by 5.8 MSEK or 12.2% compared to the same quarter last year, an effect of an early flu season.
- o In total our pharmaceutical portfolio generated sales of 156,6 (47,6) MSEK.
- Total royalties amounted to 220,4 (11,5) MSEK in the fourth quarter of which 220,1 MSEK accounted from simeprevir global sales.
- o Total revenues during the quarter amounted to 377,0 (147,1) MSEK.

### A year of growth driven by Olysio

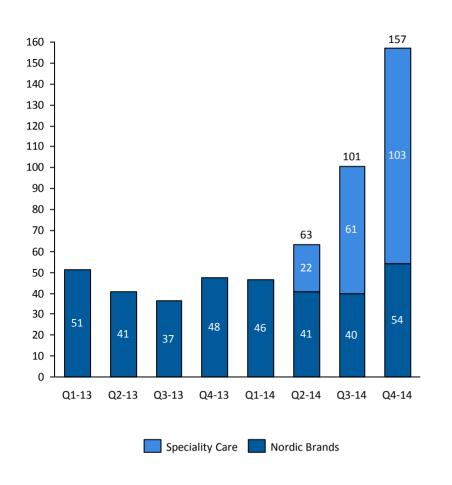


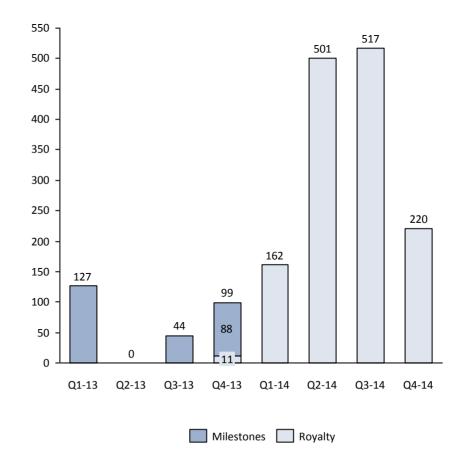




# **Specialty Care showed strong sales in the Nordics** throughout the year

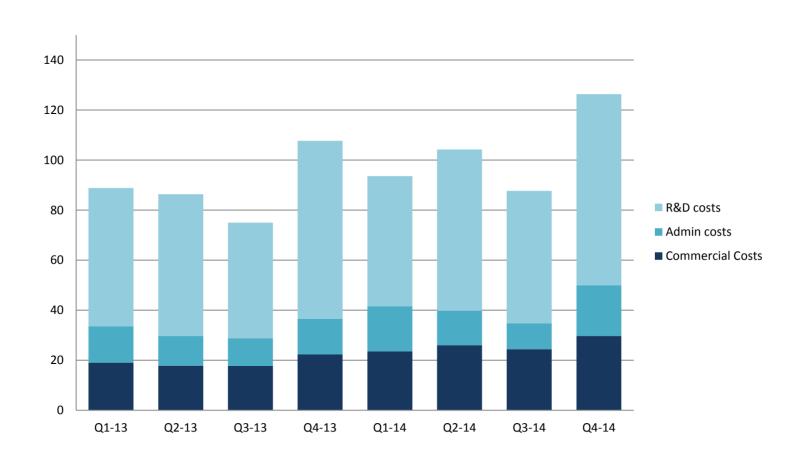






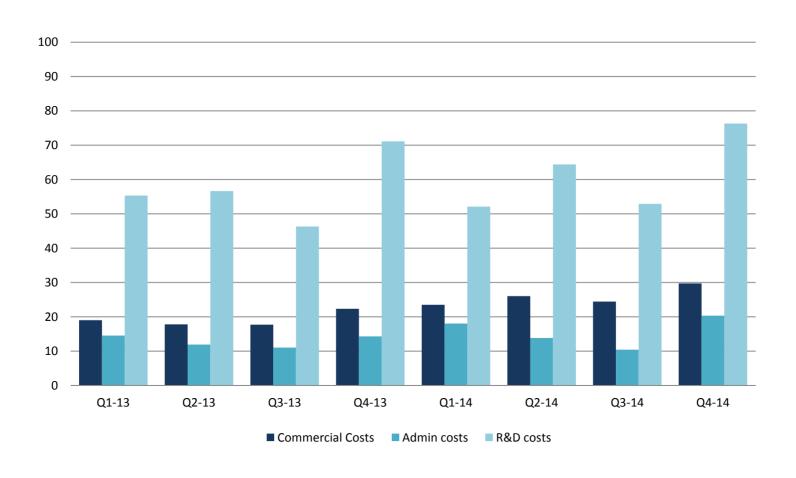
## Operating costs will be managed





### Stable quarterly pattern and increases under control

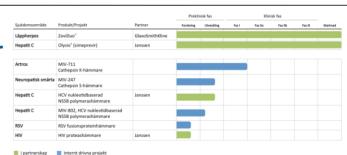




### **Continued progress in R&D**



We selected a candidate drug in our HCV nucleotide program in December - all other projects developed according to plan



#### MIV-711 - Osteoarthritis (OA)

- 6 month toxicology studies ongoing to enable start of phase IIa study in osteoarthritis patients in late 2015
- Innovative biomarker driven development path designed in collaboration with KOLs

#### MIV-247 - Neuropathic Pain (NP)

- Preclinical IND-enabling safety package initiated 3Q 2014 and ongoing
- Start of clinical Phase I program: 3Q 2015

#### **RSV Fusion Inhibitor**

Continues to advance in lead optimization

#### **Future Strategy**

Exploit protease targets and nucleotide expertise in oncology – more info at upcoming CMD 26 March in Stockholm

# MIV-802 – Wholly-owned uridine protide with potent pangenotypic activity



#### **HCV Nucleotide polymerase inhibitors**

- Prodrugs (protides) that selectively deliver high levels of the active drug to the liver
- Uridine-based compounds appear to have better safety/efficacy profiles

#### MIV-802: A liver-targeted uridine protide

- The active metabolite is a potent and selective inhibitor of the HCV NS5B polymerase
- Potent cross-genotype antiviral activity
- It generates high nucleoside triphosphate levels in the liver with a long half-life, supporting a low efficacious dose and once daily dosing
- Excellent safety profile in both in vitro toxicity assays and 7-day tox study in mice
- Favorable in vitro and in vivo ADME profile, combined with its antiviral profile, support combination with other classes of DAA

#### **Next Steps**

- Scale up of MIV-802 is ongoing
- IND-enabling safety studies will commence in 2H 2015



### Simeprevir on the global market





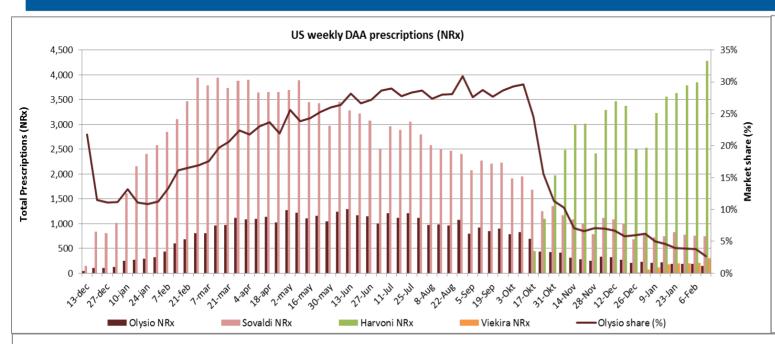
- ✓ Japan (SOVRIAD™)
- ✓ Canada (GALEXOS™)
- ✓ USA (OLYSIO<sup>™</sup>)
- ✓ Russia (SOVRIAD™)
- ✓ EU (OLYSIO™)
- ✓ Mexico (OLYSIO™)
- ✓ Australia (OLYSIO™)



# Simeprevir: New level of market share in the light of new competition since October



#### **Market Performance**



The HCV landscape is evolving very fast with new IFN-free combinations coming to the market

Continued dedication to disease area by J&J

Simeprevir will continue to play a role in different hepatitis C patient groups, combinations and treatment durations

- Global sales of OLYSIO® (excl. Nordics) in 2014 was 2,302 MUSD, continued roll-out with approvals and market introductions in major European markets on track
- Real-world efficacy rates with SMV + SOF ± RBV, primarily with 12w treatment, are comparable with those from the phase II COSMOS study
- Two phase III studies, OPTIMIST-1 & 2 (SMV + SOF) for 8-12 weeks of treatment to report results spring 2015
- Recently initiated studies :
  - o IMPACT, a phase II study with SMV, SOF and daclatasvir (DCV) in HCV GT1 and GT4 infected patients with decompensated liver disease
  - ACCORDION-1, a phase II study with SMV, SOF and DCV in treatment-naive GT1 patients for 6 weeks (early stage liver fibrosis) or 8 weeks (cirrhosis)
  - o COMMIT, a phase II study with SMV and DCV for 12 weeks in HCV GT1b-infected patients with advanced liver disease





# Nordic Commercial Q4 2014

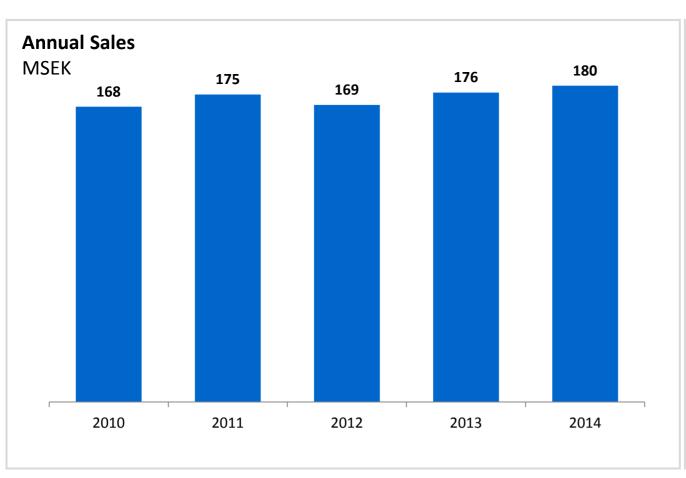
**Henrik Krook, EVP Commercial** 

# Nordic Brands – Strong Q4 performance resulted in year over year growth



#### Stable returns and continuous activities to improve gross margins further

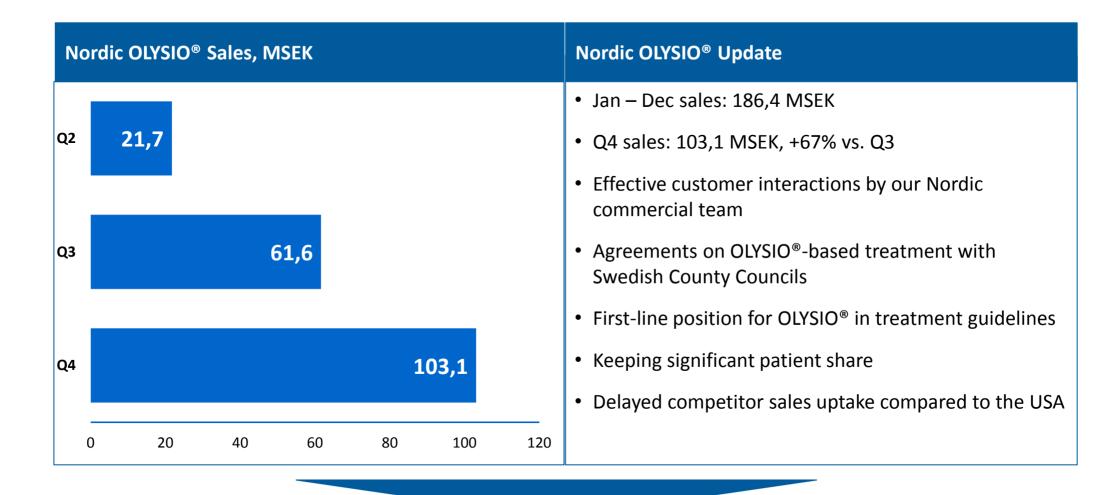
#### 2014



- Jan Dec sales
  - 180 MSEK
  - +2% vs. 2013
- Q4 sales
  - 53,4 MSEK
  - +12% vs. 2013
- The positive sales development primarily driven by Mollipect
- Technology Transfer activity to improve gross margins further

# Continued growth in sales revenue despite intensified competition





Successful Nordic OLYSIO® launch generates significant revenue & provides positive track record for in-licensing opportunities



Q/A



www.medivir

Ticker: MVIR

**Exchange: OMX / NASDAQ** 

For more information please contact

Rein Piir, EVP Corporate Affairs & IR (rein.piir@medivir.com)

**As of 1 March 2015** 

Ola Burmark, CFO (ola.burmark@medivir.com)