

# Medivir

## Q1-2015 Conference call

5 Maj, 2015

Niklas Prager - CEO

Ola Burmark - CFO

Richard Bethell - EVP Discovery Research

The logo features the word "MEDIVIR" in a bold, blue, sans-serif font. It is enclosed within a blue rectangular frame that has a slight 3D effect with a shadow on the right side.

# MEDIVIR

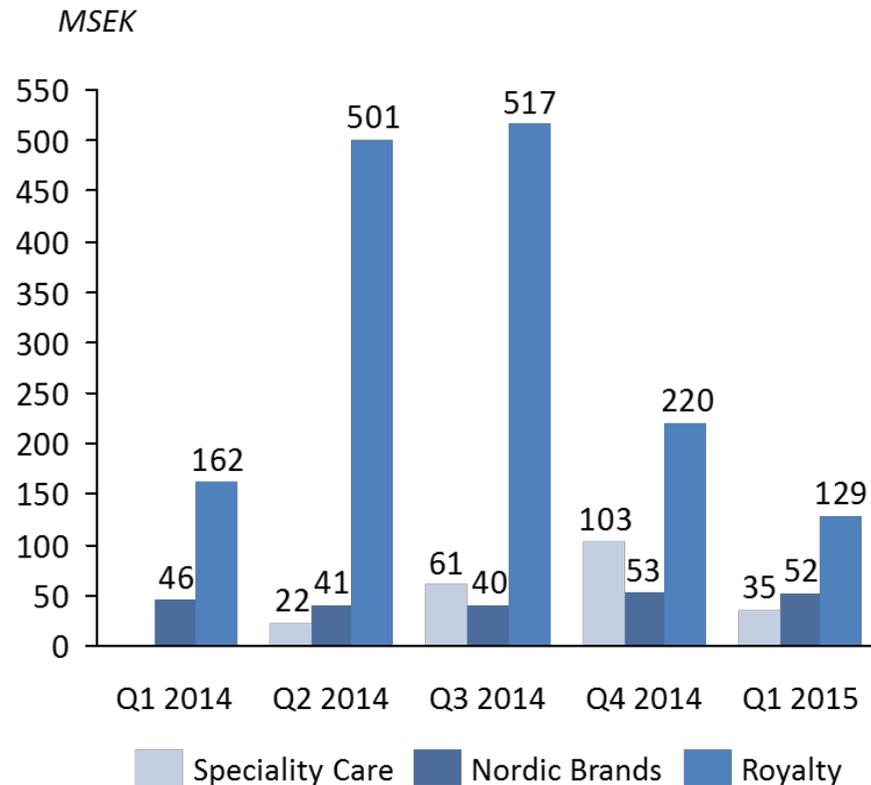
A research-based  
pharmaceutical company  
with focus on infectious  
diseases and oncology

## First Quarter in summary

Summary of the Group's figures, continuing operations (SEK m)	Q1		Full year
	2015	2014	2014
Net turnover	215.9	208.2	1 767.0
Gross profit	182.8	182.1	1 593.0
Operating profit before depreciation and amortisation (EBITDA)	84.6	96.7	1 221.9
Operating profit (EBIT)	76.2	88.6	1 188.7
Profit/loss before tax	82.9	90.3	1 192.7
Profit/loss after tax	66.7	283.8	1 132.7
Operating margin, %	35.3	42.6	67.3

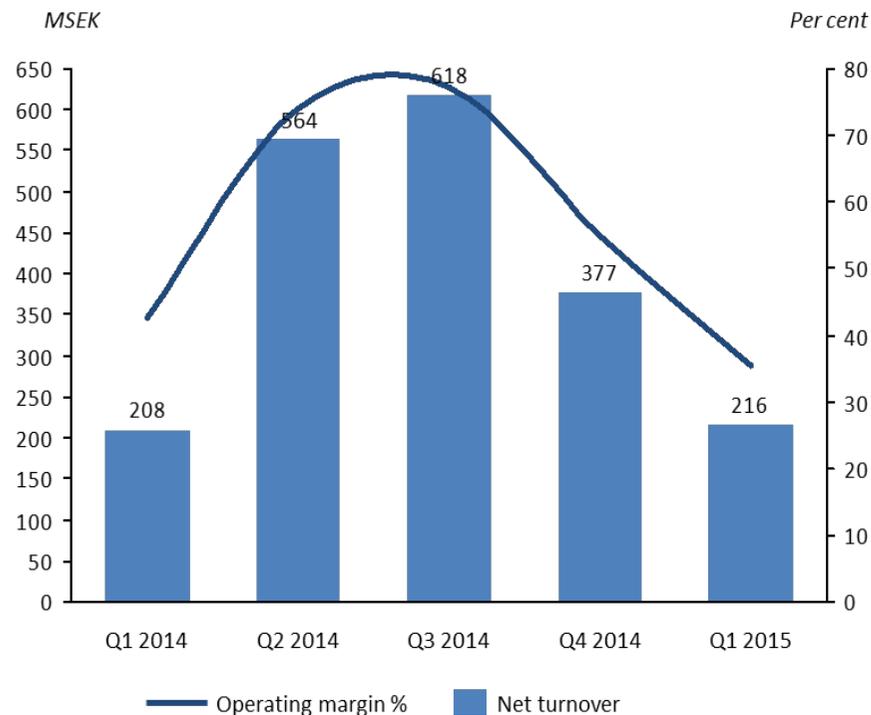
- Net turnover totalled SEK 215.9 million (208.2 m), of which SEK 128.6 million (161.5 m) comprised royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 86.8 million (46.4 m), of which SEK 34.2 million (0) derived from sales of OLYSIO® and SEK 52.6 million (46.4 m) from sales of other pharmaceuticals.
- The profit after tax was SEK 66.7 million (283.8 m).
- Basic and diluted earnings per share totaled SEK 2.29 (9.08) and SEK 2.27 (9.01), respectively.
- The cash flow from operating activities amounted to SEK 205.3 million (-57.8 m).

## Sales Break Down



- Janssen’s global sales of simeprevir amounted to 234 MUSD generating royalty income of SEK 129 million, a decline of SEK 33 million
- Pharmaceutical sales in the Nordic region totalled SEK 86.8 million. Out of the pharmaceutical sales revenues SEK 34.2 million derived from sales of OLYSIO® and SEK 52.6 million from sales of other pharmaceuticals.
- Sales Nordic Brands totalled SEK 52.3 million an increase of 6 million or 11%, primarily due to an increase in sales of Mollipect as a result of a long and severe influenza season.

# Operating income and margin



## Gross Profit

- The gross profit amounted to SEK 182.8 million, corresponding to an increase of SEK 0.7 million and equating a gross margin of 85% (87%), explained by a mix shift from royalty to pharmaceutical sales of OLYSIO®.

## Operating expenses

- Selling expenses increased by SEK 1.3 million primarily due to an increase in FTE's supporting the Nordic pharmaceutical sales.
- Administrative expenses decreased by SEK -4.7 million explained by lower spending and non-recurring personnel cost vs. the first quarter last year.
- Research and development costs increased by SEK 14.1 million, primarily as a result of planned costs for the phase I study preparation of the MIV-247 neuropathic pain project and further development of the RS-virus project in-licensed third quarter last year.
- Other operating income/expenses are negative and increased by SEK 2.3 million, largely due to exchange rate effects.
- Overall, operating expenses totaled SEK -106.6 million (-93.5 m), corresponding to an increase of SEK 13.1 million.

## Operating profit

- Operating profit totaled SEK 76.2 million or 35.3% (88.6 m or 42.6%), corresponding to a decrease of SEK 12.4 million.

# Over 600 MSEK distributed back to our shareholders as a result of the voluntary redemption program



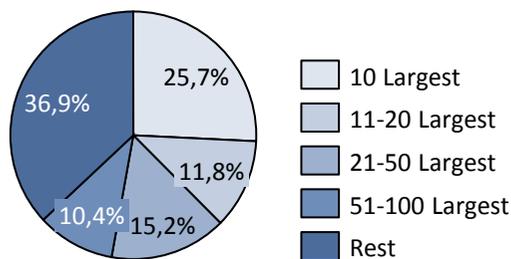
## Voluntary redemption program

- Acceptance level of 96.2 per cent, or a total of 4,293,990 shares
- SEK 601.2 million distributed to the shareholders on the 17<sup>th</sup> of March 2015
- Following completion the total number of outstanding shares amounts to 26,966,037 shares
  - 606,358 series A shares
  - 26,359,679 series B shares
- Total number of votes amounts to 32,423,259

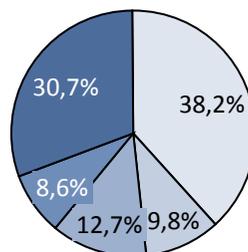
## Shareholder base

- International recognition and interest from foreign investors has increased

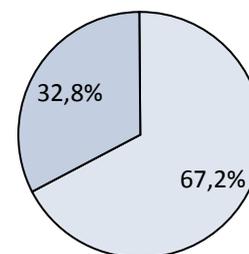
Concentration by Capital %



Concentration by Vote %

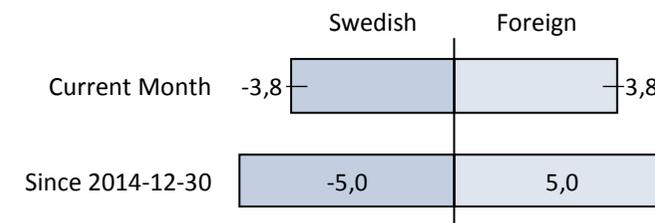


Categories



Swedish  
 Foreign

Category Changes %





# Research & Development



# Our Pipeline of wholly owned projects developed according to plan

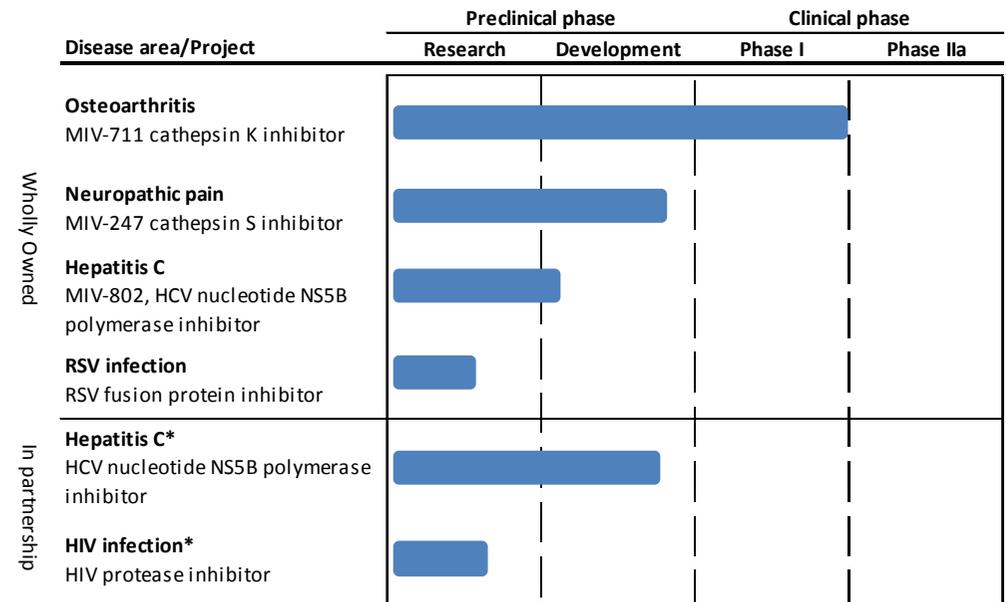


**MIV-711;** Undergoing preclinical safety testing in order to prepare for longer term phase II studies in osteoarthritis patients

**MIV 247;** Preclinical safety studies are currently in progress to prepare for phase I studies in humans

**MIV 802;** Preclinical safety studies to prepare for phase I studies in humans were recently initiated

**RSV;** Substances are being further optimised in order to identify a substance with the required profile for further development



Wholly Owned

In partnership

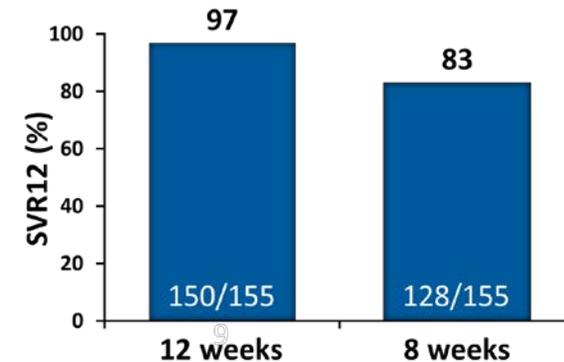
\* Partner Janssen

## Late breaker data on simeprevir presented at EASL

12 abstracts were presented by Janssen, including 3 Late Breakers:

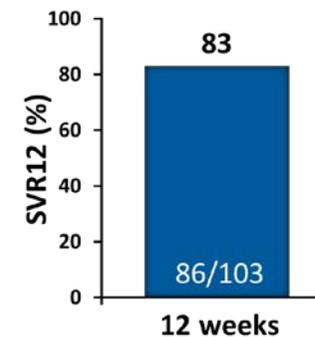
### OPTIMIST-1 (non-cirrhotic patients, Poster #LP14):

- 97% SVR12 confirms high potency of 12w simeprevir (SMV) and sofosbuvir (SOF) in GT1 non-cirrhotic patients
  - No need for ribavirin co-administration
  - No effect of Q80K in GT1a patients



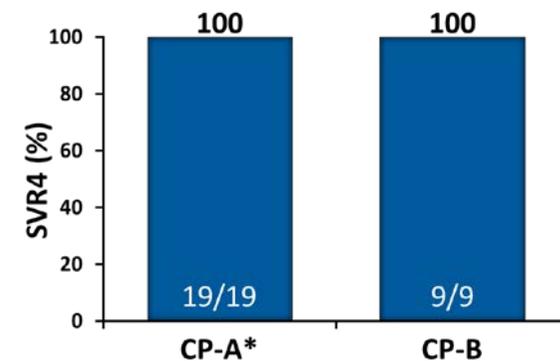
### OPTIMIST-2 (cirrhotic patients, Poster #LP04):

- 83% SVR12 with the use of 12w SMV/SOF in GT1 cirrhotic patients, consistent with published real-world data



### IMPACT (decompensated cirrhotic patients, Poster #LP07):

- 100% SVR4 following 12w simeprevir, sofosbuvir and daclatasvir in GT1 & GT4 decompensated cirrhotic patients
  - A very hard to treat population



CP-A, CP-B: Child Pugh-A or -B  
\* With evidence of portal hypertension

## Data presented at EASL: MIV-802

### MIV-802: A liver-targeted uridine protide (Poster #P0688)

#### Potent antiviral activity of MIV-802 *in vitro*:

- Pangenotypic potency in HCV GTs 1-6 with an EC<sub>50</sub> range of 17-58 nM (sofosbuvir: 48-210 nM)
- Superior antiviral activity compared to sofosbuvir against a panel of clinical isolates (GT 1-4)
  - Significantly improved activity against HCV GT3 compared to sofosbuvir

#### Resistance profile of MIV-802 *in vitro*:

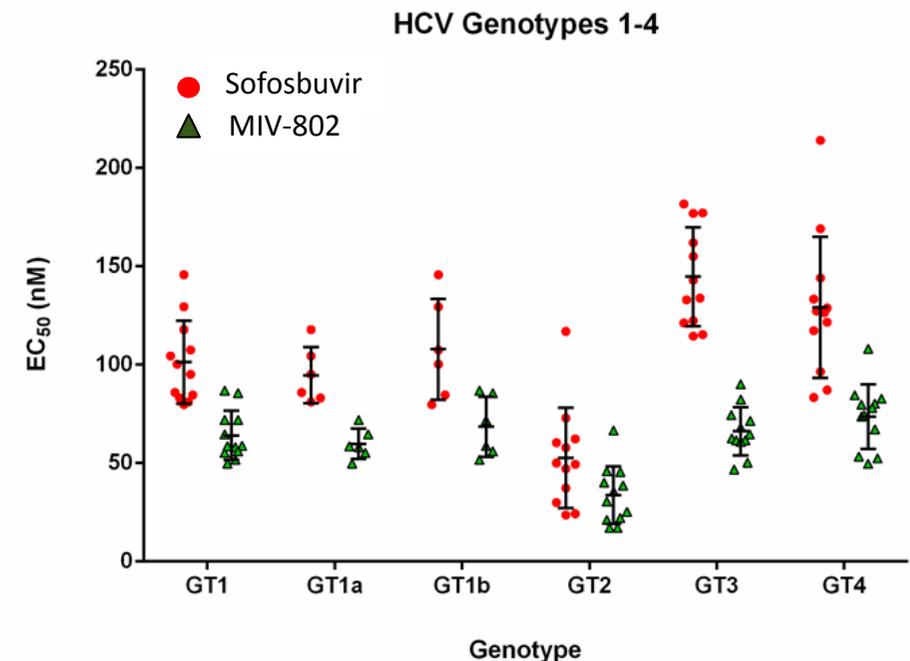
- Similar *in vitro* resistance profile to sofosbuvir, suggesting a high barrier to resistance of MIV-802

#### Safety Profile:

- Excellent safety profile in a very broad range of *in vitro* and *in vivo* toxicity assessments

#### Pharmacokinetics:

- MIV-802 generates high nucleoside triphosphate levels in the liver with a long half-life, supporting a low efficacious dose and once daily dosing in man



**Favourable *in vitro* and *in vivo* ADME profile, combined with its antiviral profile, support combination with other classes of anti HCV drugs**

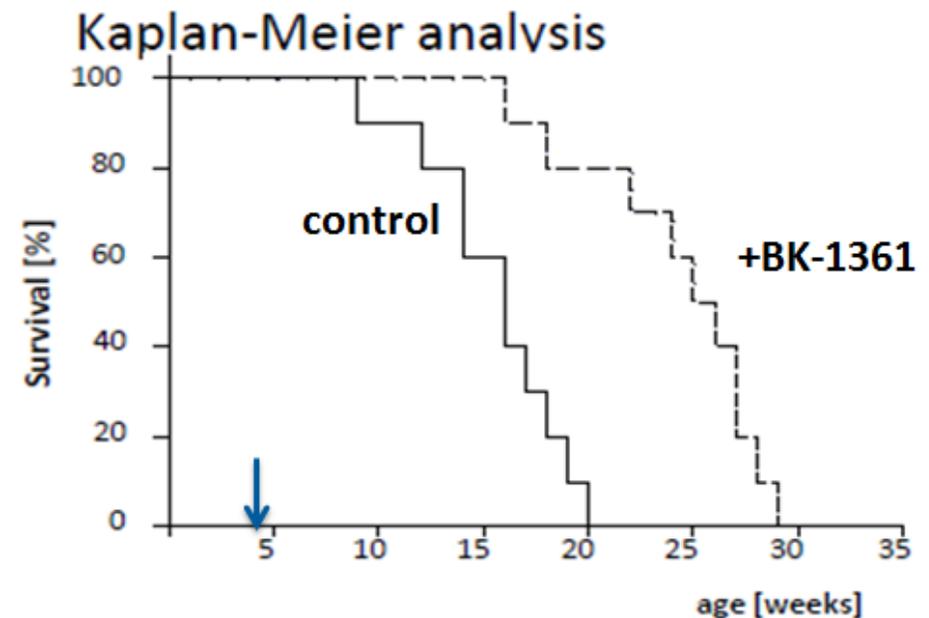
## Pancreatic Cancer – ADAM8 inhibitor

### ADAM8 – Medivir’s first protease inhibitor project in oncology

- Medivir receives an exclusive, global license to research, develop, manufacture and commercialize ADAM8 inhibitor drugs resulting from development
- Technology based around a novel class of selective ADAM8 inhibitors, including the current lead BK-1361
- ADAM8 inhibitors are being developed for pancreatic cancer and other solid tumours

### BK-1361: *in vivo* anti-tumour activity in a disease relevant mouse model of pancreatic cancer

- KPC mice spontaneously develop pancreatic cancer, recapitulating many aspects of human disease
  - Modest improvement in survival with either gemcitabine or gemcitabine/erlotinib
- BK-1361 treatment significantly extends survival, and reduces metastases and tumour infiltration





# Nordic commercial



# Q1 sales revenues:

## Decline vs. previous quarter, but increase vs. Q1 2014

### Q1 sales revenues:

- 86.8 MSEK
- -44% vs. Q4 '14
- +85% vs. Q1 '14

### Innovative Specialty Care Portfolio

- Currently selling Adasuve® and OLYSIO®
- Retaining Nordic rights for out-licensed products
- In-license patent protected growth products



### Q1 sales revenues:

- 34.5 MSEK
- -66% vs. Q4 '14

### Nordic Brands

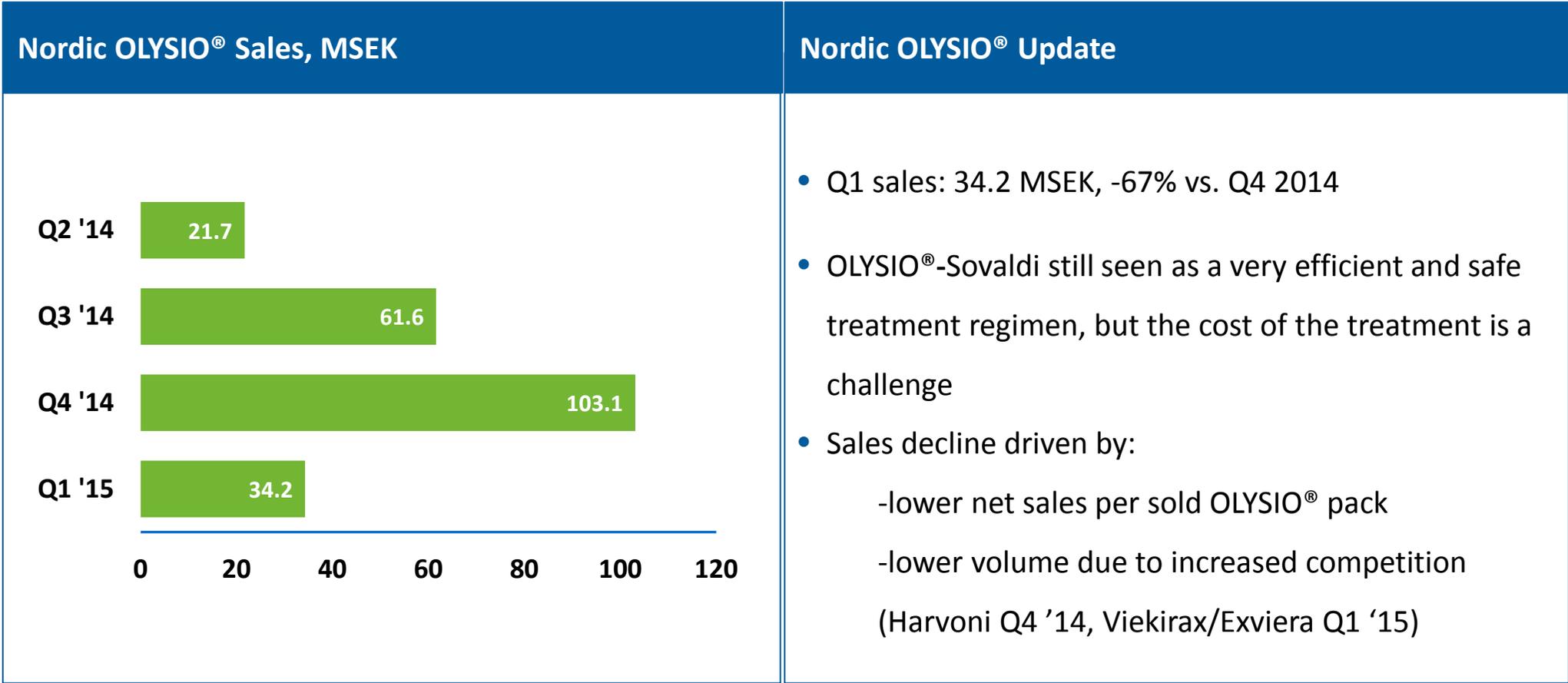
- 14 well established pharmaceuticals
- Stable annual sales revenues, 180 MSEK 2014
- Continuous activities to improve gross margins further



### Q1 sales revenues:

- 52.3 MSEK
- +2% vs. Q4 '14
- +11% vs. Q1 '14

# Significant drop in OLYSIO® sales





# Q&A



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[www.medivir.com](http://www.medivir.com)

**Ticker: MVIR**

**Exchange: OMX / NASDAQ**

For more information please contact

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A blue L-shaped graphic consisting of a vertical line on the right and a horizontal line on the bottom, positioned in the lower-right quadrant of the slide.