

# Medivir

## Q4-2015 Conference call

18 February, 2016

Niklas Prager CEO  
Ola Burmark CFO  
Richard Bethell EVP R&D

The Medivir logo consists of the word "MEDIVIR" in a bold, blue, sans-serif font. It is framed by a blue L-shaped line on the left and bottom, with a horizontal line extending to the right from the bottom of the 'L'.

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

## Q4 Highlights

### Progress of partnered projects

- Janssen's commitment to the HCV market drives continues development
- A phase IIa study to evaluate the effect of simeprevir in combination with odalasvir and AL-335 was started
- The development of the nucleotide polymerase inhibitor, AL-704 (also known as JNJ-54257099) was terminated following completion of phase I clinical studies

### ADAM 8 inhibitor for pancreatic cancer closed down

- Closure of the project following an internal review. The decision was based on data generated during the past six months

### Global Net Sales of OLYSIO® of USD 44m generating a royalty of SEK 31m

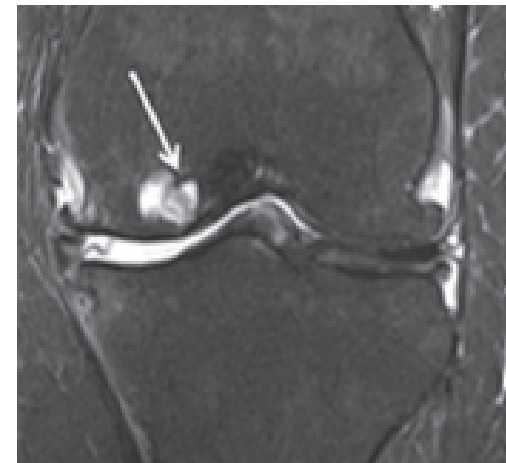
- Nordic Olysio sales reached SEK 2.7m



## Recent changes in our portfolio

### Phase IIa study of MIV-711 in knee osteoarthritis

- The first patients have now been enrolled into a randomized double-blind phase IIa clinical study of the in-house developed cathepsin K inhibitor MIV-711 in patients with moderate knee osteoarthritis (OA)
- The study will enrol 240 patients into 3 arms, each with approximately 80 patients, and compare doses at 100 mg or 200 mg once daily against a placebo
- The key objectives are to assess the effect of six months of treatment on knee joint clinical pain and on knee OA, assessed using magnetic resonance imaging, as well as the safety and tolerability of MIV-711
- Data from the study is on schedule and expected to be available in the third quarter of 2017
- Approximately SEK 140m of Medivir's cash is allocated for this study through 2017, of which approx SEK 25m was spent during 2015
- DMOADs for osteoarthritis represent a very large and attractive market opportunity. The US market alone is estimated to be greater than USD 6 billion annually for a drug that impacts disease progression, even if its use was restricted just to patient populations with moderate osteoarthritis in weight-bearing joints



*Picture modified from: Shah D et al:  
Med J DY Patil Univ 2014;7:160*



## Financial summary

Summary of Group's figures (SEK m)	Q4		Q1-Q4	
	2015	2014	2015	2014
Net turnover	84.7	377.0	657.9	1 767.0
Gross profit	60.7	324.5	548.6	1 593.0
EBITDA	-35.9	214.9	115.0	1 221.9
Operation profit (EBIT)	-44.5	206.5	114.8	1 188.7
Profit/loss before tax	-53.1	204.3	102.0	1 192.7
Profit/loss after tax	-45.2	147.3	75.1	1 132.7
Operating margin, %	-52.5%	54.8%	17.4%	67.3%
Basic earnings per share	-1.56	4.71	2.59	36.24
Diluted earnings per share	-1.54	4.67	2.56	35.90
Net worth per share	53.8	63.4	53.8	63.4
Return on Equity	-3.6%	10.7%	5.9%	84.1%
Cash flow from operating activities	-37.6	507.9	307.4	1 011.9
Liquid assets and ST investments	1 077.9	1 395.6	1 077.9	1 395.6
R&D spending/total opex, %	66.9%	64.7%	64.2%	60.8%

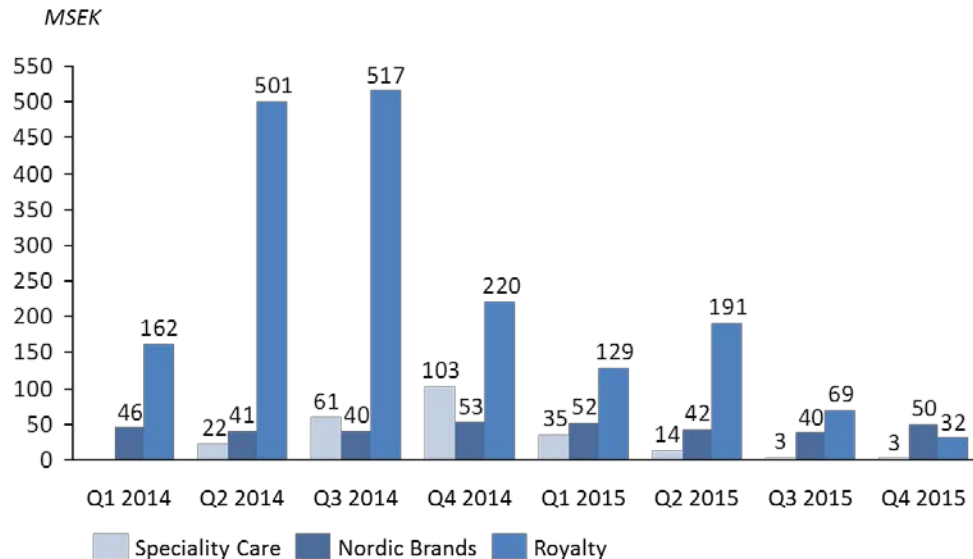
### Q4 Net turnover

- Net turnover totalled SEK 84.7m (377.0m), of which SEK 31.1m (220.1m) comprised fourth quarter royalties for simeprevir.
- Revenue from Medivir's own pharmaceutical sales totalled SEK 53.1m (156.6m), of which SEK 2.7m (103.1m) derived from sales of OLYSIO® and SEK 50.4m (53.5m) from sales of other pharmaceuticals.

### Q4 Key figures

- Operational profit/loss (EBIT) was -44.5m (214.9)
- The loss after tax was SEK -45.2m (147.3m)
- Basic and diluted earnings per share totalled SEK -1.56 (4.71) and SEK -1.54 (4.67), respectively
- The cash flow from operating activities amounted to SEK -37.6m (507.9m)

## Breakdown of net turnover



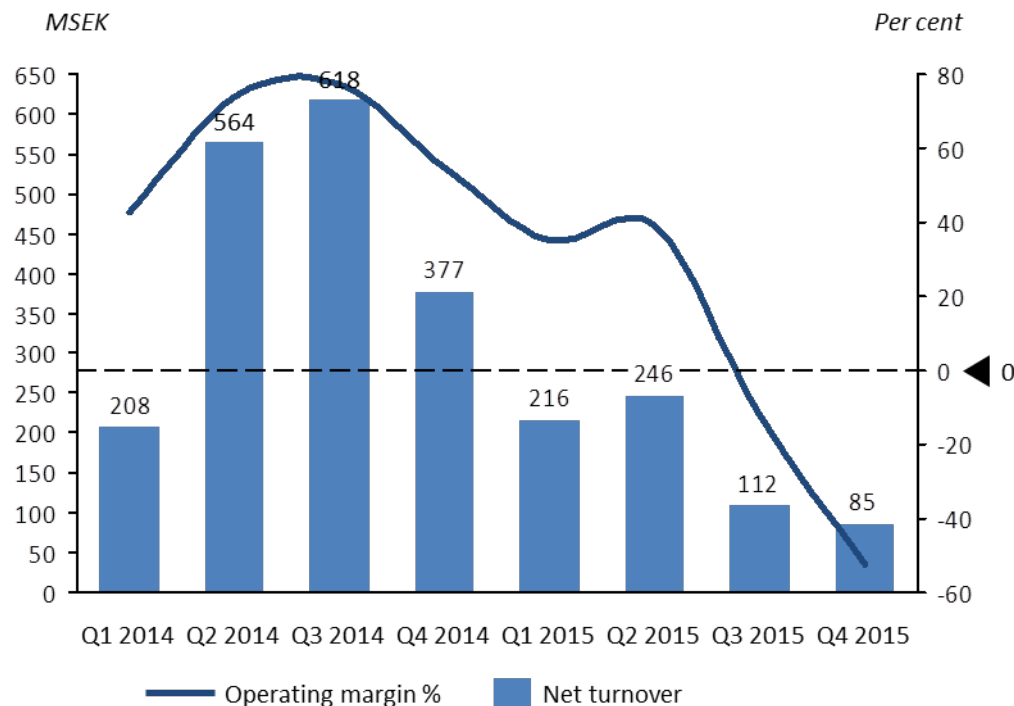
### Royalty income

- Royalty income totalled SEK 31.6m. In total a decline by SEK 188.8m
- Janssen's global net sales of simeprevir amounted to USD 44m, whereof US net sales was USD -1.0m and RoW USD 45m

### Pharmaceutical sales

- Nordic net sales totalled SEK 53.1 million, where SEK 2.7 million derived from sales of OLYSIO®
- Nordic Brands sales of SEK 50.3 million represents a decrease of 5.8% vs. same quarter last year, but an increase of 2% year-on-year. Seasonal variations are explained by the product Mollipect, which reach its sales peak when the flu season starts

# Operating income and margin



## Gross Profit

- The gross profit amounted to SEK 60.7m, corresponding to a decrease of SEK 263.8m and equating a gross margin of 72% (90%), explained by a relative shift in revenue from royalty to pharmaceutical sales

## Operating Expenses

- Selling expenses decreased by SEK 10.6m compared to the same quarter last year
- Administrative expenses decreased by SEK 4.6m
- Research and development costs decreased by SEK 6.0m, as a result of lower project-specific costs, which are determined by the different phases of the respective projects. In addition SEK 4.3m in external costs were recovered following the termination of the ADAM8 project
- Other operating income/expenses are negative and increased by SEK -8.3m, largely due to exchange rate effects
- Overall, operating expenses totaled SEK -105.1m (-117.9 m), corresponding to a cost reduction of SEK 12.8m

## Operating Loss

- Operating loss totaled SEK -44.5m (206.5m), corresponding to a decrease of SEK 251.0m

# Research & Development

# Pipeline progress

## MIV-711

Regulatory approval to start a phase IIa study in patients with moderate knee osteoarthritis was obtained. Patient recruitment in Germany was initiated early in the first quarter of 2016

## MIV-802

Preclinical safety testing to enable phase I clinical studies has been completed successfully. Partnership discussions are currently in progress

## Hepatitis C

Janssen started a phase IIa clinical trial to evaluate the combination of simeprevir, the NS5A inhibitor odalasvir and the nucleotide analogue AL-335

Disease area/Project	Discovery	Preclinical	Phase I	Phase II
<b>Osteoarthritis</b> MIV-711, cathepsin K inhibitor				
<b>Hepatitis C</b> MIV-802, nucleotide NS5B polymerase inhibitor				
<b>RSV-infection</b> Fusion protein inhibitor				
<b>Hepatocellular Carcinoma</b> Nucleotide DNA polymerase inhibitor				
<b>Hepatitis C</b> 3DAA FDC AL-335+odasvir+simeprevir*				
<b>HIV-infection</b> protease inhibitor*				

\* Partner Janssen





# Osteoarthritis

## MIV-711



# Osteoarthritis is a leading cause of chronic disability

## Overview

- **Progressive disorder** characterized by joint degeneration, pain and loss of function
- **Most prevalent joint disease;** up to 40% over 65 suffering from knee or hip OA
- **Current treatments are insufficient** focusing on symptom relief e.g. physiotherapeutic exercise, intra-articular corticosteroids or hyaluronic acid and analgesics/anti-inflammatory agents (NSAIDs) in connection with life-style changes
- **No effective and safe disease modifying osteoarthritic drugs** (DMOADs) are available

## Key unmet needs

### Suspend disease progression and relieve pain

- Prevent degradation of subchondral bone, recently recognized as a key target for OA, and cartilage
- Prevent the pain associated with the disease

**A disease-modifying OA drug (DMOAD) meeting these unmet needs has great market potential based on large and growing patient population**

# A potent – selective - once daily cathepsin K inhibitor

**Excessive cartilage degradation *and* bone resorption are key features of osteoarthritis**

**Cathepsin K inhibition is expected to have joint protective effects in human OA**

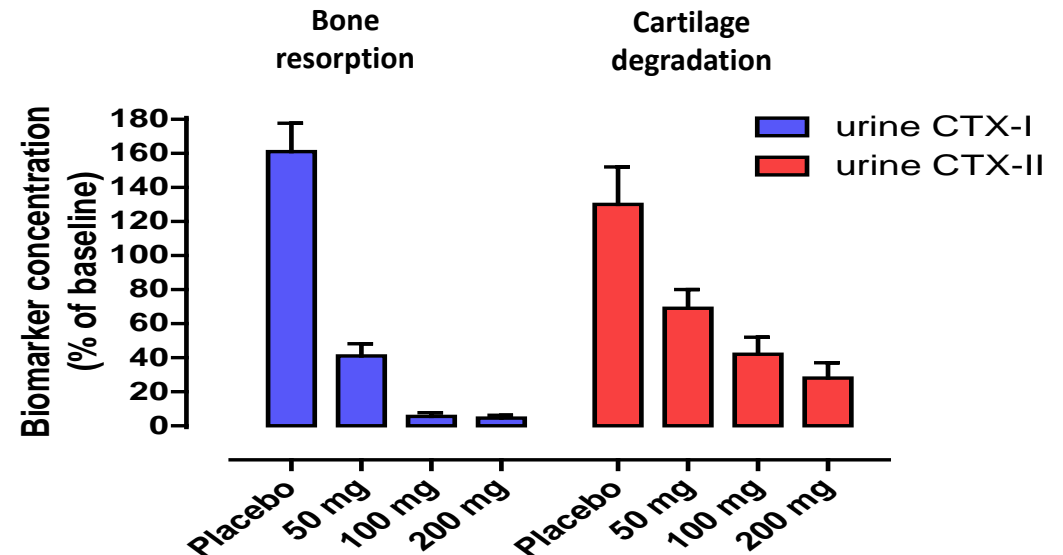
- Expressed in osteoclasts and chondrocytes and degrades both bone and cartilage collagen
- Bone-acting agents have demonstrated beneficial effects on human OA disease progression, pain and function (e.g. SEKOIA study on strontium ranelate)

**Pre-clinical data with MIV-711 in OA disease models:**

- Demonstrated joint protective effects on both bone and cartilage in preclinical OA models
- Paralleled by reduced biomarkers of cartilage degradation and bone resorption (up to 85%)

**Clinical phase I data:**

- Generally safe and well tolerated up to 28 days
- Similar dose-dependent decrease in biomarkers of cartilage degradation and bone resorption:



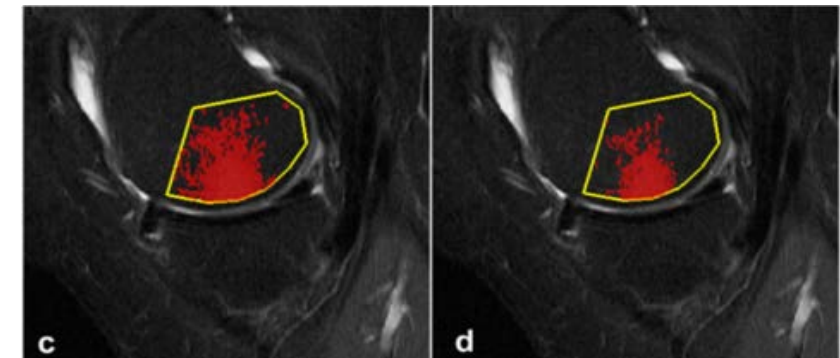
# New methodologies facilitate development of disease modifiers

## Improved magnetic resonance imaging technologies will shorten PoC studies

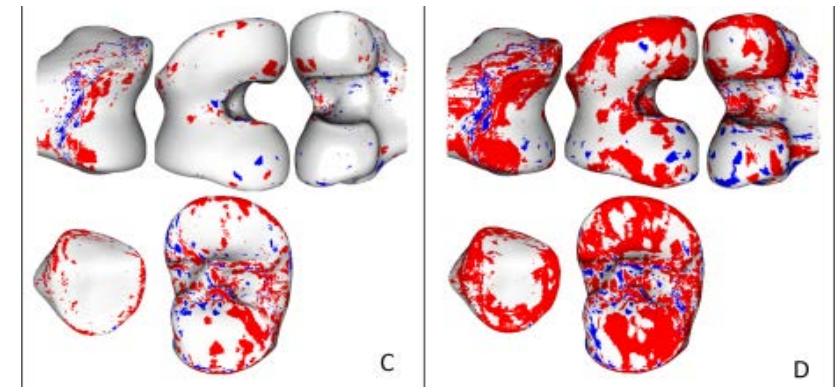
- Readily quantifies complex structures and takes 3-D surfaces into account
- Detects and quantifies soft tissue components of joint structures
- Greatly enhances sensitivity and reproducibility which facilitates new approaches such as modelling for better prediction



Picture modified from: Link TM et al., Radiology.2003 Feb;226(2):373-81



Picture modified from: Nielsen FK et al. BMC Musculoskeletal Disorders 2014, 15:447



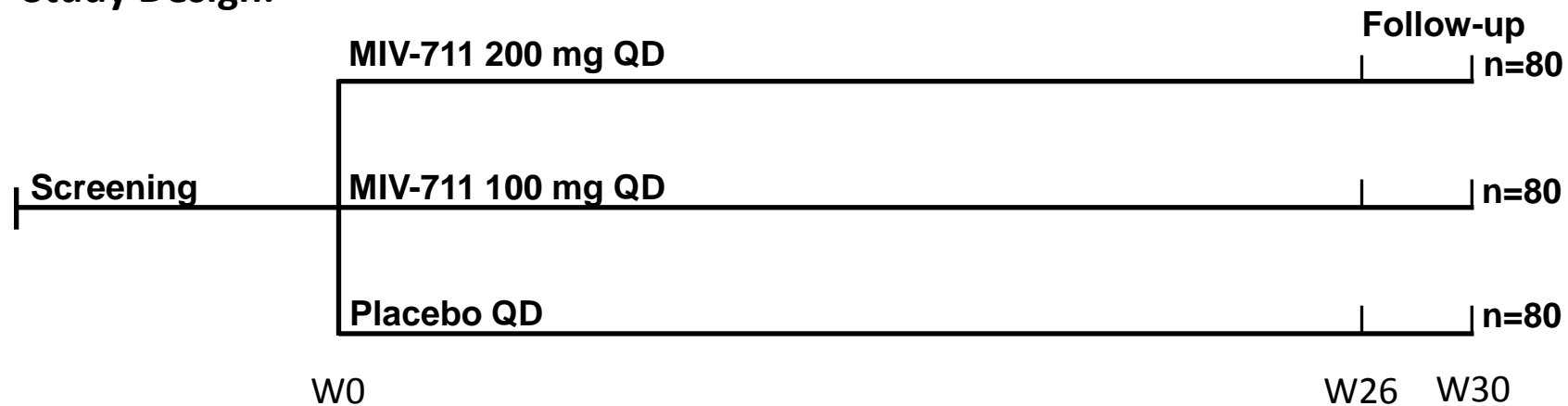
Picture modified from: Bowes MA, et al. Ann Rheum Dis 2015;74:519-525

## Phase IIa study design

### MIV-711-201:

A Randomized, Double-blind Placebo-controlled Phase IIa Study to Evaluate Efficacy, Safety and Tolerability of MIV-711 in Knee Joint Osteoarthritis (EudraCT Number: 2015-003230-26)

#### Study Design:



**Population:** Patient with moderate knee OA and chronic pain

**Countries:** Six European countries

**First Patient in:** Q1 2016

**Expected Final Data:** Q3 2017



# Q&A

A blue L-shaped graphic is positioned on the left side of the slide, consisting of a vertical line and a horizontal line meeting at a right angle.

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

**Ticker: MVIR**

**Exchange: OMX / NASDAQ**

For more information please contact

Ola Burmark, CFO

([ola.burmark@medivir.com](mailto:ola.burmark@medivir.com))

A blue L-shaped graphic is positioned on the right side of the slide, consisting of a vertical line and a horizontal line meeting at a right angle.