

# Q2-2014 Conference Call 21 August 2014

## Presenting team

**Maris Hartmanis, President and CEO**

**Henrik Krook, EVP Commercial**

**Richard Bethell, EVP Discovery Research**

**Rein Piir, EVP Corporate Affairs & IR**

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

**MEDIVIR**

A collaborative and agile  
pharmaceutical company with  
R&D focused on infectious  
diseases and a leading position  
in hepatitis C



**Reflections on second quarter 2014  
Commercial  
Maris Hartmanis, CEO**

## Our pharmaceuticals

### Performance

- Medivir's pharmaceutical portfolio comprises 17 prescription pharmaceuticals marketed in the Nordic region. Going forward we will continue to focus on specialty pharmaceuticals in a growth phase.
- In the second quarter, our pharmaceutical sales showed an increase of 22,2 MSEK, or ~55% compared to the same quarter in 2013. The increase was primarily due to our market introduction of simeprevir (Olysio).

### New product launches

- Simeprevir (Olysio) was launched in Sweden already in late May and by the end of the period it was available in all Nordic countries.
- Adasuve, a new specialty pharmaceutical for the treatment of agitation associated with bipolar disorder and schizophrenia was launched in April, along with the re-launch of Suscard, an established pharmaceutical for the treatment of angina pectoris.

### Sales and revenues

- The pharmaceutical portfolio generated sales of 62,9 MSEK, of which simeprevir made up 21,7 MSEK.
- For the second quarter we received 500,7 MSEK in royalties from our partner J&J.

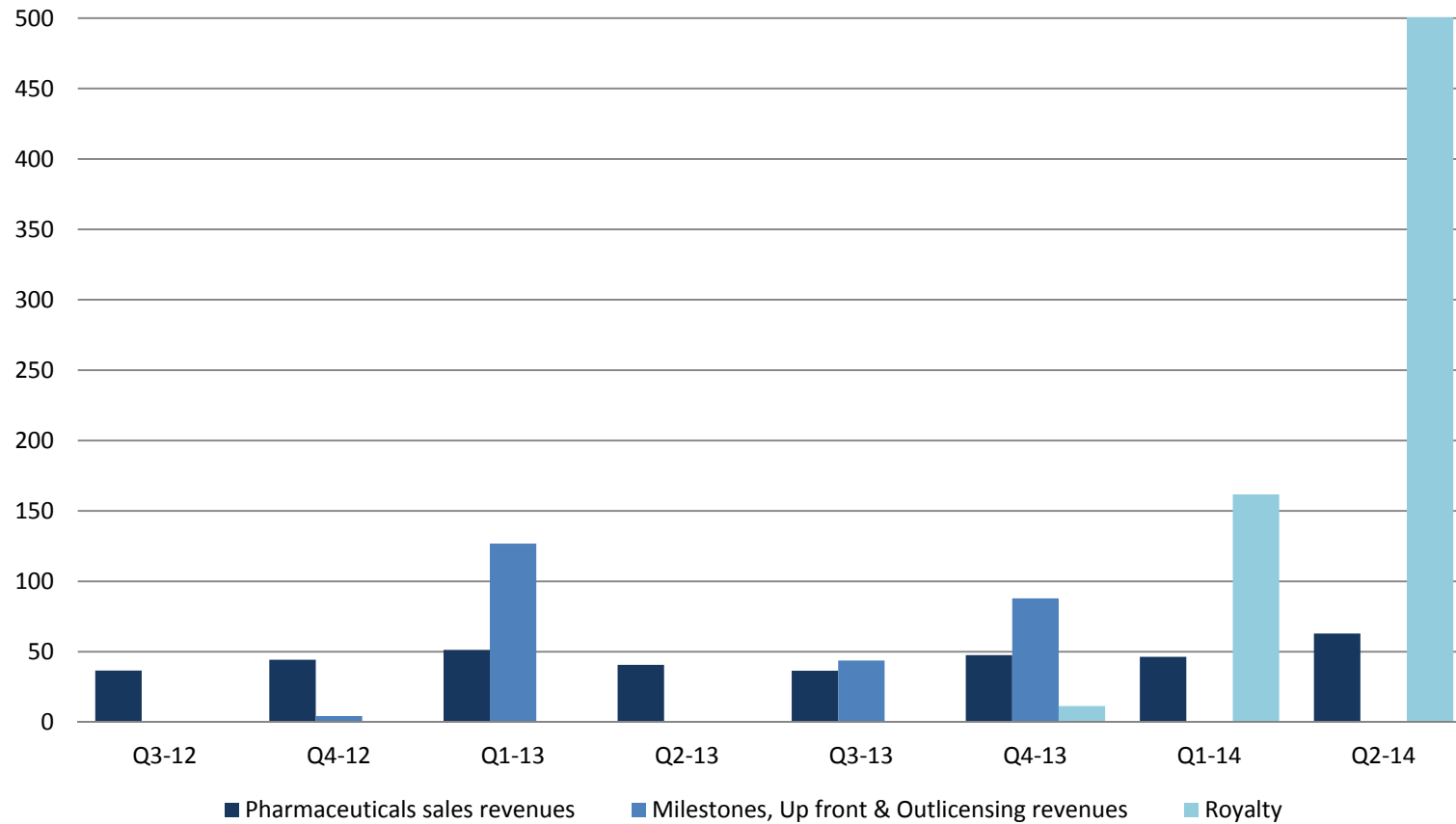
# Consolidated income statement

Summary of the Group's figures, continuing operations (SEK m)	Q2		Q1-Q2		Full year
	2014	2013	2014	2013	2013
Net turnover	564.0	40.7	772.2	218.8	446.1
Gross profit	518.8	23.5	700.9	183.8	374.3
Operating profit before depreciation and amortisation (EBITDA)	424.4	-46.9	521.2	43.6	76.4
Operating profit (EBIT)	416.2	-62.0	504.9	14.7	25.2
Profit/loss before tax	418.4	-62.1	508.7	14.5	27.7
Profit/loss after tax	327.8	-63.7	611.7	7.5	16.0

## Net turnover breakdown

Breakdown of net turnover (SEK m)	Q2		Q1-Q2		Full year
	2014	2013	2014	2013	2013
Outlicensing and partnership agreements					
Non-recurrent payments	-	-	-	126.8	258.5
Pharmaceutical sales	62.9	40.7	109.2	92	176.1
Royalties	501.1	-	662.8	-	11.5
<b>Total</b>	<b>564.0</b>	<b>40.7</b>	<b>772.0</b>	218.8	446.1

# Net turnover continuing operations per quarter, MSEK



## Simeprevir on the global market



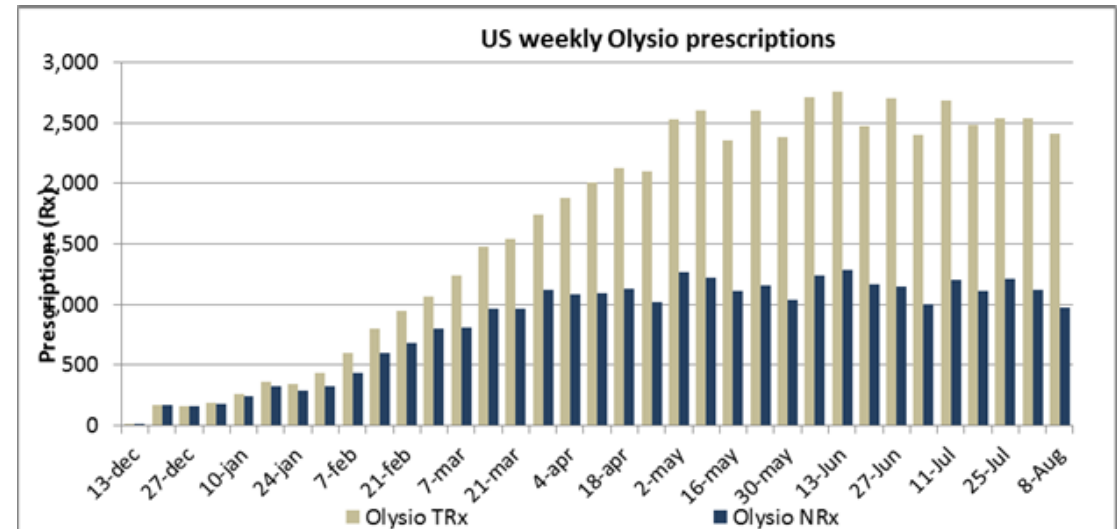
- ✓ Japan (SOVRIAD™)
- ✓ Canada (GALEXOS™)
- ✓ USA (OLYSIO™)\*
- ✓ Russia (SOVRIAD™)
- ✓ EU (OLYSIO™)
- ✓ Mexico (OLYSIO™)
- ✓ Australia (OLYSIO™)



\* A supplemental New Drug Application has been submitted to the U.S. FDA for simeprevir in combination with sofosbuvir based on the data from the COSMOS trial

# Simeprevir

- Simeprevir sales have grown rapidly. Simeprevir is part of the only IFN-free regimen currently in use, based on recent guidelines from January 2014 and has ~27% market share in the US.
- J&J's global second quarter net sales of simeprevir were 831,8 MUSD, of which 725,4 MUSD were in the US.
- Medivir's royalties based on these sales were 500,7 MSEK (54,4 MEUR) for the second quarter.



- In May, Simeprevir was approved in the EU for the treatment of adults with hepatitis C genotype 1 and 4 infection and is now also approved in Mexico and Australia.
- Phase II COSMOS study results were published in The Lancet on the World Hepatitis Day in July.
- FDA granted Priority Review for a supplementary New Drug Application for simeprevir (OLYSIO®) in combination with sofosbuvir, filed by Janssen in May.
- Two phase III studies, OPTIMIST 1 and 2, evaluating treatment of hepatitis C-infected patients with simeprevir and sofosbuvir, are well under way.
- The launch of simeprevir (OLYSIO®) in the Nordic territories began in late May and treatment of patients had been initiated in all Nordic countries by the end of June.





**Nordic Commercial  
Q2 2014**

**Henrik Krook, EVP Commercial**

# Medivir Commercial: A Nordic core plus country teams to maximize synergies & catch the full potential in each country

## NORDIC TEAM

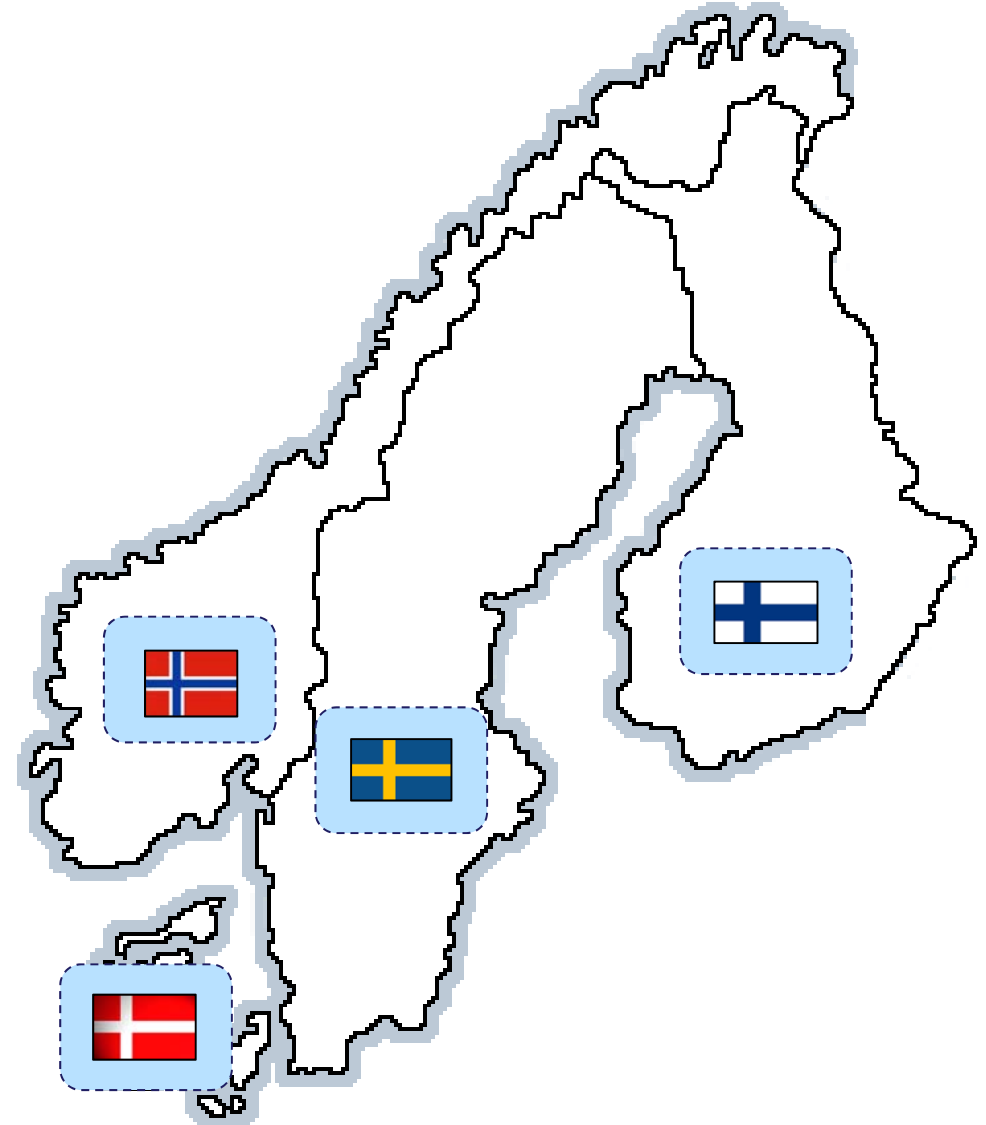
Generating strategy and leading/supporting the country teams to maximize the output of customer activities

- Marketing & Sales
- Medical Affairs
- Market Access & Public Affairs
- Support functions

## COUNTRY TEAMS

For the daily customer activities

- Market Leads
- Key Account Managers
- Medical Affairs Managers



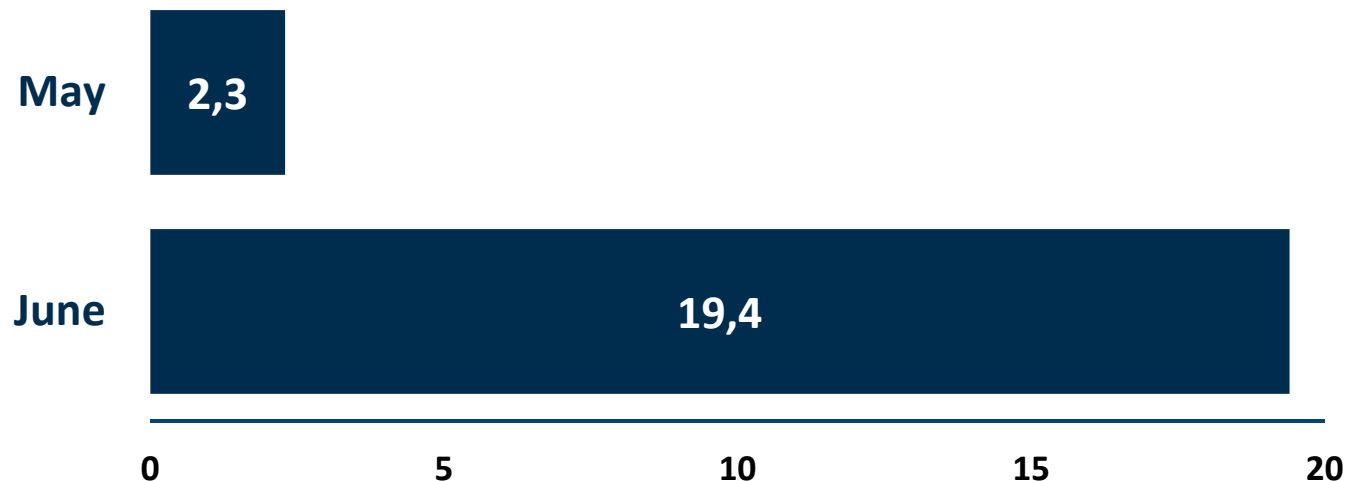
# OLYSIO launch update

## -Quick uptake and positive perception across the Nordics



- Country teams operational in NO, SE, DK and FI from Q1 to prepare successful launches
- The COSMOS data perceived as being very positive by customers
- Compassionate use experience before launch in all countries
- Quick national approval processes
- SE launch late May followed by DK, FI and NO in June
- Positive media exposure related to Medivir, Olysio and the new HCV cure opportunity
- Supporting treatment guidelines already available in SE and DK

### Nordic OLYSIO Sales, MSEK





**Reflections on second quarter 2014  
R&D  
Maris Hartmanis, CEO**

# Our R&D programs

## Our internal pipeline was strengthened during the quarter



- Phase I data have previously been reported for MIV-711, a cathepsin K inhibitor in clinical development for osteoarthritis (OA). Completion of new preclinical studies provide support of efficacy data for an OA indication. To facilitate new partnerships or joint ventures, a decision was made to initiate long term toxicology studies (6 month), which will be completed by mid 2015.
- MIV-247 – a cathepsin S inhibitor for neuropathic pain is currently in preclinical development, moving towards clinical phase I studies, expected to commence during H1-2015.
- Our nucleotide HCV inhibitor is presently being evaluated in extensive preclinical safety studies.
- A preclinical RSV Fusion Inhibitor Project was recently in-licensed from Boehringer Ingelheim. It constitutes a logical step to strengthen our presence in infectious diseases and to broaden our pipeline.



## **RSV Fusion Inhibitor Project**

**Richard Bethell, EVP Discovery Research**

## Background: RSV-associated disease

- RSV causes seasonal outbreaks (Nov-March) of upper and lower respiratory tract infections of children and adults.
- Diseases range from mild respiratory illnesses to life-threatening bronchiolitis and pneumonia.
- The virus is highly contagious and transmitted by direct contact with infected persons.
- RSV causes repeated infections throughout life
  - Immune response results in virus clearance in the immunocompetent...
  - ... but immunity wanes quickly, so people remain susceptible to infection throughout their lifetime.
  - The disease is most serious in those with an inadequate recall response to the virus.
- RSV is therefore especially dangerous in:
  - Infants, especially premature babies with lung/heart problems, or certain other chronic conditions.
  - The elderly, especially those with cardiovascular morbidities.
  - Immunocompromised, e.g. as a result of stem cell transplantation.

## Current treatment options are very limited

### Palivizumab

- RSV F protein-specific mAb for immunoprophylaxis in high-risk infants only.
- In two Phase III clinical trials in the pediatric population, palivizumab reduced the risk of hospitalization due to RSV infection by 55% and 45% compared to placebo.
- Generally safe, but hypersensitivity can occur.
- Administered by IM injection once per month during RSV season (3-5 months).
- Dosage 15mg/kg once monthly; US price is ca. \$1000/50mg vial (source: Minnesota Department of Health Services).

### Ribavirin

- Only antiviral treatment licensed - for severe RSV disease in infants only.
- Questionable risk versus benefit profile and requires specialist administration in hospital setting only.
- Side effects can be sudden and severe, e.g. bronchospasm.
- Administered by inhalation for 12-18 hours per day for 3-7 days; highly complex!
- Treatment course costs up to \$14,000 per child.

Current drugs have very limited indications and are reserved only for the highest risk patients



## Strategic Rationale for the transaction with Boehringer Ingelheim

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- RSV fusion inhibitors have been shown to have antiviral activity in early clinical studies.
- The project enables Medivir to exploit its proven strengths in antiviral drug discovery and early development.
- In-licensing of the Boehringer Ingelheim fusion inhibitor program represented a rapid and cost-effective opportunity to acquire a LO phase project into the R&D pipeline.
  - Medivir's strategic intent is to enhance its R&D pipeline with high-value, commercial opportunities.

**Q / A**

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

Ticker: MVIR

Exchange: OMX / NASDAQ

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