Medivir

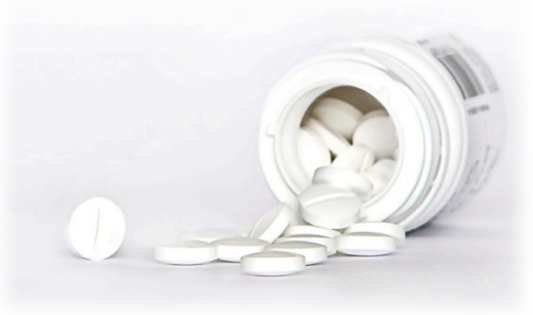
*A collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C*

**Dr. Maris Hartmanis, CEO**

**Rodman Renshaw Health Care Conference**
**New York, September 2012**

# Medivir - the emerging pharma

- **Spinout from AstraZeneca's** antiviral research unit, currently 170 employees
- Research driven pharmaceutical company **focused on infectious disease,** with a strong track record in **partnerships as part of the business model**
- World leading expertise in polymerase and protease drug targets – **strong pipeline** of innovative infectious disease drugs
- First in-house developed product on the market, a **cold sore product with unique profile**
- **Strong position in HCV drug development**, four programs including all three validated target classes, two in-house driven.
- Simeprevir (TMC435) in partnership with Janssen is considered as the best in class PI, **phase III results expected at year end**
- **Fifteen marketed products in the Nordics,** generating annual sales of ~85 MUSD with an EBITDA of ~16MUSD
- **Strong financial position**
- **Broad institutional shareholder base,** 30% outside Nordic region



# Financials in a nutshell

## *Summary H1, 2012*

| (MUSD) | 2012 April - June | 2011 April - June | 2012 January - June | 2011 January - June | 2011 January - December |
|---|---|---|---|---|---|
| **Net sales** | 22.3 | 48.9 | 42.9 | 66.6 | 105.9 |
| **Gross profit/ loss** | 5.3 | 42.8 | 11.5 | 61.1 | 68.9 |
| **EBITDA** | -6.4 | 25.5 | -10.9 | 33.3 | 20.3 |
| **EBIT** | - 7.8 | 25.0 | -13.5 | 32.7 | 16.8 |
| **Profit/ loss before tax** | -7.9 | 24.8 | -13.5 | 32.7 | 16.7 |
| **Profit/ loss after tax** | - 9.2 | 25.2 | - 14.8 | 33.1 | 17.1 |

## *Net sales split, quarterly trend*

| (MUSD) | 2012 April - June | 2012 January - March | 2011 October - December | 2011 July - September |
|---|---|---|---|---|
| **Pharma-ceutical sales** | **5.8** | **7.0** | **7.1** | **7.1** |
| **Parallel imports** | **16.3** | **13.8** | **12.7** | **11.2** |
| **Total** | **22.1** | **20.7** | **19.8** | **18.4** |

# Strategic direction and ongoing activities

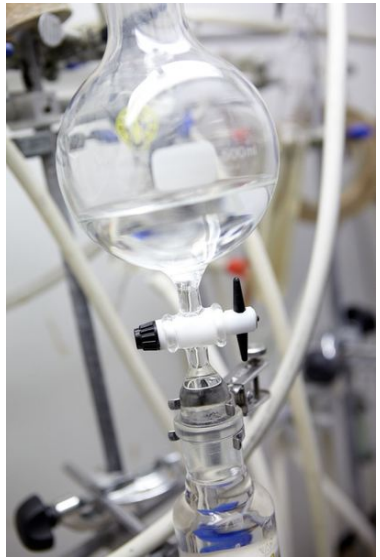
**R&D Operations**

**Further development of R&D platform**
- Continued focus in HCV and on infectious diseases
- Evaluate new therapeutic areas based on proteases and polymerases

**Create new partnership/collaborations**
- Continue to build new partnerships

**Commercial Operations**

**Expand commercially**
- Add new products for the Nordic market
- Fine-tune organisation for Nordic launch of simeprevir
- Further development of business and therapy scope



# Medivir in a 5 year perspective

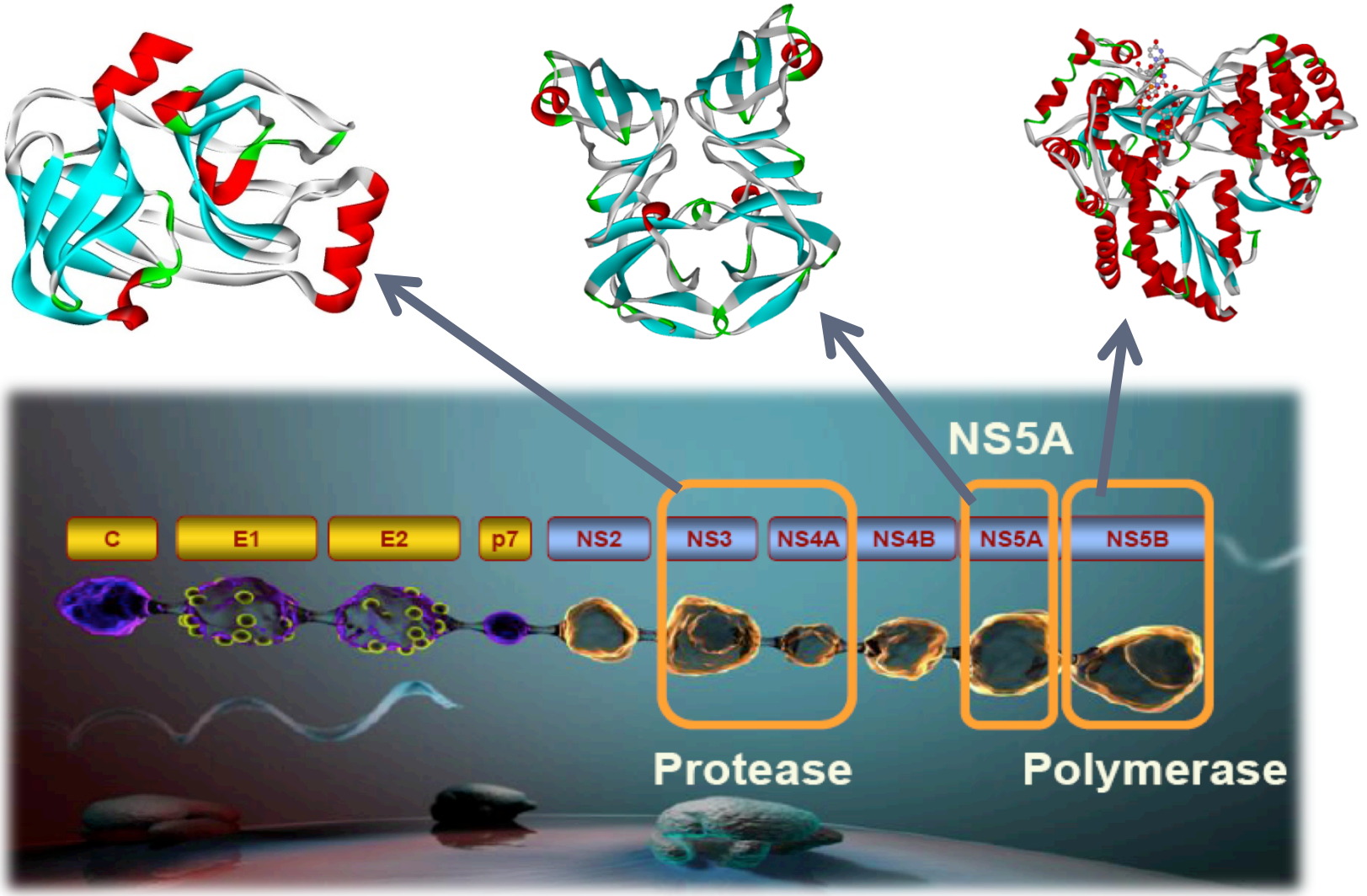
## Structure

- Partner of choice for both pharmaceuticals and development programs
- Continued commitment on targets in infectious diseases
- Adressing of new therapeutic areas based on core competence
- Aggressive expansion of product portfolio, including simeprevir and other in-house developed pharmaceuticals
- Broader, risk balanced, R&D pipeline

## External perspective

- Top ranked as a listed company
- Profitable and fast growing Nordic pharmaceutical company

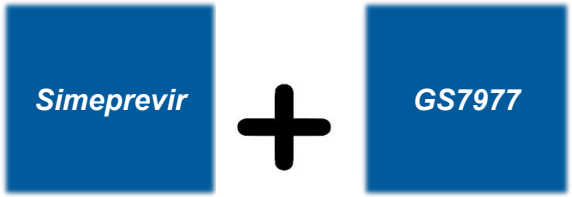
# A broad development approach in HCV



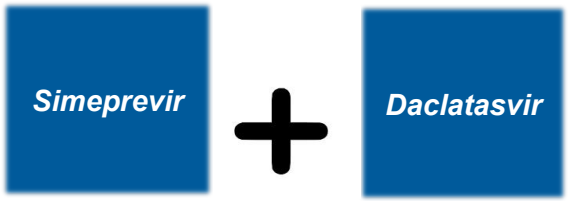
# Many ongoing activities in HCV

| | | | Preclinical phase | | Clinical phase | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Project | Therapy area | Partner | Research | Development | Phase I | Phase IIa | Phase IIb | Phase III | Market |
| Simeprevir (TMC435) | Hepatitis C | Janssen / J&J | Triple combination | | | | | | |
| HCV POL Nucleotide | Hepatitis C | Janssen / J&J | | | | | | | |
| Nucleotide inhibitor | Hepatitis C | In-house | | | | | | | |
| N5A inhibitor | Hepatitis C | In-house | | | | | | | |

## Simeprevir (TMC435) in two combination trials




***Janssen/Gilead***




***Janssen/BMS***

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# Simeprevir (TMC435), clinical development programs in HCV G1&4 infected patients

**Regulatory filings for triple combination in first half of 2013 in US, EU & Japan**

## Phase III

- **QUEST 1 and 2** treatment-naïve patients; n=375 x 2
- **PROMISE (C3007)** prior relapsed patients; n=375
- **Japan phase III program** naïve and experienced patients; n=417 (four studies)
- ***C3001*** prior partial and null responders vs telepravir; n=744
- **C3011** naïve and experienced patients; n=100 open label in G4 patients

## Ongoing IFN free combination studies

- **simeprevir and GS-7977,** a nucleotide NS5B inhibitor.

  12/24 weeks, +/- ribavirin, null responders; +/- cirrhotics, n=180

- **simeprevir and daclatasvir** (BMS-790052), an NS5A inhibitor.

  12/24 weeks, +/- ribavirin in G1 naive and null responder patients

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- **For additional information, please see** www.clinicaltrials.gov

# Simeprevir (TMC435) - triple combination summary

## Potent → low dose (150mg)

- One tablet once daily
- 12 week duration

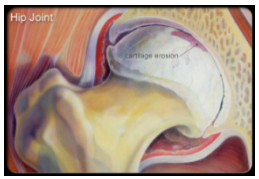
## Three large phase IIb trials demonstrating high efficacy in

- G1a and G1b
- Treatment naïve and treatment experienced
- Cirrhotic and non-cirrhotic patients
- Regardless of IP-10 level or *IL28B* genotype
- ASPIRE study demonstrated a best-in-class triple combination in all patient groups, including the difficult to treat patients

## Safe and well tolerated

- Close to 1800 patients have completed simeprevir treatment, showing it to be safe and well tolerated - important for compliance once on the market
- Long patent life, IP extending to 2026/2028

# In-house developed cathepsin inhibitors




## Cathepsin K inhibitor

### Disease

Osteoporosis, osteoarthritis and metastatic bone disease

### Mechanism of action

Cathepsin K inhibition leads to:

- Reduced bone resorption and cartilage breakdown
- Maintained bone formation in contrast to other anti-resorptives

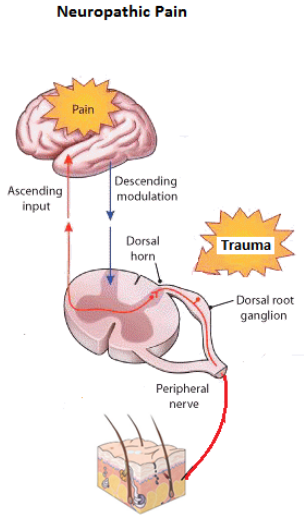
### MIV-711: Phase I ongoing

- Adaptive, placebo controlled, double-blind study in healthy volunteers incl. post meno-pausal women
- Ascending single and multiple once daily dosing
- Biomarkers for bone and cartilage turnover
- Phase I data available around year end

## Cathepsin S inhibitor

### Disease

Neuropathic pain and autoimmune disease




### Mechanism of action

**Neuropathic pain**

- Inhibition of Cathepsin S prevents inflammatory damage to the sensory system in the spinal cord by blocking Fractalkine activation

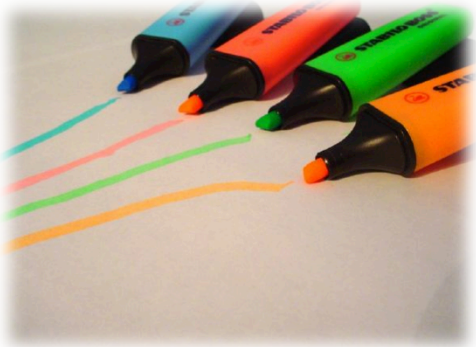
**Autoimmune disease**

- Crucial role in MHC Class II antigen presentation, which is key to establishing and perpetuating an immune response disease

### Next milestone

CD-selection around year end

# Expected key news flow highlights



- ✓ Q2-12 Full simeprevir results presented at EASL from the ASPIRE trial
- ✓ Q2-12 Janssen creates new division to launch simeprevir in EMEA
- ✓ Q2-12 Start of DAA phase II combination study with simeprevir and daclatasvir
- ✓ Q3-12 Start of Phase Ib clinical trials with MIV-711, a cathepsin K inhibitor
- Q4-12 Partial EoT-data from Cohort 1 with simeprevir and GS7977 phase II study
- Q4-12 Potential CD selection in Cathepsin S (neuropathic pain) program
- Q4-12 Results from the phase I-study with MIV-711 (bone related disorders)
- Q4-12 Potential CD selection in our internal Nucleotide NS5B inhibitor program
- Q1-13 Top line results from phase III trials with simeprevir (Quest 1+2 and Promise)
- Q1-13 Goal to start phase 1 trials with Medivir/Janssen nucleotide NS5B-inhibitor
- Q2-13 EoT-data from the phase II combination study with simeprevir and daclatasvir
- Q2-13 Filing of simeprevir in US/EU and Japan
- Q2-13 SVR data from Cohort 1 and partial EoT data from Cohort 2 with simeprevir and GS7977 phase II study
- H1-13 Step two in GSK launch strategy for Xerclear® (ZoviDuo), launch in major European OTC markets

# Value proposition

## Interesting pipeline assets

- Collaborative and innovative pharmaceutical company with an R&D focus on infectious diseases
- World class expertise in polymerase and protease drug targets

## Strong position in HCV drug development – both partnered and internal programs

- The front runner, simeprevir, is considered “best in class PI” in HCV, regulatory filing ~H1 2013
- Simeprevir has an attractive profile and will have an important role in future interferon-free combination treatments
- Our in-house programs will offer new opportunities

BioPhausia – a Medivir company

## Integrated company - commercial presence in the Nordics

- Strong brand names, annual sales ~85 MUSD
- New pharmaceuticals will be added
- Commercial platform for the launch of simeprevir in the Nordics

www.medivir.com

**Ticker: MVIR**
**Exchange: OMX / NASDAQ**

**For more info please contact**
**Rein Piir EVP Corporate Affairs & IR**
**(Rein.Piir@Medivir.com)**