



# Medivir

*A research based specialty pharmaceutical company focused on  
infectious diseases*

**Carnegie Nordic Healthcare Seminar, March 21-22, 2012**

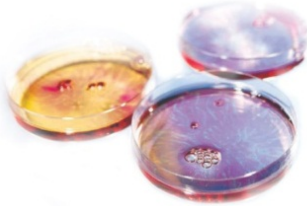
**Maris Hartmanis, President & CEO**

# Medivir today



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

- The front runner, TMC435, considered “best in class PI” hepatitis C drug
- TMC 435: Global phase III trials fully recruited in G1 patients. Expected regulatory filing in first half of 2013
- Interferon-free combination trials - next major development step



## Strong pipeline in R&D

- Strong pipeline of innovative infectious disease drugs
- World class expertise in polymerase and protease drug targets



## Integrated company - commercial presence and platform in the Nordics

- Strong brand names, annual sales ~500 MSEK with an EBITDA of ~100 MSEK
- Commercial platform for TMC435 launch in the Nordics



## European OTC launch by GSK initiated

- Cold sore drug with an unique, differentiated profile and blue-chip marketing partners. First in-house developed product on the market.

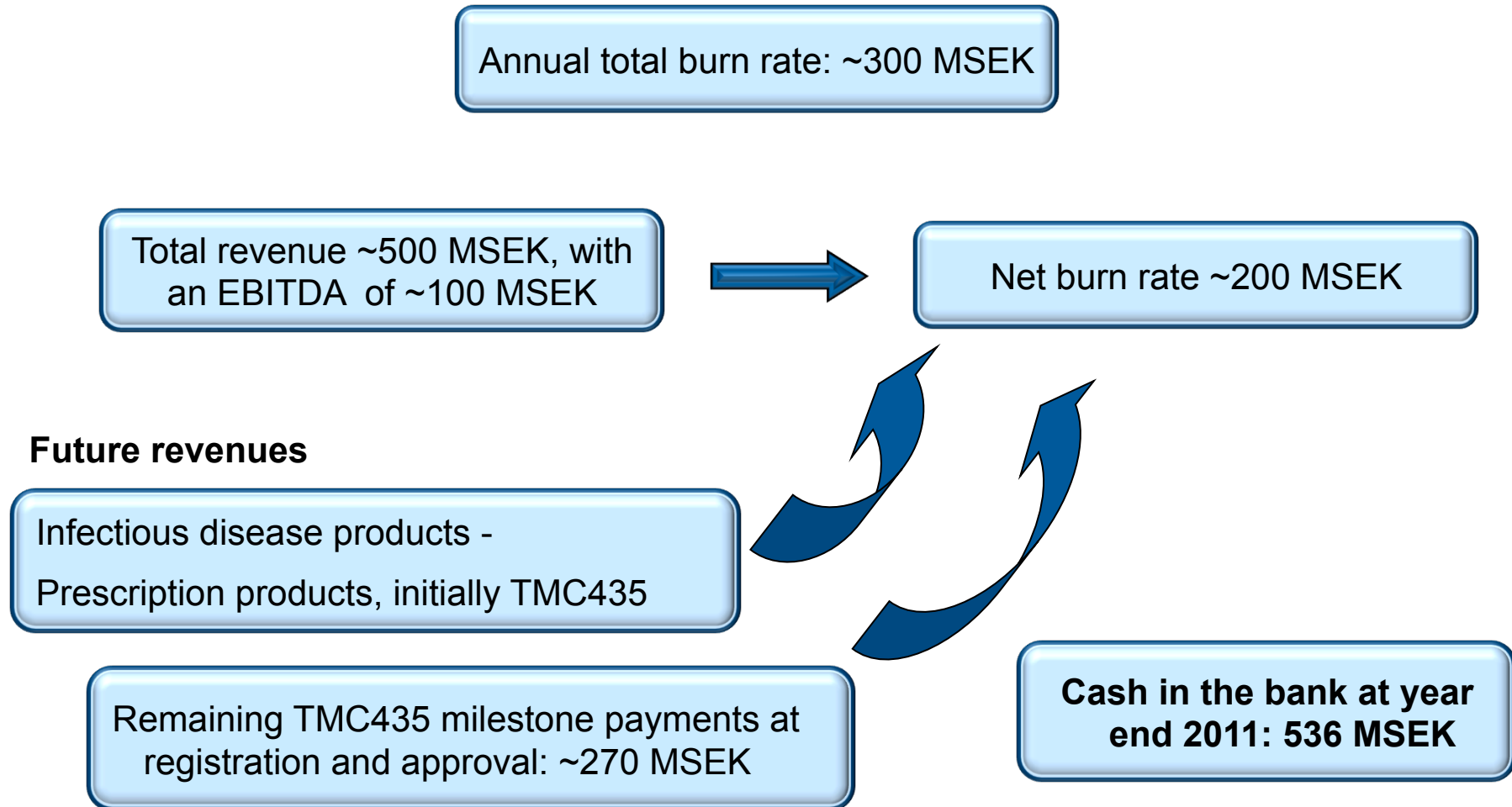
## Financial performance 2011, segment level

<b>Net sales split</b> (SEK m)	<b>2011</b> <b>Oct-Dec</b>	<b>2010</b> <b>Oct-Dec</b>	<b>2011</b> <b>Jan-Dec</b>	<b>2010</b> <b>Jan-Dec</b>
Outlicensing and partnership agreements				
One-off payments	0.0	-	401.2	47.1
Pharmaceutical sales	47.5	-	111.2	0.1
Parallel imports	84.7	-	185.9	-
Other services	-0.4	1.3	0.3	7.7
<b>Total</b>	<b>131.8</b>	<b>1.3</b>	<b>698.6</b>	<b>54.9</b>

<b>Pharmaceuticals segment</b> (SEK m)	<b>2011</b> <b>Oct-Dec</b>	<b>2010</b> <b>Oct-Dec</b>	<b>2011</b> <b>Jan-Dec</b>	<b>2010</b> <b>Jan-Dec</b>
Net sales	47.1	1.3	512.7	54.9
EBITDA	-36.3	-55.3	137.6	-128.8
EBITDA %	-77.0%	-4253.8%	26.8%	-234.6%

<b>Parallel Import segment</b> (SEK m)	<b>2011</b> <b>Oct-Dec</b>	<b>2010</b> <b>Oct-Dec</b>	<b>2011</b> <b>Jan-Dec</b>	<b>2010</b> <b>Jan-Dec</b>
Net sales	84.7	-	185.9	-
EBITDA	0.6	-	-2.3	-
EBITDA %	0.7%	-	-1.2%	-

# Commercial presence and platform in the Nordics



# Strategy

- Addition of new products to the Nordic commercial platform - allows Medivir to approach its goal of becoming profitable
- Fine-tuning of the commercial platform for launch of TMC435 in the Nordic region
- Strengthening Medivir's position within infectious diseases and in addition evaluation of potential future therapeutic areas through innovation based on the advanced protease and polymerase R&D platform



To become a profitable research-based specialty pharmaceutical company  
with main focus on infectious diseases



## **Hepatitis C - A rapidly evolving treatment landscape**

# Building a leadership position in hepatitis C

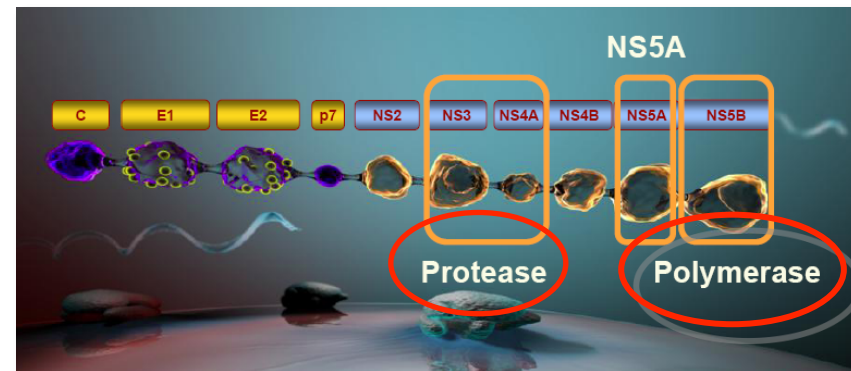
## *Two major HCV programs partnered with Janssen Pharmaceutica*

### **Protease inhibitor – TMC435**

- A potent, once-daily, safe and efficacious protease inhibitor with broad genotypic coverage
- Broad global phase III development program in genotype 1 infected patients
- Phase II interferon and ribavirin free combination studies

### **Polymerase inhibitor – nucleotide NS5B inhibitor**

- A next generation, liver targeted nucleotide polymerase inhibitor program as part of the ongoing partnership
- Clinical drug candidate selected
- Approaching clinical development



# TMC435, triple combination therapy with INF/RBV

- **Best-in-class potential based on Phase II data**

- A safe and efficacious drug with excellent tolerability
- Highly potent with advantageous low pill burden, 1 pill once daily

Study	Patient population	SVR24
<b>PILLAR</b>	Treatment naïve	<b>81 - 86%</b>
<b>DRAGON</b>	Treatment naïve (Japan)	<b>82%</b>
<b>ASPIRE</b>	Relapsers	<b>85%</b>
	Partial responders	<b>75%</b>
	Null responders	<b>51%</b>

- **Applicable in broad HCV patient populations**

- G1 population, the most prevalent and difficult-to-treat
  - Treatment naïve and treatment experienced patients
  - Cirrhotic and non-cirrhotic patients

**Robust clinical data, with approximately 1800 patients treated today**



# TMC435, broad clinical development program in HCV genotype 1 & 4 infected patients

## Phase III

**QUEST 1** treatment-naïve patients; n=375

**QUEST 2** treatment-naïve patients; n=375

**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

## IFN free combinations in Phase II development

**TMC435 and GS-7977**, a nucleotide NS5B inhibitor.

12 or 24 weeks, +/- ribavirin in prior null responders; n=180

*Trial has started*

**TMC435 and daclatasvir**

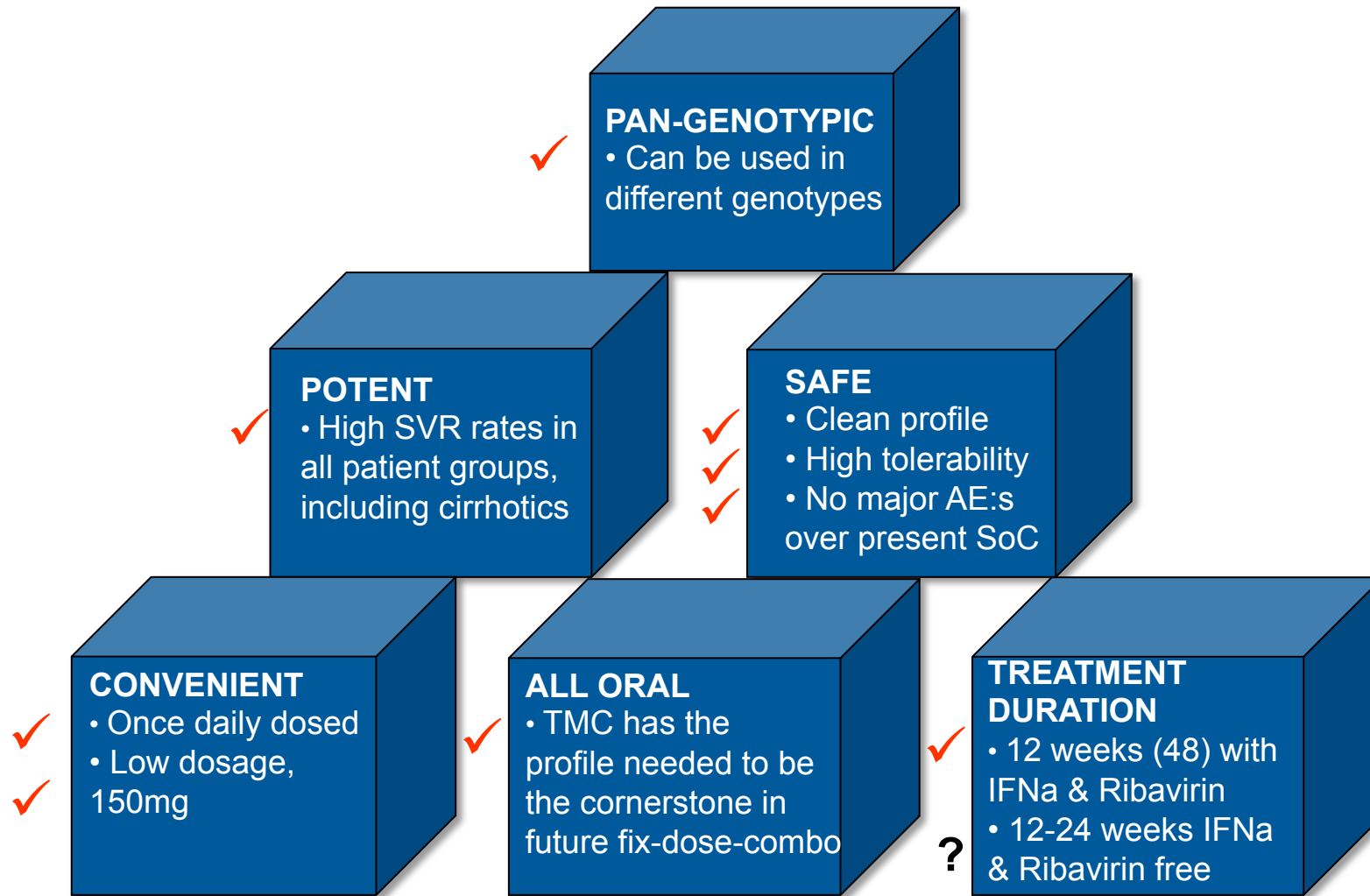
(BMS-790052), an NS5A inhibitor.

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

*Trial will start Q2, 2012*

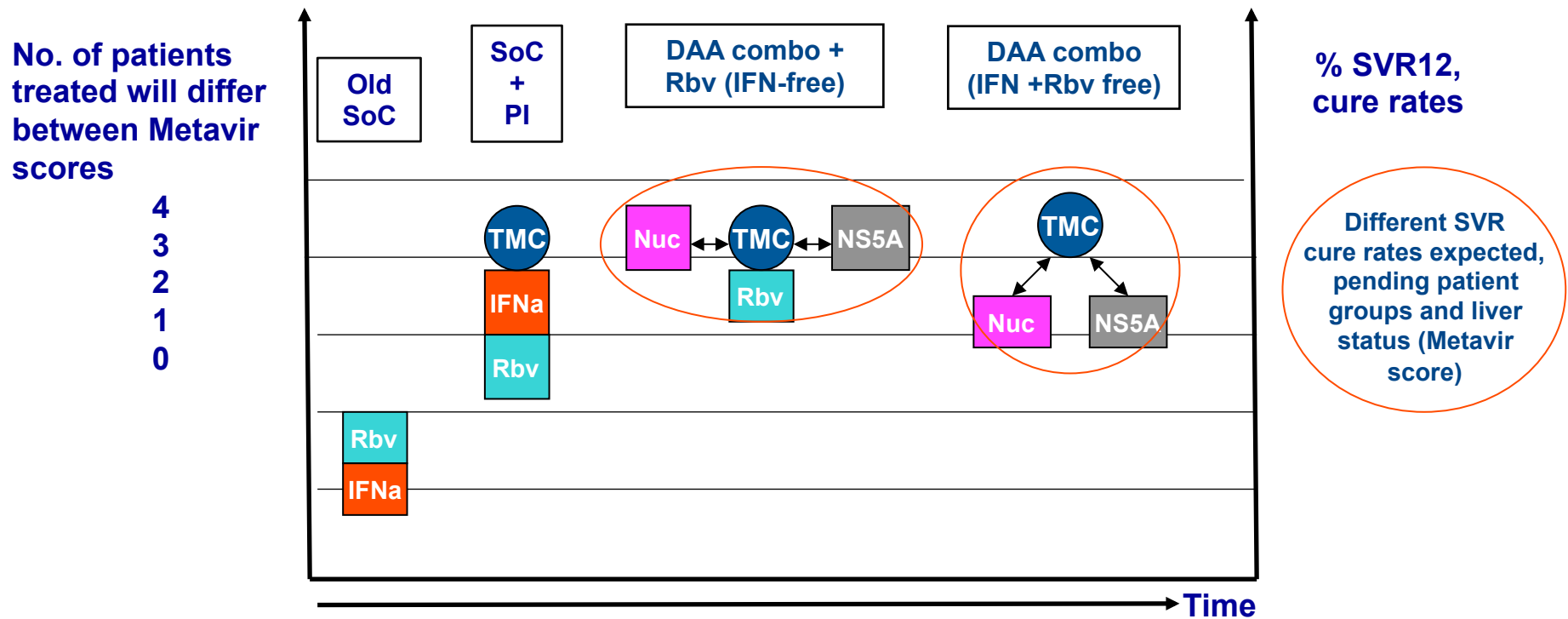
Regulatory filings in first half of 2013 in US, EU and Japan

# Hepatitis C, a rapidly evolving treatment landscape



TMC435 - key characteristics of optimal DAA cornerstone to cure HCV

# TMC435, the most advanced DAA in clinical development



**TMC435 will be a cornerstone in different future treatment regimes**

## TMC 435, summary

- Documented safe and well tolerated, close to 1800 patients have completed TMC435 treatment. Approximately 1000 additional patients are being recruited for upcoming trials in 2012
- Highly efficacious in G1a/G1b patients, both cirrhotic and non-cirrhotic and high response rates as demonstrated in three large phase 2b trials, PILLAR, ASPIRE and DRAGON
- Pan genotypic coverage G1-6, with the exception of G3
- Directly active on its HCV protease target, *i.e.* does not require serial steps for activation in the liver, like for instance nucleotides
- Can restore endogenous interferon signaling, ablated by the action of the HCV protease
- Low dose, one tablet once daily, a solid base for future combination tablets
- Advancing into two, all oral, interferon-free Phase II combination trials

**Best-in-class properties in triple combination standard of care treatment**



## **The Medivir Technology Platform and selected pipeline assets**

# Building a leadership position in hepatitis C

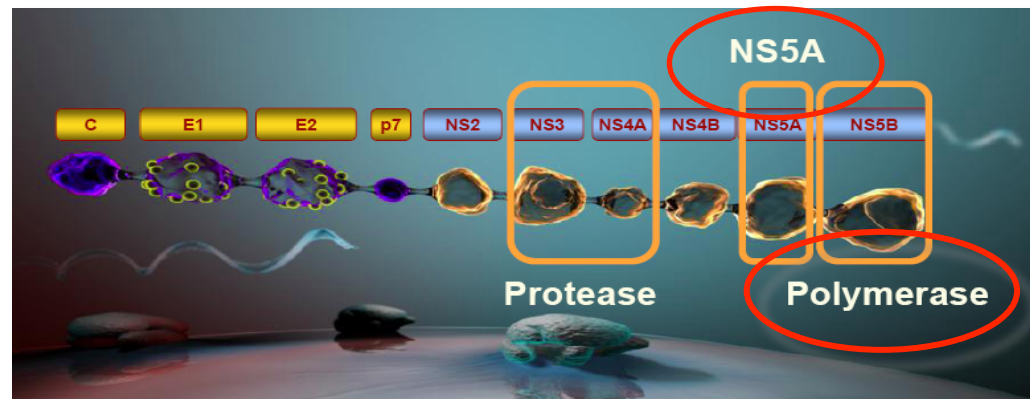
## Two major internal HCV programs, both un-partnered

### Nucleotide NS5B inhibitor: in preclinical optimization phase

- A new class of structures identified
- Highly potent molecules with characteristics comparable to the most advanced stage clinical nucleotides
- No observed cytotoxicity
- Patent applications filed
- Aiming for Candidate Drug selection in Q4, 2012

### NS5A replication complex inhibitor: in preclinical optimization phase

- A next generation NS5A inhibitor with high barrier to resistance in preclinical phase
- Patent applications filed



# Cathepsin K inhibitors – osteoarthritis (OA) and osteoporosis

## Disease and market

- **Osteoporosis, osteoarthritis and metastatic bone disease**
- Estimated combined global market opportunity in excess of 12 BUSD

## Mechanism of action: Cathepsin K inhibition

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

## Dog OA model - Results

Urinary biomarkers for bone and cartilage resorption reduced by 86% and 80% respectively ( $p < 0.001$ )

Gross scores of bone and cartilage pathology reduced by 13-37 % in OA model in dog ( $p < 0.05$ )

## Next step

- MIV-711 in preclinical development, aiming for start of phase I clinical trials in Q2 2012



**Preclinical support for beneficial effects of Cathepsin K inhibition in both osteoarthritis and osteoporosis**





## Important key messages

- Integrated pharmaceutical company - commercial platform in the Nordic region allows us to expand R<sub>x</sub> portfolio and move towards becoming a profitable research driven specialty pharmaceutical company
- TMC435, a best in class protease inhibitor is strongly positioned to become the principal cornerstone of future interferon-free therapies
- Our hepatitis C portfolio, including TMC435, gives room for a broad approach in hepatitis C drug development including DAA combinations.
- Strong track record in innovation
- Many external partnerships validating core R&D platform

**A solid platform for future growth**

## Expected key news flow highlights

- ✓ Q4-11 Agreement signed to evaluate TMC435 and daclatasvir (BMS-790052) in DAA combination trials
- ✓ Q1-12 DAA phase II combination study with TMC435 and GS-7977 started
- ✓ Q1-12 OTC launch of Xerclear® (ZoviDuo) in Europe by GSK
- ✓ Q1-12 FY report and update on projects and financials
- ✓ Q1-12 Start of Phase III trials with TMC435 + standard of care in prior null and partial responder patients (C3001) versus Telaprevir. Screening has started.
- ✓ Q1-12 Application to start phase I trials with cathepsin K filed with authorities
- Q2-12 EASL – ASPIRE full SVR24 data
- Q2-12 Start of DAA phase II combination study with TMC435 and daclatasvir
- Q2-12 Goal to start Phase I trials with MIV-711
- Q4-12 Potential CD selection in our internal Nucleotide NS5B inhibitor program
- Q4-12 EoT-data from Cohort 1 with TMC435 and GS7977 DAA phase II study
- Q4-12 Potential CD selection in Cathepsin S (Neuropathic pain) program
- Q4-12 Goal to start phase 1 trials with Medivir/Janssen Nucleotide NS5B inhibitor
- Q4-12 AASLD
- Q4-12 Top line results from phase III trials with TMC435 (Quest 1+2 and Promise)