Medivir

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

Jefferies Health Care Conference New York June 2012

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Medivir in a nutshell

Listed: 1996
Ticker: MVIR
Exchange: OMX / NASDAQ
Market Cap (SEK/USD): 1,900 / 280m

- Medivir was founded in 1988 as a spinout from AstraZeneca's antiviral research unit
- > A research based pharmaceutical company focused on infectious diseases
- Strong track record in partnerships as a part of the business model
- World class 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
- Medivir has a strong position in HCV drug development, four programs including all 3 validated target classes, two in-house driven
- > 15 marketed products in the Nordics generating annual sales of €60 m with an EBITDA of ~€12 m
- Strong financial position
- Broad institutional shareholder base 30% x Nordic



Strategy – build value and capitalise on today's platforms

Today's platforms

Future strategic direction

R&D Operations

Commercial Operations

Further development of R&D platform

- Continued focus in HCV and the infectious disease area
- Evaluate new therapeutic areas
- Explore opportunities to broaden scientific approach beyond the strong expertise within proteases and polymerases

Create new partnership/collaborations

- Continue to build new partnerships for both Commercial and R&D areas
- An integral part of Medivir's business model

Expand commercially

- Add new products
- Fine-tune organisation for TMC 435 Nordic launch
- Further development of business and therapy scope



Q1 2012 Group level financial performance

- stable sales development without one-off payments

CONSOLIDATED INCOME STATEMENT	2012	2011	2011
SUMMARY, (SEK m)	Jan-Mar	Jan-Mar	Jan-Dec
Net sales	137.9	121.6	698.6
Cost of goods sold	-97.0	-0.1	-240.6
Gross profit/loss	40.9	121.5	458.0
Selling expenses	-16.7	-2.1	-95.2
Administrative expenses	-15.1	-7.6	-47.2
Research and development costs	-46.7	-57.4	-184.1
Other operating income/expenses	-0.7	-4.3	-19.7
Operating profit/loss	-38.3	50.1	111.9
Net financial income/expense	0.8	2.8	-0.7
Profit/loss after financial items	-37.5	52.9	111.2
Tax	-0.2	0.0	2.5
Net profit/loss	-37.7	52.9	113.8

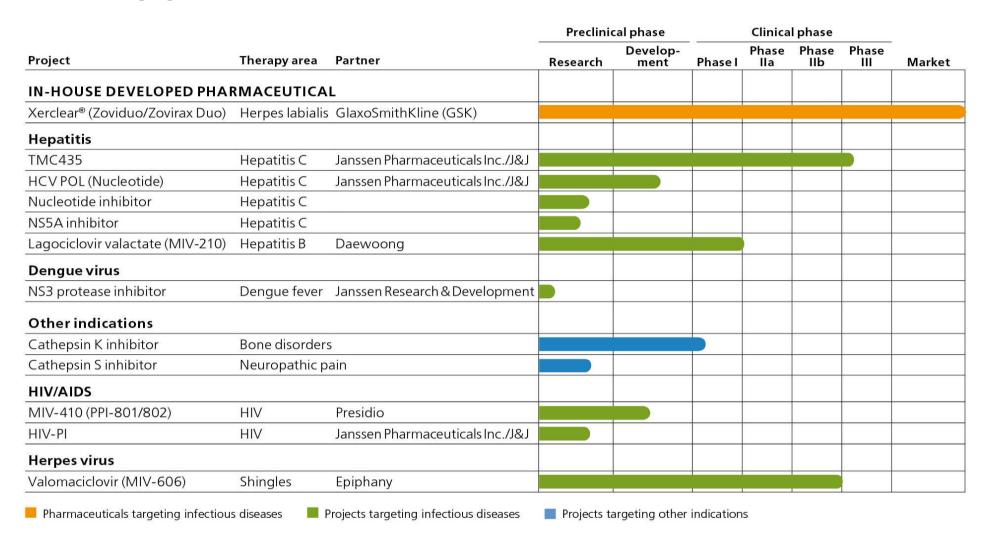
Net sales split	2012	2011	2011
(SEK m)	Jan-Mar	Jan-Mar	Jan-Dec
Outlicensing and partnership agreements			
One-off payments	-	121.3	401.2
Pharmaceutical sales	46.3	0.2	111.2
Parallel imports	91.6	-	185.9
Other services	0.0	0.1	0.3
Total	137.9	121.6	698.6



Medivir

Strongly committed to innovation driven R&D - developing novel drugs

Our pipeline





MIV-711 – an in house developed cathepsin K inhibitor in clinical phase I



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 leads to:

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

MIV-711: efficacious in dog OA model

- MIV-711 markedly reduced biomarkers for bone and cartilage resorption
- MIV-711 reduced bone and cartilage pathology

MIV-711: Phase I ongoing

- Adaptive, placebo controlled, double blind phase I study in healthy volunteers incl. post menopausal women
- Ascending single and multiple once daily dosing
- Biomarkers for bone and cartilage turnover
- Phase I data available Q1 2013

MIV-711 - a phase I clinical candidate efficacious on bone and cartilage biomarkers in models of osteoarthritis and osteoporosis



Cathepsin S inhibitor – neuropathic pain and rheumatoid arthritis

Disease and market

- Approximately 25 million patients worldwide suffer from neuropathic pain
- Estimated global market opportunity for neuropathic pain in excess of 2.3 BUSD, and rheumatoid arthritis is estimated to 7 BUSD

Mechanism of action:

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

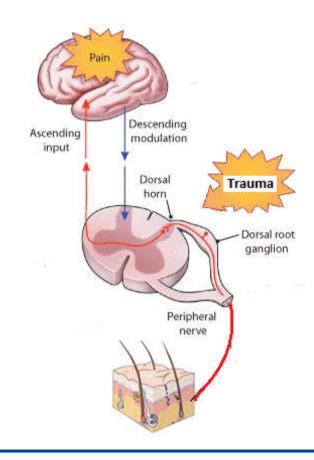
Cathepsin S inhibitor program

 Potent, selective and orally bioavailable inhibitors developed by Medivir

Next step

Aiming for candidate drug selection in Q4 2012

Principle for neuropathic pain







Hepatitis C A rapidly evolving treatment landscape

Strong platform for a leading position in hepatitis C

TMC-435

Phase III program in genotype 1 triple combination

- -Naives
- -Experienced
- -Cirrhotics

TMC-435

All oral IFN free combo with NS5B nucleotides

GS-7977 (Gilead) BMS-986094 (INX-189)

TMC-435

All oral IFN free combo with NS5A inhibitor

Daclatasavir (BMS)



Johnson Ttibotec



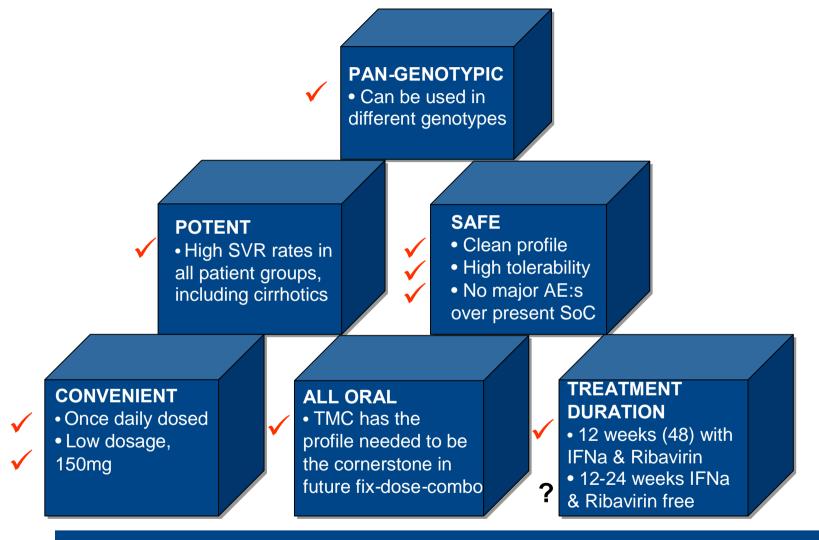


Internal **NS5B** nucleotide **Unpartnered**

> Internal **NS5A** project **Unpartnered**



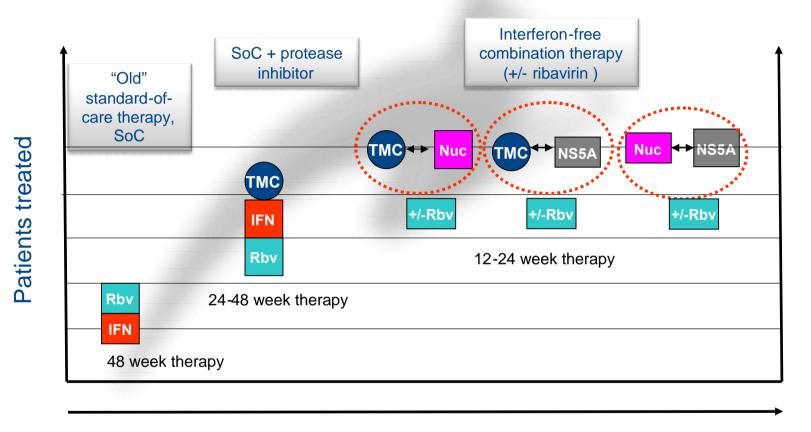
Hepatitis C, a rapidly evolving treatment landscape



TMC435 - key characteristics of optimal DAA cornerstone to cure HCV



TMC435 - evolution of HCV therapy in G1 infection



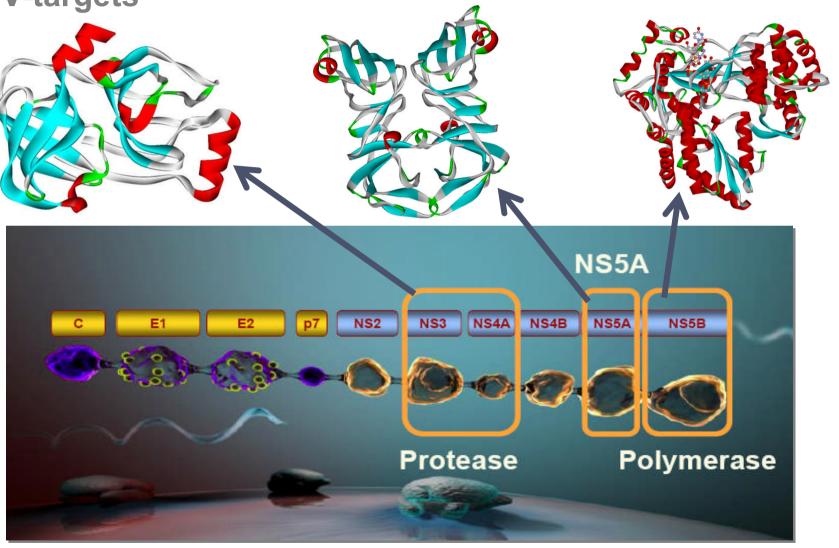
TMC435 – A best in class protease inhibitor with dual MoA



Patients cured, SVR12-24

Tid

Our hepatitis C programs are targeting three important HCV-targets





Strong commitment in hepatitis C – four major programs on-going

Protease inhibitor - TMC-435

- •One pill, once daily, oral HCV protease inhibitor
- •Potent antiviral activity in patients infected with HCV genotype 1
- •Favorable safety profile
- Currently in Phase III clinical development

Nucleotide polymerase inhibitor

- •Liver targeted nucleotide polymerase inhibitor program
- •Candidate Drug selected and IND preparatory activities on-going

Nucleotide polymerase inhibitor

- •Properties similar to the most advanced clinical nucleotides
- •Both purines and pyrimidines with high potencies in the replicon assay
- •High triphosphate levels and long triphosphate t1/2 in human hepatocytes
- •Aiming for Candidate Drug selection in Q4, 2012

NS5A inhibitor

- •A next generation NS5A inhibitor with high barrier to resistance
- Preclinical optimization phase



Internal unpartnered projects



TMC435, triple combination therapy with PegINF/RBV

- summary phase IIb data

Best-in-class potential based on Phase II data

• Safe and efficacious with excellent tolerability (150 mg, q.d., 12 w)

Study	Number of patients	Patient population	SVR24
PILLAR	386	Treatment naive	81 - 86%
DRAGON	92	Treatment naive (Japan)	82%
ASPIRE	462	Relapsers	85%
		Partial responders	75%
		Null responders	51%

Robust clinical efficacy data

Efficacious in broad HCV patient populations

- Genotype 1
- Treatment naïve and treatment experienced
- Cirrhotic patients

Large safety data base with approximately 1800 patients treated today



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

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

IFN free combinations

TMC435 and GS-7977, a nucleotide NS5B inhibitor. 12/24 weeks, +/- ribavirin, null responders; +/- cirrhotics, n=180

On-going

TMC435 and daclatasvir (BMS-790052), an NS5A inhibitor. 12/24 weeks, +/- ribavirin in G1 null responder and interferon intolerant patients

Planned to start H1-2012

TMC435 and BMS-986094 (INX-189) Clinical evaluation will start with a DDI study

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



Medivir in summary

- strong momentum in all parts of the company



Strong pipeline in R&D

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



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 were
 - TMC435 has a attractive profile



Medivir in summary

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Integrated company - commercial presence and platform in the Nordics

- > Strong brand names, annual sales ~ Euro 60 m with an EBITDA of ~Euro 12 m
- ➤ Commercial platform for TMC435 launch in the Nordics



European OTC launch by GSK initiated

- First in-house developed product on the market.
- Cold sore drug with an unique, differentiated profile and strong partner in GSK.



2012 - Expected key news flow highlights

- ✓ 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 Start of Phase III trials with TMC435 + standard of care in prior null and partial responder patients vs telaprevir.
- ✓ Q2-12 Expanded agreement signed on TMC435 and daclatasvir (BMS-790052) collaboration
- ✓ Q2-12 TMC435 and BMS-986094 (formerly INX-189), two direct-acting antivirals in combination, will be evaluated in clinical trials
- √ Q2-12 EASL ASPIRE full SVR24 data
- ✓ Q2-12 Janssen creates new division to launch TMC435 in EMEA
- ✓ Q2-12 Start of Phase I clinical trials with MIV-711 (cathepsin K inhibitor)
- Q2-12 Start of DAA phase II combination study with TMC435 and daclatasvir
- 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 Top line results from phase III trials with TMC435 (Quest 1+2 and Promise)

