Avanza Banks Börsdag 27 May 2014

Rein Piir, EVP Corporate Affairs & IR



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

This is what we are-



an research based pharmaceutical company with a strong commercial platform in the Nordics

- Headquarter and R&D facility in Stockholm, Sweden
- Around 140 employees, of which 90 in R&D
- World leading expertise in polymerase and protease drug targets
- Our R&D pipeline has three internally driven projects
- Commercial organization covering the Nordics
- 15 marketed Rx pharmaceuticals in the Nordics
- Two innovative specialty care products, Adasuve and Olysio recently launched in the Nordics
- Two own products developed from the bench to commercialization;
 - Simeprevir for the treatment of chronic hepatitis C, licensed to J&J globally excluding the Nordics
 - Xerclear for the treatment of labial herpes, licensed to GSK in Europe



Short financial facts about Medivir



- Listed on NASDAQ OMX Stockholm
- Broad institutional shareholder base, 20% EU & US shareholders
- Solid financial position (~342 MSEK end Q1-14*), on the way to sustainable profitability
- Sales in 2013: ~176 MSEK (~27 MUSD)

Market Capitalization Today:	SEK 4,300M	\$660M USD
Cash (as of March 31)*:	SEK 342 M	\$53M USD
Debt (as of March 31):	SEK 42M	\$6M USD
Revenues own products Q1-14:	SEK 46M	\$7M USD
Net burn rate:	SEK 240M	\$37M USD

Shares Outstanding: Class B: 30,600,027

Class A: 660,000 Options: 404,374 Fully Diluted: 31,664,401

 Q1 simeprevir royalties of 161 MSEK not accounted for in cash position. Including the royalties the end Q1 cash position was 500 MSEK (77 MUSD)

CONSOLIDATED INCOME STATEMENT SUMMARY	Q1	Q1	FY
Continuing operations (MSEK)	2014	2013	2013
Net turnover	208.2	178.1	446.1
Gross profit	182.1	160.2	374.3
EBITDA	96.7	90.5	76.4
EBIT	88.6	76.7	25.2
Profit/loss before tax	90.3	76.6	27.7
Profit/loss after tax	283.8	71.1	16.0

Net turnover breakdown (MSEK)	Q1 2014	Q1 2013	FY 2013
Outlicensing and partnership agreements: Non-recurrent payments	-	126.8	258.5
Pharmaceutical sales	46.4	51.3	176.1
Royalties	161.7	-	11.5
Other services	-		-
Total	208.1	178.1	446.1

Strategic direction and ongoing activities



R&D Operations

Commercial Operations

Further development of R&D platform

- Continued focus on HCV and infectious diseases
- Evaluate new therapeutic areas based on proteases and polymerases as drug targets

Create new partnership/collaborations

Continue to develop R&D assets via partnerships

Expand commercially

- Add new products for the Nordic market
- Build organisation for Nordic launch of simeprevir
- Further development of business and therapy scope





MIV-711 - in clinical development for osteoarthritis (OA) preparing phase II and partnership



R&D Operations

Osteoarthritis

 A chronic progressive disease characterized by excessive bone resorption and cartilage degradation leading to pain and disability

Medical need

 The most common joint disease, affecting 10-15% of the US population and with more than 80M sufferers in the US, Europe and Japan*

Two abstracts with MIV-711 data presented at the OA conference, Paris (April 24-29):

- <u>Non-clinical</u>: novel results demonstrate that once daily MIV-711 reverse subchondral bone loss in an experimental model of OA
- <u>Clinical:</u> 28 days treatment of post menopausal women (100 mg, OD) reduced urinary biomarkers for bone resorption and cartilage degradation with up to 98% and 55%, respectively



MIV-247 – IND phase towards clinical phase I trials



R&D Operations

Neuropathic pain

- Associated with a lesion or disease affecting the somatosensory system
- Includes e.g. diabetic neuropathic pain, postherpetic neuralgia, neuropathic lower back pain, cancer and HIV related pain,

Medical need

- Current treatments incl. anticonvulsants and antidepressants
 - Pain persists in 75% patients with at best a 50% reduction in overall pain
 - Significant side effects e.g. dizziness, somnolence

MIV-247 (Cathepsin S)

- Non-clinical in vivo studies support the development of MIV-247:
 - <u>as monotherapy</u> (fast and sustained efficacy seen in models of neuropathic pain)
 - -as combination therapy (improved efficacy shown when combined with e.g. gabapentin)

Wholly owned HCV nucleotide program towards selection of clinical candidate (CD) and start of IND



R&D Operations

- Medivir has leveraged nucleoside experience to pursue high value nucleotide compounds
- Current Medivir effort focused on novel uridine-based series
- Medivir's compounds are structurally distinct from existing nucleoside starting points

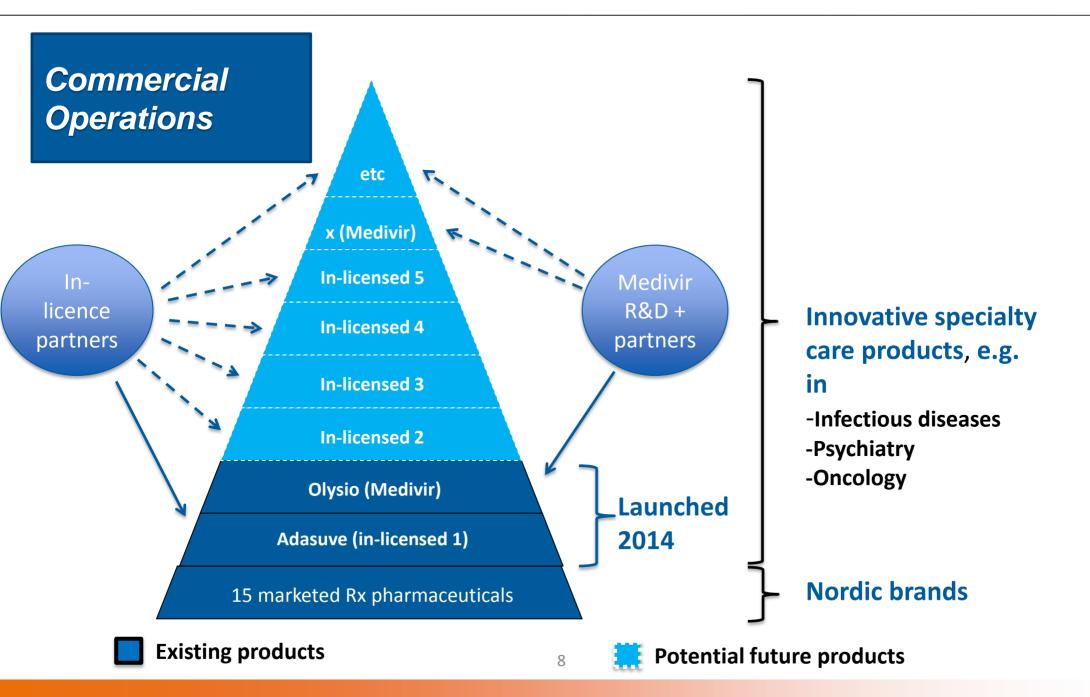


- EC₅₀ values <100nM against GT1-6
- High in vitro selectivity indices
- Attractive early pharmacokinetic profile



Focused on growth through continuous addition of innovative specialty care products to our existing product portfolio

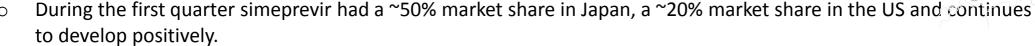




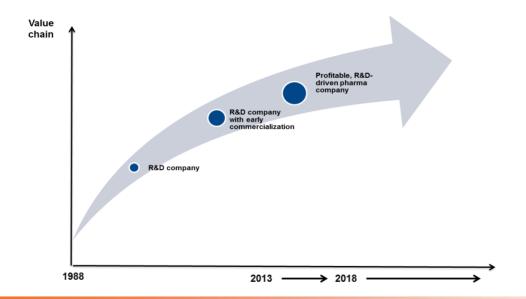
2014 – we are having a solid platform for continued development of the company



- o Moving towards sustainable profitability, simeprevir being a important component.
- Simeprevir is selling well part of the only IFN-free regimen currently in use based on recent guidelines from January 2014.



- Our Nordic commercial organization have recently launched two new products, simeprevir and Adasuve.
- Our R&D pipeline has three internally driven projects, which all are advancing and will enable new partnerships or
 joint ventures, including Medivir's nucleotide program
- This will enable us to focus on value creation and risk diversification.



Simeprevir on the market





- ✓ Japan (SOVRIAD™)
- ✓ Canada (GALEXOS™)
- ✓ USA (OLYSIO™)*
- ✓ Russia (SOVRIAD™)
- ✓ EU: (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 - ongoing and recently presented studies with PegIFN/ribavirin combination



On-going studies:

- 12 weeks full stop single-arm study in treatment naïve GT1 and GT4 patients
- **China** efficacy, safety & tolerability and pharmacokinetics in treatment naive GT1 HCV patients (results available by year end)

APASL (Brisbane, Feb)

- ATTAIN study (simeprevir vs telaprevir, prior null or partial responder patients (N=744))
 - Simeprevir demonstrated non-inferiority while having a superior safety profile (lower adverse event frequency, fewer serious adverse events, and a lower incidence of anaemia
- GT1b patient subgroup analyses of phase III data (of importance for the Asian markets)
 - 85% and 86% cure rates in treatment naïve and prior relapsed HCV GT1b infected patients

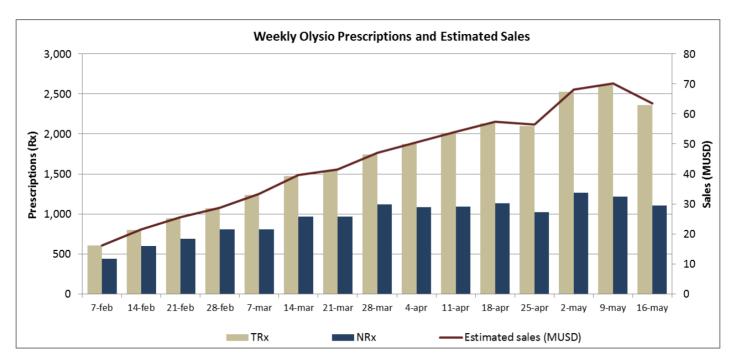
EASL (London, April)

- European patient subgroup analyses of phase III data
 - 87% and 88% cure rates in treatment naïve and prior relapsed HCV GT1 patients
- RESTORE (HCV GT4 treatment naïve and experienced including cirrhotics)
 - high SVR12 rates (83% in treatment-naïve; 86% in prior relapsers; 60% in partial responders and 40% in null responders)
 - 95% of patients with 24 weeks total treatment duration achieved SVR12



Simeprevir – strong uptake during Q1 - 2014

- o After the launch in December, simeprevir sales have grown rapidly: ~20% market share in the US currently.
- o The global first quarter net sales of simeprevir were 354 MUSD, of which 291 MUSD were sales in the US.
- o Medivir's royalties based on these sales were 161 MSEK (18 MEUR) for the first quarter.
- Simeprevir now approved in US, Canada, Japan, Europe and Russia.



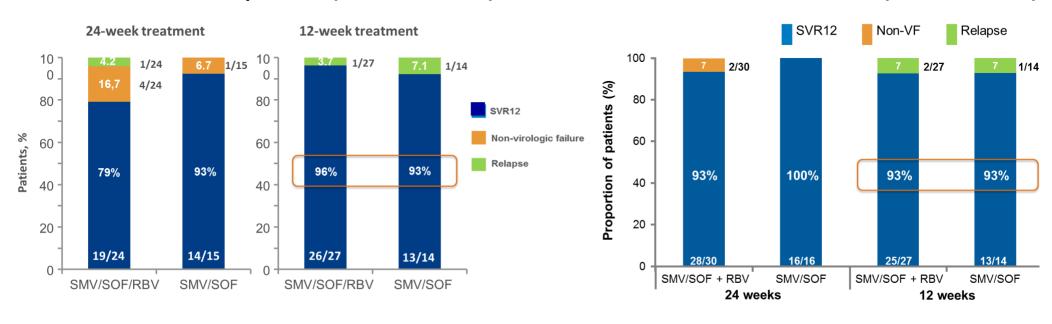
- Two phase III studies evaluating treatment of hepatitis C-infected patients with simeprevir and sofosbuvir have recently been initiated, based on the outcome from the COSMOS trial.
- A supplemental New Drug Application has been submitted to the FDA in the US for once-daily use of simeprevir in combination with sofosbuvir.

EASL: COSMOS – final data



Cohort 1: Prior null responders (METAVIR F0-F2)

Cohort 2: "naïves" and "nulls" (METAVIR F3/4)



- No benefit demonstrated by addition of ribavirin
- High SVR12 rates regardless of baseline characteristics (HCV GT 1 subtype, Q80K polymorphism, METAVIR score, IL28B GT or prior treatment history)
- SMV/SOF QD +/- RBV was safe and well tolerated

High SVR12 rates, 93- 96%, with 12 weeks once daily treatment with SMV + SOF in hard to cure patients

Ongoing IFN-free studies with simeprevir



- data driven approach to exploring different interferon-free combinations

Class	Compound	Partner	Status
PI Nuc	Simeprevir Sofosbuvir	Janssen	OPTIMIST 1: null + naives (F0-3), 8 or 12 weeks (n=300) OPTIMIST 2: null + naïve s (F4), 12 weeks duration (n=100) - no ribavirin in either study
PI NS5A	Simeprevir IDX719	Janssen Idenix	HELIX-1: Phase II , Gt1b and 4 (150 mg SMV + 50 mg SAM + RBV-> 85% SVR4)
	Simeprevir JNJ-56914845	Janssen	Phase II on its way
PI NS5A NNI	Simeprevir IDX719 TMC055	Janssen Idenix Janssen	HELIX-2: Phase II started Dec-13 (Gt1)
	Simeprevir JNJ-56914845 TMC055	Janssen	Phase II started Dec-13

IFN: interferon; Nuc: nucleotide polymerase inhibitor; NNI: non-nucleoside polymerase inhibitor; NS5A: NS5A replication complex inhibitor; PI: protease inhibitor



www.medivir.com

Ticker: MVIR

Exchange: OMX / NASDAQ

For more information please contact Rein Piir, EVP Corporate Affairs & IR (rein.piir@medivir.com)