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

Q2-2013 Conference Call 22 August 2013
Presenting team

Maris Hartmanis, CEO
Charlotte Edenius, EVP Development
Richard Bethell, EVP Discovery Research
Rein Piir, EVP Corporate Affairs & IR

Reflections on Q2 2013

Maris Hartmanis, CEO

We streamlined operations and sharpened our focus in Q2, 2013

Overall operations

- Our Rx pharmaceutical portfolio was affected by typical seasonal variations but continued to show stability
- To increase focus in our Nordic pharmaceuticals business we divested our parallel trading franchise, Cross Pharma, which strengthened our financial position
- Henrik Krook was appointed EVP Commercial and joined Medivir on August 19

Simeprevir

- Simeprevir was granted priority Review by the FDA. The Advisory Committee meeting is confirmed for October 24
- A Marketing Authorization Application for the treatment of patients with genotype 1 and genotype 4 chronic hepatitis C was filed with the European Medicines Agency (EMA)
- Positive efficacy and safety data were presented from four Japanese phase III studies
- All interferon-free combination trials with simeprevir continue to make progress. The phase II trial (HELIX-1) with simeprevir and samatasvir (IDX719) was initiated

R&D

- We refocused the internal HCV efforts and are exploring the nucleotide-based polymerase inhibitors following a discontinuation of our NS5A program
- The Cathepsin K phase I trial was completed
- The Cathepsin S project is moving towards CD selection during H2, 2013

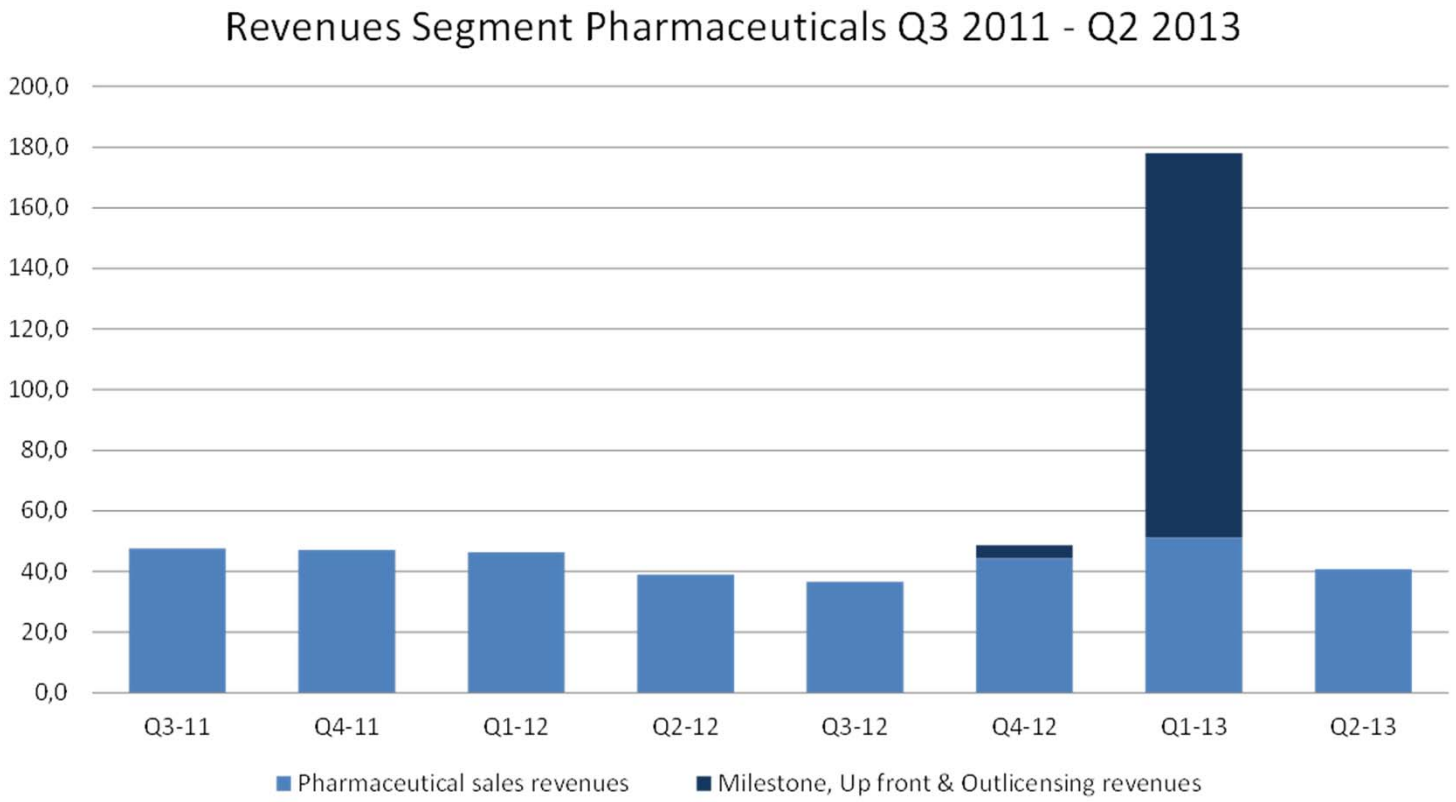
Consolidated profit performance

(SEK m)	2013 Apr-Jun	2012 Apr-Jun	2012 Jan-Dec
Net turnover	40.7	39.0	170.6
Gross profit	23.5	24.3	109.3
EBITDA	-46.9	-47.7	-165.3
EBIT	-62.0	-56.4	-201.3
Profit/loss before tax	-62.1	-57.0	-210.8
Profit/loss after tax	-63.7	-65.4	-234.1

Net turnover breakdown

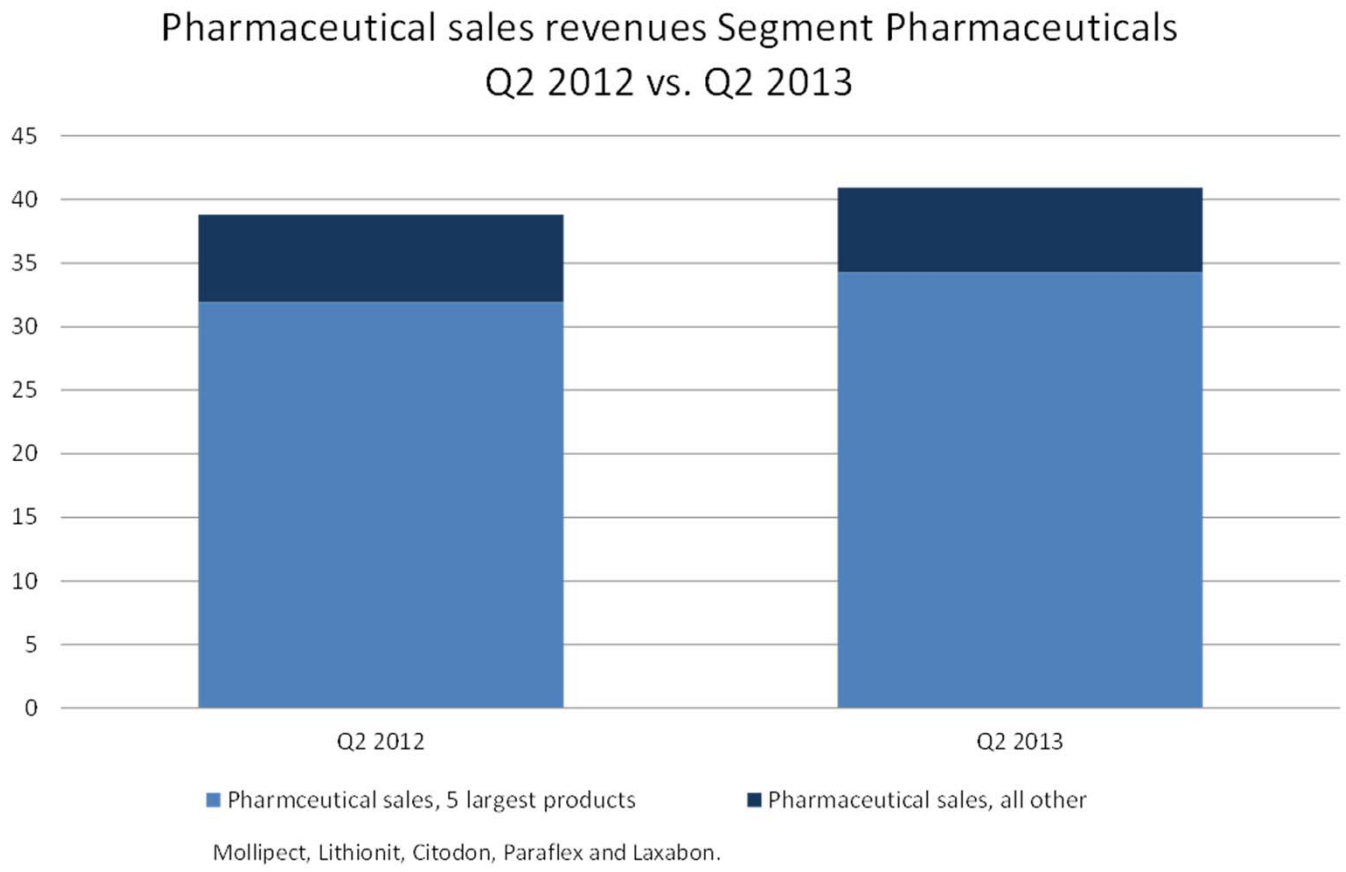
(SEK m)	2013 Apr-Jun	2012 Apr-Jun	2012 Jan-Dec
Outlicensing and partnership agreements/Non-recurrent payments	-	-	4.4
Pharmaceutical sales	40.7	39.0	164.9
Other services	-	-	1.3
Total	**40.7**	**39.0**	**170.6**

Quarterly sales trend in Pharmaceuticals, SEK m*



*The BioPhausia corporate group is included from May 31, 2011.

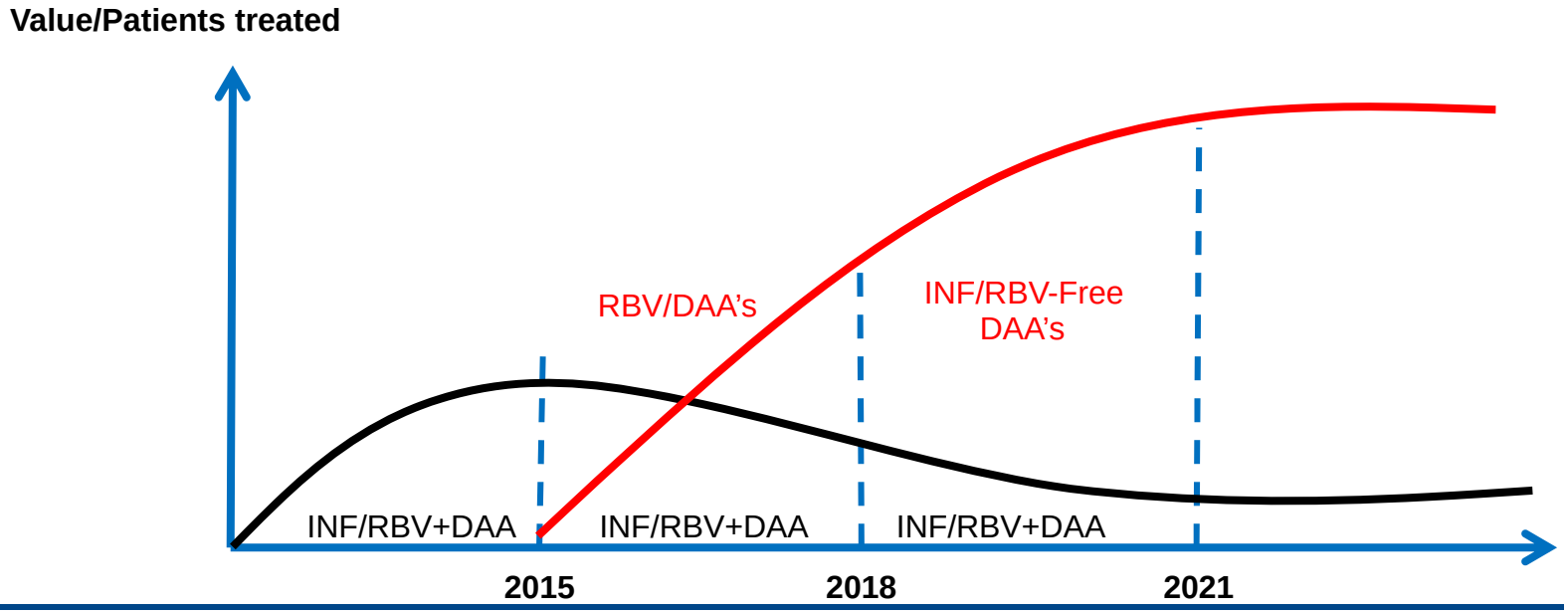
Segment Pharmaceuticals, sales Q2 2012 vs. Q2 2013



Long term goal – eradication of hepatitis C

The evolution in treating hepatitis C will expand the market value, number of patients treated and regions over the next 10-15 years

Regional, patient and pricing differences will drive the segments in the future



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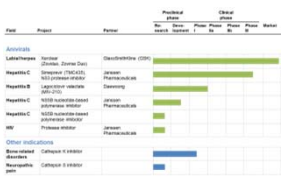
Value proposition – a platform for growth and profitability



Innovative portfolio will evolve over time

- World class expertise in polymerase and protease drug targets
- R&D focus on infectious diseases

Long term commitment in the HCV area

- Simeprevir, partnered with Janssen Pharmaceuticals
  - Regulatory files submitted in EU, US and Japan
  - On-going interferon-free combination trials will guide us in treatment opportunities
- In-house un-partnered HCV nucleotide-based polymerase inhibitor program will offer new combination treatment opportunities

Commercial presence in the Nordic region creates revenue

BioPhausia® – a Medivir sales company

- 15 solid Rx pharmaceutical brands with annual sales of ~25 MUSD
- Commercial platform for the launch of simeprevir in the Nordics in 2014
- Pharmaceutical portfolio of Rx drugs will be broadened

Solid financial position

- Current assets will take us to profitability

Key R&D highlights from Q2 2013

Charlotte Edenius, EVP Development

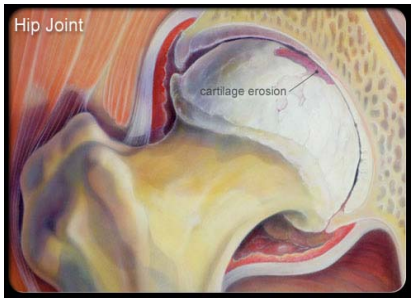
Pipeline status

Field	Project	Partner	Preclinical phase: Re-search	Preclinical phase: Deve-lopment	Clinical phase: Phase I	Clinical phase: Phase IIa	Clinical phase: Phase IIb	Clinical phase: Phase III	Market
Anivirals									
Labial herpes	Xerclear (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)							
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals							
Hepatitis B	Lagociclovir valactate (MIV-210)	Daewoong							
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals							
Hepatitis C	NS5B nucleotide-based polymerase inhibotor								
HIV	Protease inhibitor	Janssen Pharmaceuticals							
Other indications									
Bone related disorders	Cathepsin K inhibitor								
Neuropathic pain	Cathepsin S inhibitor								

MIV-711 - A cathepsin K inhibitor for bone related disorders, including osteoarthritis

Mechanism of action

- Cathepsin K dissolves collagen I in bone and collagen II in cartilage
- Genetic, animal and human data shows that cathepsin K inhibition improves bone quality

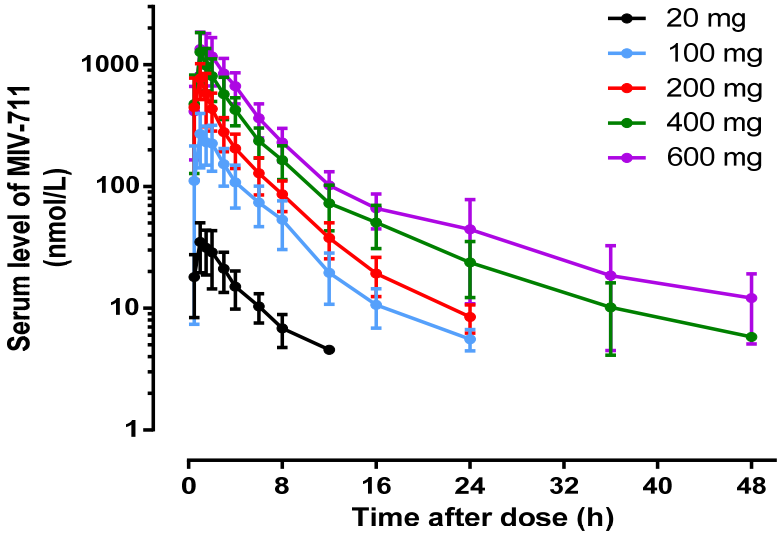


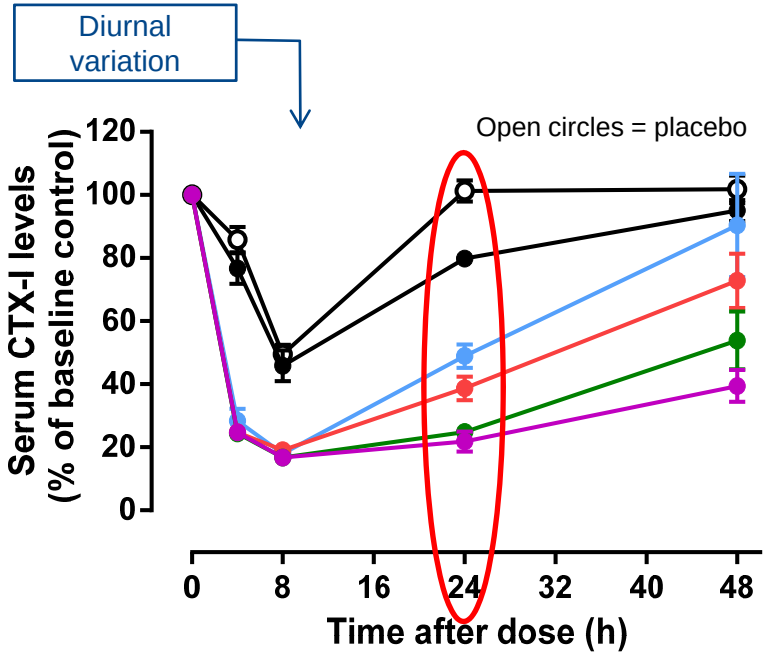
Phase I study recently finished

- Placebo controlled, double-blind study in healthy subjects
- Ascending single and multiple (7 - 28 days) once daily dosing
- Biomarkers for bone and cartilage turnover (CTX-I, CTX-II etc)
- Single dose data presented recently
- Business development activities initiated aiming for partnership for further clinical development

MIV-711 - a phase I clinical candidate efficacious in preclinical models of osteoarthritis and osteoporosis

Pharmacokinetics and effect on CTX-1, a bone resorption biomarker of single doses of MIV-711





- **Uncomplicated PK supporting once daily dosage**
- **Safe and well tolerated at all doses tested (up to 600 mg)**
- **Serum levels of CTX-I were reduced by up to 79% at 24 h after dose**

Simeprevir

- A potent HCV protease inhibitor in registration phase

Simeprevir - phase III development program in HCV G1 & 4 infected patients

- **QUEST 1 and 2 (**treatment-naïve) - *final data presented at EASL*
- **PROMISE (**prior relapser) - *final data presented at Digestive Week*
- **CONCERTO 1-4 in Japan** (treatment naïve & experienced) - *results presented at Japan Society of Hepatology's Annual Meeting*

Ongoing phase III studies:

- **China:** naive GT1 HCV patients – *fully enrolled (n=444)*
- **ATTAIN:** prior non-responders (SMV vs TVR) – *fully enrolled (n=765)*
- **RESTORE:** HCV GT4 infected patients – *fully enrolled (n=107)*
- **C212: HIV-HCV** co-infected patients – *fully enrolled (n=109)*
- **12 weeks full stop,** open-label, single-arm study in treatment naïve GT1 patients

Regulatory applications filed in JPN, US and EU aiming for a broad label

Simeprevir - Regulatory status and summary phase III

Regulatory applications filed in:

- **Japan** for hepatitis C genotype 1, naïve, prior non-responders or relapsed – Feb, 2013
- **US** for hepatitis C genotype 1 – Priority Review granted in May, 2013
- **EU** for hepatitis C genotype 1 and 4 – April, 2013

Overall SVR12 rates

- 80-81% in naive and 79% relapsed patients (including 22-31% F3-F4)
- 89-91% in naive and 96-100% in relapsed patients in Japan

83-91% SVR12 rates with 24 weeks treatment

- 85-91% of patients stopped all treatment at 24 weeks in QUEST-1, -2 and PROMISE

Excellent safety and tolerability

- Overall incidence of adverse events similar to placebo, including rash and anemia
- Safety and tolerability confirmed in Japanese program

Simeprevir

- All oral interferon-free combination update

Simeprevir in interferon-free combinations

			Ribavirin			
Simeprevir	**+**	**Sofosbuvir** (nucleotide)	**+/-**	12w	N=80 Cohort a: nulls, F0-F2 N= 87 Cohort b: only METVIR score **F3 and 4 patients** (nulls + naives)
			+/-	24w	
Simeprevir	**+**	**Daclatasvir** (NS5A inhibitor)	**+/-**	12w	N=180 Naives and nulls **Incl. F3/4 up to 35 %**
			+/-	24w	
Simeprevir	**+**	**TMC647055/r** (NNI; non-nucleoside)	**+/-**	12w	Naives/relapser and nulls Non-cirrhotics
Simeprevir	**+**	**VX-135** (nucleotide)	**+/-**	12w	DDI study completed Phase II to start H2 2013 on track
Simeprevir	**+**	**IDX719** (NS5A inhibitor) **+/- TMC647055/r**	**+/-**	12w	HELIX-1 Phase II started during Q2 HELIX-2 to start during Q3

Simeprevir is strongly positioned to become a principal component of future IFN-free therapies

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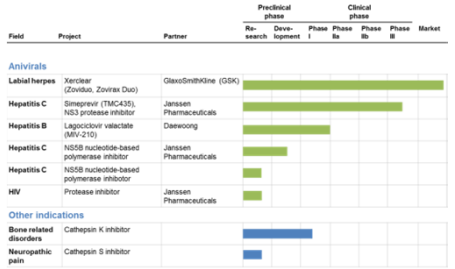
For additional information, please see www.clinicaltrials.gov

Key events in the coming 12 month



H2-13 Results from phase I-study with MIV-711, our cathepsin K inhibitor (bone related disorders)

H2-13 Start of the phase II study - HELIX-2 (simeprevir + TMC647055 and samatasvir - IDENIX)

H2-13 Start of Phase II with simeprevir and VX-135 (Vertex)

H2-13 Potential CD selection in Cathepsin S (neuropathic pain) program

H2-13 Anticipated approval in Japan for simeprevir

H2-13 Goal to start phase I trials with Medivir/Janssen nucleotide NS5B-inhibitor

H2-13 Data from the phase II combination study with simeprevir and daclatasvir (BMS)

H2-13 Presentations at AASLD

H2-13 SVR data from Cohort 2 with simeprevir and sofosbuvir phase II study

H1-14 Anticipated approval of simeprevir in the US

H1-14 Anticipated approval of simeprevir (triple) in EU

H1-14 Potential CD selection in our internal Nucleotide NS5B inhibitor program

H1-14 Presentations at EASL

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

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