

# Swedbank Healthcare Seminar

## 27 November 2014

Niklas Prager, President and CEO  
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# MEDIVIR

A Nordic research-based  
pharmaceutical company  
focused on infectious  
diseases and oncology



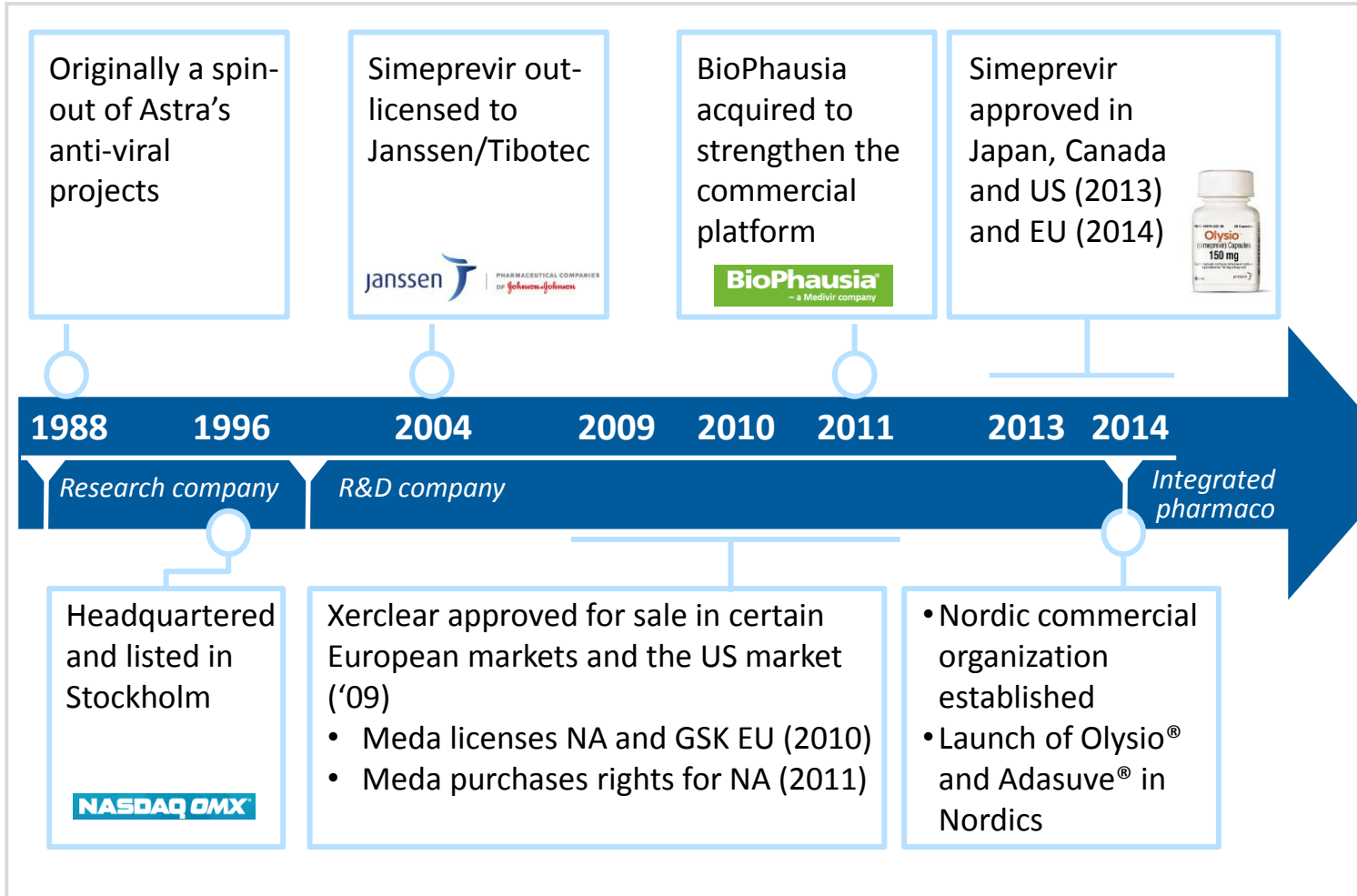
## **Key highlights from strategy update in October**

# Medivir is a Nordic research-based pharma company focused on infectious diseases and oncology (1/2)



Medivir has made significant progress in transforming into an integrated pharmaco

Year 2014 short facts / data



**Strong financial performance and position**

- Market cap of ~4 BSEK
- Solid financial position
- Transforming to sustainable profitability

**140 highly qualified and diverse employees (90 in R&D)**

- Doctorates 47%
- University degrees 29%
- > 10 different nationalities

# Medivir is a Nordic research-based pharma company focused on infectious diseases and oncology (2/2)



## Balanced platform consisting of four cornerstones

### Innovation *High risk / high reward*

<b>R&amp;D</b>	<ul style="list-style-type: none"> <li>• Unrivaled expertise in protease inhibitor design and nucleoside/nucleotide science with focus on infectious diseases and oncology</li> <li>• Strong pipeline from discovery to development with four internal projects disclosed</li> </ul>
<b>Royalties &amp; Milestones</b>	<ul style="list-style-type: none"> <li>• Two products, Olysio® and Xerclear®, taken from idea to market and out-licensed to premier big pharma partners</li> <li>• New deals will add to high-margin cash flow</li> </ul>
<b>Innovative Specialty Care Portfolio</b>	<ul style="list-style-type: none"> <li>• Two innovative specialty care products, Olysio® and Adasuve®, recently launched in the Nordics and negotiations in process</li> <li>• Experienced and specialized commercial organization</li> </ul>

### Established Brands *stable revenue stream*

<b>Nordic Brands</b>	<ul style="list-style-type: none"> <li>• 14 Rx pharmaceuticals with very stable revenue and earnings generation through efficient organization</li> </ul>
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**World class high risk/high reward R&D capabilities with strong current and future cash generation from Nordic commercial operations and global milestones/royalties**

## Secure current and future value creation through profitable growth

### Deliver sustainable value creation

Through world-class R&D productivity, increased commercial focus and operational excellence



#### Strengthen R&D pipeline without increasing costs

- Focus on areas of expertise: infectious disease and oncology
- Maintain an average of one project in phase I clinical development



#### Capture more pipeline value

- Advance projects further (e.g. Phase II)



#### Generate diversified revenue from milestones & royalties

- Out-license projects from R&D pipeline



#### Become top-tier pharma company in Nordic region, by sales

- Increase commercial focus
- Further expand Innovative Specialty Care Portfolio



#### Improve profit margin of Nordic brands

- Ensure operational excellence





# Proven ability to create value through R&D efforts, Nordic commercial operation



## Innovation



Proven ability to discover and develop innovative breakthrough products, partner with premier big pharma companies for late stage development and global distribution, and commercialize own and in-licensed products through strong Nordic platform with economies of scale

# Established brands enhance stability and strength of Nordic commercial operations



## Established Brands

### Nordic Commercial Operations

- Essential supporting functions are common between Nordic Brands & Innovative Specialty Care Portfolio

### Nordic Brands

- Opportunity to further improve margins for broad range of well-known brands with stable revenue stream

### Innovative Specialty Care Portfolio

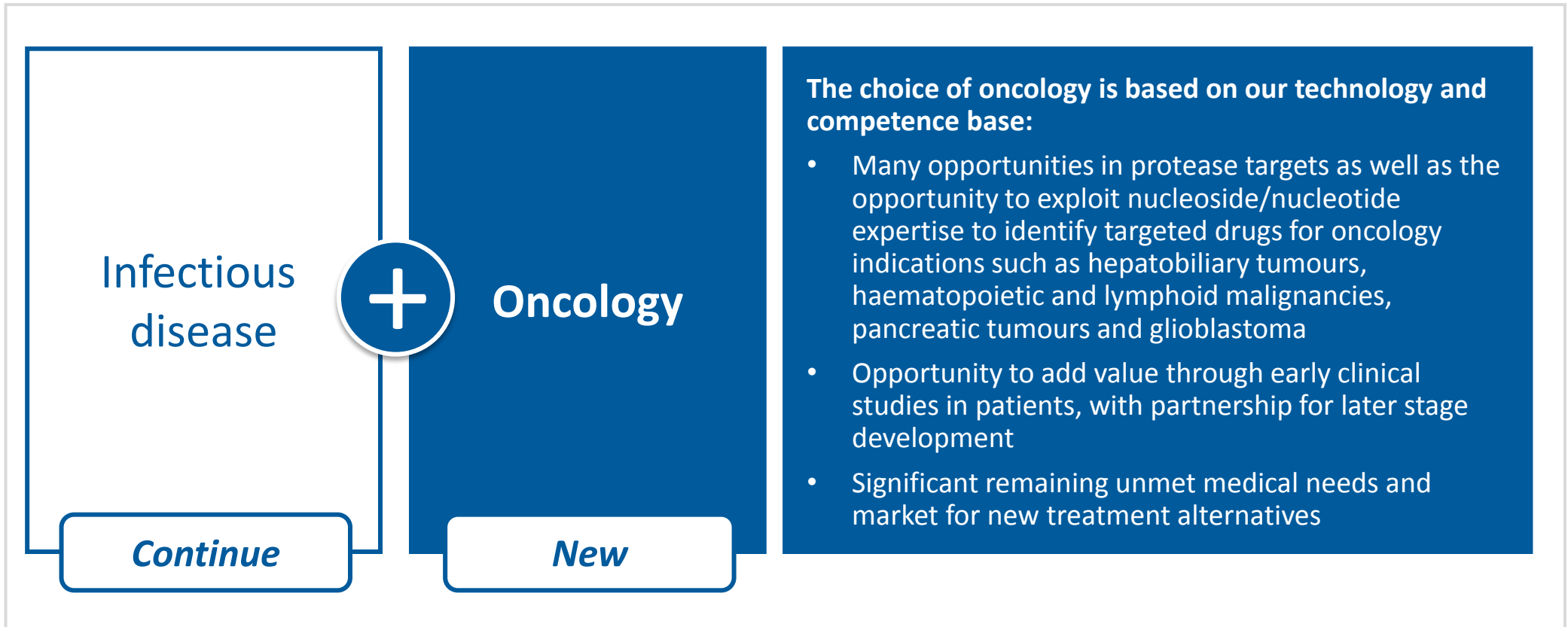
- Significant upside & economies of scale
- Retain Nordic rights for out-licensed products
- In-license products with strong growth potential

**Stable revenue stream and economies of scale and scope with Innovative Specialty Care Portfolio**

Broad portfolio of established brands with close operational synergies with Medivir's innovative product portfolio

## Leverage our technology platform to capture opportunities in new focus areas for future value creation




Alongside continued focus on infectious diseases, we will direct the company's technological expertise towards specific areas in oncology over the course of the coming years





# A focused strategy for value creation based on the four cornerstones

■ Innovation  
■ Established Brands

Cornerstones	Strategy
 <p>R&amp;D</p>	<p><b>I. Project generation and development in R&amp;D</b></p> <ul style="list-style-type: none"> <li>• Cutting edge competence in protease inhibitor design and nucleoside/nucleotide science with distinct discovery focus on infectious diseases and oncology</li> <li>• Focus on true innovation for unmet medical needs to maximize patient benefit and value creation</li> <li>• Prudent R&amp;D expense for defined portfolio scope and output (lower spend than 2013/2014)</li> <li>• Strategic investments outside of the run-rate to be made through in-licensing, partnerships/collaborations, advancing internal projects into phase II and M&amp;A</li> </ul>
 <p>Royalties &amp; Milestones</p>	<p><b>II. Partnerships and out-licensing</b></p> <ul style="list-style-type: none"> <li>• Key component in business model established through proven track record with big pharma</li> <li>• Firm commitment to early development in-house before partnership with/out-licensing to global partner to balance risk and optimize value</li> <li>• Targeting strong global partners for high quality late stage development and maximum reach in global commercialization</li> </ul>
 <p>Innovative Specialty Care Portfolio</p> <p>Nordic Brands</p>	<p><b>III. Commercial operations in the Nordics with focus on innovative products</b></p> <ul style="list-style-type: none"> <li>• Leverage Nordic commercial platform with focus on cost effective utilisation of highly specialised organization by:                         <ul style="list-style-type: none"> <li>- in-licensing innovative growth products primarily in Infectious diseases and oncology to match R&amp;D focus, but will act opportunistically if synergies can be secured</li> <li>- retaining Nordic rights for in-house developed products</li> </ul> </li> <li>• Provides knowledge and insight into entire value chain, including patient benefits, health economics and regulatory matters</li> </ul>





**Highlights from Q3**  
**Niklas Prager, CEO**

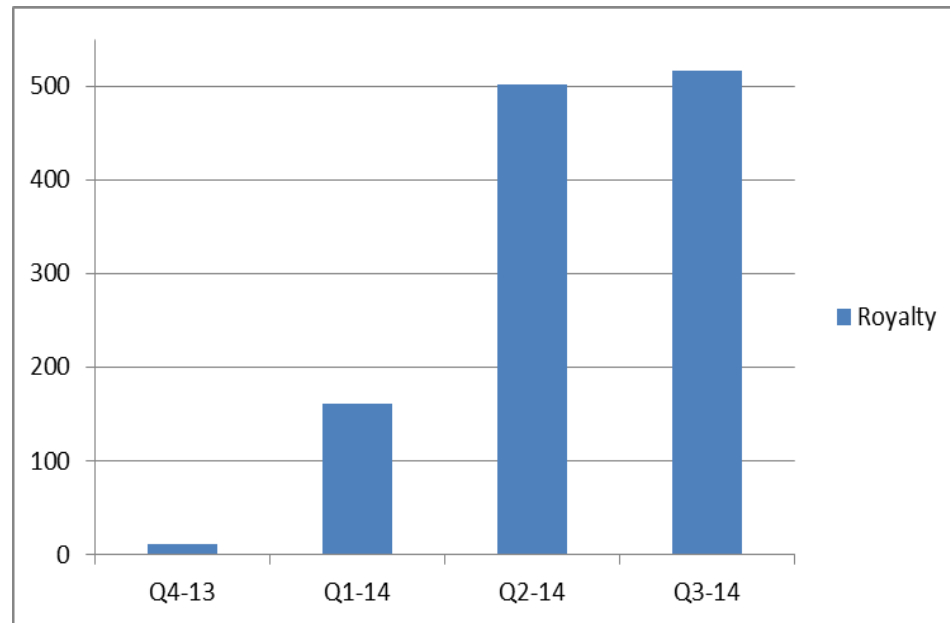
## Third quarter 2014 – continued progress made in all areas

- In the third quarter, our pharmaceutical sales showed an increase of 64,2 MSEK, or ~175% compared to the same quarter in 2013. The increase was primarily due to our market introduction of simeprevir (OLYSIO®).
- Our pharmaceutical portfolio generated sales of 100,8 (36,6) MSEK, of which simeprevir made up 61,6 (0) MSEK.
- For the third quarter we received 516,4 MSEK in royalties from our partner J&J.
- Total revenues during the quarter amounted to 617,8 (80,2) MSEK

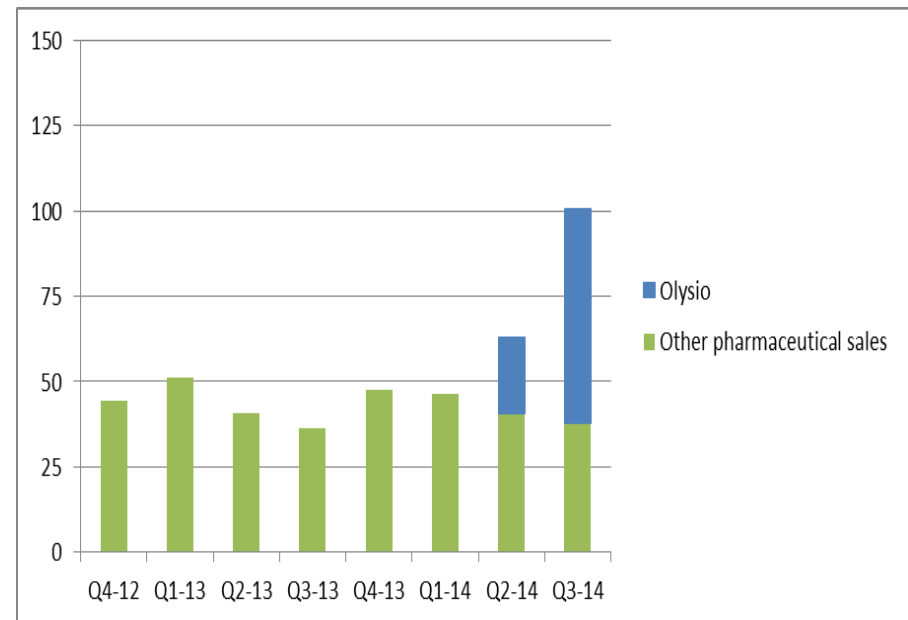
Breakdown of net turnover (SEK m)	Q3		Q1-Q3		Full year
	2014	2013	2014	2013	2013
Outlicensing and partnership agreements					
Non-recurrent payments	-	43,6	-	170,5	258,5
Pharmaceutical sales	100,8	36,6	210,2	128,5	176,1
Royalties	517,0	-	1 179,8	-	11,5
<b>Total</b>	<b>617,8</b>	<b>80,2</b>	<b>1 390,0</b>	<b>299,0</b>	<b>446,1</b>

# Royalties and own pharmaceutical sales

Royalties, SEK m, Q4 2013 – Q3 2014

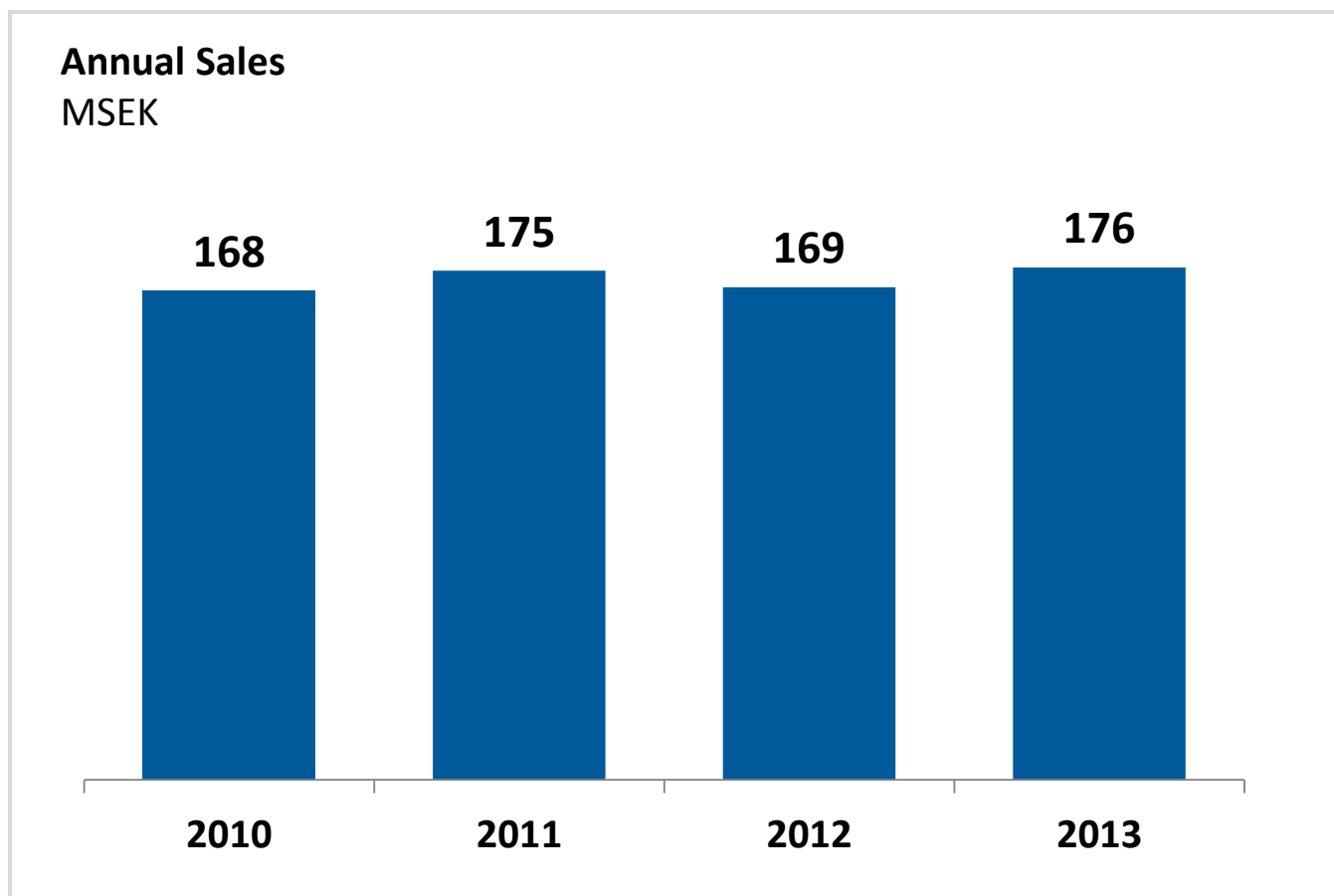


Own pharmaceutical sales, SEK m, Q4 2012 – Q3 2014



### Stable returns and continuous activities to improve gross margins further

#### Stable returns



#### 2014

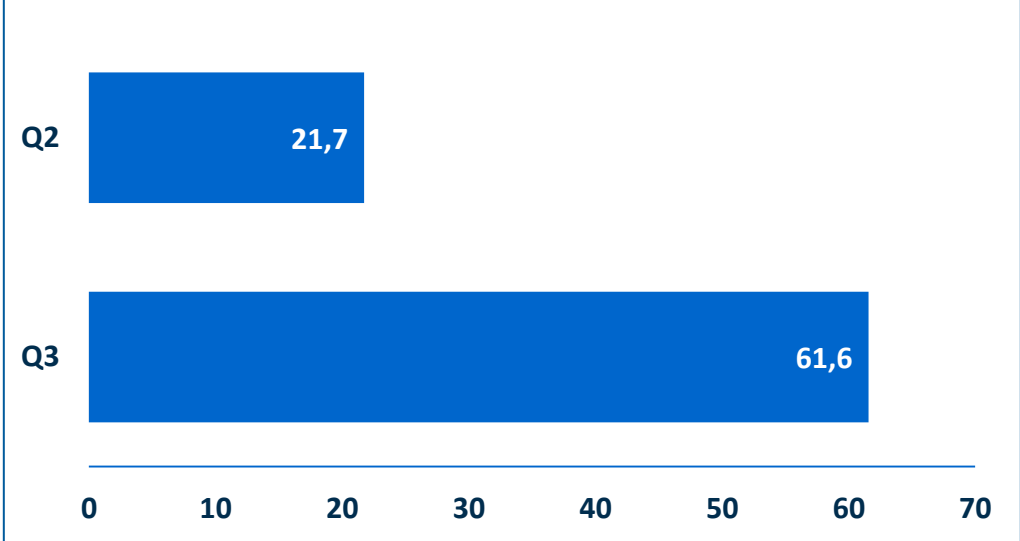
- Jan – Sep sales
  - 127 MSEK
  - 99 % vs. 2013
- Q3 sales
  - 39 MSEK
  - 107 % vs. 2013
- The positive sales trend primarily driven by Mollipect due to early flu/cold season
- Citodon tablet production costs have been reduced

# Successful Nordic OLYSIO<sup>®</sup> launch generates significant revenues & provides positive track record for in-licensing opportunities

## Nordic OLYSIO<sup>®</sup> Launch Update

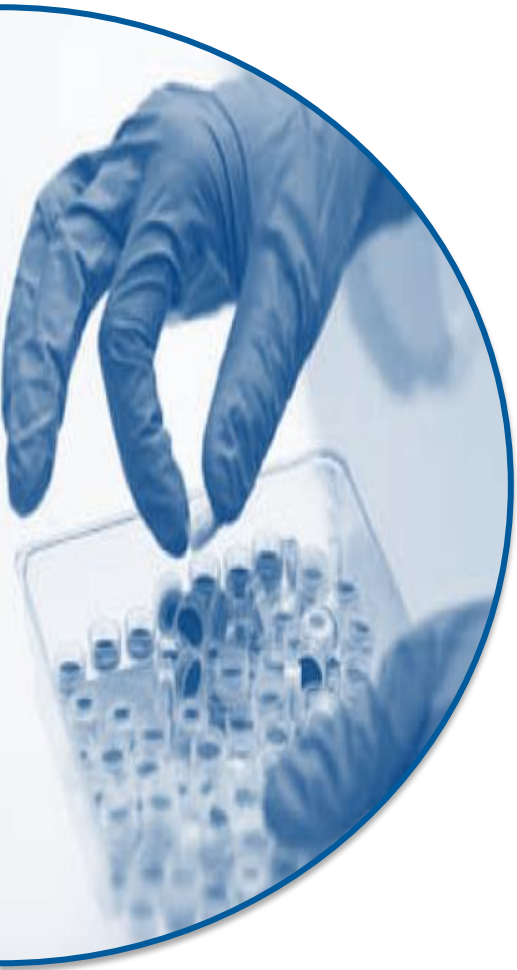
- Broad usage & positive experience across the Nordics
- Positive perception of the real world data recently presented at AASLD
- Agreements on OLYSIO<sup>®</sup>-based treatment with Swedish County Councils

## Nordic OLYSIO<sup>®</sup> Sales, MSEK



Growing user experience, strong real-world data and agreements with healthcare payers/providers is positive news as competition for OLYSIO<sup>®</sup> increases





## **Research and Development**

*World class science working toward next breakthroughs*

# Extensive partnering and collaboration track record with major pharma



## R&D portfolio

Therapeutic area	Product / Project	Partner	Preclinical phase		Clinical phase				Market
			Research	Development	Phase I	Phase IIa	Phase IIb	Phase III	
Labial herpes	ZoviDuo®/Xerclear®	GlaxoSmithKline	[Green bar spanning Research, Development, Phase I, Phase IIa, Phase IIb, Phase III, and Market]						
HCV infection	Olysio® (simeprevir)	Janssen	[Green bar spanning Research, Development, Phase I, Phase IIa, Phase IIb, Phase III, and Market]						
Osteoarthritis	MIV-711 Cathepsin K inhibitor		[Blue bar spanning Research and Development]						
Neuropathic pain	MIV-247 Cathepsin S inhibitor		[Blue bar spanning Research and Development]						
HCV infection	HCV nucleotide NS5B polymerase inhibitor	Janssen	[Green bar spanning Research and Development]						
HCV infection	HCV nucleotide NS5B polymerase inhibitor		[Blue bar in Research]						
RSV	RSV fusion protein inhibitor		[Blue bar in Research]						
HIV infection	HIV protease inhibitor	Janssen	[Green bar in Research]						

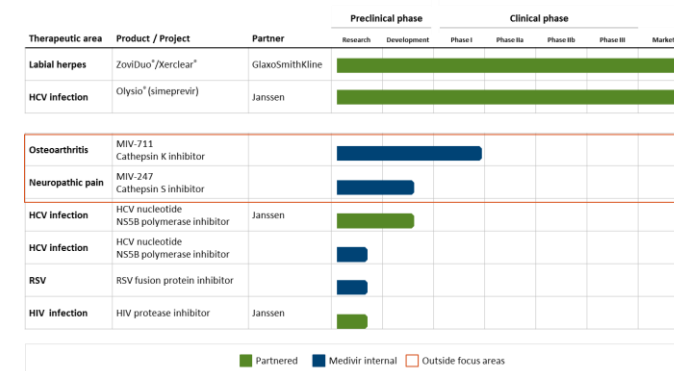
■ Partnered   
 ■ Medivir internal   
  Outside focus areas

## Comment

- Strong and diverse early development pipeline
- All future projects will fall within the new focus of infectious disease and oncology
- Ongoing projects include two that are outside the new focus

# Our R&D programs

## All internal projects developed according to plan during the quarter



- MIV-711 – Positive phase I data have previously been reported for MIV-711, a cathepsin K inhibitor in clinical development for osteoarthritis (OA). Long term toxicology studies (6 month) have now been initiated in order to enable for a clinical phase IIa proof of concept study in osteoarthritis patients with potential start in late 2015.
- MIV-247 – a cathepsin S inhibitor for neuropathic pain is currently in preclinical development, moving towards clinical phase I studies, expected to commence mid 2015. Medivir also presented data from preclinical models that supports the use of MIV-247 for the treatment of neuropathic pain, either alone or in combination with other therapies, at the 15th World Congress on Pain.
- Our lead nucleotide HCV inhibitor is presently being evaluated in extensive preclinical safety studies, results expected by year end 2014.
- The RSV Fusion Inhibitor Project that was in-licensed from Boehringer Ingelheim in August continues to advance in lead optimization.

## Near term milestones in our R&D projects

### Year 2014

- Q4: Phase II enabling, 6 month toxicology studies initiated with MIV-711
- Q4: Olysio Real-World-Data to be presented at AASLD in November
- Nov. 6: PDUFA date for Olysio FDA label on combination treatment based on COSMOS data
- YE 2014: Potential decision on continued program for nucleotide project

### Year 2015

- Q2: Submission of MIV-247 Clinical Trial Application
- Q2: Initiation of MIV-247 Phase I program
- Q3: Completion of MIV-711 Phase II enabling safety studies
- Q4: Potential initiation of MIV-711 Proof of Concept Phase IIa study

## Simeprevir on the global market



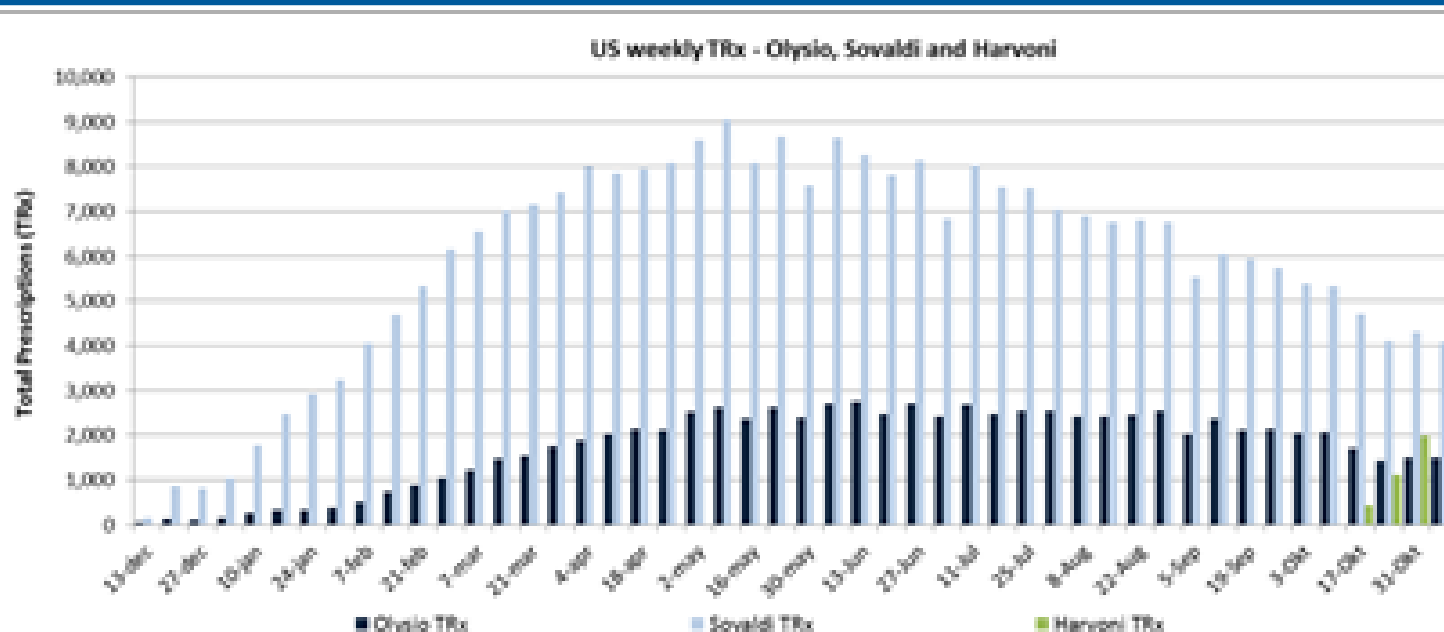
- ✓ Japan (SOVRIAD™)
- ✓ Canada (GALEXOS™)
- ✓ USA (OLYSIO™)
- ✓ Russia (SOVRIAD™)
- ✓ EU (OLYSIO™)
- ✓ Mexico (OLYSIO™)
- ✓ Australia (OLYSIO™)



# Simeprevir: Relatively stable market performance in the light of new competition and continued dedication to disease area by J&J



## Market Performance



The HCV landscape is evolving very fast with new IFN-free combinations coming to the market. Simeprevir recently received a upgraded label (sNDA) including INF-free treatment. Simeprevir will continue to play a role in different hepatitis C patient groups and durations

- Global sales of OLYSIO® (excl. Nordics) Q1 to Q3 2014 is 1,981 MUSD
- J&J's global third quarter sales of simeprevir were 796 MUSD, of which 671 MUSD were in the US
- Medivir's royalties based on these sales were 516,4 MSEK (56,2 MEUR) for the third quarter
- Continued roll-out with approvals and market introductions in major European markets on track
- The phase II study, IMPACT, for the evaluation of simeprevir in combination with sofosbuvir and daclatasvir in decompensated HCV patients was announced



Large number of studies of real-world experience with simeprevir in combination with sofosbuvir presented at the 2014 AASLD conference (Boston, 7-11 November)

- Treatment-naïve and treatment-experienced, including patients with prior PI experience
- Non-cirrhotic and cirrhotic, including patients with prior decompensation
- Post-liver transplantation

Data presented included results from two large longitudinal studies of real-world use of DAAs, HCV-TARGET and HCV-Trio\*. The data come from both academic and community centres, with the choice of treatment selected by the patient's physician. Key conclusions from these studies:

- Real-world efficacy rates with SMV + SOF ± RBV, primarily with 12w treatment, are comparable with those from the COSMOS study
- Low rates of virologic failure with SMV + SOF ± RBV in non-cirrhotic and compensated cirrhotic patients
- Confirmation of the favourable safety profile of simeprevir in combination with sofosbuvir

\*DM Jensen *et al.*, *Hepatology* (2014), 60, 219A-220A; D Dieterich *et al.* *Hepatology* (2014), 60, 220A

## Voluntary redemption as capital distribution method

### Distribution method rationale

- **Voluntary redemption is recommended as capital distribution method for the following main reasons:**
  - **Only suitable and possible distribution method**, in the short-term perspective
  - **Flexibility** for the shareholders
  - **Tax efficiency and simplicity**

### Key dates in preliminary timeline:

Date	Activity
29 Oct 2014	Terms and conditions to be made public
20 Nov 2014	Extraordinary General Meeting
Dec 2014 to Jan 2015	Notification on unknown and known creditors to enable transformation of restricted capital to unrestricted capital
Beginning of March 2015	Payment of redemption consideration to shareholders

[www.medivir](http://www.medivir.com)

Ticker: MVIR

Exchange: OMX / NASDAQ

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