

# A Focused Strategy for Sustainable Value Creation

*Presentation at Carnegie 23 October 2014*

Niklas Prager, CEO

Rein Piir, EVP Corporate Affairs & IR

October 16, 2014

The logo for Medivir, featuring the word "MEDIVIR" in a bold, blue, sans-serif font. The text is enclosed within a blue rectangular frame that has a slight 3D effect with a shadow on the right and bottom sides.

**MEDIVIR**

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



**A focused strategy for sustainable value creation**

---

**Balance sheet optimization overview**

---

**Information going forward** (News flow, milestones and events)

---

**Questions & answers**



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



## 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>
----------------------	---

**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



# 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>





## **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

# Medivir has a strong track record of bringing innovative discoveries to market

## Marketed Products

### Xerclear® / Zovido®



**Nucleoside analogue-based treatment for labial herpes**

### Olysio® (Simeprevir)



**Protease inhibitor currently revolutionizing HCV therapy**

## Medivir's core technology platform:

- **Protease inhibitor discovery** - historically applied to several therapeutic areas including infectious diseases
- **Nucleoside/nucleotide science** - historically applied almost exclusively to infectious diseases
- **In the future these technologies will be targeted to specific indications in infectious diseases and oncology**

## Prioritized Opportunities for future R&D investments

### Strategic investments will focus on:

- 1) Bringing our internal projects to next value inflection point based on robust financial rationale, e.g.
  - MIV-711 phase IIa proof-of concept in osteoarthritis patients
  - MIV-247 phase IIa proof of concept study in neuropathic pain patients
- 2) In-licensing of oncology project(s)
  - Accelerate oncology pipeline using our internal competence in key areas
- 3) Intensify partnering and collaboration
  - Target access to external innovation and funding to accelerate portfolio development
- 4) Exploring targeted M&A
  - Strategic opportunities to expand the oncology portfolio



All opportunities evaluated as business cases

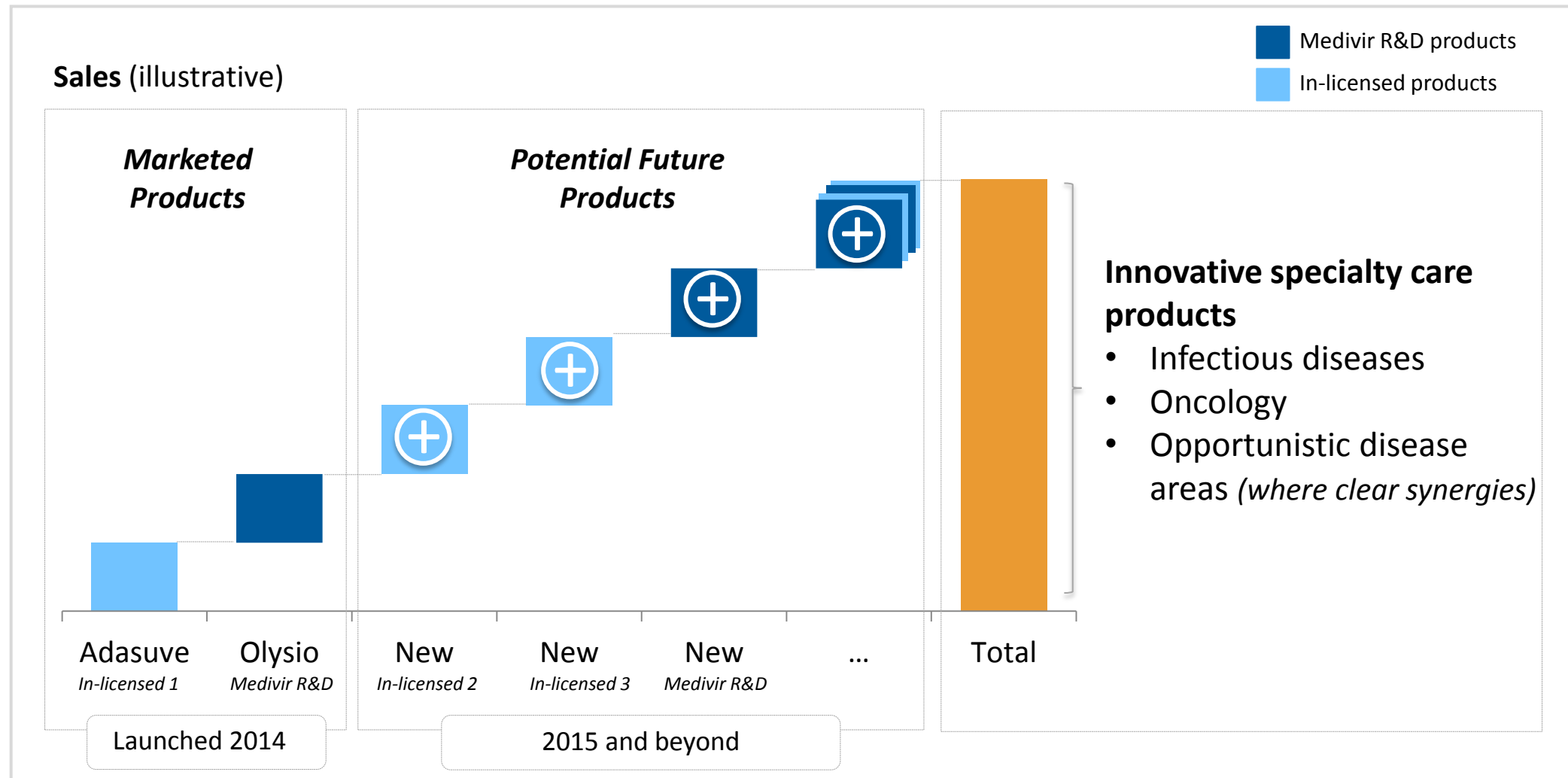


**Innovative Specialty Care Portfolio**  
*Providing a platform for organic growth*

# Growing through continuous addition of innovative specialty care pharmaceuticals



## Innovative Specialty Care Portfolio

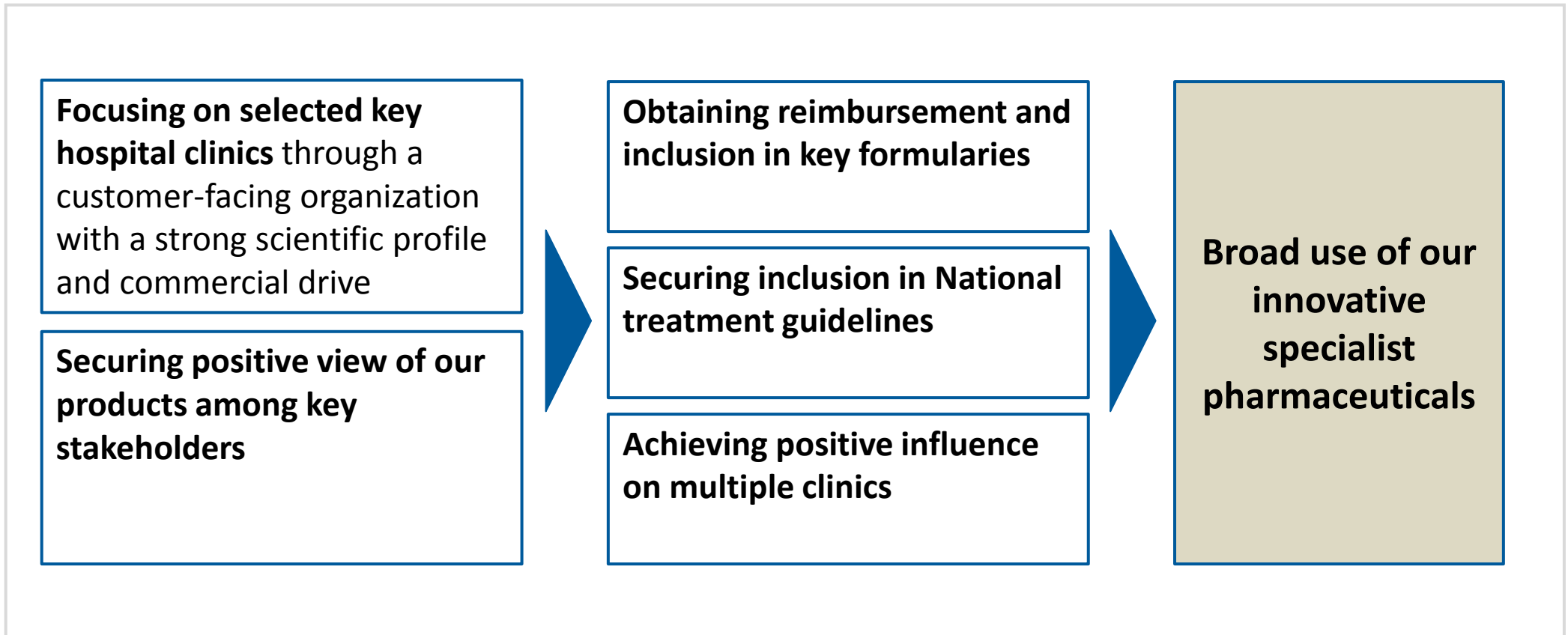


### Key assumption for value creation from in-licensing:

- Net sales per product: Peak sales of approximately 50-150 MSEK within 5 years of launch

## Specialty focused key account approach makes it possible to be successful in more therapeutic areas with the current platform

### Key account approach





## Fast and successful Nordic Olysio® launch provides positive track record for future in-licensing opportunities

### Olysio® (Simeprevir)



**Protease inhibitor currently revolutionizing HCV therapy**

### Nordic Launch Success Factors

- Trial/compassionate use experience before launch in all countries
- High Olysio® awareness and strong KOL endorsement ahead of launch
- Quick national approval processes at targeted price levels
- Supportive national treatment guidelines available in SE, DK, FI and NO

**Achieved record high market share in SE,  
27% the 1<sup>st</sup> full month on the market**



## **Royalties & Milestones**

*Proven massive potential*

## Xerclear<sup>®</sup>: Strong payback from innovation

### Xerclear<sup>®</sup> / Zovido<sup>®</sup>



**Nucleoside analogue-based treatment for labial herpes**

### Royalties and Milestones

- **US rights sold to Meda: \$45 million**

---

- **GSK RoW OTC rights: €3 million** (€1.4 million remaining)

---

- **Royalty agreement on OTC sales: up to 10%**

---

- **Royalty payments including Q2 2014: €0,1 million**

### Next steps

- **Estimated OTC market approvals in key EU countries**
  - UK: November 2014 / May 2015
  - Spain: September 2015
  - France: September 2016
- **Medivir believes that there is still more potential in the brand which the merged GSK/Novartis OTC entity can capitalize on**

## Simeprevir: Strong payback from innovation

### Olysio® (simeprevir)



Protease inhibitor currently revolutionizing HCV therapy

### Simeprevir on the global market

- |                   |                     |
|-------------------|---------------------|
| Japan (SOVRIAD®)  | EU (OLYSIO®)        |
| Canada (GALEXOS®) | Mexico (OLYSIO®)    |
| USA (OLYSIO®)     | Australia (OLYSIO®) |
| Russia (SOVRIAD®) |                     |

### Royalties and Milestones

- FTE funding over 3 years: €11 million

---

- Milestones received: €68.5 million

---

- Royalty agreement on Global sales (excl. Nordics): up to 10%

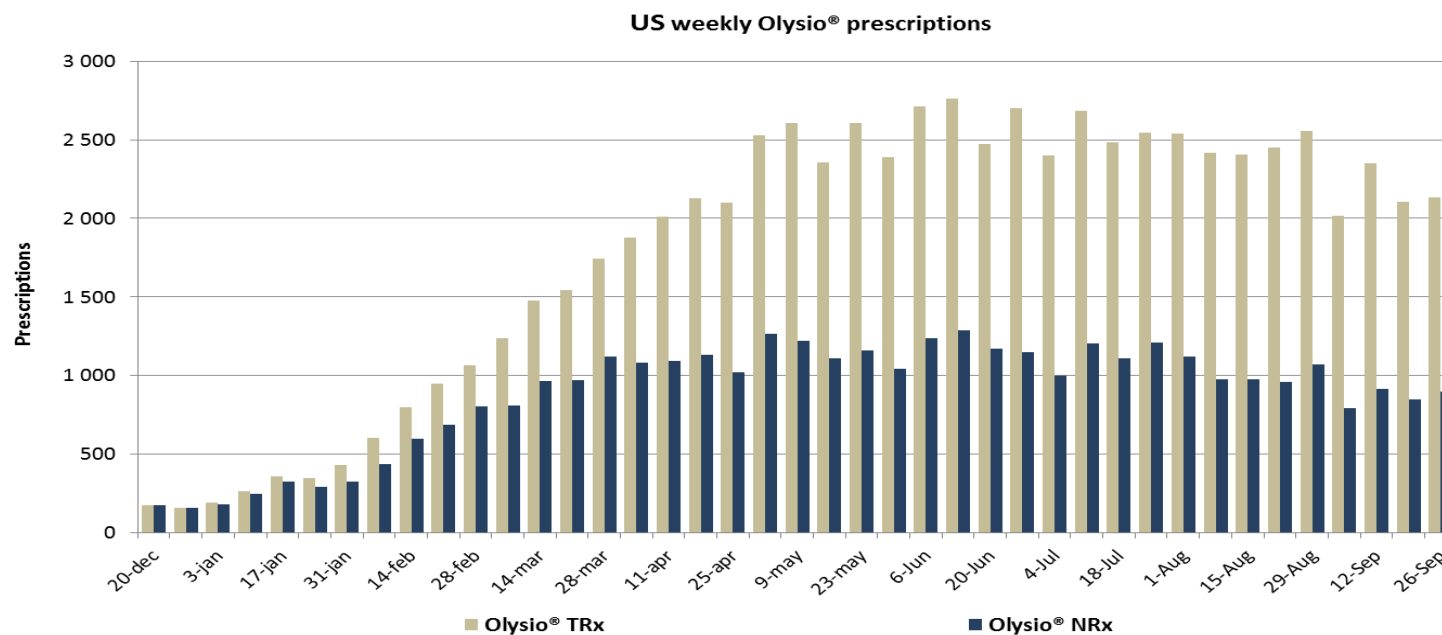
---

- Royalty payments including Q3 2014: €129 million

# Simeprevir: Continued strong market performance and clear dedication to disease area by J&J



## Market Performance



Simeprevir sales grew rapidly in the beginning of the year as a result of off-label spontaneous use, and based on the treatment guidelines from January 2014, supporting the use of the IFN-free combination therapy for genotype 1 hepatitis C-patients

- 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

## Experience from real-world

### Olysio® setting a foot print in the market

- **More than 30,000 patients\*** have or are on Olysio® treatment in the US, setting a strong foot print
- **High level of recognition among physicians and clinicians** both in US and Europe
- **Simeprevir in combination with sofosbuvir offers the first IFN – free treatment option with high acceptance**
- **High proportion of simeprevir use is in combination with sofosbuvir**
- **Real-world data confirms the strong phase II trial data on the combination\*\***
- **Very low viral breakthrough rates\*\***
- **Safe and well tolerated \*\*** - very low discontinuation and serious adverse event rates

\* Based on data from IMS

\*\* "Real world data" presented at the AASLD/EASL Conference in September 2014



## Continued J&J support for Olysio® (simeprevir)

### Continued strong commitment from J&J in the HCV area

#### J&J's commitment is supported by concrete actions

##### Clinical trial programme

- Two phase III studies, OPTIMIST 1 and 2, evaluating treatment of genotype 1 HCV-infected patients with simeprevir and sofosbuvir, are well under way.
- Yet another phase II IFN-free triple combination of simeprevir, sofosbuvir, and daclatasvir (IMPACT) in decompensated cirrhotic HCV patients has been announced
- One phase II study of an IFN-free triple combination of the three compounds simeprevir, IDX719, and TMC055 (HELIX-2)
- One phase II study including another IFN-free triple combination; simeprevir, JNJ-56914845, and TMC055

##### M&A

- On September 30, J&J announced the acquisition of Alios BioPharma that has two anti-hepatitis C virus (HCV) nucleotides in development which, if successful, would complement simeprevir and secures J&J continues to be a leader in the disease area

**Medivir believes that IFN-free treatments will be dominating, with many more options available for physicians and patients than today, but there are on-going studies including IFN and RBV that are worth highlighting:**

- 12 weeks full stop single-arm phase III study in treatment naïve GT1 and GT4 patients
- China: efficacy, safety & tolerability and pharmacokinetics in treatment naïve GT1 HCV



**Nordic Brands**  
*Stable cash generation*

# Established pharmaceutical drugs with strong brand names and long prescription traditions



## 14 unique drugs\*

- |                              |                                    |
|------------------------------|------------------------------------|
| <b>1. Citodon</b>            | <b>8. Nitroglycerin BioPhausia</b> |
| <b>2. Digoxin BioPhausia</b> | <b>9. Paraflex</b>                 |
| <b>3. Egazil</b>             | <b>10. Probecid</b>                |
| <b>4. Laxabon</b>            | <b>11. Solvezink</b>               |
| <b>5. Lithionit</b>          | <b>12. Suscard</b>                 |
| <b>6. Mollitect</b>          | <b>13. Teovent</b>                 |
| <b>7. Morfin Special</b>     | <b>14. Theo-Dur</b>                |

## Examples

**Citodon**



**Market leading analgesic**

**Mollitect**

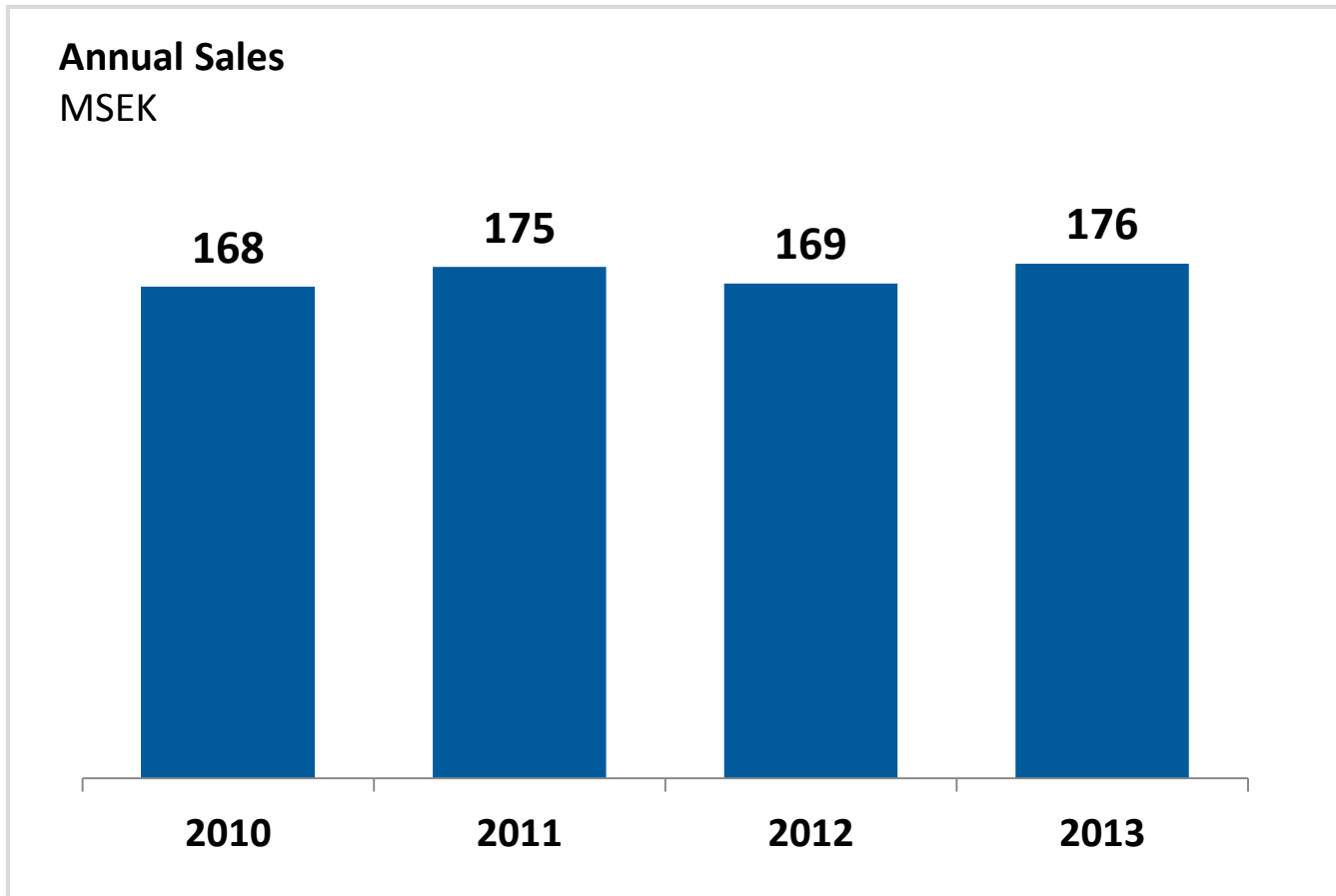


**Cough medicine with double actions**

\* Obtained through the acquisition of BioPhausia

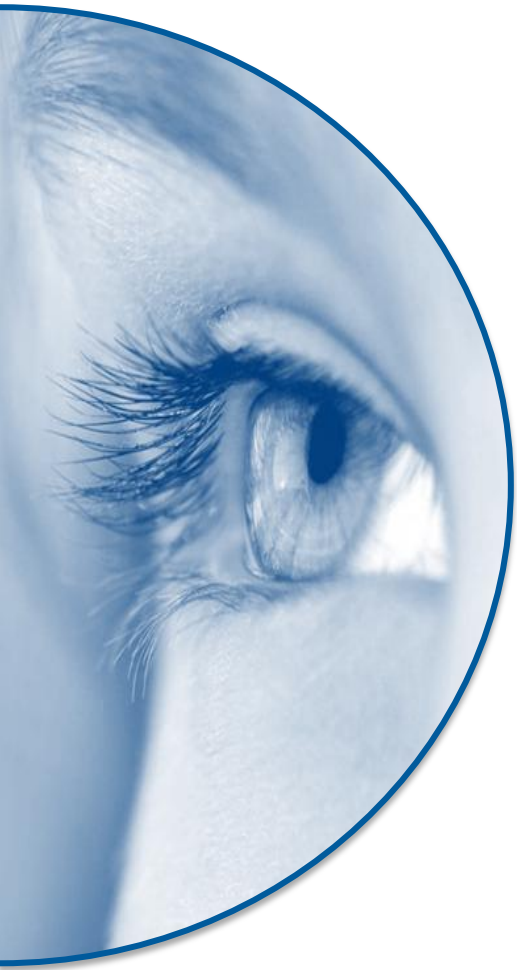
## Stable returns, minimal costs and continuous activities to improve gross margins even further

### Stable returns



### Activities to improve gross margins (e.g.)

- Streamline internal processes
- Improve forecasting to minimize stock without risking stock-outs
- Continue to drive down production costs with our CMOs
- Secure price level reflects benefit to patients and society



## **Strong outlook for coming years**

### *Summary*

## Targeted investments to enhance value, while also distributing cash to shareholders (1/2)

**Financial strength enables Medivir to benefit shareholders and ensure investment in future value creation**

### Optimization of capital structure

- **Strong financial position allows for cash distribution to shareholders and investments in future value creation**

### Prudent use of resources

- **Corporate running costs will be tightly-controlled and reduced compared to 2014**
- **Investments will be made in well-defined areas:**
  - to increase output from R&D
  - to maximize the value of current projects
  - to accelerate revenue growth in Innovative Specialty Care Portfolio



## Targeted investments to enhance value of R&D portfolio and improve revenue growth, while also distributing cash to shareholders (2/2)



■ Innovation  
■ Established Brands

Dedication and focus from everyone at Medivir on building and visualizing the value of each cornerstone

### R&D

- R&D expected to:
  - **Focus on specific areas in oncology** in addition to infectious diseases
  - **Strengthen early development pipeline**
  - **Advance current projects to out-licensing** while balancing risk and value maximization

### Royalties & Milestones

- **Royalties from simeprevir expected to decline vs. 2014, but to remain a significant contribution to Medivir both medium and long term**
- **Income from new out-licensed projects expected to provide growth and risk diversification**

### Innovative Specialty Care Portfolio

- **Sales expected to grow in the medium and long term on the launch of new products, after initial decline in Olysio® sales in 2015**

### Nordic Brands

- **Expected to provide stable revenues and become increasingly profitable as margins improve**



**A focused strategy for sustainable value creation**

---

**Balance sheet optimization overview**

---

**Information going forward** (News flow, milestones and events)

---

**Questions & answers**



## Optimization of capital structure – aligned with company strategy

### Background

- Current strong momentum with the successful market introduction of simeprevir has led to a very strong cash position and profitability for Medivir within a short time-frame
- Based on Medivir's strategy update and plan, the Company has analysed its capital structure and come to the conclusion that there is currently room for a larger capital distribution to the shareholders

### Board recommendation

- The Board has decided to recommend a two-step approach:
  - (I) Short-term, a one-off distribution of 625 MSEK (20 SEK/share) through a voluntary redemption of shares to be decided at an Extraordinary General Meeting on 20 November 2014 – the process will run into Q1 2015
  - (II) Seek mandate for a share buy-back programme at the Annual General Meeting in May 2015

### Future capital structure

- Medivir has the intention to work continuously with optimising the capital structure (e.g. dividends, share-buy-back or redemption programmes), based on an assessment of financial position and investment opportunities

## 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



**A focused strategy for sustainable value creation**

---

**Balance sheet optimization overview**

---

**Information going forward** (News flow, milestones and events)

---

**Questions & answers**



## Our ambition is to be transparent in our communication

### We will continue to announce / communicate

- Our Nordic sales Quarter by Quarter
- Important agreements or collaborations
- Milestone or progress in our internally-driven projects
- Relevant and important study results related to Olysio®

### We will improve

- We will raise the visibility of Medivir on our web-site, and also around what has been published externally about us and our projects

### We will not

- Report monthly sales statistics on our own products
- Comment on weekly sales on Olysio®
- Provide guidance on expected revenues

## 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