

# Medivir

## Corporate Presentation Stockholm Corp, 2016

**MEDIVIR**

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

# Balanced platform of innovation and revenue generation

## Locations and personnel

- Headquarters in Stockholm, Sweden
- Around 130 employees, 75% of which are in R&D

## Innovation

### Discovery Research and Development

- Leading competence in protease inhibitor design and nucleot(s)ide science
- Focus on infectious diseases and oncology
- Pipeline breadth from discovery to early development
- Strong R&D infrastructure and competence

## Revenue generation

### Global Partnerships

- Successfully developed 2 pharmaceuticals that have been approved and launched in key markets
  - Xerclear® / Zoviduo® (GSK EU; Meda North America)
  - OLYSIO® (Simeprevir) (Janssen; Global Sales of USD 2.3 Billion in 2014)



### Nordic Commercial Operations

- **Innovative Specialty Care Portfolio**
  - Two innovative specialty care products, Olysio® and Adasuve®, launched in the Nordics
  - Experienced and specialized commercial organization
- **Nordic Brands**
  - 13 Rx pharmaceuticals with stable revenue and earnings generation through efficient organization

## Ability to invest in innovation for sustainable value creation

- Strong financial position: Market cap of 1.6 BSEK, ~1,078 MSEK in cash by end of Q4 2015
- More diversified shareholder base with 43% international shareholders



## Key milestones 2015

- ✓ The new focus area oncology delivers its first internal cancer project within Hepatocellular Carcinoma (liver cancer)
- ✓ 600m SEK was distributed to the shareholders
- ✓ Declining royalty revenue of OLYSIO® driven by global launches of competitive products
- ✓ Continued development of simeprevir in different combination studies by our partner Janssen
- ✓ A more efficient, flexible and focused organisation was created through changes in the management team, R&D and the Commercial organisation
- ✓ Started a phase IIa trial with MIV-711 in osteoarthritis patients in the beginning of 2016



# Financial summary

Summary of Group's figures (SEK m)	Q4		Full Year	
	2015	2014	2015	2014
Net turnover	84.7	377.0	657.9	1 767.0
Gross profit	60.7	324.5	548.6	1 593.0
EBITDA	-35.9	214.9	115.0	1 221.9
Operation profit (EBIT)	-44.5	206.5	114.8	1 188.7
Profit/loss before tax	-53.1	204.3	102.0	1 192.7
Profit/loss after tax	-45.2	147.3	75.1	1 132.7
Operating margin, %	-52.5%	54.8%	17.4%	67.3%
Basic earnings per share	-1.56	4.71	2.59	36.24
Diluted earnings per share	-1.54	4.67	2.56	35.90
Net worth per share	53.8	63.4	53.8	63.4
Return on Equity	-3.6%	10.7%	5.9%	84.1%
Cash flow from operating activities	-37.6	507.9	307.4	1 011.9
Liquid assets and ST investments	1 077.9	1 395.6	1 077.9	1 395.6
R&D spending/total opex, %	66.9%	64.7%	64.2%	60.8%

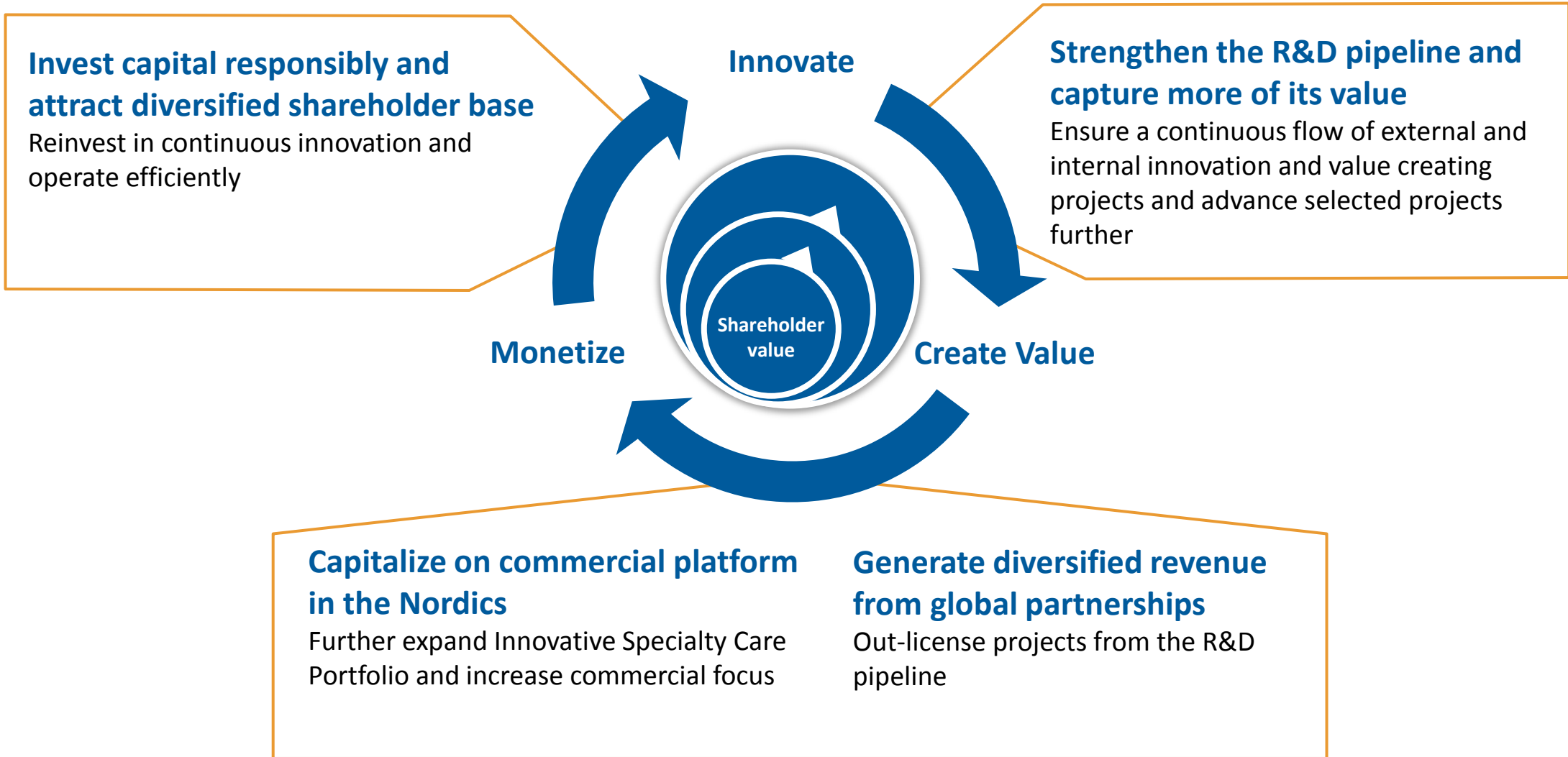
## 2015 Net turnover

- Net turnover totalled SEK 658m (1 767m), of which SEK 419m (1 399m) comprised royalties for simeprevir.
- Revenue from Medivir's own pharmaceutical sales totalled SEK 237m (367m), of which SEK 53m (186m) derived from sales of OLYSIO® and SEK 184m (180) from sales of other pharmaceuticals.

## Key figures

- Operational profit (EBIT) was 115m (1 189)
- The profit after tax was SEK 75m (1 133m)
- The cash flow from operating activities amounted to SEK 307m (1 012m)

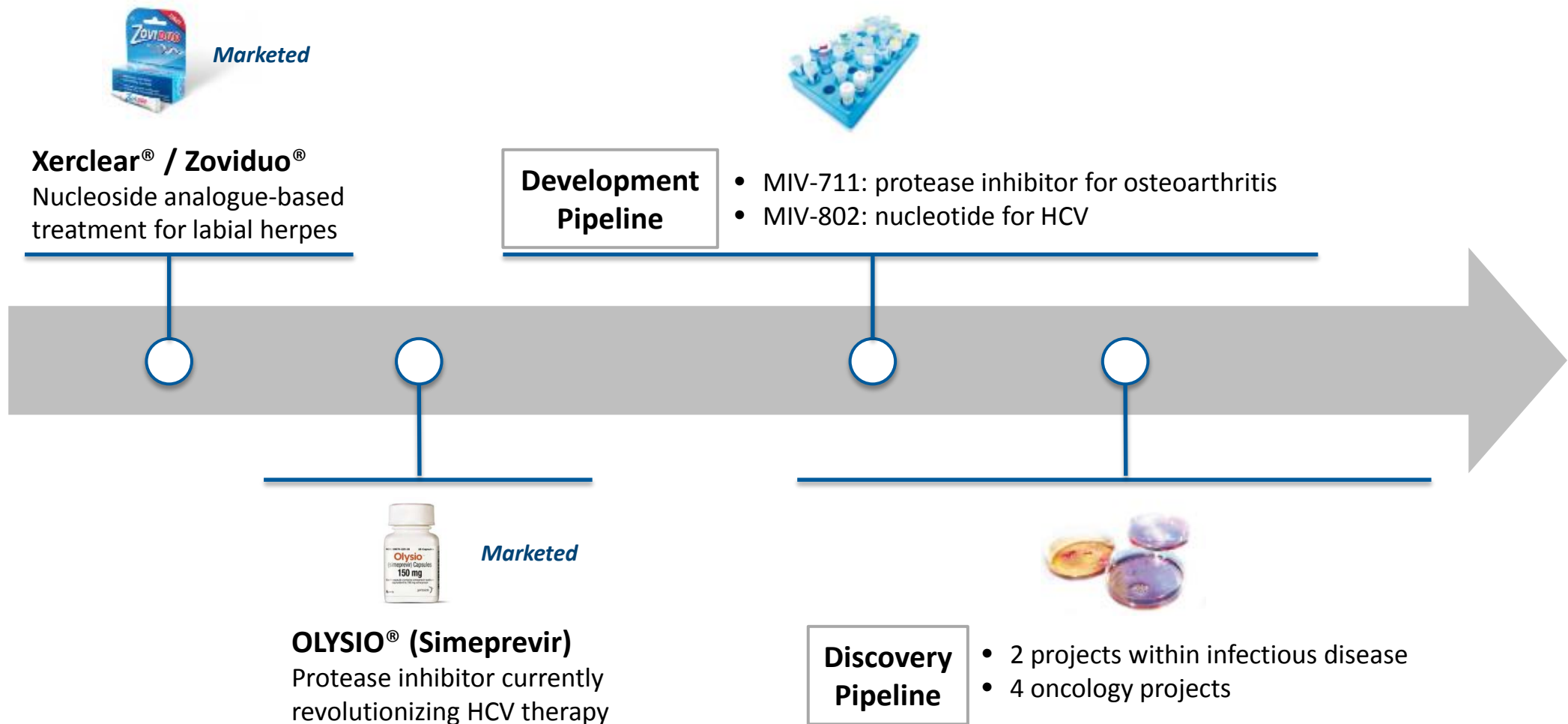
# Sustainable value creation



# Continuous innovation through proprietary technology platform



## Proven capabilities in protease inhibitor design and nucleotide/nucleoside science



# Innovative projects with potential for significant value creation



Project	Pre-clinical		Clinical	
	Res.	Dev.	Ph. I	Ph. II
<b>Osteoarthritis</b> MIV-711 Cathepsin K inhibitor				
<b>HCV infection</b> MIV-802 HCV nucleotide NS5B polymerase inhibitor				
<b>RSV</b> RSV fusion protein inhibitor				
<b>Hepatocellular Carcinoma</b> Nucleotide polymerase inhibitor				

## Market potential overview

- 250 million people worldwide estimated to suffer from knee OA in 2012
- Unmet needs in suspending disease progression & relieving pain
  - › **Every 10% of the target population on the US market alone represents a potential of 600 MUSD\* in annual sales**
- Nucleotides are the cornerstone of most effective drug combinations
- **Large potential for nucleotide class; MIV-802's potential depends on future competitive landscape & development in combination with other DAAs**
- Major cause of lower respiratory tract infections and hospital visits
  - › **Market potential is estimated to be 500 MUSD in annual sales (based on health-care utilization by young children and elderly patients infected by RSV)**
- Liver cancer is the second leading cause of cancer-related death world-wide, and one of the fastest growing cancers in US based on incidence and mortality.
  - › **Substantial opportunities for an effective liver-targeted agent in all patient segments**

\* 10% market share represents 200,000 patients multiplied by an annual treatment cost of 3,000 USD/Year

# Osteoarthritis is a leading cause of chronic disability

## Overview

- **Progressive disorder** characterized by joint degeneration, pain and loss of function
- **Most prevalent joint disease;** up to 40% over 65 suffering from knee or hip OA
- **Current treatments are insufficient** focusing on symptom relief e.g. physiotherapeutic exercise, intra-articular corticosteroids or hyaluronic acid and analgesics/anti-inflammatory agents (NSAIDs) in connection with life-style changes
- **No effective and safe disease modifying osteoarthritic drugs** (DMOADs) are available

## Key unmet needs

### Suspend disease progression and relieve pain

- Prevent degradation of subchondral bone, recently recognized as a key target for OA, and cartilage
- Prevent the pain associated with the disease

**A disease-modifying OA drug (DMOAD) meeting these unmet needs has great market potential based on large and growing patient population**



# A potent – selective - once daily cathepsin K inhibitor

Excessive cartilage degradation *and* bone resorption are key features of osteoarthritis

Cathepsin K inhibition is expected to have joint protective effects in human OA

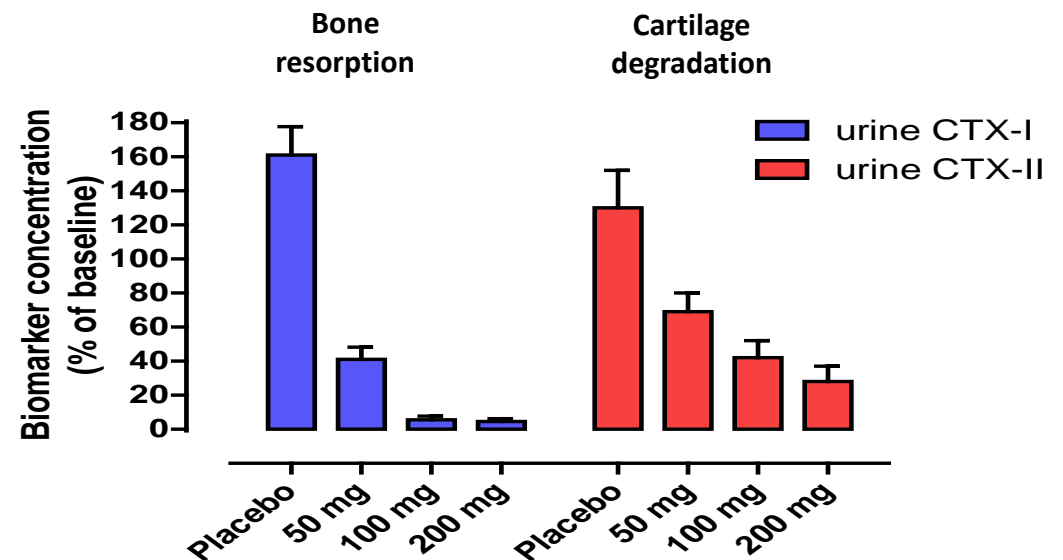
- Expressed in osteoclasts and chondrocytes and degrades both bone and cartilage collagen
- Bone-acting agents have demonstrated beneficial effects on human OA disease progression, pain and function (e.g. SEKOIA study on strontium ranelate)

Pre-clinical data with MIV-711 in OA disease models:

- Demonstrated joint protective effects on both bone and cartilage in preclinical OA models
- Paralleled by reduced biomarkers of cartilage degradation and bone resorption (up to 85%)

Clinical phase I data:

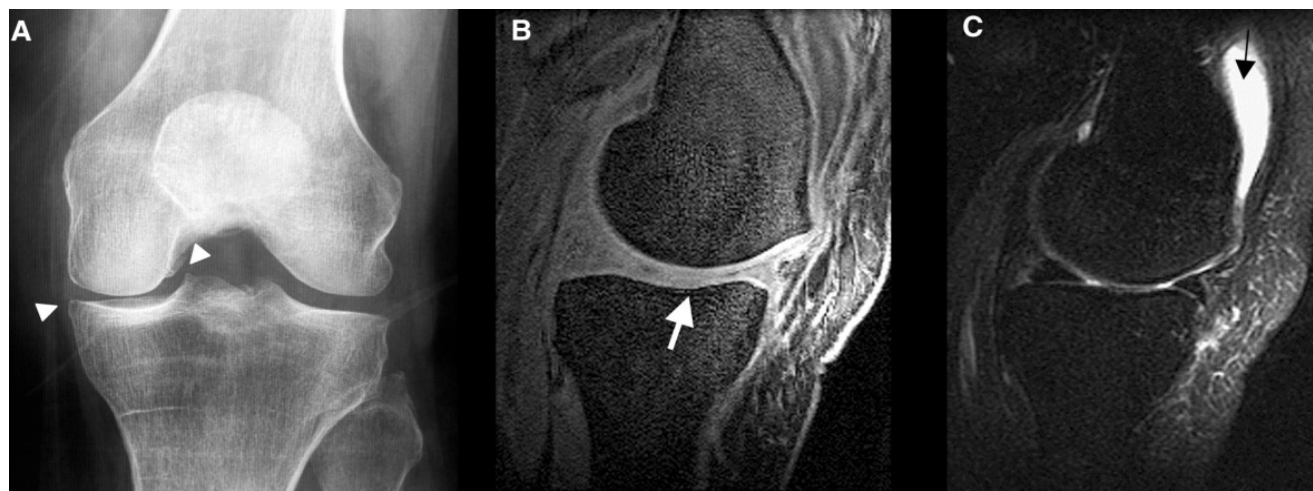
- Generally safe and well tolerated up to 28 days
- Similar dose-dependent decrease in biomarkers of cartilage degradation and bone resorption:



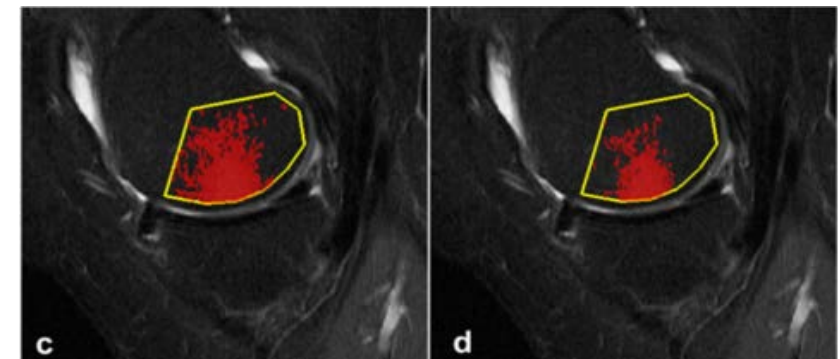
# New methodologies facilitate development of disease modifiers

## Improved magnetic resonance imaging technologies will shorten PoC studies

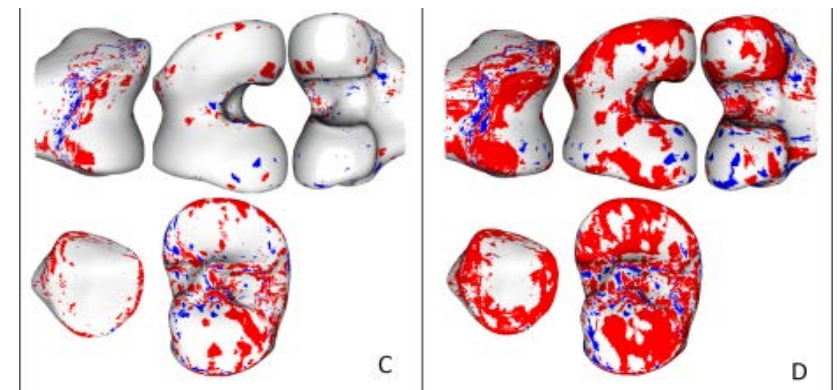
- Readily quantifies complex structures and takes 3-D surfaces into account
- Detects and quantifies soft tissue components of joint structures
- Greatly enhances sensitivity and reproducibility which facilitates new approaches such as modelling for better prediction



Picture modified from: Link TM et al., *Radiology*.2003 Feb;226(2):373-81



Picture modified from: Nielsen FK et al. *BMC Musculoskeletal Disorders* 2014, 15:447



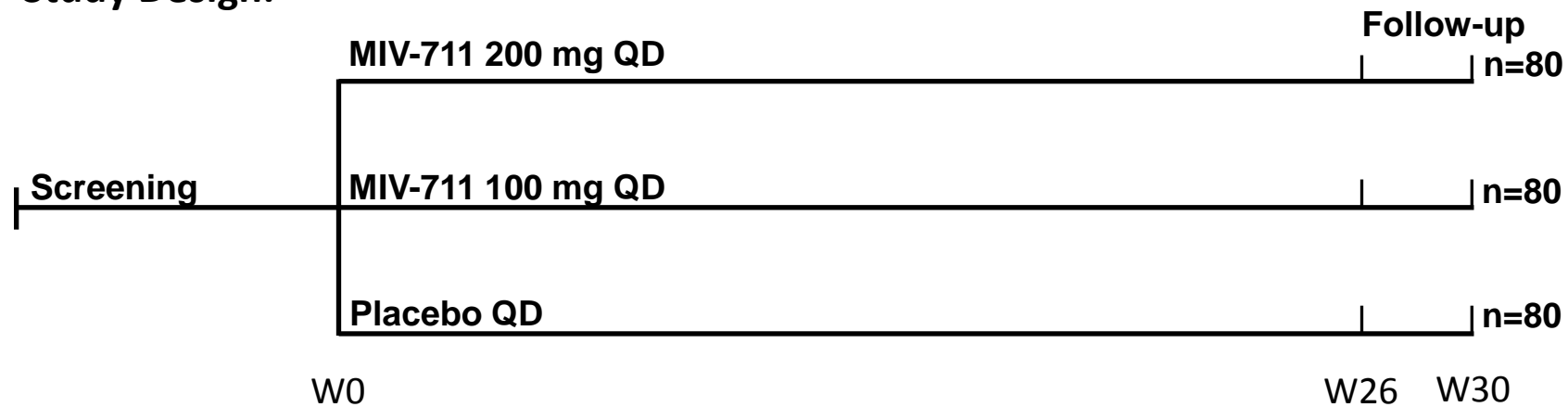
Picture modified from: Bowes MA, et al. *Ann Rheum Dis* 2015;74:519-525

# Phase IIa study design

## MIV-711-201:

A Randomized, Double-blind Placebo-controlled phase IIa Study to Evaluate Efficacy, Safety and Tolerability of MIV-711 in Knee Joint Osteoarthritis (EudraCT Number: 2015-003230-26)

### Study Design:



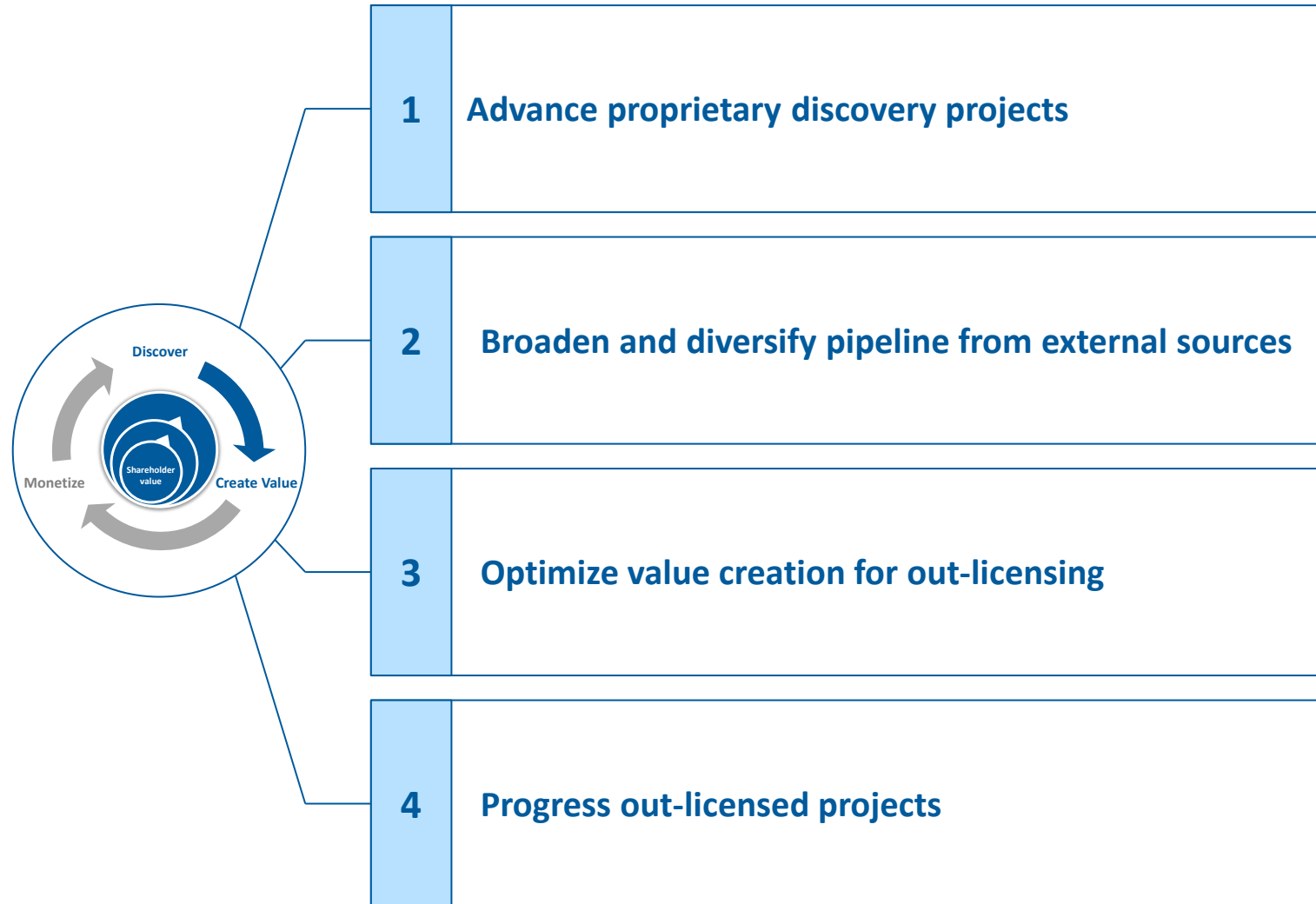
**Population:** Patients with moderate knee OA and chronic pain

**Countries:** Six European countries

**First patient in:** Q1 2016

**Expected final data:** Q3 2017

# Four part strategy to strengthen the R&D pipeline and capture more of its value



**R&D**  
*Focus on infectious disease and oncology*

## Strategic transactions

*creating longer-term independent growth opportunities*

- Bolster pipeline by adding novel assets and complementary technology platform(s)



## Operational efficiency

*ensuring prudent use of our cash*

- Harness in-house development expertise and ensure access to external expertise
- Out-source when relevant to secure flexibility, speed and quality
- Run multiple projects and development steps in parallel

**Nordic Commercial Operations**

- In-licensing / acquiring products to our specialty care portfolio



- Leverage market insights in development and in discussions with partners
- Capture synergies between Nordic Brands and Innovative Specialty Care portfolio

## Medivir has the platform for sustainable value creation



- **R&D capabilities and financial resources to continue to innovate** within our focus areas infectious disease and oncology
- **End-to-end ability to drive multiple projects in parallel** from discovery through clinical proof of concept
- **Attractive partner** for in- and out-licensing
- Proven **ability to monetize** (projects into partnerships)
- **Commercial strength in the Nordics** to launch and market specialty care products
- **More diversified shareholder base** as success has increased interest from international investors



# Path to Long-term Value Creation

## Strengthen the R&D pipeline and capture more of its value

Ensure a continuous flow of external and internal innovation and value creating projects and advance selected projects further. Four part approach:

1. Advance proprietary discovery projects
2. Broaden and diversify pipeline from external sources
3. Optimize value creation for out-licensing
4. Progress out-licensed projects



### Accomplished

- MIV-711 phase IIa study initiation
- First in vivo efficacy studies with advanced leads from HCC nuc project in progress
- MIV-802 IND-enabling toxicology study completion
- MIV-711 phase IIa study – first patient in (1Q16)

### Upcoming Milestones

- HCC nuc - IND-enabling tox studies initiation (4Q16)
- RSV – IND-enabling tox studies initiation (1H17)
- External transaction(s) (including potential acquisitions)
- MIV-711 phase IIa study – extension trial (Q416)

## Generate diversified revenue from global partnerships

Out-license projects from the R&D



- Janssen started simeprevir-based 3DAA combination Phase I study

- Janssen simeprevir-based 3DAA Phase II study completion (3Q16)
- Partnering discussions for MIV-802

## Capitalize on commercial platform in the Nordics

Expand Innovative Specialty Care Portfolio through in-licensing



- Olysio launched
- Adasuve in-licensed and launched

- In-license products for Nordic commercialization

## Invest capital responsibly and attract diversified shareholder base

Reinvest in continuous innovation and operate efficiently



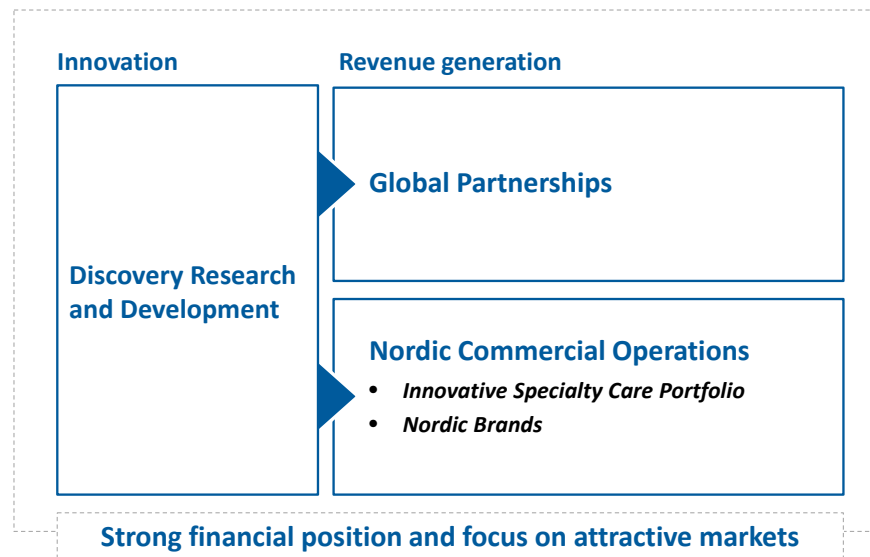
- Price increases on Nordic Brands implemented
- Increased cost flexibility through GVK collaboration
- International ownership increased from 28% to 43% in 2015

- Continued gross margin improvements in Nordic Brands
- G&A cost efficiency from full year effect of organizational changes

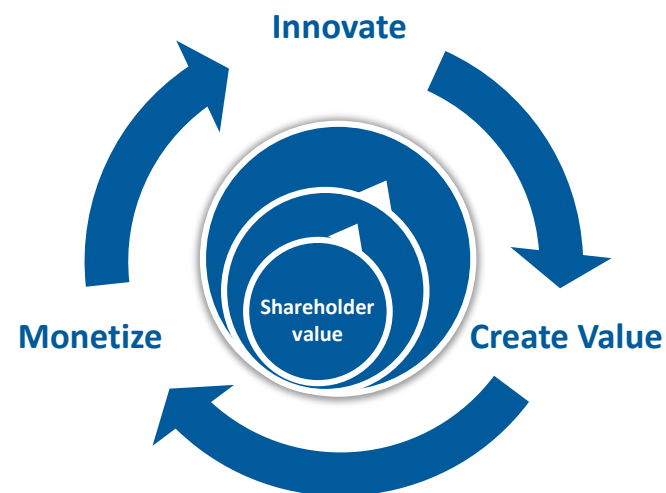
To summarize, Medivir is in a strong position to continue to discover, develop and capitalize on investments in innovation



Medivir has the platform for sustainable value creation...



...and will utilize proven track-record to further build shareholder value



*Take advantage of Medivir's history of bringing valuable drugs from bench to bedside*





# Q&A

