# Carnegie Small & Mid Cap Seminar
# 3 September 2014

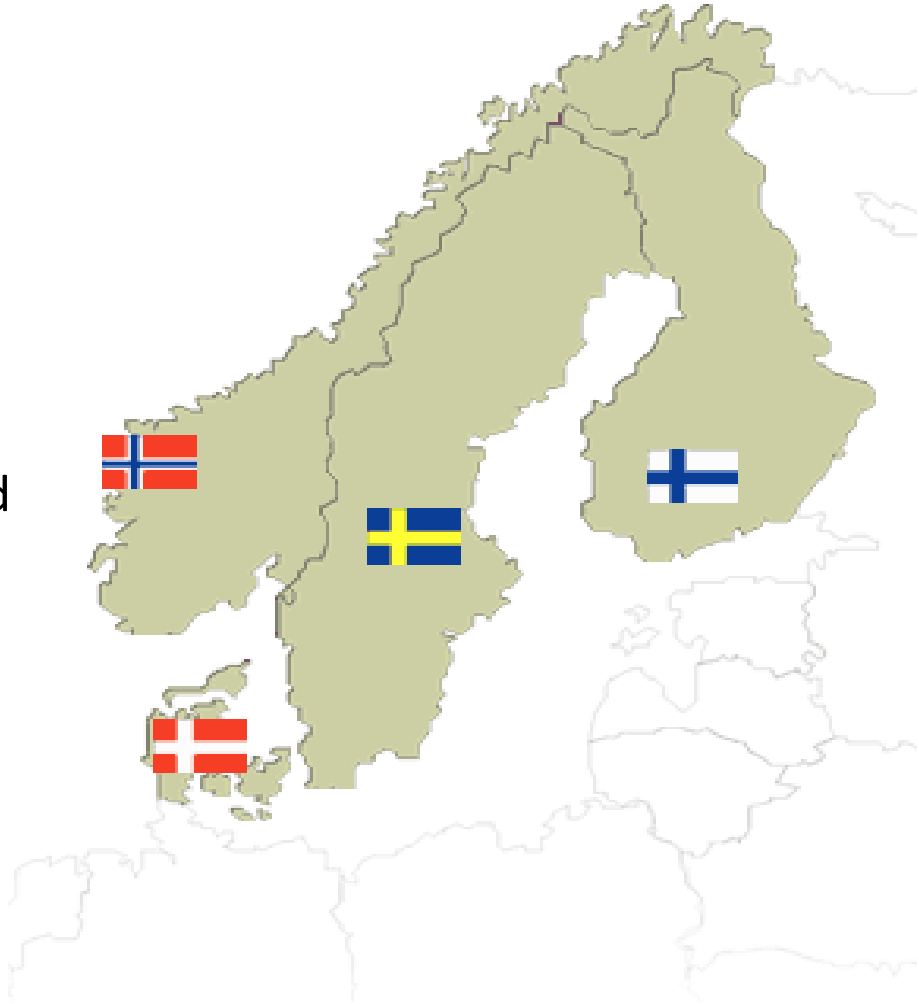
**Rein Piir, EVP Corporate Affairs & IR**

MEDIVIR

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

# Medivir – Nordic base with global R&D

- Headquartered and listed in Stockholm, Sweden
- ~ 140 employees, of which 90 are in R&D
- World leading expertise in polymerase and protease drug targets
- R&D pipeline: 4 major internally driven projects
- Nordic  commercial organization marketing 16 Rx pharmaceuticals
- Two innovative specialty care products, Olysio and Adasuve recently launched in the Nordics
- Two pharmaceuticals taken from idea to market:
  - Olysio (simeprevir) for treatment of chronic hepatitis C, licensed to J&J globally excluding the Nordics
  - Xerclear for treatment of labial herpes, licensed to GSK in Europe



# Financial facts

- Listed on NASDAQ OMX Stockholm since 1996
- Broad institutional shareholder base, >25% EU & US shareholders
- Solid financial position (430 MSEK end Q2, 14*), on the way to sustainable profitability
- Sales in 2013 were 176 MSEK (~25MUSD)

| | | |
|---|---|---|
| **Market Capitalization:** | 4,000 MSEK | 575MUSD |
| **Cash (March 31)*:** | 430 MSEK | 61 MUSD |
| **Debt (March 31):** | 42MSEK | 6 MUSD |
| **Revenues Q2, 14:** | 564 MSEK | 81 MUSD |
| **Shares Outstanding:** | Class B: | 30,600,027 |
| | Class A: | 660,000 |
| | Options: | 404,374 |
| | Fully Diluted: | 31,664,401 |

| CONSOLIDATED INCOME STATEMENT SUMMARY Continuing operations (MSEK) | Q2 2014 | Q2 2013 | FY 2013 |
|---|---|---|---|
| Net turnover | 564.0 | 40.7 | 446.1 |
| Gross profit | 518.8 | 23.5 | 374.3 |
| EBITDA | 424.4 | -46.9 | 76.4 |
| EBIT | 416.2 | -62.0 | 25.2 |
| Profit/loss before tax | 418.4 | -62.1 | 27.7 |
| Profit/loss after tax | 327.8 | -63.7 | 16.0 |

| Net turnover breakdown (MSEK) | Q2 2014 | Q2 2013 | FY 2013 |
|---|---|---|---|
| Outlicensing and partnership agreements: Non-recurrent payments | - | - | 258.5 |
| Pharmaceutical sales | 62.9 | 40.7 | 176.1 |
| Royalties | 501.1 | - | 11.5 |
| Other services | - | - | - |
| **Total** | **564.0** | **40.7** | **446.1** |

*Q2 simeprevir royalties of 500 MSEK not accounted for in cash position. Including the royalties, the end Q2 cash position was 930 MSEK (133 MUSD)

# Second quarter 2014 – good performance for our Rx portfolio

## Our pharmaceuticals

### Performance

- Medivir´s pharmaceutical portfolio comprises 16 prescription pharmaceuticals marketed in the Nordic region. Going forward we will continue to focus on specialty pharmaceuticals in a growth phase.
- In the second quarter, our pharmaceutical sales showed an increase of 22,2 MSEK, or ~55% compared to the same quarter in 2013. The increase was primarily due to our market introduction of simeprevir (Olysio).

### New product launches

- Simeprevir (Olysio) was launched in Sweden already in late May and by the end of the period it was available in all Nordic countries.
- Adasuve, a new specialty pharmaceutical for the treatment of agitation associated with bipolar disorder and schizophrenia was launched in April, along with the re-launch of Suscard, an established pharmaceutical for the treatment of angina pectoris.

### Sales and revenues

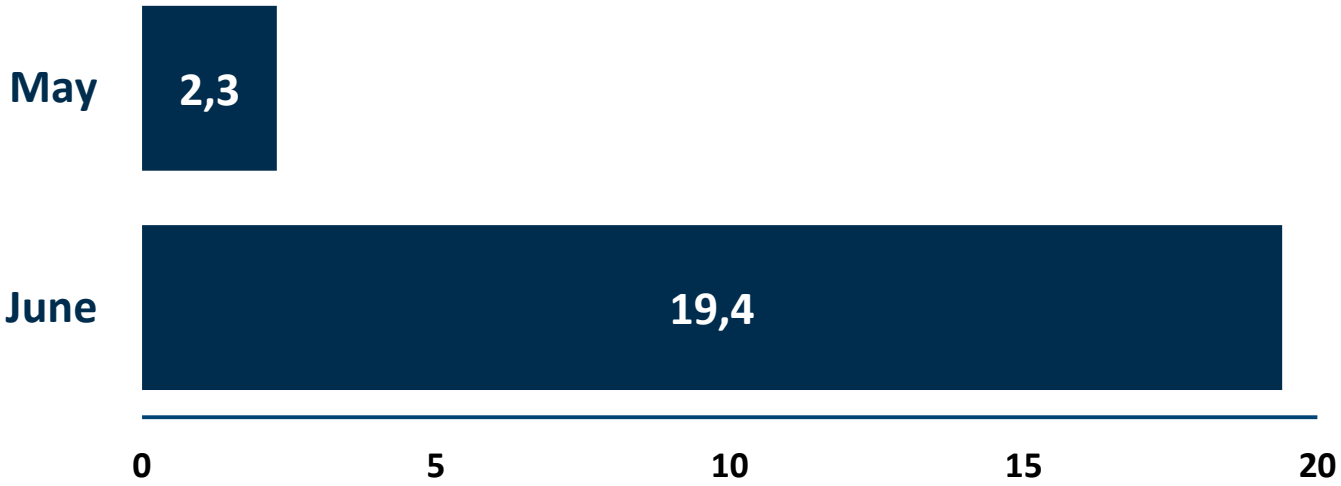
- The pharmaceutical portfolio generated sales of 62,9 MSEK, of which simeprevir made up 21,7 MSEK.
- For the second quarter we received 500,7 MSEK in royalties from our partner J&J.

# OLYSIO launch update

## -Quick uptake and positive perception across the Nordics

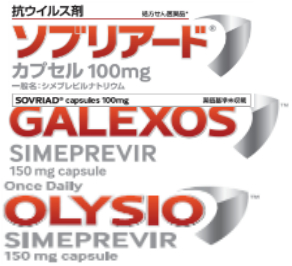
- Country teams operational in NO, SE, DK and FI from Q1 to prepare successful launches
- The COSMOS data perceived as being very positive by customers
- Compassionate use experience before launch in all countries
- Quick national approval processes
- SE launch late May followed by DK, FI and NO in June
- Positive media exposure related to Medivir, Olysio and the new HCV cure opportunity
- Supporting treatment guidelines already available in SE and DK

## Nordic OLYSIO Sales, MSEK



# Simeprevir on the global market

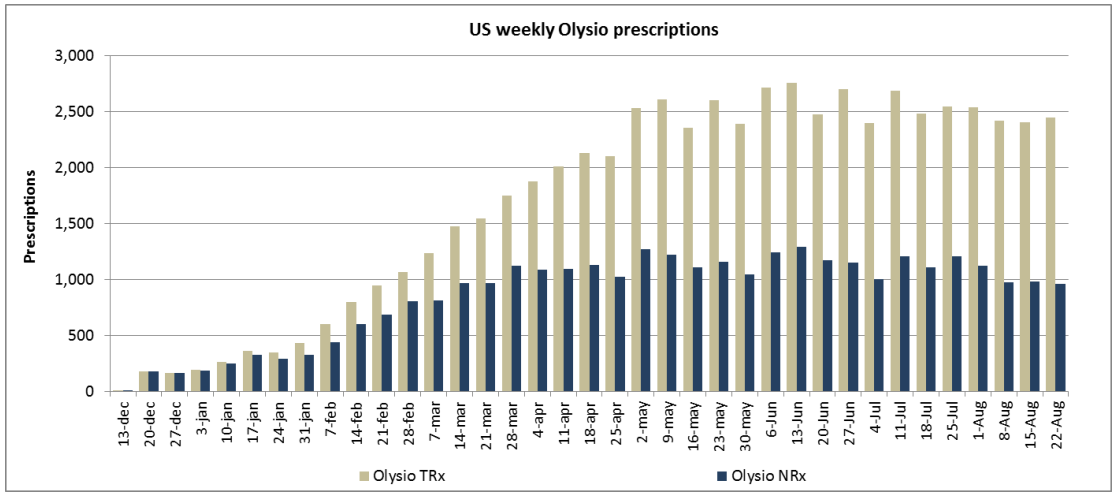
- ✓ Japan (SOVRIAD™)
- ✓ Canada (GALEXOS™)
- ✓ USA (OLYSIO™)*
- ✓ Russia (SOVRIAD™)
- ✓ EU (OLYSIO™)
- ✓ Mexico (OLYSIO™)
- ✓ Australia (OLYSIO™)




* 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

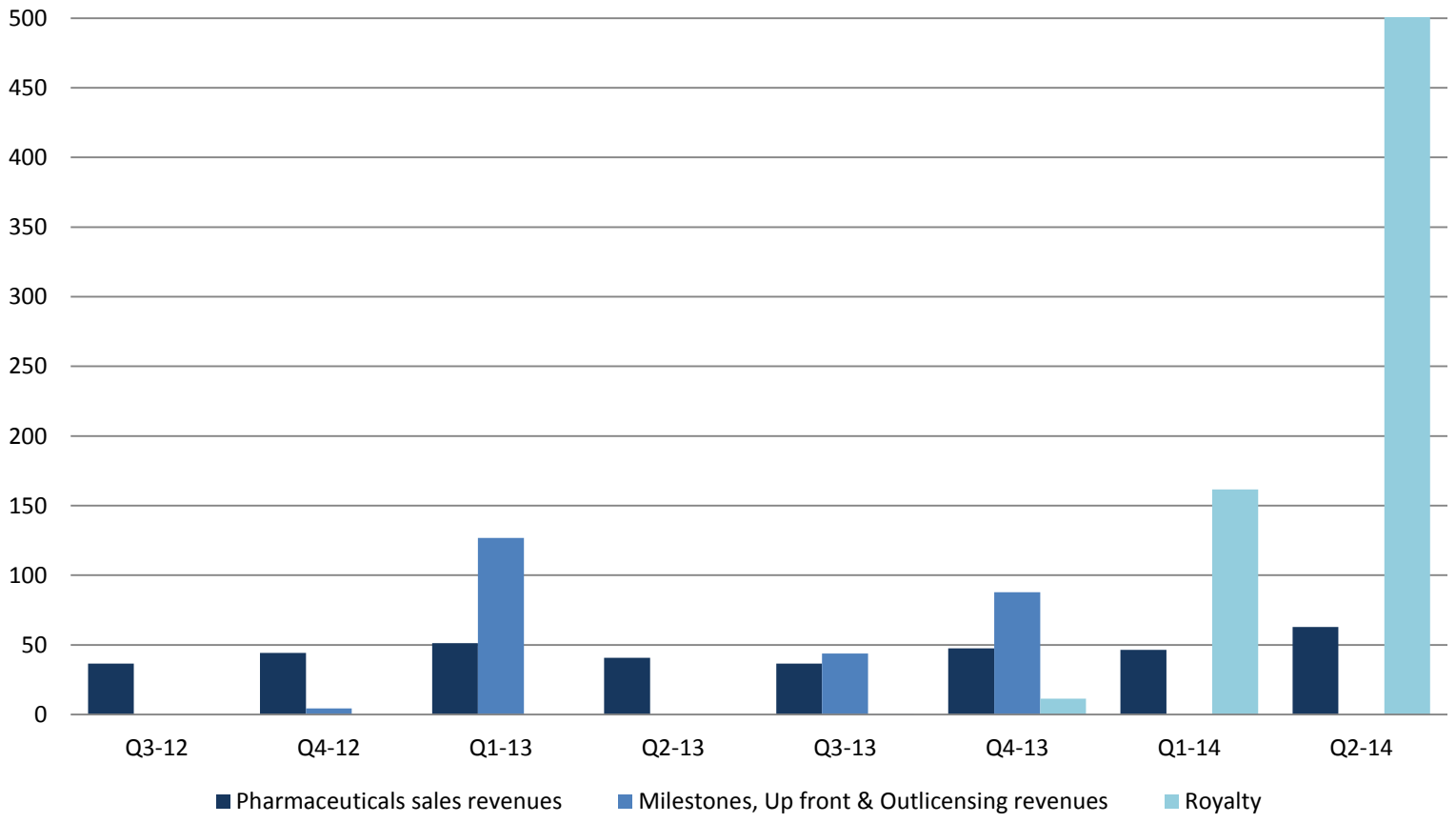
# Simeprevir

- Simeprevir sales have grown rapidly. Simeprevir is part of the only IFN-free regimen currently in use, based on recent guidelines from January 2014 and has ~27% market share in the US.
- J&J`s global second quarter net sales of simeprevir were 831,8 MUSD, of which 725,4 MUSD were in the US.
- Medivir's royalties based on these sales were 500,7 MSEK (54,4 MEUR) for the second quarter.




- In May, Simeprevir was approved in the EU for the treatment of adults with hepatitis C genotype 1 and 4 infection and is now also approved in Mexico and Australia.
- Phase II COSMOS study results were published in The Lancet on the World Hepatitis Day in July.
- FDA granted Priority Review for a supplementary New Drug Application for simeprevir (OLYSIO®) in combination with sofosbuvir, filed by Janssen in May.
- Two phase III studies, OPTIMIST 1 and 2, evaluating treatment of hepatitis C-infected patients with simeprevir and sofosbuvir, are well under way.
- The launch of simeprevir (OLYSIO®) in the Nordic territories began in late May and treatment of patients had been initiated in all Nordic countries by the end of June.

# Olysio is driving our revenues



# Strategic direction

## *R&D Operations*

**Development of R&D platform**

- Build value in four major internally driven projects
- Evaluate new therapeutic areas based on protease and polymerase core competence

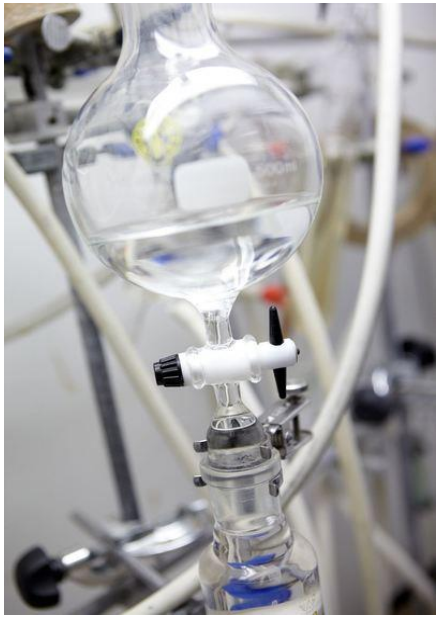
**Creation of new partnerships/collaborations**

- Continue to develop R&D assets via partnerships

## *Commercial Operations*

**Commercial expansion**

- Add new pharmaceuticals for the Nordic market
- Develop business and therapy scope further



# Ongoing IFN-free studies with simeprevir to explore interferon-free combinations will be followed by additional activities

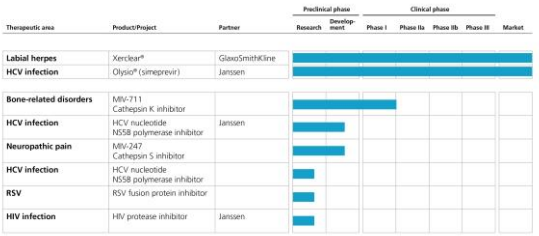
| Class | Compound | Partner | Status |
|---|---|---|---|
| PI + Nuc | Simeprevir<br>Sofosbuvir | Janssen | **OPTIMIST 1:** null + naives (F0-3), 8 or 12 weeks (n=300)<br>**OPTIMIST 2:** null + naïves (F4), 12 weeks duration (n=100)<br>- no ribavirin in either study |
| PI + NS5A | Simeprevir<br>IDX719 | Janssen<br>Idenix | HELIX-1: Phase II , Gt1b and 4<br>(150 mg SMV + 50 mg SAM + RBV-> 85% SVR4) |
| | Simeprevir<br>JNJ-56914845 | Janssen | Phase II on its way |
| PI + NS5A + NNI | Simeprevir<br>IDX719<br>TMC055 | Janssen<br>Idenix<br>Janssen | HELIX-2: Phase II started Dec-13 (Genotype1) |
| | Simeprevir<br>JNJ-56914845<br>TMC055 | Janssen | Phase II started Dec-13 |

***Other on-going studies IFN and RBV containing:***

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

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

# Our four internally driven R&D programs




## The pipeline was strengthened during the quarter

- Phase I data have previously been reported for MIV-711, a cathepsin K inhibitor in clinical development for osteoarthritis (OA). Completion of new preclinical studies provide support of efficacy data for an OA indication. To facilitate new partnerships or joint ventures, a decision was made to initiate long term toxicology studies (6 month), which will be completed by mid 2015.

- MIV-247 – a cathepsin S inhibitor for neuropathic pain is currently in preclinical development, moving towards clinical phase I studies, expected to commence during H1-2015.

- Our nucleotide HCV inhibitor is presently being evaluated in extensive preclinical safety studies.

- A preclinical RSV Fusion Inhibitor Project was recently in-licensed from Boehringer Ingelheim. It constitutes a logical step to strengthen our presence in infectious diseases and to broaden our pipeline.

# RSV Fusion Inhibitor Project

# Strategic Rationale for the transaction with Boehringer Ingelheim

- RSV fusion inhibitors have been shown to have antiviral activity in early clinical studies.
- The project enables Medivir to exploit its proven strengths in antiviral drug discovery and early development.
- In-licensing of the Boehringer Ingelheim fusion inhibitor program represented a rapid and cost-effective opportunity to acquire a LO phase project into the R&D pipeline.
  - Medivir's strategic intent is to enhance its R&D pipeline with high-value, commercial opportunities.

# Background: RSV-associated disease

- RSV causes seasonal outbreaks (Nov-March) of upper and lower repiratory tract infections of children and adults.
- Diseases range from mild respiratory illnesses to life-threatening bronchiolitis and pneumonia.
- The virus is highly contagious and transmitted by direct contact with infected persons.
- RSV causes repeated infections throughout life
  - Immune response results in virus clearance in the immunocompetent…
  - … but immunity wanes quickly, so people remain susceptible to infection throughout their lifetime.
  - The disease is most serious in those with an inadequate recall response to the virus.

- RSV is therefore especially dangerous in:
  - Infants, especially premature babies with lung/heart problems, or certain other chronic conditions.
  - The elderly, especially those with cardiovascular morbidities.
  - Immunocompromised, e.g. as a result of stem cell transplantation.

# Medivir Commercial: A Nordic core plus country teams to maximize synergies & catch the full potential in each country

**NORDIC TEAM**

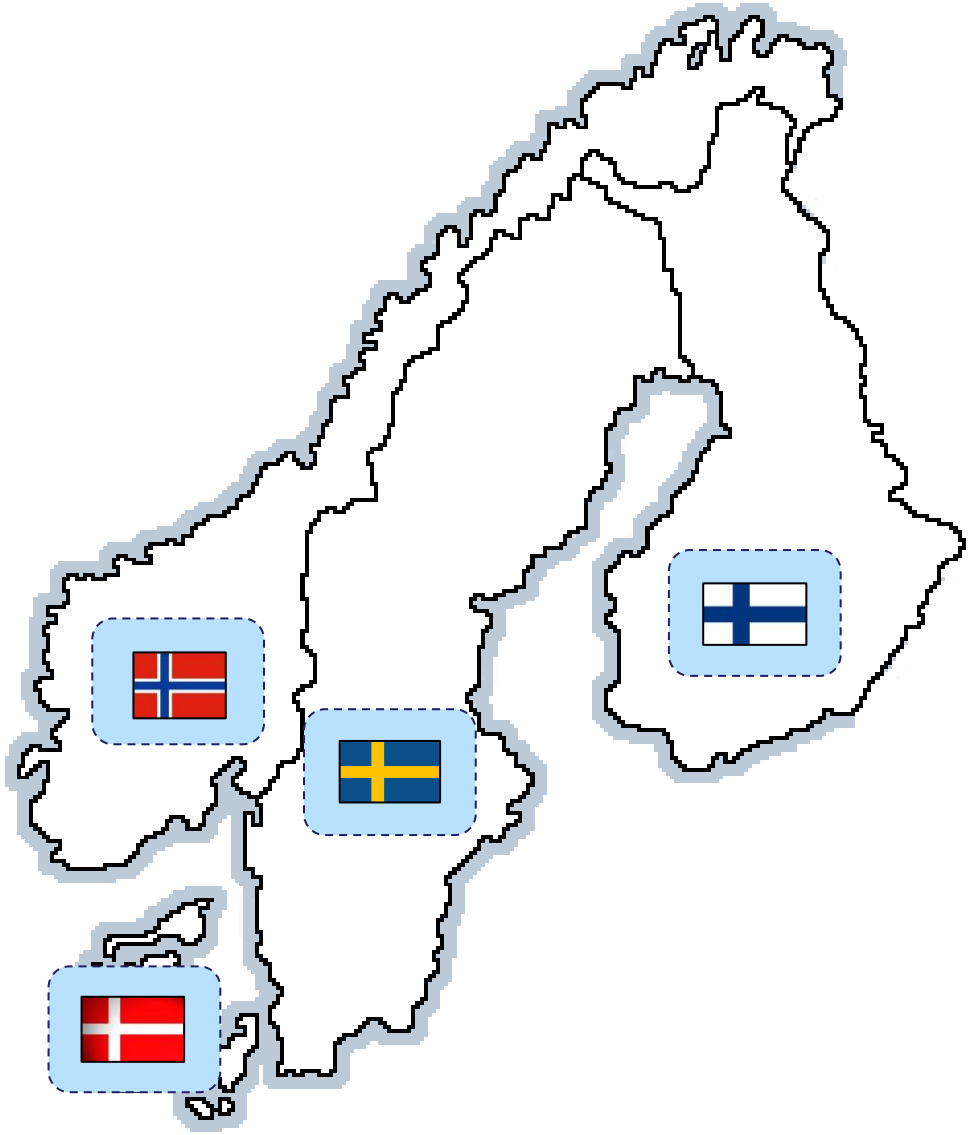
**Generating strategy and leading/supporting the country teams to maximize the output of customer activities**

- Marketing & Sales
- Medical Affairs
- Market Access & Public Affairs
- Support functions

**COUNTRY TEAMS**

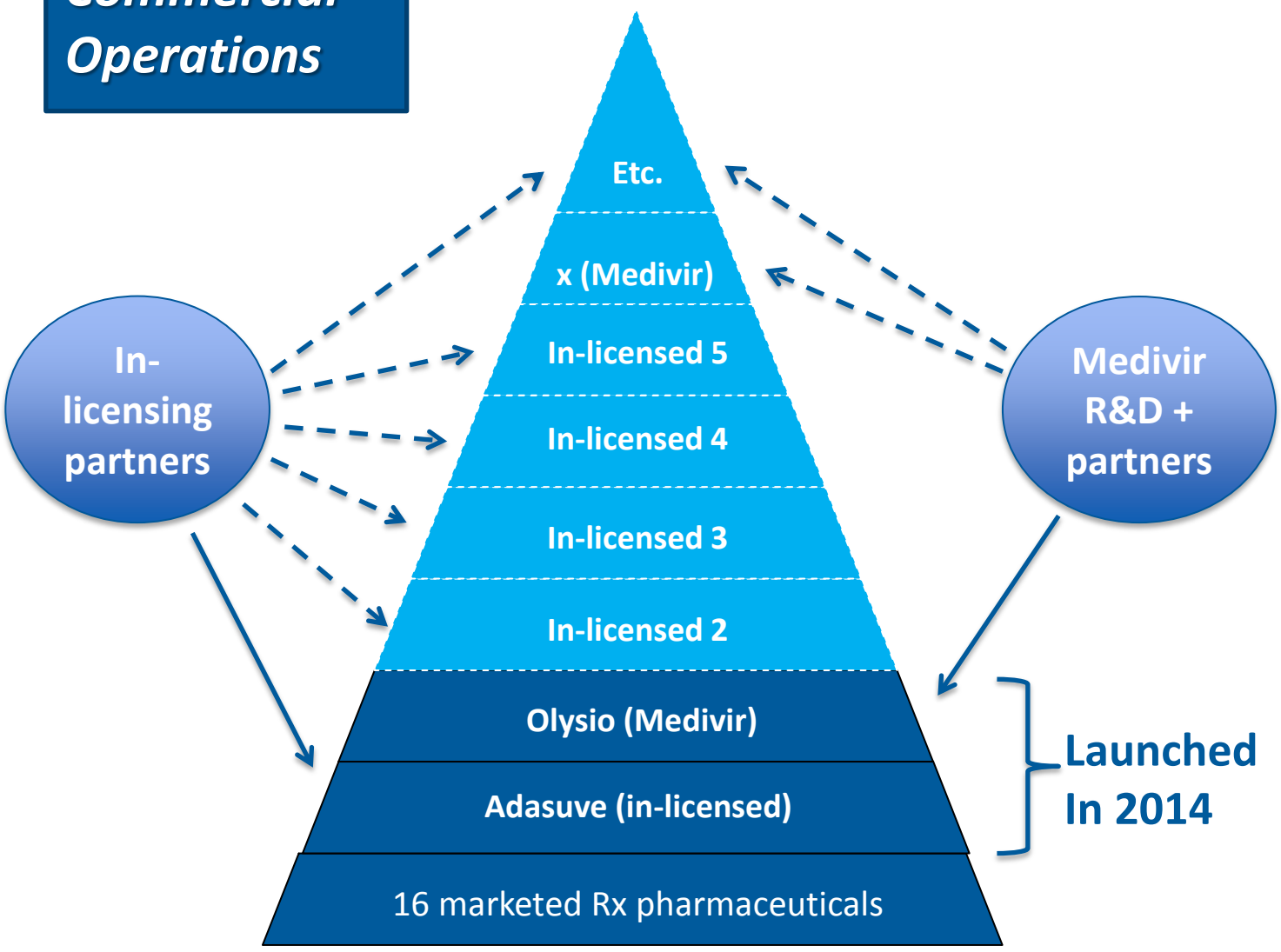
**For the daily customer activities**

- Market Leads
- Key Account Managers
- Medical Affairs Managers



# Growth by adding innovative specialty care products to existing pharmaceutical portfolio

***Commercial Operations***




**Launched In 2014**

**Innovative specialty care pharmaceuticals, in areas like:**
- **Infectious disease**
- **Psychiatry**
- **Oncology**

**Nordic brands**

**Existing pharmaceuticals**

**Potential future pharmaceuticals**

**www.medivir**
**Ticker: MVIR**
**Exchange: OMX / NASDAQ**

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