



## MEDIVIR AB – INTERIM REPORT, SECOND QUARTER 2015

### Financial summary

#### Second quarter 2015 (2014)

- Net turnover totalled SEK 245.8 million (564.0 m), of which SEK 165.6 million (500.7 m) comprised second quarter royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 55.1 million (62.9 m), of which SEK 13.2 million (21.7 m) derived from sales of OLYSIO® and SEK 41.9 million (41.2 m) from sales of other pharmaceuticals.
- The profit after tax was SEK 64.1 million (327.8 m).
- Basic and diluted earnings per share totalled SEK 2.21 (10.49) and SEK 2.19 (10.28), respectively.
- The cash flow from operating activities amounted to SEK 64.3 million (88.7 m).

#### Six months 2015 (2014)

- Net turnover totalled SEK 461.7 million (772.2 m), of which SEK 294.2 million (662.4 m) comprised the first six months royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 141.9 million (109.2 m), of which SEK 47.4 million (21.7 m) derived from sales of OLYSIO® and SEK 94.5 million (87.5 m) from sales of other pharmaceuticals.
- The profit after tax was SEK 130.7 million (611.7 m).
- Basic and diluted earnings per share totalled SEK 4.50 (19.57) and SEK 4.46 (19.18), respectively.
- The cash flow from operating activities amounted to SEK 269.6 million (31.0 m).

Summary of the Group's figures, continuing operations (SEK m)	Q2		Q1-Q2		Full year
	2015	2014	2015	2014	2014
Net turnover	245.8	564.0	461.7	772.2	1 767.0
Gross profit	214.9	518.8	397.7	700.9	1 593.0
Operating profit before depreciation and amortisation (EBITDA)	104.9	424.4	189.6	521.2	1 221.9
Operating profit (EBIT)	96.1	416.2	172.2	504.9	1 188.7
Profit/loss before tax	85.4	418.4	168.2	508.7	1 192.7
Profit/loss after tax	64.1	327.8	130.7	611.7	1 132.7
Operating margin, %	39.1	73.8	37.3	70.0	67.3
Basic earnings per share, SEK	2.21	10.49	4.50	19.57	36.24
Diluted earnings per share, SEK	2.19	10.28	4.46	19.18	35.90
Net worth per share, SEK	55.7	46.9	55.7	46.9	63.4
Return on equity	5.8	32.2	9.7	43.9	84.1
Cash flow from operating activities	64.3	88.7	269.6	31.0	1 014.4
Liquid assets and short-term investments at the period end	1 043.4	430.4	1 043.4	430.4	1 395.6
R&D spending/total opex, %	60.2	62.8	61.1	59.4	60.8

## CEO's comments

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Q2 saw us continuing to both build our research portfolio's value and to increase our focus on the core areas of infectious diseases and oncology.

We strengthened the oncology component of our research portfolio by initiating a partnership with Cancer Research Technology (CRT) and The University of Marburg to develop a new class of drugs to treat cancer. The collaboration aims to develop molecules that target the ADAM8 protein, which is linked to tumour survival, cell invasion and metastasis. CRT has an excellent reputation in the international cancer research community and the partnership not only demonstrates the strength of Medivir's technology platform, but also validates its potential in the field of cancer research.

The progress being made by our in-house oncology projects was evidenced by the announcement to progress the development of the HCC project for the treatment of hepatocellular carcinoma with already identified promising lead molecules. The aim is to develop specifically liver targeted nucleotide prodrugs using our expertise in nucleotide and nucleoside science.

Medivir elected to end its development of the MIV-247 cathepsin S inhibitor after the preclinical safety studies produced unfavourable findings, and which constituted a further step in focusing on our core areas. This decision marked our withdrawal from research into neuropathic pain.

The preparations for a clinical phase II trial with MIV-711 in osteoarthritis by the year-end are proceeding according to plan with ongoing preclinical regulatory safety studies.

Partnership discussions are continuing with a number of potential partners with regard to our internal hepatitis C project, MIV-802.

After the quarter end, we announced that our outlicensed projects partnered with Janssen have also made progress: The AL-704 HCV nucleotide, also known as JNJ-54257099, entered clinical phase I development in early July. In addition, a phase I trial with a triple combination product, where the primary objective is to investigate the effect of the combination of simeprevir and odalasvir on the pharmacokinetics of AL-335 (a nucleotide-based HCV polymerase inhibitor) was initiated.

We conducted a reorganisation of our research operations as part of our ongoing work with operational optimisation, and entered into a partnership with GVK BIO, as part of this change. All of our external synthetic chemistry activities will now be concentrated within a single research unit at GVK, and the addition there of a further 20 or so research staff will enable us to accelerate our synthesis work. The aim is to enhance the efficiency and improve the quality of our research projects, but also, in the longer term, to cut research costs and increase flexibility. These changes meant that around 10 employees at Medivir's research units in Sweden and the UK were made redundant.

Royalty income attributable to the hepatitis C drug, OLYSIO® (simeprevir) totalled SEK 166 million in the second quarter. Increased competition resulted in a fall in global net sales of OLYSIO® in comparison with the corresponding quarter of the previous year.

Our Nordic pharmaceutical sales organisation with its two arms, Innovative Specialty Care and Nordic Brands, posted combined sales of SEK 55 million during the quarter. Sales of OLYSIO® accounted for SEK 13 million of this total, while Nordic Brands posted a year-on-year increase in sales of 1 per cent. OLYSIO® has established a niche position in the Nordic region, with the drug primarily prescribed for those patients who have proved most difficult to treat.

Overall, the second quarter has delivered progress in both our partnered projects and our in-house projects at the same time as we broadened our pipeline through external partnerships. This is all according to plan and I am convinced that the ongoing progress of our projects will ensure that we continue to build long-term value within Medivir.

### **Niklas Prager**

*President and CEO*

#### **Medivir in brief**

Medivir is a research based pharmaceutical company with a research focus on infectious diseases and oncology. We have a leading competence within protease inhibitor design and nucleotide/nucleoside science and we are dedicated to developing innovative pharmaceuticals that meet great unmet medical need. Our commercial organization provides a growing portfolio of specialty care pharmaceuticals on the Nordic market. Medivir is listed on the Nasdaq Stockholm Mid Cap List.

*For more information about Medivir, please visit [www.medivir.com](http://www.medivir.com).*

## Significant events during the second quarter

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Medivir strengthened its research portfolio within oncology through the licensing of a project aimed at the development of a new class of cancer drugs from Cancer Research Technology (CRT). The programme is being advanced through a two-year research collaboration with the University of Maburg, Germany, with the aim of optimizing and developing small molecules targeting the cell surface protein ADAM8, which has been linked to tumour survival, cell invasion and metastasis.

Medivir's partner, Janssen Sciences Ireland UC, published positive results for simeprevir at The International Liver Congress™ 2015, highlighting the clinical outcomes of simeprevir in an all-oral combination regimen in a wide range of patients with hepatitis C virus (HCV) infection.

During the Liver Congress Medivir also presented the highly competitive preclinical antiviral and safety profile of its internal hepatitis C project, MIV-802.

In the middle of June, Medivir announced a reorganization within its Discovery Research department, increasing its focus within the core areas of oncology and infectious diseases, and a partnership with GVK Biosciences Private Ltd. (GVK BIO) of Hyderabad in India. The objective is to deliver enhanced efficiency and quality within Medivir's portfolio of research projects. The company also decided to discontinue development in the neuropathic pain area, following unfavourable findings in non-clinical safety studies of MIV-247. As a result of these changes, around ten scientific employees at Medivir's facilities in the UK and Sweden were made redundant. Non-recurring personnel costs of SEK 8.0 million are reported as Administrative costs in the quarter.

Medivir also published details of its first cancer project derived from its in-house nucleotide platform. The project is a liver-targeted nucleotide prodrug for the treatment of hepatocellular carcinoma (HCC).

### Annual General Meeting

The 2015 AGM authorized the Board of Medivir to repurchase shares corresponding to an ownership of up to 10 percent of the shares in the company, in order to generate the opportunity to adapt the capital structure in line with the company's capital requirements.

During the second quarter the Board resolved to utilize a portion of the mandate approved by the AGM. Medivir bought back 130,000 class B shares for a total of SEK 10.4 million, corresponding to 0.5 per cent of the total number of shares.

The Annual General Meeting also resolved to authorize the Board to approve the issue of new class B shares up to an amount not in excess of 10 per cent of the total number of outstanding class B shares in the company following utilization of the authorization. The purpose of the authorization is to provide the Board with flexibility in its work in order to ensure that the company can be appropriately provided with capital for the financing of the business, acquisition of companies and products, and to enable a broadening of the ownership of the company.

Anders Ekblom, Anders Hallberg, Anna Malm Bernsten, Bertil Samuelsson and Birgitta Stymne Göransson were re-elected as Board members and Johan Harmenberg and Helena Levander were elected as new Board members, in accordance with the proposal of the Nomination Committee. Birgitta Stymne Göransson was re-elected as Chairman of the Board.

PricewaterhouseCoopers AB was re-elected as Medivir's Auditor.

## Financial overview, second quarter 2015

### Revenues

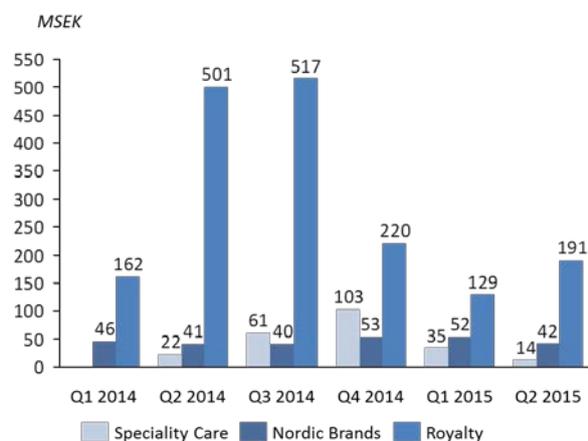
Net turnover totalled SEK 245.8 million (564.0 m), corresponding to a decrease of SEK 318.2 million. Royalty income totalled SEK 190.7 million (501.1 m), with royalties from Janssen's global sales of simeprevir, which totalled USD 264 million, amounting to SEK 165.6 million (500.7 m). In addition Medivir received SEK 24.3 million in royalty currency adjustments related to the previous year. Royalties based on GSK's global sales of Xerclear (Zoviduo) during the second quarter amounted to SEK 0.7 million.

The revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 55.1 million (62.9 m), of which SEK 13.2 million (21.7 m) derived from sales of OLYSIO® and SEK 41.9 million (41.2 m) from sales of other pharmaceuticals. Sales of other pharmaceuticals increased by SEK 0.7 million, primarily driven by the strong brands Mollipect, Suscard, Paraflex and Lithionit.

### Breakdown of net turnover (SEK m)

	Q2		Q1-Q2		Full year
	2015	2014	2015	2014	2014
Outlicensing and partnership agreements					
Pharmaceutical sales, where of					
<i>Nordic brands</i>	55.1	62.9	141.9	109.2	366.8
<i>Innovative specialty care</i>	41.6	41.2	93.9	87.5	180.1
Royalties	13.5	21.7	48.0	21.7	186.7
<b>Total</b>	<b>190.7</b>	<b>501.1</b>	<b>319.8</b>	<b>662.8</b>	<b>1 400.2</b>
<b>Total</b>	<b>245.8</b>	<b>564.0</b>	<b>461.7</b>	<b>772.0</b>	<b>1 767.0</b>

### Net turnover (SEK m), Q1 2014 – Q2 2015



\*All figures refer to the Group, unless otherwise stated. Comparisons in the Interim Report are, unless otherwise stated, with the corresponding period in 2014.

### Results

#### Gross profit

The cost of goods sold was SEK -30.9 million (-45.2 m), corresponding to a decrease of SEK 14.3 million. The gross profit amounted to SEK 214.9 million (518.8 m), corresponding to a decrease of SEK 303.9 million and equating a gross margin of 87% (92%), explained by the shift from royalty to pharmaceutical sales.

#### Operational expenses

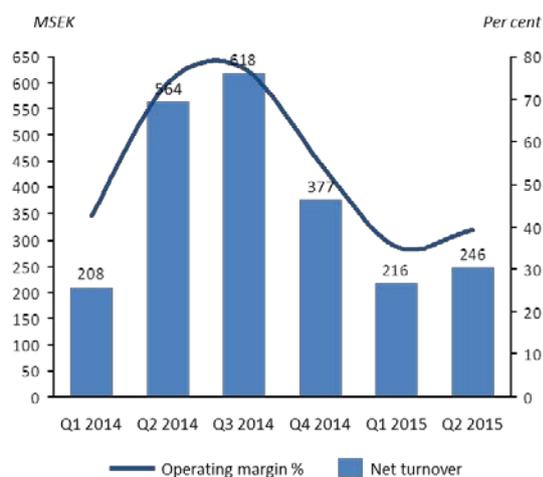
Selling expenses have increased by SEK 1.7 million compared to the same quarter last year. This is primarily due to an increase in FTE's supporting Nordic pharmaceutical sales. Administrative expenses increased by SEK 4.4 million, with generally lower spending that was offset by a non-recurring personnel cost related to the re-organisation within Discovery Research during the quarter. Research and Development costs increased by SEK 7.0 million, primarily as a result of projects inlicensed since the third quarter last year, such as the RSV- and the ADAM8 projects but also due to extended toxicology studies for the MIV-247 project that was closed down during the quarter. Other operating income/expenses are negative and decreased by SEK 3.1 million, largely due to exchange rate effects. Overall, operating expenses totalled

SEK -118.7 million (-102.6 m), corresponding to an increase of SEK 16.1 million, where of SEK 8.0 million are non-recurring personnel costs.

The operating profit/loss totalled SEK 96.1 million (416.2 m), corresponding to a decrease of SEK 320.1 million.

Net financial items totalled SEK -10.7 million (2.2 m), corresponding to a decrease of SEK 12.9 million, and due to unrealised losses driven by market valuation of short-term interest-bearing investments.

## Net turnover and operating margin (SEK m)



## Taxes

Tax for the second quarter totalled SEK -21.3 million (-90.6 m), corresponding to a decrease of SEK 69.3 million. The decrease primarily derives from a shift in Royalty income in comparison with the second quarter of 2014.

The groups' income and deferred tax are calculated using the legally stipulated tax rate of 22%, which is expected to be the effective rate.

## Financial overview, six months 2015

### Revenues

Net turnover totalled SEK 461.7 million (772.2 m), corresponding to a decrease of SEK 310.5 million. Royalty income totalled SEK 319.8 million (662.8 m), with royalties from Janssen's global sales of simeprevir, which totalled USD 498 million, amounting to SEK 294.2 million (662.4 m). In addition, royalties based on GSK's global sales on Xerclear (Zoviduo) during the period amounted to SEK 1.3 million. Revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 141.9 million (109.2m) of total pharmaceutical sales, where SEK 47.4 million (21.7 m) derived from sales of OLYSIO® and SEK 94.5 million (87.5 m) from sales of other pharmaceuticals. Sales of other pharmaceuticals increased by SEK 7.0 million, primarily driven by the strong brands, Mollipect, Suscard, Paraflex and Lithionit.

### Results

#### Gross profit

The cost of goods sold was SEK -64.0 million (-71.3 m), corresponding to a decrease of SEK 7.3 million. The gross profit amounted to SEK 397.7 million (700.9 m), corresponding to a decrease of SEK 303.2 million and equating a gross margin of 86% (91%), explained by the shift from royalty to pharmaceutical sales.

#### Operational expenses

Selling expenses increased by SEK 3.1 million, primarily due to an increase in FTE's supporting the Nordic pharmaceutical sales compared to the same period last year. Administrative expenses decreased by SEK 0.3 million as a result of lower spending that was offset by non-recurring personnel costs in the period. Research and development costs increased by SEK 21.2 million, primarily as a result of projects inlicensed since the third quarter of last year, such as the RSV-and the ADAM8 projects, but also due to extended toxicology studies for the MIV-247 project that was closed down during the period. Other operating income/expenses are negative and decreased by SEK 5.4 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -225.4 million (-196.0 m), corresponding to an increase of SEK 29.4 million, whereof SEK 8.0 million are non-recurring personnel costs.

The operating profit/loss totalled SEK 172.2 million (504.9 m), corresponding to a decrease of SEK 332.7 million.

Net financial items totalled SEK -4.0 million (3.8 m), corresponding to a decrease of SEK 7.8 million, and due to unrealised losses driven by market valuation of short-term interest-bearing investments.

### Taxes

Tax for the period totalled SEK -37.5 million (103.0 m), corresponding to a decrease of SEK 65.5 million. The decrease primarily derives from capitalisations of loss carry forwards activated in the first quarter of 2014. The groups' income and deferred tax are calculated from the legally stipulated tax rate of 22%, which is expected to be the effective rate.

### Cash flow, Investments and Financial Position

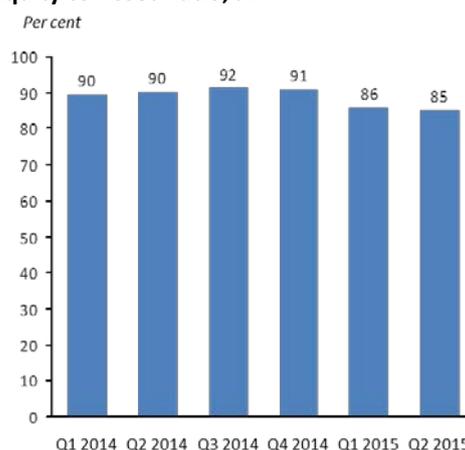
Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 1,043.4 million (430.4 m) at the end of the period, compared to 1,395.6 million (402.2 m) at the beginning of 2015, a decrease of SEK 352.2 million. An additional SEK 190.7 million in royalties are due for payment during the third quarter. Pledged assets at the end of the period totalled SEK 54.3 million (54.3 m). Medivir's financial assets are, in accordance with its financial policy, invested in low-risk, interest-bearing securities.

Cash flow from operating activities totalled SEK 269.6 million (31.0 m), with changes in working capital accounting for SEK 92.3 million (-18.7 m). The positive cash flow derives, primarily, from incoming royalties for the previous quarter.

Cash flow from investing activities totalled SEK -10.5 million (-2.8 m). Investments in research and facility equipment and IT systems totalled SEK -5.4 million (-5.9 m), and a tranche of the purchase price from the sale of Cross Pharma totalled SEK 2.5 million (2.5 m).

Cash flow from financing activities totalled SEK -611.6 million (0.0 m), which referred to cash distributed as a result of the voluntary redemption program and the repurchase of Medivir's own shares.

### Equity to Asset Ratio, %



Investments in tangible fixed assets during the period amounted to SEK -7.6 million (-5.2 m) and comprised research, facility and IT equipment. Depreciation of tangible fixed assets totalling SEK -5.4 million (-5.0 m) and of intangible fixed assets of SEK -11.7 million (-11.3 m) respectively were charged to the profit/loss for the period.

## Research and development

Medivir's pharmaceutical product research and development portfolio is based on the company's expertise in the design of protease inhibitors and in the science of nucleotides and nucleosides. The focus is both on infectious diseases and oncology, and on the ongoing clinical project in the area of osteoarthritis.

Medivir has successfully developed products all the way from concept to marketed products. In 2009, Xerclear (Zovido®) was approved for the treatment of labial herpes. Meda owns the market authorisations in the USA, Canada and Mexico. The market authorisations for Europe and the rest of the world (except for those for South America, South Korea, Israel and China, which still are held by Medivir) are out-licensed to GlaxoSmithKline. In 2013, simeprevir

(OLYSIO®) was approved in the USA, and in May 2014, it was granted marketing authorisation in the EU. Subsequent marketing authorisations have followed in several other countries around the world. Simeprevir is approved for the treatment of chronic hepatitis C infection as part of an antiviral treatment programme in genotype 1-infected adults with compensated liver disease, including cirrhosis (indications vary by market). Janssen is responsible for the global clinical development of simeprevir and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir retains marketing rights for simeprevir in these countries under the marketing authorisation held by Janssen-Cilag International NV.

Disease area/Project	Discovery	Preclinical	Phase I	Phase II
<b>Osteoarthritis</b> MIV-711, cathepsin K inhibitor	[Progress bar spanning Discovery, Preclinical, and Phase I]			
<b>Hepatitis C</b> MIV-802, nucleotide NS5B polymerase inhibitor	[Progress bar spanning Discovery and Preclinical]			
<b>RSV infection</b> RSV fusion protein inhibitor	[Progress bar in Discovery]			
<b>Pancreatic cancer</b> ADAM8 inhibitor	[Progress bar in Discovery]			
<b>Hepatocellular carcinoma</b> Nucleotide DNA polymerase inhibitor	[Progress bar in Discovery]			
<b>Hepatitis C</b> AL-704, nucleotide NS5B polymerase inhibitor*	[Progress bar spanning Discovery, Preclinical, and Phase I]			
<b>HIV infection</b> HIV protease inhibitor*	[Progress bar in Discovery]			

\* Partner Janssen

For further information about our projects, please visit [www.medivir.com](http://www.medivir.com)

### **MIV-711**

MIV-711 is a cathepsin K inhibitor in clinical development for the treatment of osteoarthritis. Cathepsin K is a protease, which can break down the collagen in bone and cartilage, and hence an inhibitor of cathepsin K has the potential to reduce joint structural disease progression and attenuate pain. In support of this, MIV-711 has been demonstrated to exert joint protective effects in preclinical models of osteoarthritis. In a phase I study including postmenopausal women, MIV-711 reduced biomarkers for bone resorption and cartilage degradation by up to 98 per cent and 62 per cent, respectively, compared with placebo.

#### **Status/significant events:**

MIV-711 is currently undergoing preclinical safety testing in order to enable longer term phase II studies in osteoarthritis patients.

### **MIV-802**

MIV-802 is a potent, pan-genotypic nucleotide-based inhibitor of the HCV NS5B polymerase, which recently entered preclinical development. Hepatitis C treatment comprises a combination of several pharmaceuticals with different mechanisms. Nucleotides are regarded as the most important component of any such combination, due to their potent and broad spectrum antiviral effect on multiple HCV genotypes and high barriers to the emergence of resistance. Preclinical data indicate that MIV-802 can be used effectively in combination with other classes of antiviral agents for the treatment of HCV, including protease inhibitors and NS5A inhibitors.

#### **Status/significant events:**

Preclinical safety studies are currently in progress to prepare for first studies in humans.

### **RSV fusion protein inhibitor**

The aim of the project is to develop an oral inhibitor of the RSV fusion protein. Respiratory syncytial virus (RSV) can cause life-threatening pulmonary and respiratory tract infections, particularly in children, the elderly, and the immunocompromised. The RSV fusion protein is a mediator of viral entry into host cells and an important target for new medicines. Medivir has an in-licensing agreement for the RSV programme with Boehringer Ingelheim. The agreement offers exclusive, global rights to a drug programme for the treatment and prevention of RSV infections.

#### **Status/significant events:**

The programme licensed from Boehringer Ingelheim included several series of molecules that inhibit the RSV fusion protein. These substances are being further optimised in order to identifying a substance with the required profile for further development.

### **ADAM8 inhibitor**

The aim of the project is to develop a molecule that inhibits the protease activity of ADAM8 for the treatment of pancreatic cancer. Pancreatic cancer is one of the deadliest malignancies, with very few treatment options. When the disease is discovered early, pancreatic cancer patients' 5-year survival rate is approximately 20% but the majority of cases are discovered at a later stage and in such cases the prognosis is even poorer. There is consequently a great medical need for better treatments. ADAM8 is a cell surface metalloprotease that regulates multiple cellular processes, including inflammation, tumour survival, cell invasion and metastasis. Blocking ADAM8 in mice with pancreatic cancer prevents the spread of the disease, and significantly extends their lifespan.

#### **Status/significant events:**

The programme was licensed in April 2015 from Cancer Research Technology in the UK, based on a lead series of ADAM8 inhibitors with in vivo activity in relevant models of pancreatic cancer, and is being advanced through a collaboration with the University of Marburg, Germany. The ADAM8 inhibitors are being optimized for the treatment of pancreatic cancer and other solid tumours.

### **HCC nucleotide based DNA polymerase inhibitor**

Nucleotide project for Hepatocellular Carcinoma aimed for delivering cancer therapeutics selectively to the liver. Non-surgical approaches to manage HCC rely to a large extent on the targeting of drugs to the liver. Medivir has developed substantial capabilities to selectively deliver the active metabolites of nucleoside and nucleotide analogues to the liver, based on its long-standing interests in discovering improved treatments for chronic hepatitis B virus and hepatitis C virus infection. These approaches are now being applied to HCC. The intention is to develop orally administered therapeutics that are targeted to the tumour in the liver.

#### **Status/significant events:**

Medivir has identified molecules with excellent activity against a range of HCC cell lines and with the required distribution properties to enable them to be delivered selectively to the liver. Preclinical testing of these molecules will begin early in the third quarter.

### **MIV-247**

MIV-247, a cathepsin S inhibitor that was in preclinical development for the treatment of neuropathic pain.

#### **Status/significant events:**

Following unfavourable findings in non-clinical safety studies of MIV-247, the development of the project was discontinued.

## Patents

Securing patent protection is the foundation for all new pharmaceutical projects, whether a project derives from our own laboratories or is in-licensed. Patents and other exclusive rights, such as data exclusivity and trademark protection are crucial to companies' future commercial prospects. Medivir currently has around 50 active patent families, with over 300 granted national patents. During the second quarter, four additional patent families were filed within the RSV project.

## Royalty undertakings

A significant percentage of Medivir's research and development project work has been carried out exclusively in-house and Medivir is consequently entitled to all revenues in respect of these inventions. Some of Medivir's research and development projects also originate from Swedish universities and pharmaceutical companies, and Medivir is consequently entitled to the revenues generated by these projects but obliged to pay royalties on their commercialisation. Certain projects have been progressed with patented research tools which are in-licensed from other companies and for which royalties are payable. The combined royalty costs for the period were SEK 20.0 million (35.0 m)

## Other disclosures (six months period)

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### Employees

Medivir had 138 (142) employees (FTE's) at the period end, 57% (57%) of whom were women. The decrease is related to the re-organizations made over the last year in management and Discovery Research.

### Share-related incentive plans

The objective of share-related incentive plans is to promote the company's long-term interests by motivating and rewarding the company's senior executives and other members of staff. Medivir currently has two active share-related incentive plans, LTI 2013 and 2014. The cost of both plans, including social security contributions, based on certain assumptions such as share price performance, participation and staff turnover, was charged to the profit/loss for the period in the sum of SEK 0.9 million.

### The Parent Company in brief

Medivir AB (publ.), corporate ID no. 556238-4361, is the Parent Company of the Group. Its operations consist of research and development, marketing and sales, and administrative and company management functions. The Parent Company's net turnover totalled SEK 380.3 million (700.9 m). Intra-Group sales amounted to SEK 12.5 million (16.2 m).

The gross profit amounted to SEK 336.2 million (648.6 m). Combined operating expenses totalled SEK -179.6 million (-168.8 m). The operating profit/loss was SEK 156.6 million (479.8 m), corresponding to a decrease of SEK 323.2 million. Net financial items totalled SEK -2.5 million (3.3 m), corresponding to a decrease of SEK 5.8 million, and due to unrealised losses driven by market valuation of short-term interest-bearing investments.

The tax for the period totalled SEK -34.5 million (107.0 m). The net profit/loss for the period was SEK 119.6 million (590.1 m), corresponding to a decrease of SEK 470.5 million, primarily as result of the earlier reported tax income of SEK 107.0 million.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 941.4 million (420.3 m).

Please see the section titled "Financial Overview" for further comments on the operations.

A sub lease agreement for the Chesterford Park facility was signed, securing the payment obligations for the remaining period of the lease up to 2025.

### Transactions with related parties

Transactions with related parties are on market terms. There are existing agreements between companies owned by senior executives and Medivir, dating from 2005, which entitle the senior executives to royalties on products that the company may develop based on patented inventions that the company has purchased from the parties in question. During the period, transactions with related parties totalled SEK 9.4 million (15.1 m) whereof royalty payments to Uppsala Hallbechem AB (Board Member, Anders Hallberg) totalled SEK 2.5 million (4.8 m) and to Sybesam AB (Board Member, Bertil Samuelsson) totalled SEK 6.9 million (10.3)<sup>1</sup>. Other services were purchased from related parties for a total of SEK 0.0 million (SEK 0.2 m).

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<sup>1</sup> Sybesam AB received a royalty payment of SEK 3.2 m in the first quarter 2014, but it did not qualify as a related party transaction as Bertil Samuelsson became a Board Member in May 2014.

### **Significant risks and uncertainty factors**

An effective risk assessment reconciles Medivir's business opportunities and results with the requirements of shareholders and other stakeholders for stable, long-term value growth and control. The process of research and pharmaceutical development, all the way up to approved registration, is both high risk and capital intensive. The majority of projects initiated will never achieve market registration. If competing pharmaceuticals take market shares, or competing research projects achieve better efficacy and reach the market more quickly, the future value of Medivir's product and project portfolio may be lower than expected. Medivir's ability to produce new candidate drugs, to enter into partnerships for its projects, to successfully develop its projects to market launch and continued sale, and to secure funding for its operations, are decisive in terms of the company's future.

#### **Medivir is exposed to the following main risk categories:**

**Exogenous risks** – such as regulatory approval, competition, price changes, external seasonality and patent protection.

**Operating risks** – such as integration risk, production risk, and a reliance on key employees and partnerships.

**Financial risks** – such as liquidity, interest, currency and credit risk.

A more detailed description of the exposure to risk, and of the ways in which Medivir manages it, is provided in the 2014 Annual Report, see page 35 and Note 8.

#### **Significant events after end of Q2**

In July, Janssen submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) to update the label for once-daily, all-oral OLYSIO® (simeprevir) in combination with sofosbuvir. OLYSIO® was approved in November 2014 in combination with sofosbuvir, based on the phase II COSMOS clinical trial. This sNDA is based on results from the phase III OPTIMIST-1 and OPTIMIST-2 trials,

which evaluated 12 and 8 weeks of therapy for genotype 1 adult patients with chronic hepatitis C (CHC) without cirrhosis, and 12 weeks of therapy for genotype 1 CHC adult patients with cirrhosis.

A phase I clinical trial was started in July 2015 with AL-704, also known as JNJ-54257099, by Alios Biopharma Inc., part of the Janssen Pharmaceutical Companies.

The study will evaluate the safety, tolerability, and pharmacokinetics of single and multiple doses in healthy volunteers and subjects with chronic hepatitis C infection of genotypes 1 and 3. Medivir entered into a Research & Development agreement in the field of HCV polymerase inhibitors with Janssen Products LP in May 2008. AL-704 is the second candidate drug under this agreement that has entered into clinical development. The structure of the agreement means that no additional milestone payment is due for this specific step of development. AL-704 is a nucleotide-based NS5B polymerase inhibitor intended for the treatment of chronic hepatitis C virus (HCV) infection in combination with other direct acting antiviral agents.

In early August, Alios Biopharma Inc., also started a phase I clinical trial to evaluate the effect of simeprevir and odalasvir (also known as ACH-3102, an NS5A inhibitor), on the pharmacokinetics of AL-335. The primary objective of the study is to investigate the potential effect of simeprevir and odalasvir on the pharmacokinetics of AL-335 when administered in combination to healthy volunteers.

#### **Outlook**

Medivir is well positioned for the future with a globally recognized technology platform in a proven R&D infrastructure, as well as the financial and organizational ability to invest in innovation for continued value creation. We foresee continued increased competition in the Hepatitis C market. In the Nordics, this is driven primarily by changed treatment guidelines where competitors have received a differentiated position than OLYSIO®.

## Attestation

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The Board of Directors and the President & CEO hereby affirm that the Interim Report constitutes a faithful representation of the company's and the Group's operations, position and profit/loss, and that it describes the significant risks and uncertainty factors faced by the company and the companies that make up the Group.

Stockholm, 20 August 2015

**Susana Ayesa Alvarez**  
*Member of the Board,  
Employee Representative*

**Anders Ekblom**  
*Member of the Board*

**Anders Hallberg**  
*Member of the Board*

**Johan Harmenberg**  
*Member of the Board*

**Helena Levander**  
*Member of the Board*

**Anna Malm Bernsten**  
*Member of the Board*

**Bertil Samuelsson**  
*Member of the Board*

**Birgitta Stymne Göransson**  
*Chairman of the Board*

**Veronica Werlinder**  
*Member of the Board,  
Employee Representative*

**Niklas Prager**  
*President and CEO*

*This report has not been subject to auditors' review.*

*The information in this report comprises the information that Medivir is obliged to disclose under the provisions of the Swedish Securities Markets Act.*

*This information was released for publication at 08.30 AM CET on 20 August 2015.*

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### For further information, please contact

Niklas Prager, President & CEO, +46 (0) 8 407 64 30  
Ola Burmark, CFO, +46 (0) 725 480 580

The conference call will also be streamed via a link on the website: [www.medivir.com](http://www.medivir.com)

### Conference call for investors, analysts and the media

The Interim Report for the second quarter of 2015 will be presented by Medivir's President & CEO, Niklas Prager and members of Medivir's management group.

Time: Thursday, 20 August 2015, at 14.00 (CET).

Phone numbers for participants from:  
Sweden +46 (0)8 566 426 62  
Europe +44 20 342 814 09  
USA +1 855 831 5945

The presentation will be available on Medivir's website after completion of the conference.

#### Upcoming reporting dates:

##### Interim Report Q3 (January–September)

20 November 2015

##### Full year report

18 February 2016.

## Consolidated Income Statement, summary (SEK m)

	Q2		Q1-Q2		Full year
	2015	2014	2015	2014	2014
<b>Continuing operations</b>					
Net turnover	245.8	564.0	461.7	772.2	1 767.0
Cost of goods sold	-30.9	-45.2	-64.0	-71.3	-174.0
<b>Gross profit</b>	<b>214.9</b>	<b>518.8</b>	<b>397.7</b>	<b>700.9</b>	<b>1 593.0</b>
Selling expenses	-27.6	-26.0	-52.5	-49.4	-103.6
Administrative expenses	-18.2	-13.8	-31.5	-31.8	-62.5
Research and development costs	-71.4	-64.4	-137.7	-116.5	-245.8
Other operating income/expenses	-1.5	1.6	-3.7	1.7	7.6
<b>Operating profit/loss</b>	<b>96.1</b>	<b>416.2</b>	<b>172.2</b>	<b>504.9</b>	<b>1 188.7</b>
Net financial items	-10.7	2.2	-4.0	3.8	4.0
<b>Profit/loss after financial items</b>	<b>85.4</b>	<b>418.4</b>	<b>168.2</b>	<b>508.7</b>	<b>1 192.7</b>
Tax	-21.3	-90.6	-37.5	103.0	-60.0
<b>Net profit/loss for the period</b>	<b>64.1</b>	<b>327.8</b>	<b>130.7</b>	<b>611.7</b>	<b>1 132.7</b>
<b>Net profit/loss for the period attributable to:</b>					
Parent Company shareholders	64.1	327.8	130.7	611.7	1 132.7
<b>Earnings per share, calculated from the net profit/loss attributable to Parent Company shareholders during the period</b>					
Earnings per share (SEK per share)					
- Continuing operations, basic earnings	2.21	10.49	4.50	19.57	36.24
- Continuing operations, diluted earnings	2.19	10.28	4.46	19.18	35.90
- Total operations, basic earnings	2.21	19.57	4.50	19.57	36.24
- Total operations, diluted earnings	2.19	19.18	4.46	19.18	35.90
Average number of shares, '000	29 048	31 260	29 048	31 260	31 260
Number of shares at period end, '000	26 836	31 260	26 836	31 260	31 260

## Notes

### Accounting principles

Medivir applies International Financial Reporting Standards (IFRS) as endorsed by the European Union. Significant accounting and valuation principles are presented on pages 58-65 of the 2014 Annual Report. The Group's Interim Report has been prepared in accordance with IAS 34. The Parent Company applies the principles recommended by the Swedish Financial Reporting Board in its recommendation, RFR 2. Other new or revised IFRS standards and IFRIC interpretations that have come into force since 31 December 2014 have had no significant effect on the Group's or Parent Company's financial position or results.

## Consolidated Statement of Comprehensive Income (SEK m)

	Q2		Q1-Q2		Full year
	2015	2014	2015	2014	2014
<b>Net profit/loss for the period</b>	<b>64.1</b>	<b>327.8</b>	<b>130.7</b>	<b>611.7</b>	<b>1 132.7</b>
<b>Other comprehensive income</b>					
<i>Items that may be reclassified in the Income Statement</i>					
Exchange rate differences	0.0	-0.7	0.8	-0.7	-5.4
<b>Total other comprehensive income for the period, net after tax</b>	<b>0.0</b>	<b>-0.7</b>	<b>0.8</b>	<b>-0.7</b>	<b>-5.4</b>
<b>Total comprehensive income for the period</b>	<b>64.1</b>	<b>327.1</b>	<b>131.5</b>	<b>611.0</b>	<b>1 127.3</b>
<b>Total net profit/loss</b>	<b>64.1</b>	<b>327.1</b>	<b>131.5</b>	<b>611.0</b>	<b>1 127.3</b>

## Consolidated Balance Sheet, summary (SEK m)

	2015	2014	2014
	30 June	30 June	31 Dec
<b>Assets</b>			
Intangible fixed assets	410.9	421.4	417.6
Tangible fixed assets	29.1	27.6	26.9
Financial fixed assets	2.5	7.5	2.5
Deferred tax receivable	0.0	144.5	0.0
Inventories	23.8	18.8	23.6
Current receivables	253.9	572.9	317.7
Short-term investments	862.4	405.4	1 309.6
Cash and bank balances	181.0	25.0	86.0
<b>Total assets</b>	<b>1 763.8</b>	<b>1 623.1</b>	<b>2 183.9</b>
<b>Shareholders' equity and liabilities</b>			
Shareholders' equity	1 502.5	1 464.7	1 982.6
Long-term liabilities	0.0	40.0	0.0
Current liabilities	261.2	118.4	201.3
<b>Total shareholders' equity and liabilities</b>	<b>1 763.8</b>	<b>1 623.1</b>	<b>2 183.9</b>

## Consolidated Statement of Changes in Shareholders' Equity (SEK m)

	Share capital	Other paid-in capital	Exchange rate difference	Accumulated loss	Total shareholders' equity
<b>Opening balance, 1 January 2014</b>	<b>156.3</b>	<b>1 759.1</b>	<b>1.4</b>	<b>-1 064.2</b>	<b>852.6</b>
Total comprehensive income for the period	-	-	-5.4	1 132.7	1 127.3
Share incentive plan: value of employee service	-	2.7	-	-	2.7
<b>Closing balance, 31 December 2014</b>	<b>156.3</b>	<b>1 761.8</b>	<b>-4.0</b>	<b>68.5</b>	<b>1 982.6</b>
<b>Opening balance, 1 January 2014</b>	<b>156.3</b>	<b>1 759.1</b>	<b>1.4</b>	<b>-1 064.2</b>	<b>852.6</b>
Total comprehensive income for the period	-	-	-0.7	611.7	611.0
Share incentive plan: value of employee service	-	1.1	-	-	1.1
<b>Closing balance, 30 June 2014</b>	<b>156.3</b>	<b>1 760.2</b>	<b>0.7</b>	<b>-452.5</b>	<b>1 464.7</b>
<b>Opening balance, 1 January 2015</b>	<b>156.3</b>	<b>1 761.8</b>	<b>-4.0</b>	<b>68.5</b>	<b>1 982.6</b>
Total comprehensive income for the period	-	-	0.8	130.7	131.5
Share incentive plan: value of employee service	-	1.1	-	-	1.1
Redemption program	-21.5	-579.7	-	-	-601.2
Stock dividend issue	21.5	-21.5	-	-	0.0
Transaction costs	-	-	-	-1.4	-1.4
Tax effect on transaction costs	-	-	-	0.3	0.3
Repurchase of own shares	-	-10.4	-	-	-10.4
<b>Closing balance, 30 June 2015</b>	<b>156.3</b>	<b>1 151.4</b>	<b>-3.2</b>	<b>198.1</b>	<b>1 502.5</b>

## Consolidated Cash Flow Statement, summary (SEK m)

	Q2		Q1-Q2		Full Year
	2015	2014	2015	2014	2014
<b>Cash flow from operating activities before changes in working capital</b>	<b>92.8</b>	<b>113.1</b>	<b>177.3</b>	<b>49.7</b>	<b>1016.5</b>
Changes in working capital	-28.4	-24.4	92.3	-18.7	-2.1
<b>Cash flow from operating activities</b>	<b>64.3</b>	<b>88.7</b>	<b>269.6</b>	<b>31.0</b>	<b>1014.4</b>
<b>Investing activities</b>					
Acquisition/sale of fixed assets	-9.0	-2.6	-13.0	-7.8	-20.2
Sale of operations	0.0	2.5	2.5	5.0	2.5
<b>Cash flow from investing activities</b>	<b>-9.0</b>	<b>-0.1</b>	<b>-10.5</b>	<b>-2.8</b>	<b>-17.7</b>
<b>Financing activities</b>					
Redemption program	-	-	-601.2	-	-
Repurchase of own shares	-10.4	-	-10.4	-	-
<b>Cash flow from financing activities</b>	<b>-10.4</b>	<b>-</b>	<b>-611.6</b>	<b>-</b>	<b>-</b>
<b>Cash flow for the period</b>	<b>44.9</b>	<b>88.6</b>	<b>-352.5</b>	<b>28.2</b>	<b>996.7</b>
Liquid assets at beginning of period	998.4	341.8	1395.6	402.2	402.2
Change in liquid assets	44.9	88.6	-352.5	28.2	996.7
Exchange rate difference, liquid assets	0.1	0.0	0.2	0.0	-3.3
<b>Liquid assets at period end</b>	<b>1 043.4</b>	<b>430.4</b>	<b>1 043.4</b>	<b>430.4</b>	<b>1395.6</b>

### Parent company income statement, summary (SEK m)

	Q2		Q1-Q2		Full Year
	2015	2014	2015	2014	2014
Net turnover	210.5	531.1	380.3	700.9	1 646.4
Cost of goods and services sold	-23.2	-36.2	-44.1	-52.3	-128.5
<b>Gross profit</b>	<b>187.3</b>	<b>494.9</b>	<b>336.2</b>	<b>648.6</b>	<b>1 517.9</b>
Selling expenses	-14.2	-15.1	-28.8	-26.8	-62.2
Administrative expenses	-15.1	-11.3	-26.5	-28.2	-54.3
Research and development costs	-60.4	-63.9	-119.9	-115.2	-227.7
Other operating income/expenses	-2.1	1.4	-4.4	1.4	7.4
<b>Operating profit/loss</b>	<b>95.5</b>	<b>406.0</b>	<b>156.6</b>	<b>479.8</b>	<b>1 181.1</b>
Net financial items	-10.0	1.5	-2.5	3.3	-48.9
<b>Profit/loss after financial items</b>	<b>85.5</b>	<b>407.5</b>	<b>154.1</b>	<b>483.1</b>	<b>1 132.2</b>
Appropriations	-	-	-	-	-181.0
Tax	-19.4	-89.8	-34.5	107.0	-8.8
<b>Net profit/loss for the period</b>	<b>66.1</b>	<b>317.8</b>	<b>119.6</b>	<b>590.1</b>	<b>942.4</b>

### Parent company statement of comprehensive income (SEK m)

	Q2		Q1-Q2		Full year
	2015	2014	2015	2014	2014
Net profit/loss for the period	66.1	317.8	119.6	590.1	942.4
Other comprehensive income for the period, net after tax	66.1	317.8	119.6	590.1	942.4
<b>Total comprehensive income for the period</b>	<b>66.1</b>	<b>317.8</b>	<b>119.6</b>	<b>590.1</b>	<b>942.4</b>

### Parent company balance sheet, summary (SEK m)

	2015	2014	2014
	30 Jun	30 Jun	31 Dec
<b>Assets</b>			
Intangible fixed assets	19.0	7.3	14.6
Tangible fixed assets	28.9	27.1	26.6
Financial fixed assets	624.5	604.2	604.2
Deferred tax receivable	0.0	107.0	0.0
Inventories	2.1	1.8	3.6
Current receivables	231.2	555.7	292.2
Short-term investments	862.4	405.4	1 309.6
Cash and bank balances	79.1	14.9	43.3
<b>Total assets</b>	<b>1 847.2</b>	<b>1 723.4</b>	<b>2 294.0</b>
<b>Shareholders' equity and liabilities</b>			
Shareholders' equity	1 436.6	1 574.6	1 928.6
Long-term liabilities	0.0	40.0	0.0
Current liabilities	410.6	108.8	365.5
<b>Total shareholders' equity and liabilities</b>	<b>1 847.2</b>	<b>1 723.4</b>	<b>2 294.0</b>

## Key ratios, share data, options

	Q1-Q2 2015	Q1-Q2 2014	Full year 2014
Return on:			
- shareholders' equity, %	9.7	36.1	84.1
- capital employed, %	7.6	35.0	82.0
- total capital, %	8.7	32.1	75.2
Number of shares at beginning of period, '000	31 260	31 260	31 260
Number of shares at period end, '000	26 966	31 260	31 260
- of which class A shares	606	660	660
- of which class B shares	26 230	30 600	30 600
- of which repurchased B shares	130	-	-
Average number of shares, '000	29 048	31 260	31 260
Outstanding warrants, '000	250	639	294
Share capital at period end, SEK m	156.3	156.3	156.3
Shareholders' equity at period end, SEK m	1 502.5	1 464.7	1 982.6
Earnings per share, SEK			
- Continuing operations, basic earnings	4.50	19.57	36.24
- Continuing operations, diluted earnings	4.46	19.18	35.90
- Discontinued operations, basic and diluted earnings	-	-	-
- Total operations, basic earnings	4.50	19.57	36.24
- Total operations, diluted earnings	4.46	19.18	35.90
Shareholders' equity per share, SEK	56.0	46.9	63.4
Net worth per share, SEK	56.0	46.9	63.4
Cash flow per share after investments, SEK	8.9	2.8	31.9
Equity/assets ratio, %	85.2	90.2	90.8
EBITDA	189.6	432.5	1 221.9
EBIT	172.2	416.2	1 188.7
Operating margin, %	37.3	73.8	67.3
R&D spending/total opex, %	61.1	59.4	60.8

### Key ratio definitions

**Average number of shares.** The unweighted average number of shares during the year.

**Basic earnings per share.** Profit/loss per share after financial items divided by the average number of shares.

**Capital employed.** Balance Sheet total less non-interest-bearing liabilities including deferred tax liabilities.

**Cash flow per share after investments.** Cash flow after investments divided by the average number of shares.

**Diluted earnings per share.** Profit/loss per share after financial items divided by the average number of shares and outstanding warrants adjusted for any dilution effect.

**EBIT (Earnings before interest and taxes).** Operating profit/loss after depreciation and amortisation.

**EBITDA (Earnings before interest, taxes, depreciation and amortisation).** Operating profit/loss before depreciation and amortisation.

**Equity/assets ratio.** Shareholders' equity in relation to the Balance Sheet total.

**Net worth per share.** Shareholders' equity plus hidden assets in listed equities divided by the number of shares at the period end.

**Operating margin.** Operating profit/loss as a percentage of net turnover.

**R&D spending/total OPEX.** Research and development costs divided by total operating costs.

**Return on capital employed.** Profit/loss after financial items plus financial expenses as a percentage of the average capital employed.

**Return on shareholders' equity.** Profit/loss after financial items as a percentage of the average shareholders' equity.

**Return on total assets.** Profit/loss after financial items plus financial expenses as a percentage of the average Balance Sheet total.

**Shareholders' equity per share.** Shareholders' equity divided by the number of shares at the period end.