# MEDIVIR

# **MEDIVIR AB – INTERIM REPORT, THIRD QUARTER 2015**

# **Financial summary**

## Third quarter 2015 (2014)

- Net turnover totalled SEK 111.5 million (617.8 m), of which SEK 69.0 million (516.4 m) comprised royalties for simeprevir, where of SEK 11.5 million referred to past periods.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 42.6 million (100.8 m), of which SEK 2.8 million (61.6 m) derived from sales of OLYSIO<sup>®</sup> and SEK 39.8 million (39.2 m) from sales of other pharmaceuticals.
- The loss after tax was SEK -10.5 million (373.7 m).
- Basic and diluted earnings per share totalled SEK -0.36 (11.95) and SEK -0.36 (11.83), respectively.
- The cash flow from operating activities amounted to SEK 75.4 million (473.0 m).

#### Nine months 2015 (2014)

- Net turnover totalled SEK 573.2 million (1,390.0 m), of which SEK 387.5 million (1,178.7 m) comprised the first nine months' royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 184.5 million (210.2 m), of which SEK 50.2 million (83.3 m) derived from sales of OLYSIO<sup>®</sup> and SEK 134.3 million (126.9 m) from sales of other pharmaceuticals.
- The profit after tax was SEK 120.3 million (985.4 m).
- Basic and diluted earnings per share totalled SEK 4.14 (31.52) and SEK 4.11 (31.21), respectively.
- The cash flow from operating activities amounted to SEK 345.0 million (896.4 m).

	Q	3	Q1-Q3		Full year	
Summary of the Group's figures, continuing operations (SEK m)	2015	2014	2015	2014	2014	
Net turnover	111.5	617.8	573.2	1 390.0	1 767.0	
Gross profit	90.2	567.6	487.9	1 268.5	1 593.0	
Operating profit before depreciation and amortisation (EBITDA)	1.3	485.7	190.9	1 006.9	1 221.9	
Operating profit (EBIT)	-13.1	477.3	159.2	982.2	1 188.7	
Profit/loss before tax	-13.3	479.6	155.0	988.3	1 192.7	
Profit/loss after tax	-10.5	373.7	120.3	985.4	1 132.7	
Operating margin, %	-11.8	77.3	27.8	70.7	67.3	
Basic earnings per share, SEK	-0.36	11.95	4.14	31.52	36.24	
Diluted earnings per share, SEK	-0.36	11.83	4.11	31.21	35.90	
Net worth per share, SEK	55.4	58.8	55.4	58.8	63.4	
Return on equity	-0.9	29.0	8.9	73.4	84.1	
Cash flow from operating activities	75.4	473.0	345.0	504.0	1 014.4	
Liquid assets and short-term investments at the period end	1 118.1	896.4	1 118.1	896.4	1 395.6	
R&D spending/total opex, %	68.1	58.6	63.3	59.2	60.8	

# **CEO's comments**

The third quarter saw us continuing to build the value of our research portfolio, based on Medivir's established and documented successful technology platform.

Our projects' progress in Q3 included the launch in July by our partner, Janssen, of a phase I clinical trial of AL-704, a nucleotide-based NS5B polymerase inhibitor from Medivir for the treatment of chronic hepatitis C infection in combination with other direct-acting antivirals.

The quarter also marked the launch by Janssen of a phase I clinical trial to evaluate the potential effect of simeprevir and odalasvir on AL-335 pharmacokinetics in healthy volunteers.

We were also able to announce, after the quarter end, that Janssen has started a phase IIa clinical trial to evaluate the effect of a triple combination treatment regimen comprising simeprevir, odalasvir and AL-335 in treatment-naïve patients with genotype 1 chronic hepatitis C virus infection.

The preclinical safety testing of MIV-711 has been completed and submission of regulatory approval documentation to support this study is underway. Our aim is to start a phase IIa trial at the end of the year.

We are engaged in ongoing discussions with potential partners for some time now with regard to the MIV-802 project for the treatment of hepatitis C, and we are now awaiting the results of the ongoing preclinical safety trials before continuing these discussions.

These successes in our development projects were very pleasing, but one of our early discovery projects unfortunately failed to live up to expectations. Earlier this year, we launched a partnership with Cancer Research Technology (CRT) for the development of a new class of cancer drugs. Based on data generated during the last six months and after internal reviews of the project, we decided to deprioritise and close down the ADAM8 inhibitor project for pancreatic cancer.

In order to continue building long-term value in Medivir as efficiently as possible we have re-sized the commercial organisation during the period, adapting it in line with the declining levels of OLYSIO<sup>®</sup> sales in the Nordics. We have, accordingly, as of 1<sup>st</sup> of October, grouped all of our R&D work under the banner of a single, joint unit that will span the entire process, from early discovery to the clinical development phases. I am convinced that not only will this change enhance our ability to prioritise and enhance the efficiency of our research operations; it will also increase our flexibility and ability to broaden the portfolio of projects in clinical development phases. We also, at the same time, created a new function – Strategic Regulatory Affairs – which will house all regulatory skills and areas of responsibility and which is headed by Åsa Holmgren. Åsa has become a member of Medivir's management group.

Royalties attributable to the hepatitis C drug, OLYSIO<sup>®</sup> (simeprevir), totalled SEK 57.5 million during the third quarter, signalling that the declining trend in net sales of OLYSIO<sup>®</sup> is continuing, year on year.

Our Nordic pharmaceutical sales organisation, comprising Innovative Specialty Care and Nordic Brands, posted combined sales of SEK 42.6 million during the third quarter. OLYSIO<sup>®</sup> contributed SEK 2.8 million to this total and Nordic Brands posted an increase in sales of 1.3 per cent, year on year.

Overall, the quarter has seen the ongoing progress by the majority of our projects enable us to continue building long-term value, despite one set of negative results from our discovery research, and I have every reason to believe that this progress will continue.

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 organisation 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.

# Significant events during the third quarter

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 (an NS5B polymerase inhibitor). 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.

In mid-September Medivir announced that as the next step in the company's optimisation process, its research and development operations will be merged into a joint unit as of 1 October 2015. The unit is headed by Richard Bethell who will hold the new title of EVP Research & Development. The new unit will span the entire process, from the early discovery research to the clinical development phases.

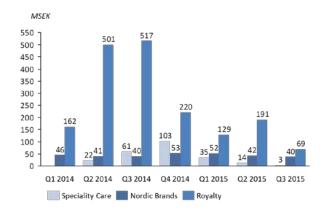
Medivir will also create a new function to house all regulatory skills and areas of responsibility, headed by Åsa Holmgren.

#### Revenues

Net turnover totalled SEK 111.5 million (617.8 m), corresponding to a decrease of SEK 506.3 million. Royalty income totalled SEK 69.0 million (517.0 m), with royalties from Janssen's global sales of simeprevir, which totalled USD 79 million, amounting to SEK 57.5 million (516.4 m). In addition Medivir received SEK 11.5 million in royalty adjustments related to previous periods. Royalties based on GSK's global sales of Xerclear (Zoviduo) during the third quarter amounted to SEK 0.4 million. The revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 42.5 million (100.8 m), of which SEK 2.8 million (61.6 m) derived from sales of OLYSIO<sup>®</sup> and SEK 39.7 million (39.2 m) from sales of other pharmaceuticals. Sales of other pharmaceuticals excluding OLYSIO<sup>®</sup> increased by SEK 0.5 million, primarily driven by the strong brands Mollipect, Laxabon, Paraflex and Lithionit.

Breakdown of net turnover (SEK m)	Q	Q3		Q1-Q3	
Breakdown of net turnover (SEK m)	2015	2014	2015	2014	2014
Pharmaceutical sales, where of	 42.5	100.8	184.5	210.2	366.8
Nordic brands	39.5	39.0	133.4	126.6	180.1
Innovative specialty care	3.0	61.8	51.0	83.6	186.7
Royalties	 69.0	517.0	388.8	1 179.8	1 400.2
Total	111.5	617.8	573.2	1 390.0	1 767.0

#### Net turnover (SEK m), Q1 2014 - Q3 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 -21.3 million (-50.2 m), corresponding to a decrease of SEK 28.9 million. The gross profit amounted to SEK 90.2 million (567.6 m), corresponding to a decrease of SEK 477.4 million and equating to a gross margin of 81% (92%), explained by the continued shift from royalty to pharmaceutical sales.

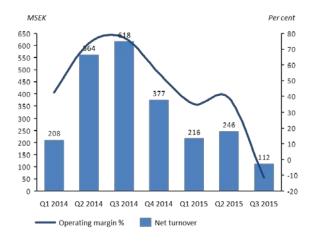
#### **Operational expenses**

Selling expenses have increased by SEK 2.3 million compared to the same quarter last year. The third quarter increase relates to the re-sizing of the commercial organisation as the result of a decline in OLYSIO<sup>®</sup> Nordic sales, and non-recurring personnel costs of 3.7 million have also impacted the quarter. Administrative expenses increased by SEK 2.7 million, with underlying decreased spending being offset by a non-recurring personnel cost of SEK 5.4 million. Research and Development costs increased by SEK 17.5 million compared to the same quarter last year, as a result of the MIV-802 and MIV-711 projects, which have progressed into pre-clinical and clinical development, respectively. Other operating income/expenses are positive and increased by SEK 9.4 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -103.3 million (-90.3 m), corresponding to an increase of SEK 13.0 million, where of SEK 9.1 million comprise non-recurring personnel costs. This represents a cost reduction of approximately SEK 14 million over the coming four quarters.

The operating profit/loss totalled SEK -13.1 million (477.3 m), corresponding to a decrease of SEK 490.4 million.

Net financial items totalled SEK -0.2 million (2.3 m), corresponding to a decrease of SEK 2.5 million, and due to unrealised losses driven by market valuation of short-term interest-bearing investments.

#### Net turnover (SEKm) and operating margin (%)



#### Taxes

Tax for the third quarter totalled SEK 2.8 million (-105.9 m), corresponding to a decrease of SEK 108.7 million. The decrease primarily derives from a decline in Royalty income in comparison with the third quarter of 2014.

The Group's income and deferred tax are calculated using the legally stipulated tax rate of 22%.

# Financial overview, nine months 2015

#### Revenues

Net turnover totalled SEK 573.2 million (1,390.0 m), corresponding to a decrease of SEK 816.8 million. Royalty income totalled SEK 388.8 million (1,179.8 m), with royalties from Janssen's global sales of simeprevir, which totalled USD 577 million, amounting to SEK 387.5 million (1,178.7 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 184.5 million (210.2 m) of total pharmaceutical sales, where SEK 50.2 million (83.3 m) derived from sales of OLYSIO<sup>®</sup> and SEK 134.3 million (126.9 m) from sales of other pharmaceuticals. Sales of other pharmaceuticals increased by SEK 7.4 million, primarily driven by the strong brands, Mollipect, Suscard, Paraflex and Lithionit.

#### Results

#### **Gross profit**

The cost of goods sold was SEK -85.3 million (-121.5 m), corresponding to a decrease of SEK 36.2 million. The gross profit amounted to SEK 487.9 million (1,268.5 m), corresponding to a decrease of SEK 780.6 million and equating to a gross margin of 85% (91%), explained by the shift from royalty to pharmaceutical sales.

#### **Operational expenses**

Selling expenses increased by SEK 5.3 million, primarily due to the re-sizing of the commercial organisation as the result of a decline in OLYSIO® Nordic sales and nonrecurring personnel costs of SEK 3.7m. Administrative expenses increased by SEK 2.4 million, with underlying lower spending being offset by non-recurring personnel costs in the period. Research and development costs increased by SEK 38.7 million, primary as a result of the MIV-802 and MIV-711 projects which have progressed into pre-clinical and clinical development, and of the RSV project inlicensed in the third quarter last year. Other operating income/expenses are positive and increased by SEK 4.0 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -328.7 million (-286.3 m), corresponding to an increase of SEK 42.4 million, whereof SEK 17.1 million are non-recurring personnel costs.

The operating profit/loss totalled SEK 159.2 million (982.2 m), corresponding to a decrease of SEK 823.0 million.

Net financial items totalled SEK -4.2 million (6.1 m), corresponding to a decrease of SEK 10.3 million, and due to unrealised losses driven by market valuation of short-term interest-bearing investments.

#### Taxes

Tax for the period totalled SEK -34.7 million (-2.9 m), corresponding to an increase of SEK 31.8 million. The increase primarily derives from capitalisations of loss carry forwards activated in the first quarter of 2014. The Group's income and deferred tax are calculated from the legally stipulated tax rate of 22%.

#### Cash flow, Investments and Financial Position

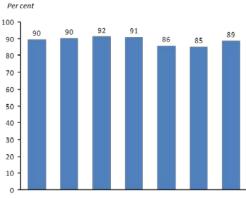
Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 1,118.1 million (896.4 m) at the end of the period, compared to 1,395.6 million (402.2 m) at the beginning of 2015 - a decrease of SEK 277.5 million. An additional SEK 57.5 million in royalties are due for payment during the fourth 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 345.0 million (504.0 m), with changes in working capital accounting for SEK 174.6 million (-18.4 m). The positive cash flow derives, primarily, from incoming royalties for the previous quarter.

Cash flow from investing activities totalled SEK -11.1 million (-9.9 m). Investments in research and facility equipment and IT systems totalled SEK -16.1 million (-14.9 m), and a tranche of the purchase price from the sale of Cross Pharma totalled SEK 5.0 million (5.0 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.

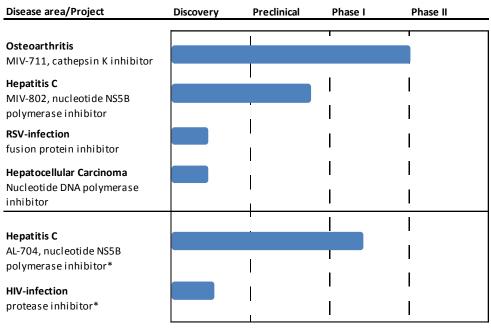
#### Equity to Asset Ratio, %



Q1 2014 Q2 2014 Q3 2014 Q4 2014 Q1 2015 Q2 2015 Q3 2015

Investments in tangible fixed assets during the period amounted to SEK -7.2 million (-3.7 m) and comprised research, facility and IT equipment. Depreciation of tangible fixed assets totalling SEK -8.0 million (-7.5 m) and of intangible fixed assets of SEK -17.6 million (-17.2 m) respectively were charged to the profit/loss for the period. 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 (Zoviduo<sup>®</sup>) 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, Israel and China, which still are held by Medivir, are out-licenced to GlaxoSmithKline. In 2013, simeprevir (OLYSIO<sup>®</sup>) 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 hepatitis C infection as part of an antiviral treatment programme in chronic genotype 1 and 4 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.



\* Partner Janssen

For further information about our projects, please visit <u>www.medivir.com</u>

#### 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 has completed preclinical safety testing, enabling a longer term phase II study in osteoarthritis patients to be initiated. Submission of regulatory approval documentation to support this clinical study is underway.

#### **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 testing is currently in progress to enable phase I clinical studies to be initiated.

#### **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 identify a substance with the required profile for further development.

#### HCC nucleotide based DNA polymerase inhibitor

Nucleotide project for Hepatocellular Carcinoma aimed at delivering cancer therapeutics selectively to the liver. Non-surgical approaches to managing 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 longstanding 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. Studies to enable the profiling of compounds in disease-relevant models have been initiated.

#### ADAM8 inhibitor

The aim of the project was to develop a molecule that inhibits the protease activity of ADAM8 for the treatment of pancreatic cancer.

#### Status/significant events:

The project has been terminated, following an internal review. The decision was based on data generated during the past six months.

#### PARTNERED PROJECTS

#### AL-704

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. AL-704 is being developed in partnership with Janssen Pharmaceuticals.

#### Status/significant events:

A phase I clinical trial with AL-704, also known as JNJ-54257099, to evaluate the safety, tolerability, and pharmacokinetics was initiated during the quarter. The study is being conducted by Alios Biopharma Inc., part of the Janssen Pharmaceutical Companies.

#### Simeprevir

Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen Sciences Ireland UC and Medivir AB and indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen.

#### Status/significant events:

In July, Janssen Products, LP (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<sup>®</sup> (simeprevir).

In August, Janssen started a phase I study to evaluate the effect of simeprevir and odalasvir on AL-335 pharmacokinetics.

In mid-October, Janssen started a phase IIa clinical trial to evaluate the combination of simeprevir, odalasvir and AL-335.

#### 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 third quarter, Medivir filed new patent families within its RSV, oncology and cathepsin K projects.

#### **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 23.8 million (63.9 m).

# Other disclosures (nine months period)

#### **Employees**

Medivir had 132 (137) employees (FTE's) at the period end, 56% (57%) of whom were women.

#### 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 2.3 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 458.6 million (1,287.8 m). Intra-Group sales amounted to SEK 18.8 million (24.4 m).

The gross profit amounted to SEK 410.0 million (1,195.2 m). Combined operating expenses totalled SEK -276.7 million (-244.3 m). The operating profit/loss was SEK 133.3 million (950.9 m), corresponding to a decrease of SEK 817.6 million. Net financial items totalled SEK -2.4 million (5.5 m), corresponding to a decrease of SEK 7.9 million, and due to unrealised losses driven by market valuation of short-term interest-bearing investments.

The tax for the period totalled SEK -29.1 million (2.9 m). The net profit/loss for the period was

SEK 101.8 million (959.3 m), corresponding to a decrease of SEK 857.5 million, primarily due to decrease in royalty income.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 1,016.5 million (874.2 m).

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

#### **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 11.4 million (27.7 m) whereof royalty payments to Uppsala Hallbechem AB (Board Member, Anders Hallberg) totalled SEK 3.0 million (8.8 m) and to Sybesam AB (Board Member, Bertil Samuelsson) totalled SEK 8.4 million (17.9 m). Other services were purchased from related parties for a total of SEK 0.0 million (1.0 m).

#### 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 pages 35 and 71 (Note 8).

#### Significant events after end of Q3

In mid-October, Alios BioPharma Inc., part of the Janssen Pharmaceutical Companies (Janssen), started a phase IIa clinical trial to evaluate the combination of simeprevir, odalasvir (also known as ACH-3102), and AL-335 in treatment-naïve patients with genotype 1 chronic hepatitis C virus (HCV) infection. This phase IIa study is a randomised, open-label, three-arm study of AL-335, a nucleotide-based HCV NS5B polymerase inhibitor, odalasvir, an HCV NS5A inhibitor and simeprevir, an HCV NS3/4A protease inhibitor. Patients will be randomised to one of three treatment arms and receive once daily treatment for a duration of four, six or eight weeks. The primary objective of the study is to establish the safety of the treatment regimen with secondary endpoints consisting of pharmacokinetics, the proportion of subjects achieving sustained viral response (SVR), and the effect on the viral resistance profile after treatment. The study is expected to enrol approximately 60 patients across the three treatment arms.

Medivir's Nomination Committee for the 2016 Annual General Meeting was appointed. This year's Nomination Committee consists of: Bo Öberg, founder and A-shareholder, (Bo Öberg also represents, through an agreement, the other class A- shareholders, Nils Gunnar Johansson and Christer Sahlberg), Maria Rengefors, Nordea Fonder, Anders Hallberg, Healthinvest, and Birgitta Stymne Göransson, Chairman of the Board, Medivir AB.

Medivir will terminate its license agreement with Cancer Research Technology for ADAM8 inhibitors and discontinue its discovery efforts on this target, including the collaboration with CRT and TransMIT GmbH. The closure of the project follows an internal review of the Medivir R&D project portfolio, which deprioritised the project based on data generated during the last six months. With the closure of this project, internal resources are transferred to the company's other oncology discovery projects.

#### Outlook

Medivir is well positioned for the future with a globally recognised 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 envisage a stabilisation in the competitive landscape of the hepatitis C market. In the Nordics, OLYSIO<sup>®</sup> will generate limited sales.

Stockholm, 20 November 2015

Niklas Prager President and CEO

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 November 2015.

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# Conference call for investors, analysts and the media

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

Time: Friday, 20 November 2015, at 14.00 (CET).

Phone numbers for participants from: Sweden +46 (0)8 566 426 61 Europe +44 20 342 814 10 USA +1 866 388 1925

# The conference call will also be streamed via a link on the website: www.medivir.com

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

# Upcoming reporting dates:

Full year report 2015 18 February 2016 Interim Report (January – March 2016) 28 April 2016 Annual General Meeting 2016 3 May 2016 at 2PM, in Stockholm, Sweden

## Consolidated Income Statement, summary (SEK m)

	Q3		Q1	Q1-Q3	
	2015	2014	2015	2014	2014
Continuing operations					
Netturnover	111.5	617.8	573.2	1 390.0	1 767.0
Cost of goods sold	-21.3	-50.2	-85.3	-121.5	-174.0
Gross profit	90.2	567.6	487.9	1 268.5	1 593.0
Selling expenses	-26.7	-24.4	-79.2	-73.9	-103.6
Administrative expenses	-13.1	-10.4	-44.6	-42.2	-62.5
Research and development costs	-70.4	-52.9	-208.1	-169.4	-245.8
Other operating income/expenses	6.9	-2.5	3.2	-0.8	7.6
Operating profit/loss	-13.1	477.3	159.2	982.2	1 188.7
Net financial items	-0.2	2.3	-4.2	6.1	4.0
Profit/loss after financial items	-13.3	479.6	155.0	988.3	1 192.7
Тах	2.8	-105.9	-34.7	-2.9	-60.0
Net profit/loss for the period	-10.5	373.7	120.3	985.4	1 132.7
Net profit/loss for the period attributable to:					
Parent Company shareholders	-10.5	373.7	120.3	985.4	1 132.7
Earnings per share, calculated from the net profit/loss attributable					
to Parent Company shareholders during the period					
Earnings per share (SEK per share)					
<ul> <li>Continuing operations, basic earnings</li> </ul>	-0.36	11.95	4.14	31.52	36.24
<ul> <li>Continuing operations, diluted earnings</li> </ul>	-0.36	11.83	4.11	31.21	35.90
- Total operations, basic earnings	-0.36	11.95	4.14	31.52	36.24
- Total operations, diluted earnings	-0.36	11.83	4.11	31.21	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)

	Q	3	Q1	-Q3	Full year
	2015	2014	2015	2014	2014
Net profit/loss for the period	-10.5	373.7	120.3	985.4	1 132.7
Other comprehensive income					
Items that may be reclassified in the Income Statement					
Exchange rate differences	-0.2	-0.1	0.6	-0.8	-5.4
Total other comprehensive income for the period, net after tax	-0.2	-0.1	0.6	-0.8	-5.4
Total comprehensive income for the period	-10.7	373.6	120.8	984.6	1 127.3
Total net profit/loss	-10.7	373.6	120.8	984.6	1 127.3

# Consolidated Balance Sheet, summary (SEK m)

	2015	2014	2014
	30 Sept	30 Sept	31 Dec
Assets			
Intangible fixed assets	399.2	423.4	417.6
Tangible fixed assets	29.6	24.2	26.9
Financial fixed assets	0.0	7.5	2.5
Deferred tax receivable	0.0	38.5	0.0
Inventories	23.3	22.5	23.6
Current receivables	111.4	596.7	317.7
Short-term investments	862.9	852.4	1 309.6
Cash and bank balances	255.2	44.0	86.0
Total assets	1 681.6	2 009.2	2 183.9
Shareholders' equity and liabilities			
Shareholders' equity	1 492.9	1 839.3	1 982.6
Long-term liabilities	0.0	40.0	0.0
Current liabilities	188.7	129.9	201.3
Total shareholders' equity and liabilities	1 681.6	2 009.2	2 183.9

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

	Share capital	Other paid-in capital	Exchange rate difference	Accumulated loss	Total shareholders' equity
Opening balance, 1 January 2014	156.3	1 759.1	1.4	-1 064.2	852.6
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
Closing balance, 31 December 2014	156.3	1 761.8	-4.0	68.5	1 982.6
Opening balance, 1 January 2014	156.3	1 759.1	1.4	-1 064.2	852.6
Total comprehensive income for the period	-	-	-0.8	985.4	984.6
Share incentive plan: value of employee service	-	2.1	-	-	2.1
Closing balance, 30 September 2014	156.3	1 761.2	0.6	-78.8	1 839.3
Opening balance, 1 January 2015	156.3	1 761.8	-4.0	68.5	1 982.6
Total comprehensive income for the period	-	-	0.6	120.3	120.8
Share incentive plan: value of employee service	-	2.2	-	-	2.2
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
Closing balance, 30 September 2015	156.3	1 152.4	-3.4	187.7	1 492.9

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

	(	23	Q1-Q3		Full Year	
	2015	2014	2015	2014	2014	
Cash flow from operating activities before changes in working capital	6.4	472.7	183.7	522.4	1 016.5	
Changes in working capital	69.0	0.3	161.3	-18.4	-2.1	
Cash flow from operating activities	75.4	473.0	345.0	504.0	1 014.4	
Investing activities						
Acquisition/sale of fixed assets	-3.1	-7.1	-16.1	-14.9	-20.2	
Sale of operations	2.5	-	5.0	5.0	2.5	
Cash flow from investing activities	-0.6	-7.1	-11.1	-9.9	-17.7	
Financing activities						
Redemption program	-	-	-601.2	-	-	
Repurchase of own shares	-	-	-10.4	-	-	
Cash flow from financing activities	0.0	-	-611.6	-	-	
Cash flow for the period	74.8	465.9	-277.7	494.1	996.7	
Liquid assets at beginning of period	1 043.4	430.4	1 395.6	402.2	402.2	
Change in liquid assets	74.8	465.9	-277.7	494.1	996.7	
Exchange rate difference, liquid assets	-0.1	0.1	0.2	0.1	-3.3	
Liquid assets at period end	1 118.1	896.4	1 118.1	896.4	1 395.6	

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

	C	Q3 Q1-Q		3 Full Year	
	2015	2014	2015	2014	2014
Net turnover	78.3	586.9	458.6	1 287.8	1 646.4
Cost of goods and services sold	-4.4	-40.3	-48.6	-92.6	-128.5
Gross profit	73.9	546.6	410.0	1 195.2	1 517.9
Selling expenses	-17.1	-13.6	-45.9	-40.4	-62.2
Administrative expenses	-15.2	-8.4	-41.7	-36.6	-54.3
Research and development costs	-69.5	-51.0	-189.4	-166.2	-227.7
Other operating income/expenses	4.6	-2.5	0.2	-1.1	7.4
Operating profit/loss	-23.3	471.1	133.3	950.9	1 181.1
Net financial items	0.2	2.2	-2.4	5.5	-48.9
Profit/loss after financial items	-23.2	473.3	130.9	956.4	1 132.2
Appropriations	-	0.0	-	0.0	-181.0
Tax	5.4	-104.1	-29.1	2.9	-8.8
Net profit/loss for the period	-17.8	369.2	101.8	959.3	942.4

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

	C	Q3		Q1-Q3		
	2015	2014	2015	2014	2014	
Net profit/loss for the period	-17.8	369.2	101.8	959.3	942.4	
Other comprehensive income for the period, net after tax	-17.8	369.2	101.8	959.3	942.4	
Total comprehensive income for the period	-17.8	369.2	101.8	959.3	942.4	

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

	2015	2014	2014
	30 Sep	30 Sep	31 Dec
Assets			
Intangible fixed assets	12.8	14.9	14.6
Tangible fixed assets	29.4	23.8	26.6
Financial fixed assets	627.4	604.2	604.2
Deferred tax receivable	0.0	2.9	0.0
Inventories	2.1	1.9	3.6
Current receivables	85.2	573.3	292.2
Short-term investments	862.9	852.4	1 309.6
Cash and bank balances	153.6	21.8	43.3
Total assets	1 773.3	2 095.1	2 294.0
Shareholders' equity and liabilities			
Shareholders' equity	1 419.8	1 944.7	1 928.6
Long-term liabilities	0.0	40.0	0.0
Current liabilities	353.5	110.4	365.5
Total shareholders' equity and liabilities	1 773.3	2 095.1	2 294.0

## Key ratios, share data, options

	Q1-Q3	Q1-Q3	Full year
	2015	2014	2014
Return on:			
- shareholders' equity, %	8.9	73.4	84.1
-capital employed, %	7.3	71.5	80.6
-total capital, %	8.3	65.9	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	248	315	294
Share capital at period end, SEK m	156.3	156.3	156.3
Shareholders' equity at period end, SEK m	1 492.9	1 839.3	1 982.6
Earnings per share, SEK			
- Continuing operations, basic earnings	4.14	31.52	36.24
- Continuing operations, diluted earnings	4.11	31.21	35.90
- Discontinued operations, basic and diluted earnings	-	-	-
- Total operations, basic earnings	4.14	31.52	36.24
- Total operations, diluted earnings	4.11	31.21	35.90
Shareholders' equity per share, SEK	55.6	58.8	63.4
Net worth per share, SEK	55.6	58.8	63.4
Cash flow per share after investments, SEK	11.5	15.8	31.9
Equity/assets ratio, %	88.8	91.5	90.8
EBITDA	190.9	1 006.9	1 221.9
EBIT	159.2	982.2	1 188.7
Operating margin, %	27.8	70.7	67.3
R&D spending/total opex, %	63.3	59.2	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.

## **Report of Review of Interim Financial Information**

#### Introduction

We have reviewed the condensed interim financial information (interim report) of Medivir AB (publ) as of 30<sup>th</sup> of September 2015 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

#### **Scope of Review**

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, *Review of Interim Report Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Stockholm, 20 November 2015

PricewaterhouseCoopers AB

Hans Jönsson Authorized Public Accountant