

# MEDIVIR AB – FINANCIAL STATEMENT, JANUARY – DECEMBER 2015

## Financial summary

#### Fourth quarter 2015 (2014)

- Net turnover totalled SEK 84.7 million (377.0 m), SEK 31.1 million (220.1 m) of which comprised royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 53.1 million (156.6 m), of which SEK 2.7 million (103.1 m) derived from sales of OLYSIO® and SEK 50.4 million (53.5 m) from sales of other pharmaceuticals.
- The loss after tax was SEK -45.2 million (147.3 m).
- Basic and diluted earnings per share totalled SEK -1.56 (4.71) and SEK -1.54 (4.67), respectively.
- The cash flow from operating activities amounted to SEK -37.6 million (507.9 m).

#### Twelve months 2015 (2014)

- Net turnover totalled SEK 657.9 million (1,767.0 m), SEK 418.6 million (1,399.0 m) of which comprised full year royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 237.5 million (366.8 m), of which SEK 53.0 million (186.4 m) derived from sales of OLYSIO® and SEK 184.5 million (180.4 m) from sales of other pharmaceuticals.
- The profit after tax was SEK 75.1 million (1,132.7 m).
- Basic and diluted earnings per share totalled SEK 2.59 (36.24) and SEK 2.56 (35.9), respectively.
- The cash flow from operating activities amounted to SEK 307.4 million (1.011.9 m).

		Q4		Q1-Q4	
Summary of the Group's figures, continuing operations (SEK m)	2015	2014	2015	2014	
Net turnover	84.7	377.0	657.9	1 767.0	
Gross profit	60.7	324.5	548.6	1 593.0	
Operating profit before depreciation and amortisation (EBITDA)	-35.9	214.9	155.0	1 221.9	
Operating profit (EBIT)	-44.5	206.5	114.8	1 188.7	
Profit/loss before tax	-53.1	204.3	102.0	1 192.7	
Profit/loss after tax	-45.2	147.3	75.1	1 132.7	
Operating margin, %	-52.5	54.8	17.4	67.3	
Basic earnings per share, SEK	-1.56	4.71	2.59	36.24	
Diluted earnings per share, SEK	-1.54	4.67	2.56	35.90	
Net worth per share, SEK	53.8	63.4	53.8	63.4	
Return on equity	-3.6	10.7	5.9	84.1	
Cash flow from operating activities	-37.6	507.9	307.4	1 011.9	
Liquid assets and short-term investments at the period end	1 077.9	1 395.6	1 077.9	1 395.6	
R&D spending/total opex, %	66.9	64.7	64.2	60.8	

#### **CEO's comments**

2015 saw Medivir continue both to make important progress in our projects and to build the value of our research and development portfolio, which is based on Medivir's established and proven technology platform.

One example of this progress was the completion, on schedule, of the preclinical safety studies relating to our osteoarthritis project, MIV-711. The first patients were enrolled in the trial early in the New Year and we still anticipate being able to report the results of the trial in Q3 2017, at which time we will hopefully be able to confirm the results achieved to date. The fact that osteoarthritis is so widespread, coupled with the current lack of any pharmaceuticals that impact the progression of the disease, mean that the potential market for any such drug is considerable indeed. We estimate that the US market alone is greater than USD 6 billion annually for a drug that impacts disease progression, even if its use was restricted just to patient populations with moderate osteoarthritis in weight-bearing joints.

Our HCC oncology project for the treatment of hepatocellular carcinoma is also proceeding according to plan and we expect to commence preclinical safety studies as part of this project in the fourth quarter of 2016.

The preclinical safety studies as part of the MIV-802 project for the treatment of hepatitis C were completed according to plan at the end of the year and will now form the basis for continued discussions with potential partners.

Janssen – our partner for simeprevir – launched a clinical phase IIa trial of a simeprevir-based triple combination treatment for chronic hepatitis C infection at the beginning of Q4. The results are expected during the latter half of 2016 and will be important in terms of the potential for a subsequent launch of a competitive combination treatment. Janssen also announced in Q4 that it had discontinued the development of the AL-704 polymerase inhibitor for the treatment of hepatitis C, as the results failed to justify further clinical trials.

Q4 and full year royalties attributable to the hepatitis C drug, OLYSIO® (simeprevir), totalled SEK 31 million and SEK 419 million, respectively, corresponding to a decline in comparison with the corresponding periods in 2014 due to the increased competition OLYSIO® faced in 2015.

Our Nordic pharmaceutical sales organisation, comprising Innovative Specialty Care and Nordic Brands, achieved combined sales of SEK 237 million in 2015. Nordic Brands' net sales increased by 2.0 per cent, year on year, and the gross margin also improved following a combination of price increases and cost-cutting measures.

Our development and progress in 2015 has given us a foundation on which to continue building long-term value and I look forward with every confidence to Medivir's ongoing value creation and the exciting activities that lie ahead for us in 2016.

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 market-leading expertise in protease inhibitor design and nucleotide/nucleoside science and we are dedicated to developing innovative pharmaceuticals that meet great unmet medical needs. Our commercial organisation supplies the Nordic market with a portfolio of specialty care pharmaceuticals. Medivir is listed on the Nasdaq Stockholm Mid Cap List.

For more information about Medivir, please visit www.medivir.com.

## Significant events during the fourth quarter

In October, Janssen started a phase IIa study to evaluate the effect of simeprevir in combination with odalasvir and AL-335. 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.

In November, Medivir terminated its ADAM8 inhibitor project for pancreatic cancer. The closure of the project followed a semi-annual review of the company's R&D project portfolio, which deprioritized the project based on data generated during the last six months. As a

consequence, the license agreement with Cancer Research Technology (CRT) for ADAM8 inhibitors and the collaboration with CRT and TransMIT GmbH were terminated.

The development of the nucleotide polymerase inhibitor, AL-704 (also known as JNJ-54257099) was terminated following completion of phase I clinical studies conducted by Alios Biopharma Inc., one of the Janssen Pharmaceutical Companies. These studies demonstrated that AL-704 was safe, well tolerated and had acceptable pharmacokinetic properties. Its clinical antiviral activity in persons infected with HCV genotype 1 was, however, insufficient to justify further clinical studies.

## Financial overview, fourth quarter 2015

#### **Revenues**

Net turnover totalled SEK 84.7 million (377.0 m), corresponding to a decrease of SEK 292.3 million. Royalty income totalled SEK 31.6 million (220.4 m), with royalties from Janssen's global sales of simeprevir, totalling USD 44 million (321 m). Royalties based on GSK's global sales of Xerclear (Zoviduo) during the fourth quarter amounted to SEK 0.5 million.

The revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 53.1 million (156.6 m), of which SEK 2.7 million (103.1 m) derived from sales of OLYSIO® and SEK 50.4 million (53.5 m) from sales of other pharmaceuticals. Sales of other pharmaceuticals excluding OLYSIO® decreased by SEK 3.1 million.

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Breakdown of net turnover (SEK m)	2015	2014	2015	2014
Pharmaceutical sales, where of	53.1	156.6	237.5	366.8
Nordic brands	50.3	53.4	183.6	180.0
Innovative specialty care	2.8	103.2	53.9	186.8
Royalties	31.6	220.4	420.4	1 400.2
Total	84.7	377.0	657.9	1 767.0

#### Net turnover (SEK m), Q1 2014 - Q4 2015)



#### **Results**

#### **Gross profit**

The cost of goods sold was SEK -24.0 million (-52.5 m), corresponding to a decrease of SEK 28.5 million. The gross profit amounted to SEK 60.7 million (324.5 m), corresponding to a decrease of SEK 263.8 million and equating to a gross margin of 72% (90%), explained by the continued shift from royalty to pharmaceutical sales.

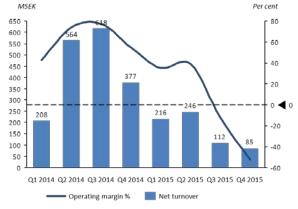
#### **Operational expenses**

Selling expenses have decreased by SEK 10.6 million compared to the same quarter last year. Administrative expenses decreased by SEK 4.6 million. Research and Development costs decreased by SEK 6.0 million in comparison with the corresponding quarter last year as a result of lower project-specific costs, which are determined by the different phases of the respective projects. Approximately SEK 4.3 million in external costs were, furthermore, successfully recovered following the termination of the ADAM8 project. Other operating income/expenses are negative and increased by SEK -8.3 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -105.1 million (-117.9 m), corresponding to a cost reduction of SEK 12.8 million.

The operating profit/loss totalled SEK -44.5 million (206.5 m), corresponding to a decrease of SEK 251.0 million.

Net financial items totalled SEK -8.6 million (-2.2 m), corresponding to a decrease of SEK 6.4 million, and due to unfavourable exchange rates and unrealised losses driven by negative market valuation of short-term interest-bearing investments.

#### Net turnover (SEK m) and operating margin (%)



#### **Taxes**

Reported losses during the fourth quarter resulted in a positive adjustments of taxes totalling SEK 7.9 million (-57.0 m).

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

## Financial overview, twelve months 2015

#### **Revenues**

Net turnover totalled SEK 657.9 million (1,767.0 m), corresponding to a decrease of SEK 1,109.1 million. Royalty income totalled SEK 420.4 million (1,400.2 m), and primarily comprised royalties from Janssen's global sales of simeprevir, which totalled USD 621 million (2,302 m). In addition, royalties based on GSK's global sales on Xerclear (Zoviduo) during the period amounted to SEK 1.8 million. Revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 237.5 million (366.8 m) of total pharmaceutical sales, with SEK 53.0 million (186.4 m) derived from sales of OLYSIO® and SEK 184.5 million (180.4 m) from sales of other pharmaceuticals. Sales of other pharmaceuticals increased by SEK 4.1 million, primarily driven by the strong brands, Mollipect, Suscard, Paraflex and Lithionit.

#### **Results**

#### **Gross profit**

The cost of goods sold was SEK -109.3 million (-174.0 m), corresponding to a decrease of SEK 64.7 million. The gross profit amounted to SEK 548.6 million (1,593.0 m), corresponding to a decrease of SEK 1,044.4 million and equating to a gross margin of 83% (90%), explained by the shift from royalty to pharmaceutical sales.

#### **Operational expenses**

Selling expenses decreased by SEK 5.2 million as a result of the re-sizing of the commercial organisation driven by the sharp decline in OLYSIO® Nordic sales. Administrative expenses have, furthermore, decreased by SEK 2.2 million. Research and development costs increased by SEK 32.6 million, primarily as a result of the MIV-711 project that has progressed into clinical development and the progress of discovery projects, such as the RSV fusion inhibitor and the HCC nucleotide projects. Other operating income/expenses are positive and decreased by SEK 4.4 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -433.8 million (-404.2 m), corresponding to an increase of SEK 29.6 million, of which SEK 17.1 million comprises non-recurring personnel costs.

The operating profit/loss totalled SEK 114.8 million (1,188.7 m), corresponding to a decrease of SEK 1,073.9 million.

Net financial items totalled SEK -12.8 million (4.0 m), corresponding to a decrease of SEK 8.8 million, and due to unfavourable exchange losses and unrealised losses driven by negative market valuation of short-term interest-bearing investments.

#### **Taxes**

Tax for the period totalled SEK -26.9 million (-60.0 m), corresponding to a decrease of SEK 33.1 million. The decrease in taxes is a result of reduced profits. The Group's income and deferred tax are calculated from the tax rate of 22%.

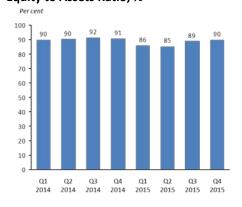
#### Cash flow, Investments and Financial Position

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 1,077.9 million (1,395.6 m) at the end of the period, compared to 1,395.6 million (402.2 m) at the beginning of 2015 and corresponding to a decrease of SEK 317.7 million. Royalty payments for the fourth quarter totalled SEK 31.6 million and are not included in liquid assets at the period end. 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 307.4 million (1,011.9 m), with changes in working capital accounting for SEK 199.8 million (-4.6 m) of this total. The positive cash flow derives, primarily, from incoming royalties during the first two quarters of the year.

Cash flow from investing activities totalled SEK -15.0 million (-15.2 m). Investments in research and facility equipment and IT systems totalled SEK -20.1 million (-20.2 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 Assets Ratio, %



Investments in tangible fixed assets during the period amounted to SEK 10.0 million (8.9 m) and comprised investments in research, facilities and IT equipment.

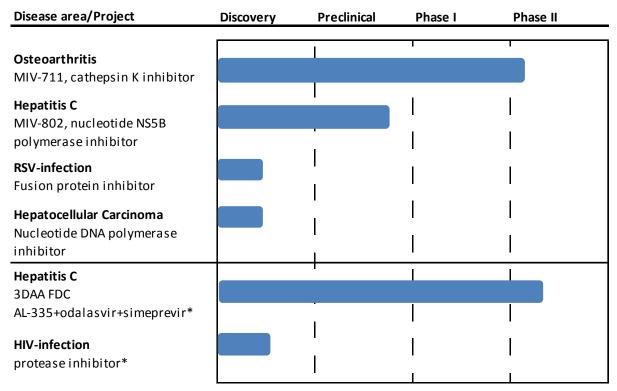
Depreciation of tangible fixed assets and intangible fixed assets totalling SEK -10.6 million (-10.1 m) and SEK -23.5 million (-23.1 m), respectively, were charged to the profit/loss for the period.

### 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 (Zoviduo®) was approved for the treatment of labial herpes. Meda holds 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®) 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.



<sup>\*</sup> Partner Janssen

For further information about our projects, please visit <a href="www.medivir.com">www.medivir.com</a>

#### **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 gave rise to substantial reductions in biomarkers of bone resorption and cartilage degradation that were sustained over the whole dosing period, compared with placebo.

#### Status/significant events:

The first approvals to start a phase IIa study of MIV-711 in patients with moderate knee osteoarthritis was obtained in Germany. The study is expected to enrol 240 patients from across Europe into three arms, each with approximately 80 patients, and compare MIV-711 dosed at 100 mg or 200 mg once daily against placebo. The key objectives are to assess the effect of six months of treatment with MIV-711 on knee joint clinical pain and on knee OA, assessed using magnetic resonance imaging, as well as the safety and tolerability of MIV-711. Patient recruitment was initiated early in the first quarter of 2016

#### **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 to enable phase I clinical studies has been completed successfully. Partnership discussions are currently in progress.

#### **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 for selectively delivering 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. Compounds are currently being profiled in disease-relevant models.

#### **PARTNERED PROJECTS**

#### 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 mid-October, Janssen started a phase IIa clinical trial to evaluate the combination of simeprevir, the NS5A inhibitor odalasvir and the nucleotide analogue AL-335.

#### 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:

The phase I study of AL-704, which was conducted by Alios Biopharma Inc., a part of the Janssen Pharmaceutical Companies, was completed. The study showed that AL-704 was safe, well tolerated and had acceptable pharmacokinetic properties, but the clinical antiviral effect in patients infected with genotype 1 hepatitis C was not sufficient to support continued clinical studies. The development of this compound has, therefore, been terminated.

#### **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 fourth quarter, Medivir filed a new patent family within its 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 25.6 million (79.3 m).

## Other disclosures (twelve month period)

#### **Employees**

Medivir had 127 (140) employees (FTEs) at the period end, 55% (60%) 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 3.1 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 500.8 million (1,646.4 m). Intra-Group sales amounted to SEK 37.5 million (59.5 m).

The gross profit amounted to SEK 443.0 million (1,517.9 m). Combined operating expenses totalled SEK -359.5 million (-336.8 m). The operating profit/loss was SEK 83.4 million (1,181.1 m), corresponding to a decrease of SEK 1,097.7 million. Net financial items totalled SEK -32.3 million (-48.9 m), corresponding to a decrease of SEK 16.6 million, and due to unrealised losses driven by market negative valuation of short-term interest-bearing investments.

The tax for the period totalled SEK -9.8 million (-8.8 m). The net profit/loss for the period was SEK 3.4 million (942.4 m), corresponding to a decrease of SEK 939.0 million, primarily due to decreases in royalty income.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 941.3 million (1,352.9 m).

Please see the section entitled "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 12.3 million (36.0 m) whereof royalty payments to Uppsala Hallbechem AB (Board Member, Anders Hallberg) totalled SEK 3.3 million (11.1 m) and those to Sybesam AB (Board Member, Bertil Samuelsson) totalled SEK 9.0 million (24.2 m). Other services were purchased from related parties for a total of SEK 0.0 million (0.7 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 authorisation. 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 sales, 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 risk, 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). The Annual Report is available at; www.medivir.com.

#### Significant events after end of Q4

In January 2016, Medivir initiated a phase IIa study of MIV-711 in knee osteoarthritis. The first patients were enrolled into a randomized double-blind phase IIa clinical study of the in-house developed cathepsin K inhibitor MIV-711 in patients with moderate knee osteoarthritis (OA). The phase IIa study will enrol 240 patients into 3 arms, each with approximately 80 patients, and compare MIV-711 dosed at 100 mg or 200 mg once daily against a placebo. The key objectives are to assess the effect of six months of treatment with MIV-711 on knee joint clinical pain and on knee OA, assessed using magnetic resonance imaging, as well as the safety and tolerability of MIV-711. Data from the study is on schedule and expected to be available in the third quarter of 2017.

#### **Annual Report**

Medivir's Annual Report is scheduled to be available on the company's website, www.medivir.se, as of beginning of April 2016. Printed copies of the Annual Report will be distributed to those shareholders who have requested it.

#### **Dividend**

The Board of Directors proposes that no dividend be paid for the 2015 financial year.

#### **Annual General Meeting**

The Annual General Meeting will be held at 14.00 (CEST) on 3 May 2016 at the Conference Centre 7A Centralen, at Vasagatan 7, Stockholm. Shareholders wishing to contact the Nomination Committee may do so by letter addressed to: The Nomination Committee, Medivir AB, Blasieholmsgatan 2, SE-111 48 Stockholm, or by email to: valberedning@medivir.se.

#### Outlook

Medivir is well positioned for the future, with a globally recognised technology platform and a proven R&D infrastructure, as well as the financial and organisational capability to invest in innovation for continued value creation.

Over time, the aim is to generate recurring revenues from milestones and royalties, but as we make these investments in a stronger R&D pipeline, we foresee a period when we will report losses.

### **Attestation**

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, 18 February 2016

**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 an 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 CET on 18 February 2016.

#### For further information, please contact

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

## Conference call for investors, analysts and the media

The 2015 Financial Statement will be presented by Medivir's President & CEO, Niklas Prager, and members of Medivir's management group.

Time: Thursday, 18 February 2016, at 14.00 (CET).

Phone numbers for participants from: Sweden +46 8 566 426 90 Europe +44 20 3008 9801 USA +1 855 753 2236 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.

#### Financial calendar:

Interim Report (January – March 2016) 28 April 2016

Annual General Meeting 2016

3 May 2016 at 2p.m., in Stockholm, Sweden

Interim Report (January – June 2016)

17 August 2016

Interim Report (January – September 2016)

10 November 2016

### Consolidated Income Statement, summary (SEK m)

	Q4		Q1	-Q4
	2015 2014		2015	2014
Continuing operations				
Net turnover	84.7	377.0	657.9	1 767.0
Cost of goods sold	-24.0	-52.5	-109.3	-174.0
Gross profit	60.7	324.5	548.6	1 593.0
Selling expenses	-19.1	-29.7	-98.4	-103.6
Administrative expenses	-15.7	-20.3	-60.3	-62.5
Research and development costs	-70.3	-76.3	-278.4	-245.8
Other operating income/expenses	0.1	8.4	3.2	7.6
Operating profit/loss	-44.5	206.5	114.8	1 188.7
Net financial items	-8.6	-2.2	-12.8	4.0
Profit/loss after financial items	-53.1	204.3	102.0	1 192.7
Tax	7.9	-57.0	-26.9	-60.0
Net profit/loss for the period	-45.2	147.3	75.1	1 132.7
Net profit/loss for the period attributable to:				
Parent Company shareholders	-45.2	147.3	75.1	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)				
- Continuing operations, basic earnings	-1.56	4.71	2.59	36.24
- Continuing operations, diluted earnings	-1.54	4.67	2.56	35.90
- Total operations, basic earnings	-1.56	4.71	2.59	36.24
- Total operations, diluted earnings	-1.54	4.67	2.56	35.90
Average number of shares, '000	29 048	31 260	29 048	31 260
Number of shares at period end, '000	26 836	31 260	26 836	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 2015 have had no significant effect on the Group's or Parent Company's financial position or results.

## Consolidated Statement of Comprehensive Income (SEK m)

	Q4		Q	1-Q4
	2015	2014	2015	2014
Net profit/loss for the period	-45.2	147.3	75.1	1 132.7
Other comprehensive income				
Items that may be reclassified in the Income Statement				
Exchange rate differences	1.7	-4.6	2.2	-5.4
Total other comprehensive income for the period, net after tax	1.7	-4.6	2.2	-5.4
Total comprehensive income for the period	-43.5	142.6	77.3	1 127.3
Total net profit/loss	-43.5	142.6	77.3	1 127.3

## Consolidated Balance Sheet, summary (SEK m)

	2015	2014
	31 Dec	31 Dec
Assets		
Intangible fixed assets	398.0	417.6
Tangible fixed assets	26.3	26.9
Financial fixed assets	0.0	2.5
Inventories	18.7	23.6
Current receivables	95.4	317.7
Short-term investments	860.4	1 309.6
Cash and bank balances	217.5	86.0
Total assets	1 616.3	2 183.9
Shareholders' equity and liabilities		
Shareholders' equity	1 450.1	1 982.6
Current liabilities	166.1	201.3
Total shareholders' equity and liabilities	1 616.3	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 2015	156.3	1 761.8	-4.0	68.5	1 982.6
Total comprehensive income for the period	-	-	2.2	75.1	77.3
Share incentive plan: value of employee service	-	2.9	-	-	2.9
Redemption program	-21.5	-579.7	-	-	-601.2
Stock dividend issue	22.3	-22.3	-	-	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, 31 December 2015	157.1	1 152.3	-1.7	142.5	1 450.1

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

	(	Q4		·Q4
	2015	2014	2015	2014
Cash flow from operating activities before changes in working capital	-76.1	494.1	107.6	1 016.5
Changes in working capital	38.5	13.8	199.8	-4.6
Cash flow from operating activities	-37.6	507.9	307.4	1 011.9
Investing activities				
Acquisition/sale of fixed assets	-4.0	-5.3	-20.1	-20.2
Sale of operations	0.0	0.0	5.0	5.0
Cash flow from investing activities	-3.9	-5.3	-15.0	-15.2
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	-41.5	502.6	-319.2	996.7
Liquid assets at beginning of period	1 118.1	896.4	1 395.6	402.2
Change in liquid assets	-41.5	502.6	-319.2	996.7
Exchange rate difference, liquid assets	1.4	-3.4	1.6	-3.3
Liquid assets at period end	1 077.9	1 395.6	1 077.9	1 395.6

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

	Q4		Q1-0	<b>Q</b> 4
	2015	2014	2015	2014
Net turnover	42.2	358.6	500.8	1 646.4
Cost of goods and services sold	-9.2	-35.9	-57.8	-128.5
Gross profit	32.9	322.7	443.0	1 517.9
Selling expenses	-11.9	-21.8	-57.8	-62.2
Administrative expenses	-12.0	-17.7	-53.7	-54.3
Research and development costs	-68.5	-61.5	-257.8	-227.7
Other operating income/expenses	9.6	8.5	9.8	7.4
Operating profit/loss	-49.9	230.2	83.4	1 181.1
Net financial items	-29.9	-54.4	-32.3	-48.9
Profit/loss after financial items	-79.8	175.8	51.2	1 132.2
Appropriations	-37.9	-181.0	-37.9	-181.0
Tax	19.3	-11.7	-9.8	-8.8
Net profit/loss for the period	-98.4	-16.9	3.4	942.4

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

	C	Q4		24
	2015	2014	2015	2014
Net profit/loss for the period	-98.4	-16.9	3.4	942.4
Other comprehensive income for the period, net after tax	0.0	0.0	0.0	0.0
Total comprehensive income for the period	-98.4	-16.9	3.4	942.4

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

	2015	2014
	31 Dec	31 Dec
Assets		
Intangible fixed assets	17.1	14.6
Tangible fixed assets	26.1	26.6
Financial fixed assets	628.5	611.5
Inventories	2.3	3.6
Current receivables	80.3	284.9
Short-term investments	860.4	1 309.6
Cash and bank balances	80.9	43.3
Total assets	1 695.6	2 294.0
Shareholders' equity and liabilities		
Shareholders' equity	1 322.2	1 928.6
Appropriations	37.9	0.0
Current liabilities	335.5	365.5
Total shareholders' equity and liabilities	1 695.6	2 294.0

#### Key ratios, share data, options

	Q1-Q4	Q1-Q4
	2015	2014
Return on:		
- shareholders' equity, %	5.9	84.1
-capital employed, %	5.3	82.0
-total capital, %	5.9	75.2
Number of shares at beginning of period, '000	31 260	31 260
Number of shares at period end, '000	26 966	31 260
-of which class A shares	606	660
-of which class B shares	26 230	30 600
-of which repurchased B shares	130	-
Average number of shares, '000	29 048	31 260
Outstanding warrants, '000	238	294
Share capital at period end, SEK m	157.2	156.3
Shareholders' equity at period end, SEK m	1 450.1	1 982.6
Earnings per share, SEK		
- Continuing operations, basic earnings	2.59	36.24
- Continuing operations, diluted earnings	2.56	35.90
- Discontinued operations, basic and diluted earnings	-	-
- Total operations, basic earnings	2.59	36.24
- Total operations, diluted earnings	2.56	35.90
Shareholders' equity per share, SEK	54.0	63.4
Net worth per share, SEK	54.0	63.4
Cash flow per share after investments, SEK	10.1	31.9
Equity/assets ratio, %	89.7	90.8
EBITDA	155.0	1 221.9
EBIT	114.8	1 188.7
Operating margin, %	17.4	67.3
R&D spending/total opex, %	64.2	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.