



## MEDIVIR AB – FINANCIAL STATEMENT JANUARY – DECEMBER 2016

### *Financial summary*

#### Significant events during the fourth quarter

- Medivir focuses research and development operations exclusively on oncology and reorganises in order to achieve significant cost savings. As a result of the operative transformation a non-recurring sum of SEK 49.1 million was charged to the profit/loss for the period and of SEK 52.6 million for the full year.
- Medivir divests its pharmaceutical company, BioPhausia (Nordic Brands), to Karo Pharma for SEK 908 million and reports a consolidated capital gain of SEK 534.8 million, thereby applying IFRS 5 (see p. 12).
- Medivir strengthens its clinical pipeline by entering into an agreement on the acquisition of a portfolio of clinical phase oncology programmes, which has increased its intangible fixed assets by SEK 89 million and current receivables by SEK 22 million.

#### October – December 2016

- Net turnover for the continuing operations totalled SEK 9.9 million (34.5 m), SEK 5.6 million (31.1 m) of which comprised royalties for simeprevir.
- Revenues from Medivir's continuing pharmaceutical sales totalled SEK 2.9 million (2.9 m), of which SEK 2.9 million (2.7 m) derived from sales of OLYSIO®.
- The profit after tax for the continuing operations was SEK -121.3 million (-56.9 m).
- Basic and diluted earnings per share totalled SEK -4.50 (-2.11) and SEK -4.50 (-2.11), respectively.
- The cash flow from operating activities amounted to SEK -69.6 million (-37.6 m).

#### January – December 2016

- Net turnover for the continuing operations totalled SEK 93.0 million (474.3 m), SEK 60.3 million (418.6 m) of which comprised full year royalties for simeprevir.
- Revenues from Medivir's continuing pharmaceutical sales totalled SEK 12.3 million (53.9 m), of which SEK 12.0 million (53.0 m) derived from sales of OLYSIO®.
- The profit after tax for the continuing operations was SEK -294.9 million (31.7 m).
- Basic and diluted earnings per share totalled SEK -10.94 (1.09) and SEK -10.94 (1.08), respectively.
- The cash flow from operating activities amounted to SEK -180.1 million (307.4 m).

#### Summary of the Group's figures (SEK m)

##### Continuing operations

	Q4		Q1-Q4	
	2016	2015	2016	2015
Net turnover	9.9	34.5	93.0	474.3
Gross profit	7.7	30.0	77.1	436.0
Operating profit before depreciation and amortisation (EBITDA)	-120.7	-51.9	-278.9	95.7
Operating profit (EBIT)	-128.9	-60.4	-312.4	55.4
Profit/loss before tax	-129.9	-67.8	-306.7	46.2
Profit/loss after tax	-121.3	-56.9	-294.9	31.7
Operating margin, %	-1,306.1	-175.3	-335.7	11.7
Basic earnings per share, SEK	-4.50	-2.12	-10.94	1.09
Diluted earnings per share, SEK	-4.50	-2.12	-10.94	1.08
Net worth per share, SEK	64.38	54.04	64.38	54.04
Return on equity	-30.5	-15.5	-18.5	1.8
Cash flow from operating activities	-69.6	-37.6	-180.1	307.4
Cash and cash equivalents at period end	1,698.5	1,077.9	1,698.5	1,077.9
R&D spending/total opex, %	65.9	77.8	78.8	73.1

## CEO's comments

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We took several significant steps in the restructuring of Medivir during the fourth quarter. In all essentials, we completed the transformation of the company that had been in progress throughout the year. A key part of this transformation was the focusing of the company's operations exclusively onto research and development in the field of oncology. This focus was given extra emphasis with the acquisition of two oncology projects in late development phases, both of which have considerable potential. The acquisition strengthens and balances our research portfolio and gives us a wider range of projects in different phases, shifting the company's primary focus from early stage research to clinical development.

As a further step in this process, we also divested BioPhausia with its drug portfolio Nordic Brands. After having considered and prepared a separate stock exchange listing of BioPhausia, we judged that a sale to Karo Pharma AB was the best alternative for our shareholders. An Extraordinary General Meeting in early February 2017 endorsed the Board's proposal that the net proceeds from the sale of SEK 870 million should be distributed to Medivir's shareholders in the form of a voluntary redemption programme.

We also reorganised the company's early stage research and administrative functions during the quarter. It is estimated that this will give annual savings totalling approximately SEK 110 million.

Furthermore, we continued to make progress in our research projects during the quarter, both in our internal portfolio and in partner projects. I would like to make particular mention of the fact that we selected two new candidate drugs from our own research portfolio that have now proceeded to preclinical development: MIV-323 for the treatment of RSV infections and MIV-818 for the treatment of liver cancer. In keeping with our new exclusive oncology focus, we will continue to pursue the development of MIV-818 in-house, while for that of MIV-323 we will be seeking a partner.

Along with MIV-802 for the treatment of hepatitis C, which we licensed out to Trek Therapeutics in the third quarter of 2016, these projects are clear indications of the improved productivity of our early stage research operations and ability to continue to produce new, well-differentiated candidate drugs in areas of great unmet medical needs on the basis of our own technology platform.

The osteoarthritis trial MIV-711 proceeded according to plan and is now fully enrolled. As before, we expect to report data from the study during the third quarter of 2017.

In November our partner, Janssen Research & Development, announced that they are building on earlier interesting results by initiating a phase IIb study with the combination of simeprevir, odalasvir and AL-335 for the treatment of hepatitis C.

Q4 royalties attributable to the hepatitis C drug OLYSIO® (simeprevir) amounted to SEK 5.6 million as a result of the decline in global net sales.

The extensive transformation we have now achieved gives me great hope for the future. Our strong, balanced research and development portfolio with a focus on oncology, based on our exciting technology platforms for protease inhibitors and nucleosides/nucleotides, has considerable potential to create long-term value for the shareholders and will generate a continuous news flow in 2017 and the years to come. It is therefore with a sense of pride and great confidence that I feel spring 2017 is the right time to hand over the baton to a new CEO, Christine Lind. I would like to take this opportunity to thank all our engaged shareholders, the Board of Medivir, all our employees and business partners for the stimulating and intense years at the helm of Medivir and I wish the company every success in the future. As a shareholder, I will be following the progress with great interest!

**Niklas Prager**

*President and CEO*

### Medivir in brief

Medivir is a research based pharmaceutical company with a research focus on 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. Medivir's class "B" share 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, October – December 2016*

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A reorganisation of the company's operations was announced in October, with significant savings in early stage research and administrative functions. It was decided that the company will henceforth focus exclusively on oncology, basing operations on its technology platforms and expertise in protease inhibitors and nucleotide/nucleoside science. The reorganisation is estimated to generate annual savings of approximately SEK 110 million compared with current cost levels in the affected functions. Consequently, some 40 employees will have to leave the company. As a result of the organisational changes, a redundancy cost totalling SEK 19.1 million will be charged to the profit/loss for the fourth quarter.

In November, Medivir entered into an agreement with Karo Pharma AB regarding the divestment of Medivir's subsidiary, BioPhausia AB (Nordic Brands). The purchase price totalled SEK 908 million on a cash and debt-free basis, including a normalised working capital. A non-recurring cost totalling SEK 33.5 million for the quarter incurred by the split-up process and the operative transformation that the transaction entailed was charged to the profit/loss for the fourth quarter.

The transaction was concluded in December, after which Medivir's Board of Directors called an Extraordinary General Meeting and proposed that it decide on a transfer of the net proceeds from the divestment of BioPhausia (approx. SEK 870 million, corresponding to approx. SEK 32/share) to the shareholders through a voluntary redemption offer.

In November, Medivir also announced that it had entered into an agreement to acquire two clinical stage oncology programmes from Tetralogic Pharmaceuticals Corporation, advancing and expanding Medivir's clinical pipeline. The acquisition includes remetinostat, a topical, skin-directed inhibitor of histone deacetylases (HDACs); birinapant, a bivalent, second mitochondrial activator of caspases (SMAC) mimetic; and all intellectual property and data associated with Tetralogic's HDAC inhibitor and SMAC mimetic projects.

## Financial overview, October – December 2016

### Revenues

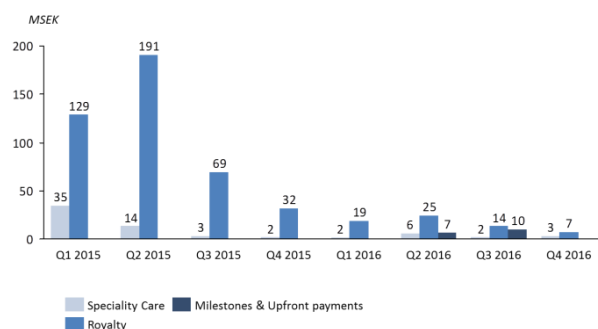
Net turnover for the continuing operations totalled SEK 9.9 million (34.5 m), for the fourth quarter, corresponding to a decrease of SEK 24.6 million. The revenues from Medivir's continuing pharmaceutical sales in the Nordic region totalled SEK 2.9 million (2.9 m).

The total value of Janssen's global sales of simeprevir totalled USD 6 million (44 m), which generated royalties for the fourth quarter of SEK 5.6 million (31.1 m). Royalties from GlaxoSmithKline's sales of Xerclear (Zovido) during the period totalled SEK 1.5 million (0.5 m).

### Breakdown of net turnover (SEK m)

	Q4		Q1-Q4	
	2016	2015	2016	2015
Upfront- and milestone payments	-0.1	-	16.7	-
Pharmaceutical sales	2.9	2.9	12.3	53.9
Royalties	7.1	31.6	64.0	420.4
<b>Total</b>	<b>9.9</b>	<b>34.5</b>	<b>93.0</b>	<b>474.3</b>

### Net turnover (SEK m), Q1 – Q4 2016



## Results

### Gross profit

The cost of goods sold was SEK -2.2 million (-4.5 m), corresponding to a decrease of SEK 2.3 million. The gross profit amounted to SEK 7.7 million (30.0 m), equating to a gross margin of 77.8% (86.9%) and a decrease of SEK 22.3 million, which is explained by the reduction in royalties attributable to simeprevir (OLYSIO®).

### Operating expenses

A cost of SEK 49.1 million relating to the transformation of the company, and thereby its reorganisation into a research and development company, has been charged to the operating expenses for the period. Consequently, the administrative expenses for the period totalled SEK 44.0 million (14.1 m).

Research and development costs totalled SEK 89.9 million (70.3 m), an increase according to plan of SEK 19.6 million as a result of the ongoing phase IIa study MIV-711, phase II completion costs for remetinostat and preparatory preclinical costs for MIV-818. Other operating income/expenses increased by SEK 2.3 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -136.5 million (-90.4 m), an increase of SEK 46.1 million, of which SEK 49.1 million comprised non-recurring costs.

The operating profit/loss totalled SEK -128.9 million (-60.4 m), corresponding to a decrease of SEK 68.5 million.

Net financial items totalled SEK -1.0 million (-7.4 m), an improvement of SEK 6.4 million, and due to a year-on-year reduction in unrealised losses driven by negative market valuation of short-term interest-bearing investments.

### Taxes

Tax income for the period totalled SEK 8.6 million (10.9 m).

The Group's tax is calculated using the official rate of 22%, which is also expected to be the effective rate. Deficits in the parent company, Medivir AB, are not capitalised and no deferred tax has, therefore, been credited to the result.

## Financial overview, January – December 2016

### Revenues

Net turnover for the continuing operations for the period from January–December totalled SEK 93.0 million (474.3 m), corresponding to a decrease of SEK 381.3 million. Continuing pharmaceutical sales reported revenues of SEK 12.3 million (53.9 m) as a result of the decrease in sales of OLYSIO®.

The value of Janssen's global sales of simeprevir during the period totalled USD 106 million (621 m), which has generated royalties of SEK 60.3 million (418.6m).

Royalties based on GlaxoSmithKline's global sales of Xerclear (Zoviduo) during the year totalled SEK 3.7 million (1.8 m).

A milestone payment of SEK 6.5 million (0) was received during the period from GlaxoSmithKline and the out-licensing of MIV-802 generated additional non-recurring income of SEK 10.2 million (0).

### Results

#### Gross profit

The cost of goods sold was SEK -15.9 million (-38.3 m), corresponding to a decrease of SEK 22.4 million. The gross profit amounted to SEK 77.1 million (436.0 m), corresponding to a decrease of SEK 358.9 million and equating to a gross margin of 82.9% (91.9%).

#### Operating expenses

A cost of SEK 52.6 million relating to the transformation of the company, and thereby its reorganisation into a research and development company, has been charged to the operating expenses for the period. Consequently, the administrative expenses for the period totalled SEK -70.7 million (-57.3 m). Research and development costs totalled SEK -307.1 million (-278.4 m), an increase according to plan of SEK 28.7 million as a result of the advancement of the company's research portfolio and the year-on-year rise in the number of projects/studies being run in later phases. Other operating income/expenses decreased by SEK 2.0 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -389.5 million (-380.6 m), which corresponds to an increase of SEK 8.9 million, of which SEK 52.6 million were non-recurring costs.

The operating profit/loss totalled SEK -312.4 million (55.4 m), corresponding to a decrease of SEK 367.8 million.

The profit from divested shares in subsidiaries totalled SEK 534.8 million (0.0 m) and net financial items totalled SEK 5.7 million (-9.2 m), corresponding to a year-on-year increase of SEK 14.9 million, and due to unrealised profits attributable to market valuations of short-term interest-bearing investments.

The loss from continuing operations for the period totalled SEK -294.9 million (31.7 m) and the profit from discontinued operations totalled SEK 577.7 million (43.4 m).

### Taxes

Tax income totalled SEK 11.9 million (-14.5 m) for the period. The Group's tax is calculated using the official rate of 22%. Deficits in the parent company, Medivir AB, are not capitalised and no deferred tax has, therefore, been credited to the result.

### Cash flow, investments, and financial position

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 1,698.5 million (1,077.9 m) at the end of the period, corresponding to an increase of SEK 620.6 million. The corresponding figure at the beginning of 2016 was SEK 1,077.9 million (1,395.6 m). Liquid assets at the period end exclude the Q4 royalties of SEK 7.1 million. Pledged assets at the end of the period totalled SEK 90.0 million (54.3 m). Medivir's financial assets are, in accordance with its financial policy, invested in low-risk, interest-bearing securities.

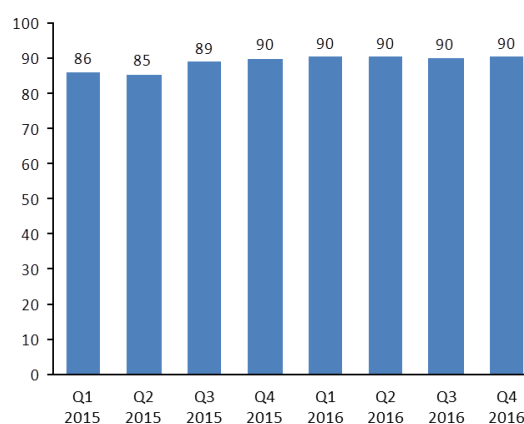
Cash flow from operating activities totalled SEK -180.1 million (307.4 m), with changes in working capital accounting for SEK 13.7 million (199.8 m) of this total.

Cash flow from investing activities totalled SEK 801.0 million (-15.0 m), comprising SEK 908.3 million attributable to the divestment of the subsidiary BioPhausia AB and SEK -107.4 million attributable to the acquisition of research assets from Tetralogic Inc.

Cash flow from financing activities totalled SEK 0.0 million (-611.6 m).

### Equities/Assets ratio, %

Per cent



Investments in tangible fixed assets during the period amounted to SEK -10.1 million (-10.0 m) and comprised investments in research, facilities, and IT systems.

Depreciation, amortisation and write-down of tangible fixed assets and intangible fixed assets totalling SEK -10.9 million (-10.5 m) and SEK -0.9 million (-7.5 m), respectively, was 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 company's research and development focus throughout 2016 was on oncology and infectious diseases, and on the ongoing clinical project in the area of osteoarthritis. However the company is currently seeking partners for its remaining infectious projects and will be exclusively focusing on oncology once the Phase IIa programme for MIV-711 has been completed.

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. The marketing rights to Xerclear in the USA, Canada and Mexico were divested in 2010, while the corresponding rights in Europe and the rest of the world have been out-licensed to GlaxoSmithKline, with

the exception of China, Israel and South America where Medivir has retained the rights.

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 many other countries around the world. Simeprevir is approved as part of an antiviral combination treatment regimen for chronic genotype 1 and 4 hepatitis C infection in adult patients without cirrhosis or with compensated liver disease (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.

### Proprietary Pipeline

Project, Mechanism	Disease area	Discovery	Preclinical	Phase I	Phase II	Phase III	Market
<b>Remetinostat</b> Topical HDAC inhibitor	Cutaneous T-cell lymphoma						
<b>MIV-711</b> Cathepsin K inhibitor	Osteoarthritis						
<b>Birinapant</b> SMAC mimetic	Solid tumors (combo with Keytruda™)						
	High-grade serous carcinomas						
<b>MIV-818</b> , Nucleotide DNA polymerase inhibitor	Hepatocellular carcinoma						
<b>MIV-323</b> Fusion protein inhibitor	RSV-infection						

### Partnership Pipeline

Project	Disease area	Partner	Discovery	Preclinical	Phase I	Phase II	Phase III	Market
<b>Olysis (simeprevir)</b>	Hepatitis C	Janssen						
<b>JNJ-4178</b> AL-335+odalasvir+simeprevir	Hepatitis C	Janssen						
<b>Xerclear</b>	Labial herpes	GSK and Meda						
<b>MIV-802</b> , nucleotide NS5B polymerase inhibitor	Hepatitis C	Trek Therapeutics						

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

## PROPRIETARY PROJECTS

### Remetinostat

Cutaneous T-cell lymphoma (CTCL) is a chronic and rare form of cancer. Remetinostat is expected to be an important additional treatment option for patients who suffer from this cancer, and the dermatologists who treat them. Remetinostat is a new histone deacetylase (HDAC) inhibitor that is in clinical development for the topical treatment of CTCL. The substance has been designed to be stable in skin and to degrade rapidly in blood in order to avoid the adverse effects associated with the systemically administered HDAC inhibitors. An open-label phase II study of remetinostat in early-stage CTCL patients was initiated in late 2014.

#### Status/significant events:

Medivir completed the acquisition of the remetinostat project in December. The last patient completed the last study visit in the phase II study during Q4 2016, and data from this trial are now being analysed.

### 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. A phase IIa study (MIV-711-201) of MIV-711 in patients with moderate knee osteoarthritis was initiated in January 2016. In September 2016, the first patient was enrolled into an open label phase IIa extension study, MIV-711-202, in which patients from MIV-711-201 who had a favourable response to MIV-711 treatment, or whose disease has worsened following placebo treatment, will be treated with 200 mg MIV-711 once daily for six months.

#### Status/significant events:

The independent MIV-711-201 Data Monitoring Committee held its second and third meetings in October and December, at which time unblinded safety data from the first 100 and 150 patients who had completed three months of treatment were reviewed. The Committee's recommendation in both cases was that MIV-711-201 should proceed according to plan. Enrolment in MIV-711-201 was completed in October, and the study is on track to deliver data in Q3 2017.

### Birinapant

Birinapant is a bivalent peptidomimetic of the SMAC protein (Secondary Mitochondrial Activator of Caspase) and is therefore known as a SMAC mimetic compound. To date birinapant has been dosed in approximately 450 patients across 9 studies. The majority of studies was in oncology (one in HBV) and primarily recruited patients with refractory solid tumours and haematological malignancies (dominated by ovarian, colorectal, acute myeloid leukemia and Myelodysplastic syndromes (MDS)). Overall birinapant has shown acceptable safety and tolerability for further development in oncology indications. The current plans are to study birinapant clinically in combination with Keytruda™ for the treatment of solid tumours and in an Investigator-Initiated study at UCLA for high-grade serous carcinoma (HGSC) in combination with platinum-based chemotherapy.

#### Status/significant events:

Medivir completed the acquisition of the birinapant project in December.

### MIV-818

Liver cancer is the second highest cause of cancer-related death worldwide. Of the different forms of liver cancer, hepatocellular carcinoma (HCC) is the most prevalent. Medivir is developing drugs to deliver cancer therapeutics to the liver to treat this devastating disease. 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 long-standing interests in discovering improved treatments for chronic hepatitis B virus and hepatitis C virus infection. These approaches are now being applied to the development of an orally administered drug that is liver specific for the treatment of hepatocellular carcinoma and other liver cancers.

#### Status/significant events:

MIV-818 is a potent and selective inhibitor of the proliferation of liver cancer cell lines that has been designed to deliver high levels of the active drug selectively to the liver. It was selected as a candidate drug (CD) for the treatment of hepatocellular carcinoma (HCC) and other liver cancers in November, and has entered non-clinical development. MIV-818 has the potential to become the first liver-targeted orally administered drug to address HCC and other liver cancers.

### **MIV-323**

Human respiratory syncytial virus (RSV) is a major viral cause of respiratory tract infection in infants, the elderly and the severely immunocompromised. Almost all children will have been infected with RSV by the time of their second birthday. It has been estimated that RSV resulted in around 33.8 million lower respiratory tract infections in children younger than 5 years in 2005, with 3.4 million requiring hospitalization and between 66,000 and 199,000 child deaths. 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:**

In December MIV-323 was been selected as a candidate drug (CD) from the RSV fusion inhibitor project, and entered non-clinical development. As a result of its new R&D strategy, Medivir is currently seeking a partner for the MIV-323 project.

### **PARTNERED PROJECTS**

#### **JNJ-4178**

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. Interim data from an ongoing phase IIa study of simeprevir, odalasvir and AL-335 were presented at the European Association for the Study of the Liver (EASL) Special Conference in September 2016. All 60 treatment-naïve patients with hepatitis C virus (HCV) genotype (GT) 1 infection who were treated with the triple combination for six or eight weeks achieved sustained viral response 12 weeks after the completion of treatment (SVR12). Based on the interim safety and efficacy data from this study, the triple combination of simeprevir (75 mg, QD), odalasvir (25 mg, QD) and AL-335 (800 mg, QD), now referred to as JNJ-4178, was selected for further development.

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

A phase IIb open-label study of the combination of simeprevir, odalasvir and AL-335 (JNJ-4178) was initiated by Janssen Research & Development, LLC., part of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), in November. This study will assess the triple combination in treatment-naïve and treatment-experienced subjects with chronic hepatitis C virus infection without cirrhosis. This global, multi-center study includes clinical trial sites in North America, Europe and Asia and forms part of Janssen's global development programme for JNJ-4178. The

objectives of the phase IIb study are to investigate the efficacy, safety and pharmacokinetics of JNJ-4178 in treatment-naïve and treatment-experienced non-cirrhotic subjects with chronic hepatitis C virus genotype 1, 2, 4, 5, and 6 infection. Patients in the study will receive the triple combination for either six or eight weeks, and the primary efficacy endpoint will be the percentage of patients with a sustained virological response 12 weeks after the end of treatment (SVR12). The ongoing phase IIa study is assessing the same triple combination in patients with or without compensated cirrhosis.

#### **MIV-802**

MIV-802 is a potent, pan-genotypic nucleotide-based inhibitor of the HCV NS5B polymerase, which is currently in 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. In August 2016, Medivir entered into a licensing agreement with Trek Therapeutics for the exclusive rights to develop and commercialise MIV-802 globally, excluding China, Taiwan, Hong Kong and Macau.

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

MIV-802 is in preclinical development by Trek Therapeutics.

#### **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 200 national patents awarded.

#### **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 and milestone costs for the period

were SEK 5.2 million (25.6 m) and SEK 3.3 million (0.0 m), respectively.

## **Other disclosures, January – December 2016**

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### **Employees**

Medivir had 117 (127) employees (FTEs) at the period end, 54% (55%) of whom were women. 21 (7) of these employees have been given notice of termination of employment, but who's employment has not yet been terminated.

### **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 one active share-related incentive plan, LTI 2014. The LTI 2013 plan was finalised during the second quarter 2016 and approximately 80,500 of the shares from the buyback programme were distributed to the participants. The net effect of the active plan, based on certain assumptions such as share price performance, participation and staff turnover, including social security contributions and the dissolution of LTI 2013, increased the profit/loss for the period by SEK 1.2 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 131.0 million (500.8 m). Intra-Group sales amounted to SEK 38.0 million (37.5 m).

The gross profit amounted to SEK 115.0 million (443.0 m). Combined operating expenses totalled SEK -426.3 million (-359.6 m). The operating profit/loss was SEK -311.3 million (83.4 m), corresponding to a decrease of SEK 394.7 million. The profit from shares in subsidiaries totalled SEK 675.5 million (-23.5 m) and comprises a profit of SEK 305 million from the divestment of the subsidiary BioPhausia AB (Nordic Brands) and dividends of SEK 370.5 million from subsidiaries. Net financial items totalled SEK 4.0 million (-8.8 m), corresponding to an increase of SEK 12.8 million, and due to unrealised gains driven by positive market valuation of short-term interest-bearing investments.

The tax for the period totalled SEK 0.2 million (-9.8 m). The profit/loss for the period was SEK 406.3 million (3.4 m), corresponding to an increase of SEK 402.9 million.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 1,692.5 million (941.3 m), of which 90.0 (0) is pledged until 15 December 2017.

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 1.5 million (12.3 m), of which royalty payments to Uppsala Hallbechem AB (Board Member, Anders R Hallberg) of SEK 0.5 million (3.3 m), and to Sybesam AB (Board Member, Bertil Samuelsson) of SEK 1.0 million (9.0 m). Bertil Samuelsson is no longer a Member of the Board and is, therefore, only classified as a related party for the period from January to June 2016. No other services were purchased by the company from related parties during the period.

### **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, and patent protection.

**Operating risks** – such as integration 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 2015 Annual Report, see pages 27 and 62 (Note 8). The Annual Report is available at: [www.medivir.com](http://www.medivir.com).

### Significant events after end of Q4

The shareholders of Medivir AB were called to an Extraordinary General Meeting on Thursday 2 February 2017 at 14.00 in Stockholm. The Meeting decided on a reduction of the share capital for repayment to the shareholders and on a bonus issue without issuance of new shares.

The independent MIV-711-201 randomised double blind phase IIa study Data Monitoring Committee held its fourth scheduled meeting in February, at which time unblinded safety data were reviewed. The Committee recommended that the study should proceed. The Committee thus completed its four planned meetings during the study.

In February, it was announced that Christine Lind has been appointed as the new CEO of Medivir AB. She succeeds Niklas Prager, who accepted the role as CEO in 2014 from a position as a Director of the Board when the company faced the need of a corporate transformation. Christine Lind will take up her new position on 1 April 2017, until which time she will continue in her existing role as EVP Strategic Business Development. Niklas Prager will continue as CEO until 1 April and will also make himself available to Christine until the Annual General Meeting on 3 May, in order to ensure an optimal and smooth transition.

### Annual Report

Medivir's Annual Report is scheduled to be available on the company's website, [www.medivir.se](http://www.medivir.se), as of beginning of the week commencing 3 April 2017. Printed copies of the Annual Report will be distributed to those shareholders who request it.

### Dividend

The Board of Directors proposes that no dividend be paid for the 2016 financial year. For details of the redemption programme that was resolved on at an Extraordinary General Meeting on 2 February 2017, see the company's website: [www.medivir.com](http://www.medivir.com).

### Capital Markets Day

A Capital Markets Day is scheduled for 23 February at the IVA conference centre, Grev Turegatan 16, Stockholm. CEO Niklas Prager and CEO Designate Christine Lind and members of Medivir's Management team will present the company's operations, and give an update on the project portfolio.

### Annual General Meeting

The Annual General Meeting will be held at 14.00 (CEST) on 3 May 2017 at the IVA conference centre at Grev Turegatan 16, 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](mailto:valberedning@medivir.se).

### Outlook

Medivir's future investments will be in oncology – an area in which the company can build on its cutting-edge competences in the design of protease inhibitors and nucleotide/nucleoside science. Ongoing projects outside this therapeutic area will be prepared for out-licensing. Medivir has a strong capital base and several projects in its core area of oncology in both the early and late development phases, and this is expected to generate long-term shareholder value.

## 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, 17 February 2017**

**Thomas Axelsson**  
*Member of the Board*

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

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

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

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

**Stina Lundgren**  
*Member of the Board,  
Employee Representative*

**Anna Malm Bernsten**  
*Chairman of the Board*

**Niklas Prager**  
*President and CEO*

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

*The information in this report comprises the information that Medivir AB is obliged to disclose under the provisions of the EU's Market Abuse Directive.*

*The information was submitted for publication, through the agency of the contact persons set out above, at 08.30 (CET) on 17 February 2017.*

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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 financial statement for January – December 2016 will be presented by Medivir's President & CEO, Niklas Prager.

Time: Friday, 17 February 2017, at 14.00 (CET).

Phone numbers for participants from:  
Sweden 08- 566 426 91  
Europe +44 20 3008 9804  
USA +1 855 753 2235

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

#### Financial calendar:

**Interim Report (January – March 2017)**  
28 April 2017

**Annual General Meeting 2017**  
3 May 2017

**Interim Report (January – June 2017)**  
25 July 2017

**Interim Report (January – September 2017)**  
26 October 2017

## Consolidated Income Statement, summary (SEK m)

	Q4		Q1-Q4	
	2016	2015	2016	2015
<b>Continuing operations</b>				
Net turnover	9.9	34.5	93.0	474.3
Cost of goods sold	-2.2	-4.5	-15.9	-38.3
<b>Gross profit</b>	<b>7.7</b>	<b>30.0</b>	<b>77.1</b>	<b>436.0</b>
Selling expenses	-1.0	-6.0	-13.0	-48.2
Administrative expenses	-44.0	-14.1	-70.7	-57.3
Research and development costs	-89.9	-70.3	-307.1	-278.4
Other operating income/expenses	-1.7	0.0	1.3	3.3
<b>Operating profit/loss</b>	<b>-128.9</b>	<b>-60.4</b>	<b>-312.4</b>	<b>55.4</b>
Net financial items	-1.0	-7.4	5.7	-9.2
<b>Profit/loss after financial items</b>	<b>-129.9</b>	<b>-67.8</b>	<b>-306.7</b>	<b>46.2</b>
Tax	8.6	10.9	11.9	-14.5
<b>Net profit/loss for the period from continuing operations</b>	<b>-121.3</b>	<b>-56.9</b>	<b>-294.9</b>	<b>31.7</b>
Net profit/loss for the period from discontinued operations	534.7	11.7	577.7	43.4
<b>Net profit/loss for the period</b>	<b>413.4</b>	<b>-45.2</b>	<b>282.9</b>	<b>75.1</b>
<b>Net profit/loss for the period attributable to:</b>				
Parent Company shareholders	413.4	-45.2	282.9	75.1
<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	-4.50	-2.12	-10.94	1.09
- Continuing operations, diluted earnings	-4.50	-2.12	-10.94	1.08
- Discontinued operations, basic earnings	19.85	0.44	21.44	1.49
- Discontinued operations, diluted earnings				
- Total operations, basic earnings	15.35	-1.68	10.50	2.59
- Total operations, diluted earnings	15.31	-1.68	10.47	2.56
Average number of shares, '000	26,941	26,901	26,941	29,048
Average number of shares after dilution '000	27,004	27,139	27,004	29,286
Number of shares at period end, '000	26,917	26,836	26,917	26,836

## 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 50-57 of the 2015 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. In the fourth quarter, Medivir divested the subsidiary BioPhausia AB. BioPhausia made a significant contribution to the Consolidated Income Statement and Balance Sheet. For this reason, we have adjudged IFRS 5 to be applicable; the divested operations are, therefore, kept distinct

from the continuing operations and the profit/loss is stated as a separate item in the Income Statement.

### Additions made from Q2 2016 (incl.) with regard to APMs

Medivir has, as of Q2 2016, applied ESMA's new guidelines for APMs (Alternative Performance Measures). In brief, an APM is a financial measure of historical or future financial performance, financial position or cash flows, other than a financial measure defined or specified in IFRS. The APMs that Medivir uses are EBIT and EBITDA, which are reported in the tables entitled "Summary of the Group's figures" and "Key ratios, share data" and are defined in conjunction with the table presenting key ratios.

## Consolidated Statement of Comprehensive (SEK m)

	Q4		Q1-Q4	
	2016	2015	2016	2015
<b>Net profit/loss for the period</b>	<b>413.4</b>	<b>-45.2</b>	<b>282.9</b>	<b>75.1</b>
<b>Other comprehensive income</b>				
<i>Items that may be reclassified in the Income Statement</i>				
Exchange rate differences	0.0	1.7	-1.2	2.2
<b>Total items that may be reclassified subsequently to profit or loss</b>	<b>0.0</b>	<b>1.7</b>	<b>-1.2</b>	<b>2.2</b>
<b>Total comprehensive income for the period</b>	<b>413.4</b>	<b>-43.5</b>	<b>281.6</b>	<b>77.3</b>
Total comprehensive income attributable to:				
Continuing operations	-121.3	-55.3	-296.1	33.9
Discontinued operations	534.7	11.7	577.7	43.4
<b>Total net profit/loss</b>	<b>413.4</b>	<b>-43.5</b>	<b>281.6</b>	<b>77.3</b>

## Consolidated Balance Sheet, summary (SEK m)

	31-dec	31-dec
	2016	2015
<b>Assets</b>		
Intangible fixed assets	111.9	398.0
Tangible fixed assets	22.0	26.3
Financial fixed assets	1.0	0.0
Inventories	0.4	18.7
Current receivables	87.8	95.4
Short-term investments	1,504.6	860.4
Cash and cash equivalents	193.8	217.5
<b>Total assets</b>	<b>1,922.5</b>	<b>1,616.3</b>
<b>Shareholders' equity and liabilities</b>		
Shareholders' equity	1,732.9	1,450.1
Deferred tax liabilities	-	30.8
Provisions	30.3	-
Current liabilities	158.3	135.4
<b>Total shareholders' equity and liabilities</b>	<b>1,921.5</b>	<b>1,616.3</b>

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

	Share capital	Other paid-in capital	Exchange rate difference	Accum. Profit /loss	Total equity
<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	-	-	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	-	-	-
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, 31 December 2015</b>	<b>157.2</b>	<b>1,152.3</b>	<b>-1.8</b>	<b>142.5</b>	<b>1,450.2</b>
<b>Opening balance, 1 January 2016</b>	<b>157.2</b>	<b>1,152.3</b>	<b>-1.8</b>	<b>142.5</b>	<b>1,450.2</b>
Total comprehensive income for the period	-	-	-1.2	282.9	281.6
Share incentive plan: value of employee service	-	1.2	-	-	1.2
<b>Closing balance, 30 September 2016</b>	<b>157.2</b>	<b>1,153.5</b>	<b>-3.1</b>	<b>425.3</b>	<b>1,732.9</b>

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

	Q4		Q1-Q4	
	2016	2015	2016	2015
<b>Cash flow from operating activities before changes in working capital</b>	<b>-90.5</b>	<b>-76.1</b>	<b>-193.8</b>	<b>107.6</b>
Changes in working capital	20.9	38.5	13.7	199.8
<b>Cash flow from operating activities</b>	<b>-69.6</b>	<b>-37.6</b>	<b>-180.1</b>	<b>307.4</b>
<b>Investing activities</b>				
Acquisition/sale of fixed assets	-95.5	-3.9	-107.4	-15.0
Sale of operations	908.3	-	908.3	-
<b>Cash flow from investing activities</b>	<b>812.8</b>	<b>-3.9</b>	<b>801.0</b>	<b>-15.0</b>
<b>Financing activities</b>				
Redemption program	-	-	-	-601.2
Repurchase of own shares	-	-	-	-10.4
<b>Cash flow from financing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-611.6</b>
<b>Cash flow for the period</b>	<b>743.2</b>	<b>-41.5</b>	<b>620.9</b>	<b>-319.2</b>
Cash and cash equivalents at beginning of period	955.0	1,118.1	1,077.9	1,395.6
Exchange rate difference, liquid assets	0.3	1.4	-0.4	1.6
<b>Cash and cash equivalents at end of period</b>	<b>1,698.5</b>	<b>1,077.9</b>	<b>1,698.5</b>	<b>1,077.9</b>
<b>Cash flow attributable to discontinued operations</b>				
Cash flow from operating activities	-31.8	13.9	36.4	70.7
Cash flow from investing activities	908.3	-	908.3	-
Cash flow from financial activities	-	-	-	-
<b>Cash flow for the period</b>	<b>876.6</b>	<b>13.9</b>	<b>944.7</b>	<b>70.7</b>

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

	Q4		Q1-Q4	
	2016	2015	2016	2015
Net turnover	28.0	42.2	131.0	500.8
Cost of goods and services sold	-2.4	-9.2	-16.0	-57.8
<b>Gross profit</b>	<b>25.6</b>	<b>32.9</b>	<b>115.0</b>	<b>443.0</b>
Selling expenses	-1.8	-11.9	-14.4	-57.8
Administrative expenses	-74.5	-12.0	-157.2	-53.7
Research and development costs	-76.3	-68.5	-256.1	-257.8
Other operating income/expenses	-2.1	9.6	1.5	9.8
<b>Operating profit/loss</b>	<b>-129.1</b>	<b>-49.9</b>	<b>-311.3</b>	<b>83.4</b>
Profit/loss from participation in Group companies	675.5	-23.5	675.5	-23.5
Net financial items	-2.4	-6.4	4.0	-8.8
<b>Profit/loss after financial items</b>	<b>544.0</b>	<b>-79.8</b>	<b>368.2</b>	<b>51.2</b>
Appropriations	37.9	-37.9	37.9	-37.9
Tax	0.2	19.3	0.2	-9.8
<b>Net profit/loss for the period</b>	<b>582.2</b>	<b>-98.4</b>	<b>406.3</b>	<b>3.4</b>

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

	Q4		Q1-Q4	
	2016	2015	2016	2015
Net profit/loss for the period	582.2	-98.4	406.3	3.4
Other comprehensive income for the period, net after tax	-	-	-	-
<b>Total comprehensive income for the period</b>	<b>582.2</b>	<b>-98.4</b>	<b>406.3</b>	<b>3.4</b>

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

	31-dec	31-dec
	2016	2015
<b>Assets</b>		
Intangible fixed assets	111.9	17.1
Tangible fixed assets	22.0	26.1
Shares in subsidiaries	0.1	604.2
Financial fixed assets	22.2	24.3
Inventories	0.4	2.3
Current receivables	85.6	80.3
Short-term investments	1,504.6	860.4
Cash and bank balances	187.9	80.9
<b>Total assets</b>	<b>1,934.7</b>	<b>1,695.6</b>
<b>Shareholders' equity and liabilities</b>		
Shareholders' equity	1,729.7	1,322.2
Appropriations	-	37.9
Deferred tax liabilities	-	0.4
Other provisions	30.3	-
Liabilities to Group companies	21.0	214.9
Current liabilities	153.6	120.3
<b>Total shareholders' equity and liabilities</b>	<b>1,934.7</b>	<b>1,695.6</b>

## Key ratios, share data, options

	Q4		Q1-Q4	
	2016	2015	2016	2015
Return on:				
- shareholders' equity, %	-30.5	-15.5	-18.5	1.8
- capital employed, %	-34.0	-18.3	-19.3	2.7
- total capital, %	-30.7	-16.4	-17.3	2.5
Number of shares at beginning of period, '000	26,966	26,966	26,966	31,260
Number of shares at period end, '000	26,966	26,966	26,966	26,966
- of which class A shares	606	606	606	606
- of which class B shares	26,310	26,230	26,310	26,230
- of which repurchased B shares	49	130	49	130
Average number of shares, '000	26,941	26,901	26,941	29,048
Outstanding warrants, '000	63	238	63	238
Share capital at period end, SEK m	157.2	157.2	157.2	157.2
Shareholders' equity at period end, SEK m	1,732.9	1,450.1	1,732.9	1,450.1
Earnings per share, SEK				
- Continuing operations, basic earnings	-4.50	-2.12	-10.94	1.09
- Continuing operations, diluted earnings	-4.50	-2.12	-10.94	1.08
- Discontinued operations, basic earnings	19.85	0.44	21.44	1.49
- Discontinued operations, diluted earnings				
- Total operations, basic earnings	15.35	-1.68	10.50	2.59
- Total operations, diluted earnings	15.31	-1.68	10.47	2.56
Shareholders' equity per share, SEK	64.4	54.0	64.4	54.0
Net worth per share, SEK	64.4	54.0	64.4	54.0
Cash flow per share after investments, SEK	27.6	-1.5	23.0	10.1
Equity/assets ratio, %	90.2	89.7	90.1	89.7
EBITDA	-120.7	-51.9	-278.9	95.7
EBIT	-128.9	-60.4	-312.4	55.4
Operating margin, %	-1,306.1	-175.3	-335.7	11.7
R&D spending/total opex, %	65.9	77.8	78.8	73.1

### 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 tax 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.

The above key ratios are deemed to be relevant for the type of operations conducted by Medivir and to contribute to an increased understanding of the financial report.