

MEDIVIR AB – INTERIM REPORT JANUARY – SEPTEMBER 2016

Financial summary

July – September 2016

- Net turnover totalled SEK 67.8 million (111.5 m), of which SEK 12.4 million (69.0 m) comprised royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 44.0 million (42.5 m), of which SEK 1.3 million (2.8 m) derived from sales of OLYSIO® and SEK 42.7 million (39.7 m) from sales of other pharmaceuticals.
- The profit after tax was SEK -50.4 million (-10.5 m).
- Basic and diluted earnings per share totalled SEK -1.87 (-0.39) and SEK -1.87 (-0.39), respectively.
- The cash flow from operating activities amounted to SEK -37.0 million (75.4 m).

January – September 2016

- Net turnover totalled SEK 224.1 million (573.2 m), of which SEK 54.7 million (387.5 m) comprised the first three quarters' royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 150.4 million (184.5 m), of which SEK 9.1 million (50.3 m) derived from sales of OLYSIO® and SEK 141.3 million (134.2 m) from sales of other pharmaceuticals.
- The profit after tax was SEK -130.6 million (120.3 m).
- Basic and diluted earnings per share totalled SEK -4.85 (4.14) and SEK -4.85 (4.11), respectively.
- The cash flow from operating activities amounted to SEK -110.5 million (345.0 m).

Significant events after the period end

- Medivir focuses exclusively on oncology and reorganises to significantly reduce the cost structure.
- Enrolment to the phase IIa trial within the MIV-711 osteoarthritis programme is complete and the independent safety review committee recommends that the trial should go ahead.
- Medivir divests its pharmaceutical company, BioPhausia (Nordic Brands) to Karo Pharma.
- Medivir's nucleotide polymerase inhibitor for the treatment of liver cancer, MIV-818, enters non-clinical development.
- Medivir strengthens its clinical pipeline by signing an agreement to acquire a portfolio of clinical phase oncology programmes.

Summary of the Group's figures (SEK m)

	Q3		Q1-Q3		Full year
	2016	2015	2016	2015	2015
Net turnover	67.8	111.5	224.1	573.2	657.9
Gross profit	48.7	90.2	159.0	487.9	548.6
Operating profit before depreciation and amortisation (EBITDA)	-35.6	1.3	-108.0	190.9	155.0
Operating profit (EBIT)	-44.4	-13.1	-133.3	159.2	114.8
Profit/loss before tax	-40.4	-13.3	-122.0	155.0	102.0
Profit/loss after tax	-50.4	-10.5	-130.6	120.3	75.1
Operating margin, %	-65.5	-11.8	-59.5	27.8	17.4
Basic earnings per share, SEK	-1.87	-0.36	-4.85	4.14	2.59
Diluted earnings per share, SEK	-1.87	-0.36	-4.85	4.11	2.56
Net worth per share, SEK	48.99	55.36	48.99	55.36	54.04
Return on equity	-11.5	-0.9	-11.8	8.9	5.9
Cash flow from operating activities	-37.0	75.4	-110.5	345.0	307.4
Cash and cash equivalents at period end	955.0	1,118.1	955.0	1,118.1	1,077.9
R&D spending/total opex, %	75.9	68.1	73.4	63.3	52.8

CEO's comments

We continued to progress both our own portfolio research projects and those that make up our partnered projects during the third quarter.

The MIV-711 osteoarthritis study was given the go-ahead to proceed, based on a review of safety data, and the first patient was enrolled in a continuation study. The completion of patient enrolment was, announced after the quarter end, which means that we are on schedule and have demonstrated our competence to design and run complex clinical development projects. We consequently anticipate presenting the results of the study in Q3 2017.

We also entered into a licensing agreement that gives Trek Therapeutics exclusive rights to develop and commercialise the MIV-802 project for the treatment of hepatitis C. The agreement not only yields a one-off payment of SEK 10.3 million, it also entitles Medivir to milestone payments based on successful clinical development and royalties capped at a maximum of ca. 15% upon any future commercialisation of products containing MIV-802.

Our partner, Janssen Research & Development, reported interesting progress during the quarter of a phase IIa study with interim data showing that the combination of simeprevir, odalasvir and AL-335 has a high level of efficacy in HCV patients. The results show that 100% of the patients treated with the triple combination achieved a sustained viral response after as little as six weeks of treatment. Simeprevir was shown to have a decisive effect and Jansen will consequently continue its phase IIb studies by evaluating the effect of using this triple combination for treatment of a broader group of patients with different hepatitis C virus genotypes over periods of 6 and 8 weeks.

Royalties attributable to the hepatitis C pharmaceutical, OLYSIO® (simeprevir), totalled SEK 12.4 million during the third quarter. Our Nordic pharmaceutical sales saw the Nordic Brands portfolio achieve revenues of SEK 42.1 million during the quarter, corresponding to an increase of 8% in comparison with the same period in 2015.

Important decisions on Medivir's future orientation

Medivir continued to develop positively, overall, during the third quarter, and several key decisions of great importance in terms of Medivir's future orientation and development have also been taken since the quarter ended.

One of the decisions announced was the reorganisation, along with substantial cost reductions, in the early stage research portfolio and in administrative functions. The reorganisation is expected to result in a total cost reduction of approximately SEK 110 million per year compared to levels under the current organisation. We also decided to focus our operations exclusively on oncology. As a consequence of these changes, a total of around 30 of Medivir's employees will, unfortunately, have to leave the company.

We have also, as part of our efforts to achieve a more focused approach, been working for some time now to separate the company's operations into two independent companies, with the intention of obtaining a separate listing for the new commercial company based on the Nordic Brands portfolio. A number of proposals were received during the in-depth evaluation of the potential for a separate listing, and after a structured process during which the various alternatives were compared, the Board decided that the sale of BioPhausia AB to Karo Pharma would better serve the interests of Medivir's shareholders than a separate listing.

We also announced, in early November, that we had acquired two promising new clinical phase oncology projects. This constitutes a fundamentally transformative transaction for Medivir and is an important component of the strategy of broadening our pipeline with later stage clinical phase programmes and shifting the emphasis from early stage to clinical phase research, whilst simultaneously also strengthening our focus on oncology.

We are also pleased to note that MIV-818 has been selected as a candidate drug for the treatment of hepatocellular carcinoma (HCC) and has now entered non-clinical development. MIV-818 is unique in that it is the only orally administered chemotherapeutic being developed specifically for liver cancers. It is extremely satisfying to be able to deliver the first candidate drug from our internal portfolio of early-stage anti-cancer and immune-oncology projects.

I am convinced that all of these new ventures and changes constitute important steps in Medivir's transformation into an exclusively oncology-focused pharmaceutical company and thereby further enhance our ability to create long-term value.

Niklas Prager

President and CEO

Medivir in brief

Medivir is a research based pharmaceutical company with a focus on oncology and infectious diseases. 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, July – September 2016

In August, 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. MIV-802 is a nucleotide polymerase inhibitor under development for the treatment of hepatitis C virus (HCV) infection. Under the terms of the agreement, Medivir is entitled to receive milestones based on successful clinical development and royalties capped at approximately 15% upon any future commercialisation of products containing MIV-802. The agreement also grants Medivir's BioPhausia subsidiary options to commercialise products containing MIV-802 in the Nordic market and a number of western European markets.

In August, Medivir's Board of Directors authorised the company management to continue the implementation of a separation of the company's operations into two independent companies, with the intention of obtaining a separate listing on First North Premium for the new commercial company based on Medivir's pharmaceutical portfolio. The aim of the separation was to visualise the value of both the commercial operations and the pharmaceutical projects that make up the R&D portfolio.

In September, Medivir's ongoing osteoarthritis study, MIV-711-201, was given the go-ahead to

continue and the first patient was enrolled in the open label phase IIa study, MIV-711-202. Unblinded safety data from the first 50 patients having completed three months of treatment form the basis for the Data Monitoring Committee's recommendation that the phase IIa study should go ahead. It is expected that data from MIV-711-201 will be available in the third quarter of 2017 and that data from the MIV-711-202 extension study will be available in the first half of 2018.

In September, updated interim data from an ongoing phase IIa study were presented, showing that the combination of simeprevir, odalasvir and AL-335 has a high level of efficacy in hepatitis C virus patients. The study is being conducted by Alios BioPharma Inc., part of Janssen Pharmaceutical Companies (Janssen). The data show that 100% of patients receiving treatment for as little as six weeks with a triple combination of simeprevir (75 mg, QD), AL-335 (800 mg, QD) and odalasvir (50 mg, QOD) achieved a sustained viral response 12 weeks after completion of treatment (SVR12). Based on the interim data from this study, the triple combination of simeprevir (75 mg, QD), odalasvir (25 mg, QD) and AL-335 (800 mg, QD) has been selected for further development.

Financial overview, July – September 2016

Revenues

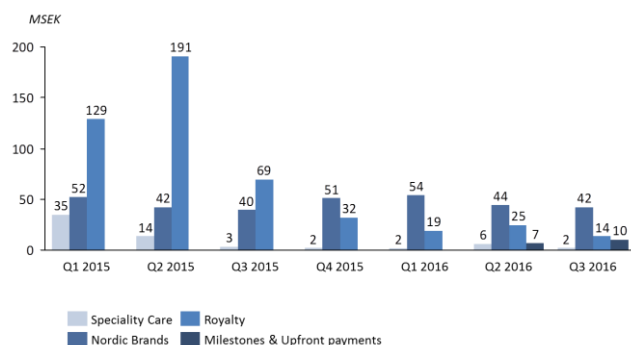
Net turnover for the period from July to September totalled SEK 67.8 million (111.5 m), corresponding to a decrease of SEK 43.7 million. Revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 44.0 million (42.5 m), of which SEK 42.1 million (39.0 m) was generated by the Nordic Brands portfolio. The Innovative Specialty Care portfolio achieved sales of SEK 1.9 million (3.6 m).

The combined value of Janssen's global sales of simeprevir was USD 21 million (79 m), generating royalties during the quarter of SEK 12.4 million (69.0 m). Royalties based on GlaxoSmithKline's sales of Xerclear (Zovido) during the period totalled SEK 1.1 million. The out-licensing of MIV-802 has also generated non-recurring income totalling SEK 10.3 million (0).

Breakdown of net turnover (SEK m)

	Q3		Q1-Q3		Full year
	2016	2015	2016	2015	2015
Upfront- and milestone payments	10.3	-	16.8	-	-
Pharmaceutical sales, where of	44.0	42.5	150.4	184.5	237.5
<i>Nordic brands</i>	42.1	39.0	141.0	132.9	183.6
<i>Innovative specialty care</i>	1.9	3.6	9.4	51.6	53.9
Royalties	13.5	69.0	57.0	388.8	420.4
Total	67.8	111.5	224.1	573.2	657.9

Net turnover (SEK m), Q1 2015 – Q3 2016



Results

Gross profit

The cost of goods sold was SEK -19.1 million (-21.3 m), corresponding to a decrease of SEK 2.2 million. The gross profit amounted to SEK 48.7 million (90.2 m), corresponding to a decrease of SEK 41.5 million and equating to a gross margin of 71.8% (80.9%), explained by the shift from royalties to pharmaceutical sales.

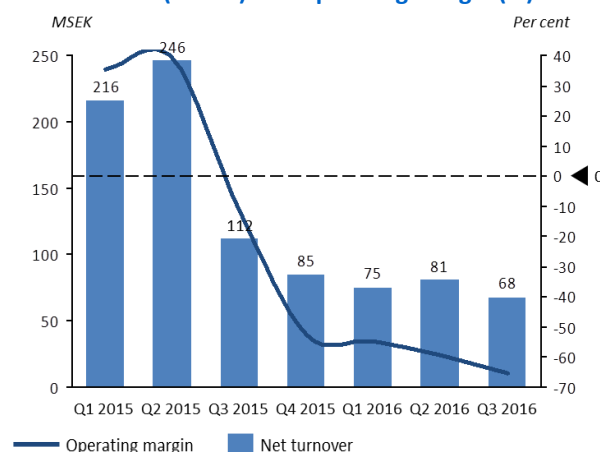
Operating expenses

The reorganisation of the sales organisation last year has resulted in a decrease in selling expenses of SEK 12.6 million. Administrative expenses have, furthermore, decreased by SEK 4.2 million. Research and development costs increased by SEK 0.3 million, primarily as a result of the ongoing phase IIa study of MIV-711. Other operating income/expenses have decreased by SEK 6.3 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -93.0 million (-103.3 m), corresponding to a decrease of SEK 10.3 million.

The operating profit/loss totalled SEK -44.4 million (-13.1 m), corresponding to a decrease of SEK 31.3 million.

Net financial items totalled SEK 4.0 million (-0.2 m), corresponding to an increase of SEK 4.2 million, and due to unrealised gains driven by market valuation of short-term interest-bearing investments.

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



Taxes

The tax cost for the period totalled SEK -10.0 million (2.8 m), corresponding to an increase of SEK 12.8 million resulting from increased profits by the commercial pharmaceutical operations.

The Group's income and deferred tax are calculated using the legally stipulated tax 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.

Revenues

Net turnover for the period from January–September totalled SEK 224.1 million (573.2 m), corresponding to a decrease of SEK 349.1 million. Revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 150.4 million (184.5 m), of which SEK 141.0 million (132.9 m) was generated by the Nordic Brands portfolio. Innovative Specialty Care reported sales of SEK 9.4 million (51.6 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 96 million (577 m), which has generated royalties of SEK 54.7 million (387.5 m).

Royalties based on GlaxoSmithKline's global sales of Xerclear (Zovido) during the first nine months of the year totalled SEK 2.3 million (1.3 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 10.3 million (0).

Results

Gross profit

The cost of goods sold was SEK -65.1 million (-85.3 m), corresponding to a decrease of SEK 20.2 million. The gross profit amounted to SEK 159.0 million (487.9 m), corresponding to a decrease of SEK 328.9 million and equating to a gross margin of 71.0% (85.1%), explained by the shift from royalties to pharmaceutical sales.

Operating expenses

The reorganisation of the sales organisation last year has resulted in a decrease in selling expenses of SEK 31.0 million. Administrative expenses have, furthermore, decreased by SEK 12.8 million during the first nine months of the year. Research and development costs increased by SEK 6.5 million, primarily as a result of the ongoing phase IIa study of MIV-711 and the progress of discovery projects, such as the RSV fusion inhibitor and the HCC nucleotide. Other operating income/expenses are positive but decreased by SEK 0.9 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -292.3 million (-328.7 m), corresponding to a decrease of SEK 36.4 million.

The operating profit/loss totalled SEK -133.3 million (159.2 m), corresponding to a decrease of SEK 292.5 million.

Net financial items totalled SEK 11.3 million (-4.2 m), corresponding to an increase of SEK 15.5 million, and due to market valuation of short-term interest-bearing investments.

Taxes

Tax for the period totalled SEK -8.6 million (-34.7 m), corresponding to a decrease of SEK 26.1 m and resulting from a reduction in profits. The Group's income and deferred tax are calculated at the tax 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 955.0 million (1,118.1 m) at the end of the period. The corresponding figure at the beginning of 2016 was SEK 1,077.9 million (1,395.6 m), corresponding to a decrease of SEK 122.9 million. Liquid assets at the period end exclude the Q3 royalties of SEK 13.5 million. Pledged assets at the end of the period totalled SEK 0.0 million (54.3 m). Medivir's financial assets are, in accordance with its financial policy, invested in low-risk, interest-bearing securities.

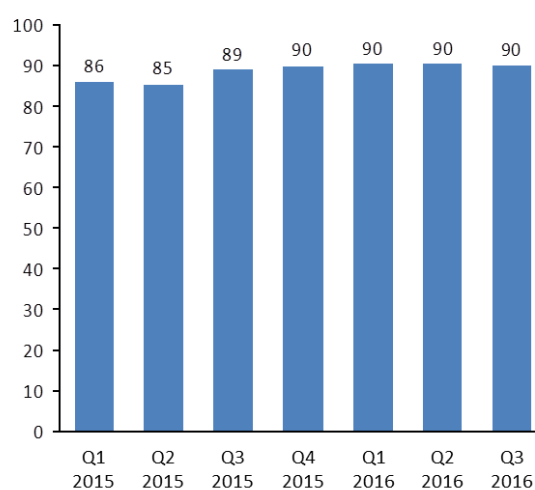
Cash flow from operating activities totalled SEK -110.5 million (345.0 m), with changes in working capital accounting for SEK -7.1 million (161.3 m) of this total.

Cash flow from investing activities totalled SEK -11.8 million (-11.1 m). Investments in research, facilities and IT systems totalled SEK -11.8 million (-16.1 m), and revenues from the sales of operations amounted to SEK 0 million (5.0 m).

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

Equity/Assets ratio, %

Per cent



Investments in tangible fixed assets during the period amounted to SEK -10.0 million (-7.2 m) and comprised investments in research, facilities, and IT systems.

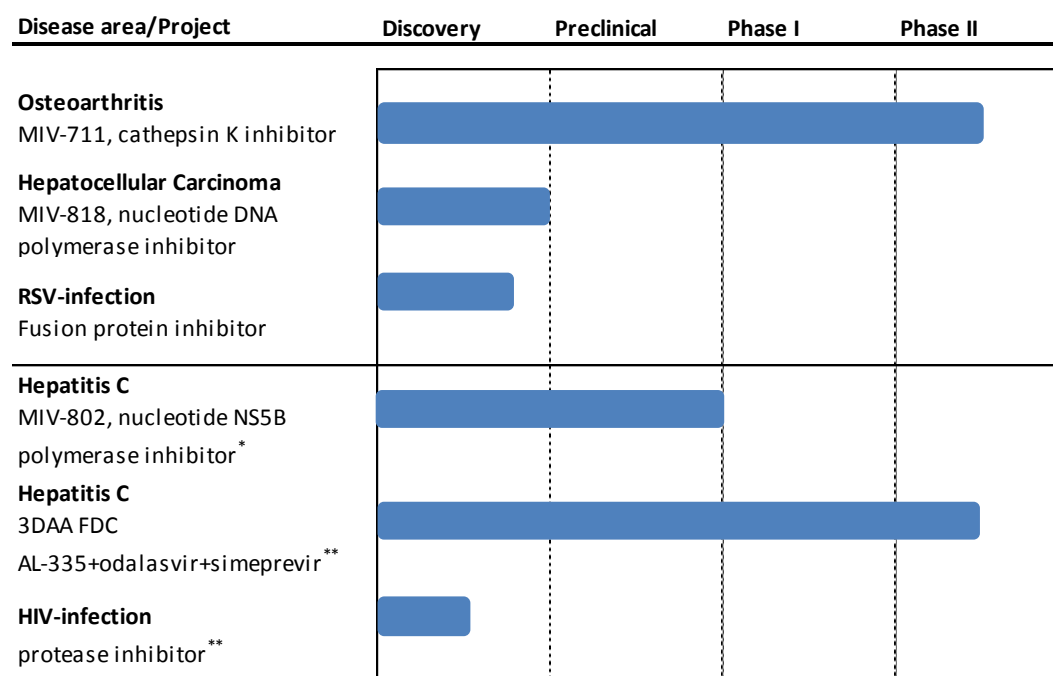
Depreciation of tangible fixed assets and intangible fixed assets totalling SEK -8.1 million (-8.0 m) and SEK -17.2 million (-17.6 m), respectively, were charged to the profit/loss for the period.

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 oncology and infectious diseases, and on the ongoing clinical project in the area of osteoarthritis.

Medivir has successfully developed products all the way from concept to marketed products. In 2009, Xerclear (Zovido®) was approved for the treatment of labial herpes. 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, where Medivir has appointed a local distributor, and 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 several other countries around the world. Simeprevir is approved for the treatment of hepatitis C infection as part of an antiviral treatment regimen in adults without cirrhosis or with compensated cirrhosis who are chronically infected with HCV genotype 1 or 4, (indications vary by market). Janssen is responsible for the global clinical development of simeprevir and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir retains marketing rights for simeprevir in these countries under the marketing authorisation held by Janssen-Cilag International NV.



* Partner Trek Therapeutics

** Partner Janssen

For further information about our projects, please visit: www.medivir.com

MIV-711

MIV-711 is a cathepsin K inhibitor in clinical development for the treatment of osteoarthritis. Cathepsin K is a protease, which can break down the collagen in bone and cartilage, and hence an inhibitor of cathepsin K has the potential to reduce joint structural disease progression and attenuate pain. In support of this, MIV-711 has been demonstrated to exert joint protective effects in preclinical models of osteoarthritis. In a phase I study including postmenopausal women, MIV-711 reduced biomarkers for bone resorption and cartilage degradation by up to 98 per cent and 62 per cent, respectively, compared with placebo. A phase IIa study (MIV-711-201) of MIV-711 in patients with moderate knee osteoarthritis was initiated early in the first quarter of 2016. Enrolment of patients into the study began in January. Details of the study can be found at: www.clinicaltrials.gov/ct2/show/NCT02705625.

Status/significant events:

The independent Drug Monitoring Committee held its first meeting in relation to MIV-711-201 in September, at which time unblinded safety data from the first 50 patients who had completed three months of treatment was reviewed. The Committee's recommendation was that MIV-711-201 should proceed according to plan. In addition, the first patient has now been enrolled in the open label phase IIa extension study, MIV-711-202, which will comprise approximately fifty patients from MIV-711-201. All of the patients in MIV-711-202 will be treated with 200 mg MIV-711 once daily. Patients will be eligible to roll over into the extension if they have a favourable response to MIV-711 treatment, or if their disease has worsened following placebo treatment. The first objective of the study is to assess the safety and tolerability of six additional months of treatment with MIV-711, as well as its effect on knee joint structure assessed using magnetic resonance imaging (MRI), in patients who have shown evidence of a response to MIV-711 treatment. The other objective of the study is to explore the safety, tolerability and efficacy of six months of treatment with MIV-711 in patients previously on placebo whose osteoarthritis has worsened over the preceding six-month period.

RS-virus fusion protein inhibitor

The aim of the project is to develop an oral inhibitor of the respiratory syncytial virus (RSV) fusion protein. 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 to ensure broad coverage against clinical isolates of RSV and good pharmacokinetic properties in order to ensure that the candidate drug that emerges from this project for further development has a highly competitive profile. In September, the profile for an advanced lead substance was presented at the 10th International RSV Symposium in Argentina: For further information, see: <http://www.medivir.se/v5/images/pdf/2016/Medivir-RSV-September-2016.pdf>.

HCC nucleotide based DNA polymerase inhibitor, MIV-818

The objective of the nucleotide project for hepatocellular carcinoma (HCC) is to deliver an anticancer therapeutic selectively to the liver. Non-surgical approaches to managing HCC rely to a large extent on the targeting of drugs to the liver. Medivir has developed substantial capabilities to selectively deliver the active metabolites of nucleoside and nucleotide analogues to the liver, based on its 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 an orally administered drug that is liver specific for the treatment of hepatocellular carcinoma.

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. The profile properties of a number of molecules developed by the project were presented at the 10th Annual Conference of the International Liver Cancer Association held in Vancouver, Canada, in September: http://www.medivir.se/v5/images/pdf/2016/ILCA-2016-Poster-P035_HCC-nuc-Albertella-Bethell-final.pdf.

See also significant events after the third quarter, page 10.

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. In mid-October 2015, Alios BioPharma Inc., part of Janssen Pharmaceutical Companies (Janssen), started a phase IIa clinical trial to evaluate the combination of simeprevir, the NS5A inhibitor, sofosbuvir, and the nucleotide analogue AL-335. This trial is due to be completed by the end of 2016.

Status/significant events:

On 23 September, interim data from the ongoing phase IIa study of simeprevir, sofosbuvir and AL-335 were presented at the European Association for the Study of the Liver (EASL) Special Conference in Paris. 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 (SVR 12). Based on the interim safety and efficacy data from this study, the triple combination of simeprevir (75 mg, QD), sofosbuvir (25 mg, QD) and AL-335 (800 mg, QD), now referred to as JNJ-4178 has been selected for further development. The development programme for JNJ-4178 will comprise an open label, randomised, multicentre phase IIb study for which treatment-naïve and treatment-experienced non-cirrhotic patients chronically infected with hepatitis C virus genotypes 1, 2, 4, 5 and 6, will be enrolled. The phase IIa study will also be extended to include patients with compensated cirrhosis. Further information on ongoing and planned studies is available at www.clinicaltrials.gov, reference numbers NCT02569710 and NCT02765490.

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.

Status/significant events:

In August, 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. Under the terms of the agreement, Medivir is entitled to receive milestones based on successful clinical development and royalties capped at approximately 15% upon any future commercialisation of products containing MIV-802. The agreement also grants options to commercialise products containing MIV-802 in the Nordic market and a number of western European markets to Medivir's BioPharmacia subsidiary.

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. During the third quarter, Medivir filed two new patents within RSV and one new patent within HCC.

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 3.9 million (23.8 m) and SEK 3.2 million (0.0 m), respectively.

Employees

Medivir had 119 (132) employees (FTEs) at the period end, 53% (56%) 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 one active share-related incentive plan, LTI 2014. The LTI 2013 plan was finalized 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, was charged to the profit/loss for the period in the sum of SEK -0.4 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 103.0 million (458.6 m). Intra-Group sales amounted to SEK 19.8 million (18.8 m).

The gross profit amounted to SEK 89.4 million (410.0 m). Combined operating expenses totalled SEK -171.6 million (-276.7 m). The operating profit/loss was SEK -182.2 million (133.3 m), corresponding to a decrease of SEK 315.5 million. Net financial items totalled SEK 6.3 million (-2.4 m), corresponding to an increase of SEK 8.7 million, and due to unrealised gains driven by positive market valuation of short-term interest-bearing investments.

The tax for the period totalled SEK 0.0 million (-29.1 m). The net profit/loss for the period was SEK -175.9 million (101.8 m), corresponding to a decrease of SEK 277.7 million, and primarily due to decreases in royalty income.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 821.5 million (1,016.5 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 1.4 million (11.4 m), whereof royalty payments to Uppsala Hallbechem AB (Board Member, Anders R Hallberg) totalled SEK 0.4 million (3.0 m), and those to Sybesam AB (Board Member, Bertil Samuelsson) totalled SEK 1.0 million (8.4 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, 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 2015 Annual Report, see pages 27 and 62 (Note 8). The Annual Report is available at: www.medivir.com.

Significant events after end of Q3

In October, Medivir announced a reorganisation of the company's operations and a significant cost reduction in the early research and administrative functions. The Board has decided that the company will, henceforth, focus exclusively on oncology, utilising both Medivir's technology platforms and its competences in protease inhibition and nucleotide/nucleoside science. Partnering discussions for all remaining infectious disease assets in the R&D pipeline will be initiated by year-end. The reorganization will result in a total cost reduction of approximately SEK 110 million per year compared to current levels in the affected functions. The exclusive focus on oncology, along with a reduced number of projects in the early stage research portfolio, will lead to a reduction of around 25 positions and annual cost savings of approximately SEK 60 million vs current spending in the early stages of development. At the same time, efficiency improvements in administrative and commercial support functions will generate the additional cost savings of approximately SEK 50 million per year compared to the current levels, and resulting in around 20 positions in these departments becoming surplus to requirements. As a consequence of these changes, a total of around 30 colleagues will unfortunately have to leave the company and affected vacancies will not be filled. A redundancy cost of approximately SEK 20 million related to these organizational changes will be charged in the fourth quarter.

Enrolment in the phase IIa study of the osteoarthritis programme, MIV-711, was completed at the end of October and the independent safety review committee recommended that the extended study should go ahead. 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. It is expected that data from the study will be available in the third quarter of 2017.

In November, Medivir entered into an agreement with Karo Pharma AB regarding the sale 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. The transaction is expected to close by mid-December 2016.

Medivir's nucleotide polymerase inhibitor, MIV-818, was selected as a candidate drug from the company's nucleotide DNA polymerase inhibitor project for the treatment of hepatocellular carcinoma (HCC). MIV-818 has consequently now entered non-clinical development. 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. MIV-818 has the potential to become the first liver-targeted orally administered drug to address HCC and other liver

cancers. Medivir expects to communicate the preclinical antitumor and pharmacokinetic profile of MIV-818 at major scientific meetings in 2017.

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), and 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.

Medivir's Nomination Committee for the 2017 Annual General Meeting has now been appointed and comprises: Bo Öberg, founder and class A shareholder, (Bo Öberg also represents Nils Gunnar Johansson and Christer Sahlberg, via an agreement between the three class A shareholders), Anders Hallberg, Healthinvest, Maria Rengefors, Nordea Fonder, and Anna Malm Bernsten, Chairman of the Board of Medivir AB.

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 licensing, which is expected to generate value ahead of impending partnering. Medivir has a strong capital base and several projects in our core area of oncology in both the early and late development phases, and this is expected to generate long-term shareholder value.

Stockholm, 10 November 2016

Niklas Prager
President & CEO

The information in this report comprises the information that Medivir is obliged to disclose under the provisions of the Swedish Securities Markets Act and/or the Swedish Financial Instruments Trading Act.

The information was released for publication on 10 November 2016 at 08.30 (CET).

For further information, please contact:

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Ola Burmark, CFO, +46 (0) 725 480 580

Conference call for investors, analysts and the media

The Interim Report for the period from January to September 2016 will be presented by Medivir's President & CEO, Niklas Prager.

Time: Thursday, 10 November 2016, 14.00 (CET).

Phone numbers for participants from:

Sweden: 08-566 426 96

Europe: +44 20 3008 9817

USA: +1 855 831 5946

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 call.

Financial calendar:**Financial statement for 2016**

17 February 2017

Interim Report (January – March 2017)

28 April 2017

2017 Annual General Meeting

3 May 2017

Consolidated Income Statement, summary (SEK m)

	Q3		Q1-Q3		Full year
	2016	2015	2016	2015	2015
Continuing operations					
Net turnover	67.8	111.5	224.1	573.2	657.9
Cost of goods sold	-19.1	-21.3	-65.1	-85.3	-109.3
Gross profit	48.7	90.2	159.0	487.9	548.6
Selling expenses	-14.1	-26.7	-48.2	-79.2	-68.9
Administrative expenses	-8.9	-13.1	-31.8	-44.6	-139.1
Research and development costs	-70.7	-70.4	-214.6	-208.1	-229.0
Other operating income/expenses	0.6	6.9	2.3	3.2	3.2
Operating profit/loss	-44.4	-13.1	-133.3	159.2	114.8
Net financial items	4.0	-0.2	11.3	-4.2	-12.8
Profit/loss after financial items	-40.4	-13.3	-122.0	155.0	102.0
Tax	-10.0	2.8	-8.6	-34.7	-26.9
Net profit/loss for the period	-50.4	-10.5	-130.6	120.3	75.1
Net profit/loss for the period attributable to:					
Parent Company shareholders	-50.4	-10.5	-130.6	120.3	75.1
Earnings per share, calculated from the net profit/loss attributable to Parent Company shareholders during the period					
Earnings per share (SEK per share)					
- Total operations, basic earnings	-1.87	-0.36	-4.85	4.14	2.59
- Total operations, diluted earnings	-1.87	-0.36	-4.85	4.11	2.56
Average number of shares, '000	26 941	29 048	29 048	29 048	29 048
Number of shares at period end, '000	26 917	26 836	26 836	26 836	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.

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 Income (SEK)

	Q3		Q1-Q3		Full year
	2016	2015	2016	2015	2015
Net profit/loss for the period	-50.4	-10.5	-130.6	120.3	75.1
Other comprehensive income					
<i>Items that may be reclassified in the Income Statement</i>					
Exchange rate differences	-1.3	-0.2	-1.2	0.6	2.2
Total items that may be reclassified subsequently to profit or loss	-1.3	-0.2	-1.2	0.6	2.2
Total comprehensive income for the period	-51.7	-10.7	-131.8	120.8	77.3
Total net profit/loss	-51.7	-10.7	-131.8	120.8	77.3

Consolidated Balance Sheet, summary (SEK m)

	30-sep	30-sep	31-dec
	2016	2015	2015
Assets			
Intangible fixed assets	382.8	399.2	398.0
Tangible fixed assets	28.1	29.6	26.3
Financial fixed assets	0.0	0.0	0.0
Inventories	27.1	23.3	18.7
Current receivables	74.5	111.4	95.4
Short-term investments	779.7	862.9	860.4
Cash and cash equivalents	175.3	255.2	217.5
Total assets	1 467.5	1 681.6	1 616.3
Shareholders' equity and liabilities			
Shareholders' equity	1 318.7	1 492.9	1 450.1
Deferred tax liabilities	42.6	19.2	30.8
Long-term liabilities	0.0	-	-
Current liabilities	106.2	169.5	135.4
Total shareholders' equity and liabilities	1 467.5	1 681.6	1 616.3

Consolidated Statement of Changes in Equity (SEK m)

	Share capital	Other paid-in capital	Exchange rate difference	Accum. loss	Total equity
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	-	-	-
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	157.2	1 152.3	-1.8	142.5	1 450.2
Opening balance, 1 January 2015	156.3	1 761.8	-4.0	68.5	1 982.6
Total comprehensive income for the period	-	-	0.6	120.3	120.8
Share incentive plan: value of employee service	-	2.2	-	-	2.2
Redemption program	-21.5	-579.7	-	-	-601.2
Stock dividend issue	21.5	-21.5	-	-	-
Transaction costs	-	-	-	-1.4	-1.4
Tax effect on transaction costs	-	-	-	0.3	0.3
Repurchase of own shares	-	-10.4	-	-	-10.4
Closing balance, 30 September 2016	156.3	1 152.4	-3.4	187.7	1 492.9
Opening balance, 1 January 2016	157.2	1 152.3	-1.8	142.5	1450.15
Total comprehensive income for the period	-	-	-1.2	-130.6	-131.8
Share incentive plan: value of employee service	-	0.4	-	-	0.4
Closing balance, 30 September 2016	157.2	1 152.7	-3.0	11.9	1 318.7

Consolidated Cash Flow Statement, summary (SEK m)

	Q3		Q1-Q3		Full Year
	2016	2015	2016	2015	2015
Cash flow from operating activities before changes in working capital	-11.9	6.4	-103.3	183.7	107.6
Changes in working capital	-25.1	69.0	-7.1	161.3	199.8
Cash flow from operating activities	-37.0	75.4	-110.5	345.0	307.4
Investing activities					
Acquisition/sale of fixed assets	-5.0	-3.1	-11.8	-16.1	-20.1
Sale of operations	-	2.5	-	5.0	5.0
Cash flow from investing activities	-5.0	-0.6	-11.8	-11.1	-15.0
Financing activities					
Redemption program	-	-	-	-601.2	-601.2
Repurchase of own shares	-	-	-	-10.4	-10.4
Cash flow from financing activities	-	-	-	-611.6	-611.6
Cash flow for the period	-42.0	74.8	-122.3	-277.7	-319.2
Cash and cash equivalents at beginning of period	997.5	1 043.4	1 077.9	1 395.6	1 395.6
Change in cash and cash equivalents	-42.0	74.8	-122.3	-277.7	-319.2
Exchange rate difference, liquid assets	-0.4	-0.1	-0.6	0.2	1.6
Cash and cash equivalents at end of period	955.0	1 118.1	955.0	1 118.1	1 077.9

Parent company income statement, summary (SEK m)

	Q3		Q1-Q3		Full year
	2016	2015	2016	2015	2015
Net turnover	32.3	78.3	103.0	458.6	500.8
Cost of goods and services sold	-2.5	-4.4	-13.6	-48.6	-57.8
Gross profit	29.8	73.9	89.4	410.0	443.0
Selling expenses	-2.9	-17.1	-12.7	-45.9	-57.8
Administrative expenses	-24.7	-15.2	-82.7	-41.7	-53.7
Research and development costs	-59.8	-69.5	-179.8	-189.4	-257.8
Other operating income/expenses	0.6	4.6	3.6	0.2	9.8
Operating profit/loss	-57.0	-23.3	-182.2	133.3	83.4
Net financial items	2.0	0.2	6.3	-2.4	-32.3
Profit/loss after financial items	-55.0	-23.2	-175.9	130.9	51.2
Appropriations	-	-	-	-	-37.9
Tax	0.1	5.4	0.0	-29.1	-9.8
Net profit/loss for the period	-54.9	-17.8	-175.9	101.8	3.4

Parent company statement of comprehensive income (SEK m)

	Q3		Q1-Q3		Full year
	2016	2015	2016	2015	2015
Net profit/loss for the period	-54.9	-17.8	-175.9	101.8	3.4
Other comprehensive income for the period, net after tax	-	-	-	-	-
Total comprehensive income for the period	-54.9	-17.8	-175.9	101.8	3.4

Parent company balance sheet, summary (SEK m)

	30-sep	30-sep	31-dec
	2016	2015	2015
Assets			
Intangible fixed assets	18.5	12.8	17.1
Tangible fixed assets	27.9	29.4	26.1
Shares in subsidiaries	604.2	604.2	604.2
Financial fixed assets	21.7	23.2	24.3
Inventories	1.8	2.1	2.3
Current receivables	57.1	85.2	80.3
Short-term investments	779.7	862.9	860.4
Cash and bank balances	41.8	153.6	80.9
Total assets	1 552.6	1 773.3	1 695.6
Shareholders' equity and liabilities			
Shareholders' equity	1 147.1	1 420.0	1 322.2
Appropriations	37.9	-	37.9
Deferred tax liabilities	0.3	0.5	0.4
Liabilities to Group companies	277.3	190.8	214.9
Current liabilities	90.0	162.1	120.3
Total shareholders' equity and liabilities	1 552.6	1 773.3	1 695.6

Key ratios, share data, options

	Q3		Q1-Q3		Full year
	2016	2015	2016	2015	2015
Return on:					
- shareholders' equity, %	-11.5	-3.5	-11.8	8.9	5.9
- capital employed, %	-13.2	-3.5	-12.4	7.3	6.6
- total capital, %	-11.9	-3.0	-11.2	8.3	6.0
Number of shares at beginning of period, '000	26 966	26 966	26 966	31 260	31 260
Number of shares at period end, '000	26 966	26 966	26 966	26 966	26 966
- of which class A shares	606	606	606	606	606
- of which class B shares	26 310	26 230	26 310	26 230	26 230
- of which repurchased B shares	49	130	49	130	130
Average number of shares, '000	26 941	26 901	26 941	29 048	29 048
Outstanding warrants, '000	68	248	68	248	238
Share capital at period end, SEK m	157.2	156.3	157.2	156.3	157.2
Shareholders' equity at period end, SEK m	1 318.7	1 492.9	1 318.7	1 492.9	1 450.1
Earnings per share, SEK					
- Earnings per share, basic earnings	-1.87	-0.39	-4.85	4.14	2.59
- Earnings per share, diluted earnings	-1.87	-0.39	-4.85	4.11	2.56
Shareholders' equity per share, SEK	49.0	55.6	49.0	55.6	54.0
Net worth per share, SEK	49.0	55.6	49.0	55.6	54.0
Cash flow per share after investments, SEK	-1.6	2.8	-4.5	11.5	10.1
Equity/assets ratio, %	89.9	88.8	89.9	88.8	89.7
EBITDA	-35.6	1.3	-108.0	190.9	155.0
EBIT	-44.4	-13.1	-133.3	159.2	114.8
Operating margin, %	-65.5	-11.7	-59.5	27.8	17.4
R&D spending/total opex, %	75.9	68.1	73.4	63.3	52.8

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.

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.

Auditor's Report of Review of Interim Financial Information in accordance with IAS 34 and chapt. 9 of the Swedish Annual Accounts Act.

Introduction

We have reviewed the condensed interim financial information (interim report) of Medivir AB (publ) as of 30 September 2016 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

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

Conclusion

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

Stockholm, 10 November 2016

Öhrlings PricewaterhouseCoopers

Tobias Strähle

Authorized Public Accountant