

# MEDIVIR AB – INTERIM REPORT JANUARY – JUNE 2017

# April - June

# Significant events during the quarter

- Positive data from the phase II study of remetinostat in patients with early-stage cutaneous T-cell lymphoma was presented.
- Enrolment completed in the MIV-711 osteoarthritis extension study and data monitoring committee recommended to "Go Ahead".

#### **Financial summary**

- Net turnover for the continuing operations totalled SEK 9.5 million (36.9 m), SEK 7.7 million (24.2 m) of which comprised the second quarter's royalties for simeprevir. Other operating income totalled SEK 1.9 million (2.7 m).
- The loss before interest, tax, depreciation and amortisation (EBITDA) totalled SEK -90.9 million (-60.2 m). Basic and diluted earnings per share were SEK -3.91 (-1.48) and -3.90 (-1.48) respectively.
- The cash flow from operating activities amounted to SEK -82.1 million (-37.1).
- Non-recurring costs of SEK -1.9 million
   (-2.8 m) affected the result during the quarter.
- Liquid assets and short-term investments totalled SEK 624.2 million (997.5 m) at the period end.

# January - June

#### **Financial summary**

- Net turnover for the continuing operations totalled SEK 27.3 million (57.5 m), SEK 21.4 million (42.3 m) of which comprised royalties for simeprevir. Other operating income totalled SEK 4.4 million (7.5 m).
- The loss before interest, tax, depreciation and amortisation (EBITDA) totalled SEK -171.8 million (-121.0 m). Basic and diluted earnings per share were SEK -6.57 (-2.98) and -6.56 (-2.98) respectively.
- The cash flow from operating activities amounted to SEK -206.0 million (-73.5 m).
- Non-recurring costs of SEK -12.6 million
   (-2.7 m) affected the result during the period.
- Liquid assets and short-term investments totalled SEK 624.2 million (997.5) at the period end.

#### **Medivir in brief**

Medivir is a research and development company with a focus on oncology. We have a leading competence within protease inhibitor design and nucleotide/nucleoside science and we are dedicated to developing innovative pharmaceuticals that meet great unmet medical needs. Medivir's class B share is listed on the Nasdaq Stockholm Mid Cap List. For additional information on Medivir, please visit: www.medivir.com

# **CEO's comments**

Medivir has a strong, balanced R&D portfolio with three exciting projects in clinical development, and a portfolio of cutting edge earlier-stage projects, led by MIV-818. All projects – whether advanced in-house or by our partners – continued to develop according to plan during the quarter.

#### **Proprietary projects**

The two projects in our proprietary clinical oncology pipeline, acquired at the end of 2016, have already made strides forward. In early April, we announced positive data from the phase II clinical study of remetinostat in patients with early-stage cutaneous T-cell lymphoma showing a good effect on cancer lesions and an unmatched safety and tolerability profile. With this data, we are planning to initiate discussions with the US regulatory authority (FDA) to enable the start of a phase III study by the end of 2017. We also updated the protocol for the phase I/II combination study of birinapant with Merck's Keytruda™ during the quarter, and expect to initiate the phase I portion of that study in the third quarter.

The MIV-711 osteoarthritis project also developed according to plan, and enrolment was completed in the phase IIa extension study. We also announced the successful outcome of the fifth Data Monitoring Committee review of all available safety data, now including the extension study data so far. We continue to expect to report the headline data from the initial study towards the end of the third quarter 2017 and from the extension study during the first quarter of 2018.

We also continued to advance our five early-phase projects, as exemplified by the presentation of preclinical data and the pharmacokinetic profile for the MIV-818 liver cancer project at medical conferences globally including the EASL International Liver Congress™ in Europe and the AACR Annual Meeting in the US. We expect to complete preclinical studies with MIV-818 at the end of 2017 to enable a Phase I study start in 2018.

Medivir added the Chief Medical Officer position to the executive leadership team, to focus on the clinical development pipeline. I was pleased to be able to promote John Öhd, who was previously Director Clinical R&D, into the role.

#### **Partnered projects**

Additional data from an ongoing phase II study in HCV with JNJ-4178 (triple combination of simeprevir, odalasvir and AL-335) being conducted by our partner, Johnson & Johnson, were presented in April at The International Liver Congress™ of EASL. The results demonstrated, amongst other things, that this regimen has the potential to offer high efficacy (100% cure rates) with a shorter treatment duration (6 weeks) than the market's current alternatives. JNJ-4178 was one of the projects highlighted in Johnson & Johnson's "Pharmaceutical Business Review Day" in May, indicating its high priority to our partner. Johnson & Johnson expects to complete the phase II studies in

Royalties attributable to OLYSIO® (simeprevir), totalled SEK 7.7 million during the second quarter, reflecting the flattening-out of sales of that product.

As previously announced, Medivir's internal activities are focused on oncology and projects in other areas are consequently being out-licensed.

With the many projects that we have in various stages of development, Medivir looks forward to a very exciting second half of 2017.



**Christine Lind** *President & CEO* 

# Significant events, April – June 2017

In April, the phase II clinical study of the topical, skindirected histone deacetylase (HDAC) inhibitor, remetinostat, in patients with early stage cutaneous Tcell lymphoma (CTCL) was completed. The primary endpoint of the study was the proportion of patients with either a complete or partial confirmed response to therapy, assessed using the Composite Assessment of Index Lesion Severity (CAILS). Based on an intent-totreat analysis, patients in the 1% remetinostat gel BID arm had highest proportion of confirmed responses (8/20, 40%), including 1 complete response. The response rates in the other two arms were 5/20 (25%) and 4/20 (20%) in the 0.5% BID arm and the 1% QD arm respectively, and did not include any complete responses. Across all the dose groups, remetinostat was well-tolerated without signs of systemic adverse effects, including those previously associated with systemic HDAC inhibitors. Based on the positive data, Medivir expects to initiate discussions with regulatory authorities with the aim of initiating a phase III study later this year, and to present full phase II trial data at scientific meetings in the second half of 2017.

In June, the enrolment in the MIV-711 osteoarthritis extension study was completed and the data monitoring committee recommended continuation of the extension study based on a review of the accumulated safety data. The first objective of the extension study is to assess the safety, tolerability and efficacy of six additional months of treatment with MIV-711 in patients treated in the initial study for six months and who showed evidence of response. The initial study and the extension study together provide an opportunity to assess the effect of 12 months of treatment on the structure of the diseased knee. The other objective of the study is to explore the safety. tolerability and efficacy of six months of treatment with MIV-711 in patients who received placebo in the initial study and whose osteoarthritis worsened. These patients with rapid disease worsening may be in particular need of a disease-modifying treatment and the extension study provides a unique opportunity to study the effect of MIV-711 in this patient population.

The headline data from the initial study continues to be expected to be reported in the third quarter of 2017, and the headline data from both groups in the extension study are expected to be reported in the first half of 2018.

#### **Annual General Meeting 2017**

The 2017 AGM resolved to authorise the Board, for the period up to the next AGM, to adopt decisions, whether on one or several occasions and whether with or without pre-emption rights for the shareholders, to issue new shares of class B to an amount not exceeding in total 10 per cent of the total number of outstanding class B-shares in the company following utilization of the authorisation.

The AGM also resolved to issue warrants as part of an incentive programme to enable the staff to take part of and contribute to a positive value development for the company and to improve the possibilities for the company to keep and employ new competent and dedicated staff.

Anders Ekblom, Anders R Hallberg, Helena Levander and Anna Malm Bernsten were re-elected as Board Members and Bengt Julander and Bengt Westermark were elected as new Board Members.

Anna Malm Bernsten was re-elected as Chairman of the Board.

Öhrlings PricewaterhouseCoopers AB was re-elected as Auditors.

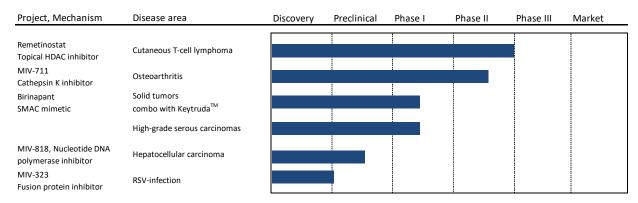
# Research and development

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

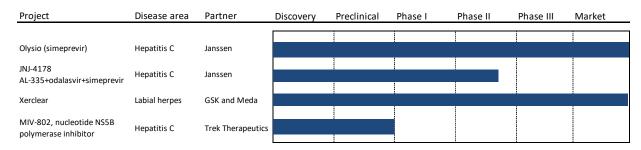
Medivir has successfully developed products all the way from concept to marketed products. In 2009, Xerclear (Zoviduo®) was approved for the treatment of labial herpes. The marketing rights to Xerclear in the USA, Canada and Mexico were divested in 2010, while the corresponding rights in Europe and the 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.

#### **Proprietary Pipeline**



#### **Partnership Pipeline**



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

#### **PROPRIETARY PROJECTS**

#### Remetinostat

Cutaneous T-cell lymphoma (CTCL) is a chronic and rare form of blood cancer that presents initially in the skin and is classified as an orphan disease. Remetinostat is a new histone deacetylase (HDAC) inhibitor that is in clinical development for the topical treatment of early-stage CTCL. The substance has been designed to be effective in the skin but to be degraded rapidly in the bloodstream to avoid the adverse effects previously associated with systemically administered HDAC inhibitors. Remetinostat is consequently expected to be an important new treatment option for patients who suffer from this cancer, and the dermato-oncologists who treat them. An open-label phase II study of remetinostat in early-stage CTCL patients was initiated in late 2014.

Medivir estimates the accessible market for early stage CTCL in the USA alone to be approximately USD 900 million per annum.

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

- Positive top line data from the phase II study in early-stage CTCL patients were reported in April 2017. Based on an intent-to-treat analysis, patients in the 1% remetinostat gel BID arm had highest proportion of confirmed responses (8/20, 40%), including 1 complete response. The response rates in the other two arms were 5/20 (25%) and 4/20 (20%) in the 0.5% BID arm and the 1% QD arm respectively, and did not include any complete responses. Across all three dose groups, topical remetinostat was well-tolerated without signs of systemic adverse effects, including those associated with systemic HDAC inhibitors.
- Based on the data from the Phase II study, Medivir expects to initiate discussions with regulatory authorities with the aim of initiating a phase III study later this year, and to present full phase II trial data at scientific meetings in the second half of 2017.

#### **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. 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, are treated with 200 mg MIV-711 once daily for six months.

Medivir estimates that the market for diseasemodifying osteoarthritis drugs in the USA alone corresponds to a value in excess of USD 6 billion per annum, even if the use is limited to patients with moderate osteoarthritis in weight-bearing joints.

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

- The MIV-711-201 study is fully enrolled and it is expected that headline data from this study will be presented in the third quarter of 2017
- Enrollment into the open-label phase IIa extension study, MIV-711-202, was completed in June, and results from the study are expected in Q1 2018.
- The independent Drug Monitoring Committee held its first scheduled meeting during the MIV-711-202 study in May The DMC reviewed all safety data from the Phase IIa studies, including unblinded data from the initial study and data to date from the extension study. Based on this review, the DMC has recommended that the extension study should go ahead as planned.

#### Birinapant

Birinapant has the potential, through its actions on tumour cells and cells of the immune system, to improve the treatment of several types of cancer when used in combination with other drugs including checkpoint inhibitors and DNA damaging agents. Birinapant is a bivalent peptidomimetic of the SMAC protein (Secondary Mitochondrial Activator of Caspase) and is therefore known as a SMAC mimetic compound. Despite breakthroughs by immunotherapeutic drugs, including PD-1 and PD-L1 antagonists, fewer than half of patients have clinically significant improvement after treatment. Global sales of these drugs nonetheless totalled USD 5.2 billion in 2016. The commercial potential available to a party capable of increasing the percentage of patients who respond to treatment is consequently significant.

# **Status/significant events:**

 The dose escalation portion of a phase I/II study, in which birinapant is administered in combination with Merck's Keytruda™ (a leading immunotherapeutic drug) for the treatment of solid tumours, is scheduled to begin in the third quarter of 2017 and will be carried out in partnership with Merck.

#### **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. It is classified as an orphan disease in the West, but is more common in Asia in general, and China in particular. Medivir has developed specialist expertise in selectively delivering active metabolites of nucleoside and nucleotide analogues to the liver as a result of the company's extensive experience of developing better treatments for chronic hepatitis B and hepatitis C virus infection. These methods are now being applied to develop orally administered, liver-specific therapeutics for the treatment of hepatocellular carcinoma and other forms of liver cancer.

Combined sales of HCC therapeutics in the seven biggest markets are expected to equate to USD 5.6 billion by 2023. MIV-818 has the potential to become the first liver-targeted, orally administered drug to address HCC and other forms of liver cancer.

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

- In November 2016, MIV-818 was selected as a candidate drug (CD) for the treatment of hepatocellular cancer (HCC) and other forms of liver cancer.
- Preclinical GLP safety studies are now ongoing in order to enable the start of clinical trials.
- Clinical trials are expected to start in the first half of 2018.

# **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. 33.8 million cases of RSV infections of the lower respiratory tract were reported for children under the age of 5 in 2005, 3.4 million of which required hospitalisation and which are estimated to have caused between 66,000 and 199,000 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 provides exclusive, global rights to a drug programme for the treatment and prevention of RSV infections.

#### Status/significant events:

- In December, MIV-323 was selected as a candidate drug (CD) from the RSV fusion inhibitor project, and entered non-clinical development.
- Medivir is actively seeking a partner for the MIV-323 project.

#### **PARTNERED PROJECTS**

#### INI\_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 Ila 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-naive 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:**

- In November 2016, Janssen Research &
   Development, LLC initiated a phase IIb open-label study of the combination treatment of simeprevir, odalasvir and AL-335 (JNJ-4178) in treatment-naive and treatment-experienced non-cirrhotic patients with chronic hepatitis C genotype 1, 2, 4, 5, and 6 infection.
- The objectives of the study are to investigate the efficacy, safety and pharmacokinetics of treatment with JNJ-4178. Patients in the study will receive the triple combination treatment 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 II study is assessing the same triple combination treatment in patients with or without compensated cirrhosis.
- Additional data from the ongoing phase II data were presented by Janssen at The International Liver Congress™ of EASL in April 2017.

#### **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 generally regarded as an important component of any such combination treatment, due to their potent and broad spectrum antiviral effect on multiple HCV genotypes and high barriers to 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.
- Medivir expects to present in the near future a partner for the development and commercialisation of the MIV-802 hepatitis C project in China, Taiwan, Hong Kong and Macau.

#### **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. Three new patent applications for protease inhibitors in the area of oncology were submitted during the first quarter, and a US patent was granted within the MIV-711 project. Medivir currently has 31 active patent families, with over 150 granted national patents.

### **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 originate from universities and pharmaceutical companies, and Medivir is consequently entitled to the revenues generated by these projects but obliged to pay royalties on their commercialisation. Certain projects have been progressed with patented research tools which are in-licensed from other companies and for which royalties are payable. The combined royalty costs for the period were SEK 1.8 million (3.1 m).

Summary of the Group's figures		Q2	Q1 -	· Q2	Full year
(SEK m)	2017	2016	2017	2016	2016
Net turnover	9.5	36.9	27.3	57.5	93.0
Operating profit before depreciation and amortisation (EBITDA)	-90.9	-60.2	-171.8	-121.0	-300.6
Operating profit (EBIT)	-92.9	-62.7	-178.6	-126.4	-312.4
Profit/loss before tax	-92.4	-59.3	-176.7	-122.3	-307.7
Basic earnings per share, SEK	-3.91	-1.48	-6.57	-2.98	10.50
Diluted earnings per share, SEK	-3.90	-1.48	-6.56	-2.98	10.41
Net worth per share, SEK	34.41	50.92	25.92	50.92	64.38
Cash flow from operating activities	-82.1	-37.1	-206.0	-73.5	-180.1
Cash and cash equivalents at period end	624.2	997.5	624.1	997.5	1 698.5

#### Revenues

Net turnover for the period from April – June totalled SEK 9.5 million (36.9 m), corresponding to a decrease of SEK 27.4 million attributable to the reduction in royalty income from simeprevir. The revenues from Medivir's pharmaceutical sales in the second quarter have been discontinued and totalled SEK 0.0 million (5.7 m). The combined value of Janssen's global sales of simeprevir totalled USD 12.9 million (43.0 m), which generated royalties for the quarter of SEK 7.7 million (24.2 m). Royalties from GlaxoSmithKline's sales of Xerclear (Zoviduo) during the quarter totalled SEK 0.8 million (0.5 m). Other operating income amounted to SEK 1.9 million (2.7 m) and referred to the letting of research facilities in the UK.

# **Operating expenses**

The cost of goods for resale totalled SEK 0 million (-1.5 m), due to the discontinued pharmaceutical sales.

Other external costs totalled SEK -76.3 million (-63.5 m), corresponding to an increase of SEK 13.2 million which was due to the increase in the scale of the research programmes conducted through contracted research organisations. Personnel costs amounted to SEK -26.1 million (-34.1 m) and have decreased by SEK 8.0 million in comparison with the same quarter last year due to the reorganisation implemented during the fourth quarter of 2016. The total expenses totalled

SEK -102.4 million (-97.6 m), whereof SEK 1.9 million (2.8 m) were non-recurring cost.

Depreciation and amortisation totalled SEK -2.0 million (-2.4 m) for the period. Other operating costs amounted to SEK 0 million (-1.7 m).

Net financial items totalled SEK 0.5 million (3.3 m), corresponding to a decrease of SEK 2.8 million due to lower financial assets and comprised of unrealised gains driven by positive market valuation of short-term, interest-bearing investments.

# Operating profit/loss

The operating profit/loss totalled SEK -92.9 million (-62.7 m), corresponding to a decrease of SEK 30.2 million attributable, in part, to the reduction in royalty income from simeprevir (OLYSIO®), in part to increased external costs attributable to ongoing research and development programmes. Adjusted for non-recurring costs, the operating profit/loss totalled SEK -91.0 million (-59.9 m).

#### **Taxes**

Tax for the period totalled SEK 0.1 million (0.1 m). The Group's tax is based on a legally stipulated tax rate of 22%, which is also expected to be the effective tax 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 – June totalled SEK 31.7 million (65.0 m), corresponding to a decrease of SEK 33.3 million attributable to the reduction in royalty income from simeprevir. The revenues from Medivir's pharmaceutical sales in the period totalled SEK 2.5 million (7.5 m). The combined value of Janssen's global sales of simeprevir totalled USD 36.0 million (75.0 m), which generated royalties for the period of SEK 21.4 million (42.3 m). Royalties from GlaxoSmithKline's sales of Xerclear (Zoviduo) during the period totalled SEK 2.4 million (1.2 m). Other operating income amounted to SEK 4.4 million (7.5 m) and referred to the letting of research facilities in the UK.

#### **Operating expenses**

The cost of goods for resale totalled SEK -1.7 million (-1.0 m), due to the discontinued pharmaceutical sales.

Other external costs totalled SEK -140.9 million (-115.9 m), corresponding to an increase of SEK 25.0 million which was due to the increase in the scale of the research programmes conducted through contracted research organisations. Personnel costs amounted to SEK -59.5 million (-68.4 m) and have decreased by SEK 8.9 million in comparison with the same period last year due to the reorganisation implemented during the fourth quarter of 2016. Adjusted for non-recurring personnel costs, the decrease totalled SEK 20.1 million. The total expenses totalled SEK -200.4 million (-184.3 m), whereof SEK 12.6 million (2.7 m) were non-recurring cost.

Depreciation and amortisation totalled SEK -6.8 million (-5.4 m) for the period. Other operating costs amounted to SEK -1.4 million (-0.7 m).

Net financial items totalled SEK 1.9 million (4.1 m), corresponding to a decrease of SEK 2.2 million due to lower financial assets and comprised of unrealised gains driven by positive market valuation of short-term, interest-bearing investments.

# Operating profit/loss

The operating profit/loss totalled SEK -178.6 million (-126.4 m), corresponding to a decrease of SEK 52.2 million attributable, in part, to the reduction in royalty income from simeprevir (OLYSIO®), in part to increased external costs attributable to ongoing research and development programmes. Adjusted for non-recurring costs, the operating profit/loss totalled SEK -166.0 million (-123.7 m).

#### **Taxes**

Tax for the period totalled SEK -0.5 million (3.3 m). The Group's tax is based on a legally stipulated tax rate of 22%, which is also expected to be the effective tax rate. 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

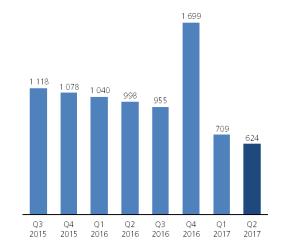
Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 624.1 million (997.5 m) at the end of the period, corresponding to a decrease of SEK 373.4 million. The corresponding figure at the beginning of 2017 was SEK 1,698.5 million (1,077.9 m). Liquid assets at the period end exclude the Q2 royalties of SEK 8.5 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 -206.0 million (-73.5 m), with changes in working capital accounting for SEK -36.6 million (17.9 m) of this total.

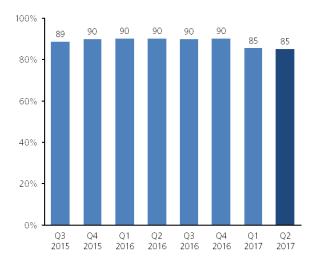
Cash flow from financing activities totalled SEK -857.0 million (0 m) and derive from the voluntary redemption programme implemented during the period. The period's investments in tangible and intangible fixed assets totalled SEK -11.3 million (-6.8 m) and referred to research and office equipment and IT systems.

Depreciation and write-downs of tangible and intangible fixed assets totalling SEK -6.8 million (-5.4 m) were charged to the profit/loss for the period.

# Liquid assets and short-term investments (SEK m)



#### Equity/assets ratio, %



# Other disclosures, January – June 2017

#### **Employees**

Medivir had 106 (120) employees (FTEs) at the period end, 58% (53%) of whom were women. 28 (1) of these employees have been given notice of termination of employment, but who's employment has not yet been terminated.

### Share-related incentive plans

To enable the staff to take part of and contribute to a positive value development for the company and to improve the possibilities for the company to keep and employ new competent and dedicated staff the company issued 48 515 warrants during the quarter as part of the incentive program approved by the AGM. The warrants were issued at a market value of SEK 9.41 each at an exercise price of SEK 89.36 per share. The exercise date is 15<sup>th</sup> of January 2021.

# 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, and administrative and company management functions.

The Parent Company's total revenues amounted to SEK 27.5 million (74.3 m). Sales to Group companies totalled SEK 0 million (13.2 m).

The operating profit/loss was SEK -178.6 million (-125.2 m), corresponding to a decrease of SEK 53.4 million. Combined operating expenses totalled SEK -206.1 million (-199.5 m). Net financial items

totalled SEK 2.1 million (4.3 m), corresponding to a decrease of SEK 2.2 million due to due to lower financial assets and comprised of unrealised gains driven by positive market valuation of short-term, interest-bearing investments.

The tax for the period totalled SEK -0.6 million (-0.1 m). The net profit/loss for the period was SEK -177.2 million (-121.0 m), corresponding to a decrease of SEK 56.2 million.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 615.9 million (883.5 m), of which SEK 90.0 million (0) is pledged until 15 December 2017.

See the section entitled "Financial overview" for additional 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 0.1 million (0.3 m), attributable to royalty payments to Uppsala Hallbechem AB (Board Member, Anders R Hallberg). 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:

credit risk.

on pages 73-75.

**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

A more detailed description of the exposure to risk, and of the ways in which Medivir manages it, is provided in the 2016 Annual Report, see pages 38-40 and in Note 8

The Annual Report is available on the company's website: www.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 outlicensing. Research is time and capital consuming and like many other research and development companies, Medivir might also be dependent on external financing of its projects within the core area of oncology.

# **Attestation**

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

Huddinge, 25 July 2017

<b>Anders Ekblom</b> <i>Member of the Board</i>	Anders Hallberg Member of the Board	<b>Bengt Julander</b> <i>Member of the Board</i>
<b>Björn Klasson</b> Member of the Board, Employee Representative	<b>Helena Levander</b> <i>Member of the Board</i>	<b>Stina Lundgren</b> <i>Member of the Board, Employee Representative</i>
Anna Malm Bernsten Chairman of the Board	Bengt Westermark Member of the Board	<b>Christine Lind</b> <i>President and CEO</i>

This report has not been subject to auditors' review.

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

This information was released for publication at 08.30 AM CET on 25 July 2017.

### For further information, please contact

Christine Lind, President & CEO, +46 (0) 8 5468 3100 Ola Burmark, CFO, +46 (0) 725 480 580

# Conference call for investors, analysts and the media

The Interim Report, January – June 2017 will be presented by Medivir's President & CEO, Christine Lind.

Time: Tuesday, 25 July 2017, at 14.00 (CET).

Phone numbers for participants from: Sweden + 46 8 566 426 91 Europe + 44 20 3008 9804 USA + 1 855 753 2235

The conference call will also be streamed via a link on

the website: www.medivir.com

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

# Financial calendar:

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

Financial Statement (January – December 2017) 16 February 2018

Interim Report (January – March 2018) 27 April 2018

Interim Report (January – June 2018)

25 July 2018

Consolidated Income Statement, summary		Q2	Q1	- Q2	Full year
(SEK m)	2017	2016	2017	2016	2016
Continuing operations					
Net turnover	9.5	36.9	27.3	57.5	93.0
Other operationg income	1.9	2.7	4.4	7.5	12.7
Total income	11.5	39.6	31.7	65.0	105.7
Merchandise	0.0	-1.5	-1.7	-1.0	-3.1
Other external expenses	-76.3	-63.5	-140.9	-115.9	-237.7
Personnel costs	-26.1	-34.1	-59.5	-68.4	-162.7
Depreciations and write-downs	-2.0	-2.4	-6.8	-5.4	-11.8
Other operating expenses	-	-0.7	-1.4	-0.7	-2.9
Operating profit/loss	-92.9	-62.7	-178.6	-126.4	-312.4
Net financial items	0.5	3.3	1.9	4.1	4.7
Profit/loss after financial items	-92.4	-59.3	-176.7	-122.3	-307.7
Тах	0.1	0.1	-0.5	3.3	12.9
Net profit/loss for the period from continuing operations	-92.3	-59.2	-177.2	-118.9	-294.9
Net profit/loss for the period from discontinued operations	-	19.4	-	38.7	577.7
Net profit/loss for the period	-92.3	-39.8	-177.2	-80.2	282.9
Net profit/loss for the period attributable to:					
Parent Company shareholders	-92.3	-39.8	-177.2	-80.2	282.9
Earnings per share, calculated from the net profit/loss attributable to				-	
Parent Company shareholders during the period					
Earnings per share (SEK per share)					
- Continuing operations, basic earnings	-5.13	-2.20	-3.91	4.14	-10.94
- Continuing operations, diluted earnings	-5.12	-2.20	-3.91	4.11	-10.86
- Discontinued operations, basic earnings	22.62	0.72	-	-	21.44
- Operations discontinuing, diluted earnings	22.58	0.72	-	-	21.27
- Total operations, basic earnings	-3.91	-1.48	-6.57	-2.98	10.50
- Total operations, diluted earnings	-3.90	-1.48	-6.56	-2.98	10.41
Average number of shares, '000	23 637	26 966	26 960	26 941	26 941
Average number of shares after dilution '000	23 685	27 199	27 009	27 180	27 160
Number of shares at period end, '000	20 308	26 966	26 955	26 917	26 917

### **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 62-69 of the 2016 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. The results for the divested operations are stated on a separate line in the Income Statement.

From 1 January 2017, the Income Statement is presented in accordance with the classification by type of cost method. The classified by function method was previously used. The sole effect of the change is a revision of the Income Statement structure. The net profit/loss for the periods presented is not affected. The comparative figures for the Income Statement in the reports in 2017 will be stated in accordance with the new format.

Consolidated Statement of Comprehensive Income		Q2	Q1 - Q2		<u>Full year</u>	
(SEK m)	2017	2016	2017	2016	2016	
Net profit/loss for the period	-92.3	-39.8	-177.2	-80.2	282.9	
Other comprehensive income						
Items that may be reclassified in the Income Statement						
Exchange rate differences	0.2	0.1	0.2	0.1	-1.2	
Total other comprehensive income	0.2	0.1	0.2	0.1	-1.2	
Total comprehensive income for the period	-92.1	-39.7	-176.9	-80.1	281.6	
Total comprehensive income attributable to:						
- Continuing operations	-92.1	-59.1	-176.9	-118.8	-296.1	
- Discontinued operations	-	19.4	-	38.7	577.7	
Total net profit/loss	-92.1	-39.7	-176.9	-80.1	281.6	

Consolidated Balance Sheet, summary	30-jun	30-jun	31-dec
(SEK m)	2017	2016	2016
Assets			
Intangible fixed assets	121.0	386.9	111.9
Tangible fixed assets	17.3	29.4	22.0
Deferred tax receivable	-	-	1.0
Inventories	-	21.5	0.4
Current receivables	57.6	82.3	87.8
Short-term investments	458.4	841.6	1 504.6
Cash and cash equivalents	165.7	155.8	193.8
Total assets	820.0	1 517.7	1 921.5
Shareholders' equity and liabilities			
Shareholders' equity	698.7	1 370.7	1 732.9
Deferred tax liabilities	-	32.6	-
Provisions	29.8	-	30.3
Current liabilities	91.4	114.5	158.3
Total shareholders' equity and liabilities	820.0	1 517.7	1 921.5

Consolidated Statement of Changes in Equity			Exchange		
(SEK m)	Share	Other paid-	rate	Accum.	Total
	capital	in capital	difference	loss	equity
Opening balance, 1 January 2016	157.2	1 761.8	-1.8	-467.1	1 450.1
Total comprehensive income for the period	-	-	0.1	-39.8	-39.7
Share incentive plan: value of employee service	-	0.6	-	-	0.6
Closing balance, 30 June 2016	157.2	1 762.4	-1.7	-547.2	1 370.7
Opening balance, 1 January 2016	157.2	1 761.8	-1.8	-467.1	1 450.1
Total comprehensive income for the period	-	-	-1.2	282.9	281.6
Share incentive plan: value of employee service	-	1.2	-	-	1.2
Closing balance, 31 December 2016	157.2	1 763.1	-3.1	-184.3	1 732.9
Opening balance, 1 January 2017	157.2	1 763.1	-3.1	-184.3	1 732.9
Total comprehensive income for the period	-	-	0.2	-177.2	-176.9
Redemption program	-38.7	38.7	-	-857.0	-857.0
Stock dividend issue	38.7	-38.7	-	-	-
Closing balance, 30 June 2017	157.2	1 763.1	-2.8	-1 218.4	699.0

Consolidated Cash Flow Statement, summary		Q2		Q1 - Q2	
(SEK m)	2017	2016	2017	2016	2016
Cash flow from operating activities before changes in working capital	-99.0	-42.0	-169.4	-91.4	-193.8
Changes in working capital	16.9	4.9	-36.6	17.9	13.7
Cash flow from operating activities	-82.1	-37.1	-206.0	-73.5	-180.1
Investing activities					
Acquisition/sale of fixed assets	-3.0	-5.0	-11.3	-6.8	-107.4
Sale of operations	-	-	-	-	- 908.3
Cash flow from investing activities	-3.0	-5.0	-11.3	-6.8	801.0
Financing activities					
Redemption program	0.5		-857.0		
Cash flow from financing activities	0.5	-	-857.0	-	-
Cash flow for the period	-84.7	-42.0	-1 074.3	-80.3	620.9
Cash and cash equivalents at beginning of period	708.9	1 040.0	1 698.5	1 077.9	1 077.9
Cange in cash and cash equivalents	-	-42.0	-	-80.3	-
Exchange rate difference, liquid assets	-	-0.4	0.0	-0.2	-0.4
Cash and cash equivalents at end of period	624.2	997.5	624.2	997.5	1 698.5
Cash flow attributable to discontinued operations					
Cash flow from operating activities	-	32.6	-	20.0	36.4
Cash flow for the period	-	32.6	_	20.0	36.4

Parent company income statement, summary	q	2	Q1 - Q2		Full year	
(SEK m)	2017	2016	2017	2016	2016	
Net turnover	9.5	43.5	27.3	70.7	131.0	
Other operating income	-0.2	0.6	0.2	3.6	4.5	
Gross profit	9.3	44.1	27.5	74.3	135.4	
Merchandise	0.0	-1.5	-1.7	-1.0	-3.1	
Other external expenses	-74.0	-65.5	-136.7	-118.9	-255.9	
Personnel costs	-26.1	-36.7	-59.5	-73.6	-173.1	
Depreciations and write-downs	-2.0	-2.4	-6.8	-5.4	-11.8	
Other operating expenses	-	-0.7	-1.4	-0.7	-2.9	
Operating profit/loss	-92.8	-62.7	-178.6	-125.2	-311.3	
Profit/loss from participation in Group companies	-	-	-	-	675.5	
Net financial items	0.6	3.4	2.1	4.3	4.0	
Profit/loss after financial items	-92.2	-59.3	-176.5	-120.9	368.2	
Appropriations	-	-	-	-	37.9	
Tax	0.1	0.1	-0.6	-0.1	0.2	
Net profit/loss for the period	-92.1	-59.1	-177.2	-121.0	406.3	

Parent company statement of comprehensive income		Q2	Q1	- Q2	Full year
(SEK m)	2017	2017	2017	2016	2016
Net profit/loss for the period	-92.1	-59.1	-177.2	-121.0	406.3
Other comprehensive income for the period, net after tax	-		-		
Total comprehensive income for the period	-92.1	-177.2	-177.2	-121.0	3.4

Parent company balance sheet, summary	30-jun	30-jun	31-dec
(SEK m)	2017	2016	2016
Assets			
Intangible fixed assets	121.0	17.1	111.9
Tangible fixed assets	17.3	29.3	22.0
Shares in subsidiaries	0.1	604.2	0.1
Inventories	-	2.0	0.4
Receivables on Group companies	22.1	22.5	22.2
Current receivables	56.3	59.2	85.6
Short-term investments	458.4	841.6	1 504.6
Cash and bank balances	157.5	41.9	187.9
Total assets	832.6	1 617.9	1 934.7
Shareholders' equity and liabilities			
Shareholders' equity	695.1	1 202.0	1 729.7
Appropriations	-	37.9	-
Deferred tax liabilities	-	0.4	-
Other provisions	29.8	-	30.3
Liabilities to Group companies	20.7	277.7	21.0
Current liabilities	87.0	99.8	153.6
Total shareholders' equity and liabilities	832.6	1 617.9	1 934.7

Key ratios, share data, options	nare data, options Q2 Q1 - Q2		Full year		
	2017	2016	2017	2016	2016
Return on:					
- shareholders' equity, %	-30.4	-16.8	-29.1	-16.9	-18.5
- capital employed, %	-49.6	-17.1	-29.1	-17.3	-19.3
- total capital, %	-42.3	-15.4	-25.8	-15.6	-17.4
Number of shares at beginning of period, '000	26 966	26 966	26 966	26 966	26 966
Number of shares at period end, '000	20 319	26 966	26 966	26 966	26 966
- of which class A shares	475	606	475	606	606
- of which class B shares	19 881	26 310	19 881	26 310	26 310
- of which repurchased B shares	11	49	11	49	49
Average number of shares, '000	23 637	26 941	26 960	26 941	26 941
Outstanding warrants, '000	49	238	49	238	219
Share capital at period end, SEK m	157.2	157.2	157.2	157.2	157.2
Shareholders' equity at period end, SEK m	698.7	1 370.7	698.7	1 370.7	1 732.9
Earnings per share, SEK					
- Continuing operations, basic earnings	-5.13	-2.11	-10.94	1.18	2.79
- Continuing operations, diluted earnings	-5.12	-2.11	-10.94	1.17	2.76
- Discontinued operations, basic earnings	22.62	0.44	21.43	1.61	-
- Discontinued operations, diluted earnings	22.58	0.43	21.39	1.60	-
- Total operations, basic earnings	-3.91	-1.48	-6.57	-2.98	10.50
- Total operations, diluted earnings	-3.90	-1.48	-6.56	-2.98	10.41
Shareholders' equity per share, SEK	34.41	50.92	25.92	50.92	64.38
Net worth per share, SEK	34.41	50.92	25.92	50.92	64.38
Cash flow per share after investments, SEK	-3.60	-1.56	-8.06	-2.98	23.05
Equity/assets ratio, %	85.2	90.3	85.2	90.3	90.2
EBITDA	-90.9	-60.2	-171.8	-121.0	-300.6
EBIT	-92.9	-62.7	-178.6	-126.4	-312.4

#### **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 tax 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 tax 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 amortization.

**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.

**Return on capital employed.** Profit/loss after financial items plus interest 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 interest 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.