

# MEDIVIR AB – YEAR END REPORT JANUARY – DECEMBER 2018

# Two new projects into clinic

## October – December

## Significant events during the quarter

- The first patient was dosed in the phase II study with birinapant and Keytruda® as combination therapy in colorectal cancer.
- The first patient with advanced cancer in the liver was dosed with the company's drug candidate MIV-818 in a phase la study.
- MIV-828 was selected as a candidate drug for the treatment of acute myeloid leukemia (AML) and other forms of blood cancer.
- Dr Uli Hacksell was appointed new CEO of Medivir.
- A reorganization, with the aim of focusing the internal resources on the company's clinical development projects, was carried out. The organization was reduced from 75 to a total of 17 employees.
- In the quarter Medivir has recorded SEK 38.1 million as restructuring costs.

## **Financial summary**

- Net turnover totaled SEK 13.6 million (4.2 m).
- The loss before interest, tax, depreciation and amortization (EBITDA) totaled SEK -96.6 million (-92.6 m). Basic and diluted earnings per share were SEK -4.72 (-5.08) and -4.72 (-5.08) respectively.
- The cash flow from operating activities amounted to SEK -72.4 million (-88.9 m).

# January - December

#### **Financial summary**

- Net turnover totaled SEK 23.9 million (36.6 m).
- The loss before interest, tax, depreciation and amortization (EBITDA) totaled SEK -326.5 million (-342.6 m). Basic and diluted earnings per share were SEK -14.62 (-16.40) and -14.62 (-16.40) respectively.
- The cash flow from operating activities amounted to SEK -320.5 million (-358.5 m).
- Liquid assets and short-term investments totaled SEK 286,3 million (467.8 m) at the period end.

### Significant events after the quarter

 CFO Erik Björk has decided to leave the company but will remain during a transition period. Process to recruit new CFO has been initiated.

#### Medivir in brief

Medivir develops innovative drugs with a focus on cancer where the unmet medical needs are high. The company is investing in indication areas where available therapies are limited or missing and there are great opportunities to offer significant improvements to patients. Collaborations and partnerships are important parts of Medivir's business model and the drug development as well as the commercialization is conducted either by Medivir or in partnership. Medivir's share (ticker: MVIR) is listed on Nasdaq Stockholm's Small Cap list. <a href="www.medivir.com">www.medivir.com</a>.

## CEO's message

Medivir's reorganization is now complete. We have entered 2019 with a slimmed organization that has a clear focus on the exciting clinical projects

An important event in 2018 was the reorganization that was presented in connection with me becoming CEO on October 15. To ensure that our resources are used where we can create the greatest value, we have concentrated our operations on clinical development. Fundamentally, the measures are based on the positive development of our clinical projects.

Through the redundancies, primarily within research and administration, the organization has been reduced from 75 to a total of 17 employees. The measures will free up resources for Medivir's clinical development projects as they are expected to reduce our cost base by about two thirds.

The most important task for Medivir is to develop and realize the value of our clinical development portfolio, which consists of four programs.

Remetinostat is Medivir's topical HDAC inhibitor being developed for the treatment of mycosis fungoides, the most common form of cutaneous T-cell lymphoma, (MF-CTCL), a form of blood cancer that is primarily manifested in the skin. At the end of the year, we had clarifying and positive discussions with the FDA regarding the design of the phase III program for MF-CTCL. One successful phase III study is expected to be sufficient to enable a marketing approval for the treatment of patients with early stage MF-CTCL. At the same time, there are strict requirements regarding the design of such a study. Medivir is now further developing the phase III design based on the clarifications from the FDA. We intend to seek a partner for the continued development and commercialization of remetinostat.

In our collaboration with Stanford University School of Medicine in California, the first patient was dosed with remetinostat in their investigator-initiated phase II study on patients with basal cell cancer in early August.

**Birinapant** is a SMAC mimetic that is being studied for treatment in combination with MSD's anti-PD-1 treatment Keytruda® (pembrolizumab) in patients with solid tumors. In October, an interim analysis of the phase I study comprising the first 12 patients in the study was presented. The analysis showed a positive safety profile and, in addition, an interesting efficacy signal was noted, since one of the patients with microsatellite-stable (MSS) colorectal cancer, a cancer form in which treatment with Keytruda® alone rarely produces effect, achieved a confirmed partial response (according to RECIST 1.1)

which remained at the last evaluation. The patient remains on treatment more than one year after the start of therapy. Three additional patients have had periods of stable disease lasting up to 18 weeks after the start of treatment.

The inclusion of the first colorectal cancer patient in the phase II part of the study took place just before Christmas.

MIV-818 is Medivir's nucleotide prodrug that is being developed for the treatment of liver cancer. In an ongoing phase I study, four patients have been included. The purpose of this first-in-human study is to study safety, tolerability and pharmacokinetics of MIV-818 in patients with advanced cancer in the liver, a fatal disease with very few available treatment options.

At the end of November, we were able to announce an exciting addition to the development portfolio as **MIV-828** was chosen as a candidate drug for the treatment of acute myeloid leukemia (AML) and other forms of blood cancer.

At the end of the second quarter, we were able to present an acceptable safety and tolerability profile in our phase II extension study with MIV-711, Medivir's cathepsin K inhibitor for the treatment of osteoarthritis. Top-line results, presented at the end of July, showed that treatment with MIV-711 for a total of 12 months resulted in a continuing treatment effect on joint bone area growth and prevention of cartilage degradation. In August, the FDA published new preliminary guidance for the development of disease-modifying treatments for osteoarthritis. The FDA modified its previous approach to structural end-points and the new guidance discuss structural impact as treatment goals in clinical studies and how it could potentially be used for so-called "accelerated approval". Medivir continues to aim to establish a license or collaboration agreement for MIV-711.

The clinical projects have successfully moved forward. This shows that Medivir's research and development has consistently been of high quality. However, to ensure our ability to continue to develop and benefit from the potential that lies in our clinical portfolio, we chose to concentrate our operations and took measures that entailed announcing redundancies and reducing Medivir's preclinical research. Once again, I would like to thank our employees leaving the company for their valuable contribution to Medivir. They have worked loyally, diligently and professionally for Medivir, many for numerous years. We wish those who leave Medivir success in their future pursuits.

Medivir has now been turned into a organization with good ability to work virtually and with high flexibility. We have experience of both drug development and business development.

Medivir's increased focus on clinical development gives us a positive view of the future. I look forward to an exciting 2019.



**Uli Hacksell**President & CEO

# **Development portfolio**

#### **Proprietary Pipeline** Clinical phases Disease area Preclinical Phase I Phase II Phase III Market Project Remetinostat Cutaneous T-cell lymphoma (MF) HDAC inhibitor (topical) Basal cell carcinoma\* Solid tumors, Birinapant $combo \ with \ Keytruda^{TM}$ SMAC mimetic (intravenous) MIV-818. Nucleotide DNA Hepatocellular carcinoma polymerase inhibitor (oral) MIV-711 Osteoarthritis Cathepsin K inhibitor (oral)

### **Partnership Pipeline**

Project	Disease area	Partner	Preclinical	Phase I	Phase II	Phase III	Market
Xerclear	Labial herpes	GSK					
MIV-802, nucleotide NS5B polymerase inhibitor	Hepatitis C	Ascletis (Greater China) Trek Therapeutics (rest of world)					

<sup>\*</sup> Conducted by Stanford University

### Significant events in the development portfolio during the quarter

- The first patient with colorectal cancer was dosed in the phase II study of combination therapy with birinapant and Keytruda®.
- MIV-828 was selected as a candidate drug for the treatment of acute myeloid leukemia (AML) and other forms
  of blood cancer.
- Positive interim data for birinapant in combination with Keytruda® in patients with advanced solid tumors who previously received available approved treatment options were announced in October.
- The first patient was dosed with the company's drug candidate MIV-818 in a phase Ia study in patients with liver cancer. The purpose of this first human study is to study safety, tolerability and pharmacokinetics of MIV-818 in patients with advanced cancer in the liver.

### **Development Portfolio**

• Full descriptions of all Medivir's development projects, including their current status and ongoing studies, can be found on the Medivir website: <a href="http://www.medivir.com/our-projects">http://www.medivir.com/our-projects</a>.

#### PROPRIETARY PROJECTS

Remetinostat - for improved treatment of MF-CTCL. Mycosis fungoides (MF) is the most common type of cutaneous T-cell lymphoma (CTCL). MF-CTCL is a form of blood cancer that primarily presents in the skin. The primary unmet need for patients in the early stages of MF-CTCL is efficacy on skin lesions and relief from the symptom of severe itching.

It is known that orally or intravenously administered HDAC inhibitors are effective treatments against MF-CTCL but the compounds have significant side effects and are therefore used only in late stages of the disease. Remetinostat, an HDAC inhibitor applied to the skin in the form of a gel, is active only on the skin and degrades when it reaches the bloodstream, thereby reducing the risk of side effects. During the quarter, Medivir conducted a clarifying meeting with the FDA on the design of the study for phase III and the project's goal is now to find a commercial partner for the continued development of remetinostat. Remetinostat also has the potential in the treatment of other cancer indications. In an ongoing investigator-initiated study at Stanford University, remetinostat gel is given to patients with basal cell carcinoma.

**Birinapant** – for the treatment of solid tumors. Birinapant is being developed to improve the treatment response and prolong survival in patients with solid tumors where available treatments do not provide sufficient clinical benefit or where the patient no longer has other treatment options.

Medivir is now conducting a phase I / II study of birinapant in combination with Keytruda® to clinically demonstrate the efficacy of birinapant in a combination therapy for patients with treatment-resistant solid tumors. In October, Medivir announced an interim analysis of the results of the first three patient groups incuding 12 patients. No dose-limiting toxicity was observed and one patient had a confirmed partial response, which means a reduction in tumor size by 30% or more. The positive safety profile was confirmed at the completion of the study. In December, the first patient was included in the phase II part of the study, which includes patients with microsatellite-stable colorectal cancer who have failed to respond to any other available therapy. Patients receive treatment with Keytruda<sup>®</sup> and birinapant (22mg / m<sup>2</sup>) as long as the tumor does not grow or serious side effects occur. The goal is to include 28 patients with colorectal cancer in the study and a futility analysis is planned after a maximum of 14 patients.

MIV-818 – for the treatment of liver cancers. MIV-818, our proprietary prodrug of troxacitabine for the treatment of liver cancer is now in clinical development phase. Liver cancer is the third most common cause of cancer-related deaths in the world. Although existing treatments for hepatocellular carcinoma (HCC) can improve survival, benefits of the treatment are often marginal, and mortality remains high. MIV-818 has been designed with the intention of achieving maximum concentration of the active substance in the liver, while keeping the levels of the active substance in the rest of the body down to reduce side effects. In October, Medivir initiated the first clinical study with MIV-818 when the first patient was dosed in a phase Ia study. The primary purpose of this study is to study the safety, tolerability and pharmacokinetics of MIV-818 in patients with advanced cancer in the liver.

**MIV-711** – with potential to be the first disease-modifying drug in osteoarthritis.

Cathepsin K is a protease that breaks down collagen, a protein that plays an important role in the structural integrity of both bone and cartilage tissue. MIV-711 is a cathepsin K inhibitor designed to positively affect the osteoarthritis joint by by improving its bone- and cartilage structures.

Medivir has conducted a phase II study showing positive effects on both bone and cartilage in osteoarthritis patients after only six months of treatment. A further six months of treatment in a phase II extension study demonstrated an acceptable safety and tolerability profile, which was the primary objective of the study. In addition, the patient group treated with 200 mg of MIV-711 for 6 + 6 months retained the response level of the positive signals for self-reported pain as well as other clinical symptoms identified in the initial phase II study. Treatment with MIV-711 for a total of 12 months provided ongoing treatment effects on the joint bone area growth and prevention of cartilage degradation in the affected knee. In October, additional data were presented that showed disease-modifying properties in joint structures in patients with moderate knee arthritis already after 6 months, at the American College of Rheumatology (ACR). Data from the studies support further clinical development of MIV-711 as a disease-modifying drug for osteoarthritis.

Medivir continues to aim to establish a license or collaboration agreement for MIV-711.

MIV-828 - for the treatment of blood cancer. In November, Medivir's proprietary substance MIV-828 was selected as a candidate drug for the treatment of acute myeloid leukemia (AML) and other forms of blood cancer. AML occurs when cells in the bone marrow that are intended to develop into normal white blood cells instead become cancer cells. These cancer cells accumulate in the bone marrow and prevent the development of normal blood cells. Many patients are unable totolerate the treatments that are currently used to treat the disease. Preclinical data indicate that MIV-828 may offer patients with AML and other cancers in the blood a drug with better tolerability and efficacy.

an Investigational New Drug (IND) application for MIV-802 (ASC21) in China during the quarter. This resulted in a milestone payment in accordance with the terms of the agreement, which entitles Medivir to milestone payments at achieved development goals and tiered royalty payments from net sales of products where MIV-802 is included.

#### **PARTNERED PROJECTS**

MIV-802 - a potent, pan-genotypic nucleotide-based inhibitor of the HCV NS5B polymerase. Preclinical data indicate that MIV-802 can be used effectively in combination with other classes of antiviral drugs for the treatment of HCV. Ascletis, which has the exclusive rights to develop, manufacture and commercialize MIV-802 in China, Taiwan, Hong Kong and Macao, submitted

Summary of the Group's figures		Q4		Q1 - Q4	
(SEK m)	2018	2017	2018	2017	
Net turnover	13.6	4.2	23.9	36.6	
Operating profit before depreciation and amortization (EBITDA)	-96.6	-92.6	-326.5	-342.6	
Operating profit (EBIT)	-114.2	-103.6	-351.0	-362.8	
Profit/loss before tax	-114.6	-103.1	-350.5	-359.7	
Basic earnings per share, SEK	-4.72	-5.08	-14.62	-16.40	
Diluted earnings per share, SEK	-4.72	-5.08	-14.62	-16.40	
Net worth per share, SEK	12.67	25.31	12.67	25.31	
Return on equity, %	-125.6	-72.9	-85.3	-32.1	
Cash flow from operating activities	-72.4	-88.9	-320.5	-358.5	
Cash and cash equivalents at period end	286.3	467.8	286.3	467.8	

#### **Revenues**

Net turnover for the period from October – December was SEK 13.6 million (4.2 m) corresponding to a increase of SEK 9.4 million attributable to the milestone payment from Ascletis for the progress on MIV-802.

### **Operating expenses**

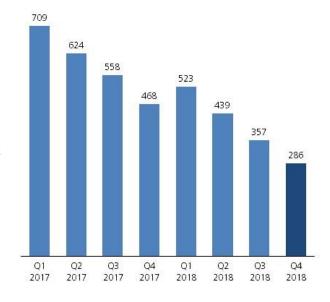
Other external costs totaled SEK -63.3 million (-73.9), corresponding to an decrease of SEK 10.6 million which was mainly from lower cost in the clinical projects.

Personnel costs amounted to SEK -45.8 million (-25.3 m) an increase of 20.5 million and the total expenses was SEK -109.2 million (-99.2 m) an increase of 10.0 million. The increased costs are due to the restructuring costs incurred in the last quarter of 2018

## Operating profit/loss

The operating profit/loss totaled SEK -114.2 million (-103.6 m), SEK 10.6 million worse than previous year due to the restructuring costs.

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



#### Revenues

Net turnover for the period from January – December was SEK 23.9 million (36.6 m) corresponding to a decrease of SEK 12.7 million attributable to the reduction in royalty income from simeprevir.

#### **Operating expenses**

Other external costs totaled SEK -235.1 million (-281.1 m), corresponding to an decrease of SEK 46.0 million which was mainly from lower cost in trhe clinical projects.

Personnel costs amounted to SEK -118.2 million (-104.9 m) and have increased by SEK 13.3 million in comparison with the same period last year due to the reorganization implemented during 2018. The total expenses totaled SEK -353.3 million (-387.7 m).

### **Operating profit/loss**

The operating profit/loss totaled SEK -351.0 million (-362.8 m), corresponding to an improvement of SEK 11.8 million. Despite the costs of restructuring the result för 2018 was an improvement compared to 2017.

#### Cash flow, investments, and financial position

Liquid assets, including short-term investments amounted to SEK 286.3 million (467.8 m) at the end of the period, corresponding to a decrease of SEK 181.5 million. The opening balance 2018 was SEK 467.8 million (1,698.5 m).

Medivir's financial assets are, in accordance with its financial policy, invested in low-risk, interest-bearing securities.

Cash flow from operating activities totaled SEK -320.5 million (-358.5 m), with changes in working capital accounting for SEK -28.0 million (-11.6 m) of this total.

Cash flow from financing activities totaled SEK 144.3 million (-858.6 m) and are mainly derived from the directed share issuance in the first quarter. The period's investments in tangible and intangible fixed assets totaled SEK -5.0 million (-13.5 m).

#### **Employees**

Medivir had 71 (88) employees (FTEs) at the period end, 53% (53%) of whom were women. Out of these employees, there are 54 (12) who have been given notice of termination of employment, but whose employment has not yet been terminated.

During the forth quarter Medivir notifyed the Public Employment Office of potential employee redundancies impacting 60 positions, mainly within pre-clinical research and administration. Notice to the employees happended in the end of the forth. The new organization will contain 17 positions.

## **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 board of directors proposed and the 2017 AGM approved a long term incentive program. The right to subscribe is vested in all of the company's senior executives and other permanent employees of Medivir. The market value was determined using the Black & Scholes valuation model, based on term, strike price, weighted share price during the subscription period (VWAP), riskfree interest rate, and volatility. The subscription price for all outstanding warrants (strike price) per share shall correspond to 133 percent of the volume weighted average rate of the class B share according to the official NASDAQ Stockholm price list during the period.

Medivir employees bought 48 515 warrants during the second quarter 2017 as part of this incentive program. The warrants were issued at a market value of SEK 9.41 each with an exercise price of SEK 89.36 per share. In the fourth quarter 2017, Medivir employees bought an additional 9 320 warrants. These warrants were issued at a market value of SEK 3.98 each with an exercise price of SEK 89.36 per share. The total 57 835 warrants may be exercised to subscribe for new class B shares during the period from 16 December 2020 up to and including 15 January 2021. The valuation calculation for 2017 was based on the following figures: term, 3.66 years; strike price, SEK 89.36; VWAP, SEK 67.19; risk-free interest rate, -0.35 percent; volatility, 32 percent.

In May 2018, the board of directors proposed and the AGM approved a new long term incentive program, in the same manner as 2017. During the second quarter 2018, Medivir employees bought 51 864 warrants at a market value of 5.63 each with an exercise price of SEK 52.75 per share. The warrants may be exercised to subscribe for new class B shares during the period from 16 December 2021 up to and including 15 January 2022. The valuation calculation for 2018 was based on the

following figures: term, 3.66 years; strike price, SEK 52.75; VWAP, SEK 39.66; risk-free interest rate, -0.16 percent; volatility, 32 percent.

## 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 24.9 million (38.5 m).

The operating profit/loss was SEK -351.1million (-362.2 m), corresponding to an improved result of SEK 11.1 million. Combined operating expenses totaled SEK -372.7 million (-401.9 m).

Net financial items totaled SEK 0.9 million (3.4 m), corresponding to a decrease of SEK 2.5 million.

The tax for the period totaled SEK 0 million (-0.6 m). The net profit/loss for the period was SEK -351.2 million (-361.3 m), corresponding to a improvement of SEK 11.1 million.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 275.8 million (458.7 m).

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 totaled SEK 0.1 million (0.2 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 pharmaceutical research and development, all the way up to regulatory market approval, is both high-risk and capital-intensive. The majority of projects initiated will never achieve market authorization. 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 success in developing medicines, to enter into partnerships and to secure funding for its operations, are decisive in terms of the company's future.

A more detailed description of the exposure to risk, and of the ways in which Medivir manages it, is provided in the 2017 Annual Report, see pages 40-41 and in Note 7 on pages 63-65. The Annual Report is available on the company's website: www.medivir.com.

#### **Annual Report**

Medivir's Annual Report is scheduled to be available on the company's website, www.medivir.com, as of the week commencing 9 April 2019.

#### Dividend

The Board of Directors proposes that no dividend be paid for the 2018 financial year.

#### **Annual General Meeting**

The Annual General Meeting will be held at 14.00 (CEST) on 9 May 2019 at the IVA conference centre at Grev Turegatan 16, Stockholm. Shareholders wishing to contact the Nomination Committee may do so by letter addressed to: The Nomination Committee, Medivir AB, PO BOX 1086, SE-141 22 Huddinge, Sweden or by email to: valberedning@medivir.se.

#### Outlook

Medivir's future investments will mainly be in clinical pharmaceutical projects within oncology. With the reorganization of Medivir the cost structure will imrove significantly after summer 2019. It is the view from Board of Directors and management that the current cash is sufficient to complete the ongoing clinical activites.

## For further information, please contact

Uli Hacksell, CEO, +46 (0) 8 5468 3100 Erik Björk, CFO, +46 (0)72-228 2831

#### Conference call for investors, analysts and the media

The Year End report 2018 will be presented by Medivir's President & CEO, Uli Hacksell.

Time: Thursday, February 14 2019, at 15.00 (CET).

Phone numbers for participants from: Sweden + 46 8 505 583 55 Europe + 44 33 3300 9030 US + 1 646 722 4957 The conference call will also be streamed via a link on the website: www.medivir.com

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

#### Financial calendar:

Interim Report (January – March 2019)

May 3, 2019

**Annual General Meeting** 

May 9, 2019

Interim Report (January - June 2019)

August 28, 2019

Interim Report (January – September 2019)

November 27, 2019

### **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, February 14 2019

**Uli Hacksell** *Member of the Board and CEO* 

Anders Hallberg
Member of the Board

**Lennart Hansson** *Member of the Board* 

**Bengt Julander** *Member of the Board* 

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

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

**Bengt Westermark** *Member of the Board* 

This report has not been subject to auditors' review.

The information was submitted for publication, through the agency of the contact persons set out above, at 08.30 (CET) on February 14, 2019.

#### **Accounting principles**

Medivir prepares its Consolidated Accounts in accordance with IFRS, International Financial Reporting Standards, as endorsed by the EU. In addition to the stated IFRS, the Group also observes the Swedish Financial Reporting Board's recommendation, RFR 1 Supplementary Accounting Rules for Groups, and applicable pronouncements from the Swedish Financial Reporting Board. The Group utilizes the acquisition value for Balance Sheet item valuation, unless otherwise indicated. IFRS are under constant development. New standards and interpretations are published on an ongoing basis. Assessments of the impact on Medivir's financial statements due to introduction of new standards and statements are made as appropriate and commented on. Comments are restricted to those changes that have had, or could have, a significant effect on Medivir's accounting.

The revenues in 2018 is related to the royalty from Janssens world wide sales of simeprevir and Glaxo Smith Klines sales of Xerclear in Europe.

The company's management of financial instruments (assets) held at and measured at fair value is described on page 54 and 63-65 in the annual report 2017. There has not been any change in measurement technique and no change in the classification of these assets regarding the fair value hierarchy.

#### New and revised standards

IFRS 15 Revenue from Contracts with Customers, replaces all previously issued standards and interpretations concerning revenues in a unified revenue recognition model. The company has applied the new standard, as of 1 January 2018, and has evaluated IFRS 15 and its effects on the consolidated accounts. The evaluation has shown that no change is needed, other than in the form of additional disclosure requirements, which will be described in more detail in the forthcoming annual report. IFRS 9 Financial Instruments, addresses the recognition of financial assets and liabilities and replaces IAS 39 Financial Instruments:

Recognition and Measurement. The Group has applied the new standard, as of 1 January 2018, and has evaluated IFRS 9 and its effects on the consolidated accounts. The evaluation has shown that IFRS 9 will have no effect on the company's profit/loss and financial position. Additionally, no changes to the Note on financial instruments are expected. From January 2019 IFRS 16 will be applicable and opening balances will show the companies leasing commitments. The numbers will be presented in the annual report.

Consolidated Income Statement, summary	Q4		Q1 - Q4	
(SEK m)	2018	2017	2018	2017
Continuing operations				
Net turnover	13.6	4.2	23.9	36.6
Other operating income	0.0	2.4	5.5	9.9
Total income	13.6	6.6	29.3	46.5
Merchandise	-	-	-	-1.7
Other external expenses	-63.3	-73.9	-235.1	-281.1
Personnel costs	-45.8	-25.3	-118.2	-104.9
Depreciations and write-downs	-17.6	-11.1	-24.5	-20.3
Other operating expenses	-1.0	-	-2.5	-1.4
Operating profit/loss	-114.2	-103.6	-351.0	-362.8
Net financial items	-0.5	0.5	0.6	3.1
Profit/loss after financial items	-114.6	-103.1	-350.5	-359.7
Tax	0.0	0.0	0.2	-0.5
Net profit/loss for the period	-114.6	-103.1	-350.3	-360.2
Net profit/loss for the period attributable to:				
Parent Company shareholders	-114.6	-103.1	-350.3	-360.2
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	-4.72	-5.08	-14.62	-16.40
- Total operations, diluted earnings	-4.72	-5.08	-14.62	-16.40
Average number of shares, '000	24 288	20 308	23 956	21 963
Average number of shares after dilution '000	24 288	20 366	23 956	22 021
Number of shares at period end, '000	24 288	20 308	24 288	20 308

Consolidated Statement of Comprehensive Income		Q4		Q1 - Q4	
(SEK m)	2018	2017	2018	2017	
Net profit/loss for the period	-114.6	-103.1	-350.3	-360.2	
Other comprehensive income					
Exchange rate differences	0.5	-0.5	-0.4	0.0	
Total other comprehensive income	0.5	-0.5	-0.4	0.0	
Total comprehensive income for the period	-114.2	-103.6	-350.8	-360.2	

Consolidated Balance Sheet, summary	31-dec	31-dec
(SEK m)	2018	2017
Assets		
Intangible fixed assets	96.9	112.8
Tangible fixed assets	10.8	14.4
Current receivables	25.4	21.2
Short-term investments	239.1	409.2
Cash and cash equivalents	47.2	58.6
Total assets	419.4	616.2
Shareholders' equity and liabilities		
Shareholders' equity	307.6	514.1
Long-term liabilities	14.8	-
Current liabilities	96.9	102.1
Total shareholders' equity and liabilities	419.4	616.2

Consolidated Statement of Changes in Equity			Exchange			
(SEK m)	Share capital	Other paid- in capital	rate difference	Accum. loss	Total equity	
Opening balance, 1 January 2017	157.2	1 153.4	-3.1	425.4	1 732.9	
Total comprehensive income for the period	-	-	0.0	-360.2	-360.2	
Redemption program	-38.7	-818.8	-	-	-857.5	
Stock dividend issue	39.3	-39.3	-	-	-	
Warrants	-	0.5	-	-	0.5	
Transaction costs	-	-	-	-1.7	-1.7	
Closing balance, 31 December 2017	157.7	295.9	-3.0	63.5	514.1	
Opening balance, 1 January 2018	157.7	295.9	-3.0	63.5	514.1	
Total comprehensive income for the period	-	-	-0.4	-350.3	-350.8	
Share issue	30.8	124.0	-	-	154.8	
Warrants	-	0.3	-	-	0.3	
Transaction costs	-	-	-	-10.8	-10.8	
Closing balance, 31 December 2018	188.5	420.1	-3.5	-297.6	307.6	

Consolidated Cash Flow Statement, summary	Q4	Q4		Q1 - Q4	
(SEK m)	2018	2017	2018	2017	
Cash flow from operating activities before changes in working capital	-57.6	-89.3	-292.5	-346.9	
Changes in working capital	-14.8	0.4	-28.0	-11.6	
Cash flow from operating activities	-72.4	-88.9	-320.5	-358.5	
Investing activities					
Acquisition/sale of fixed assets	1.7	-1.3	-5.0	-13.5	
Cash flow from investing activities	1.7	-1.3	-5.0	-13.5	
Financing activities					
Redemption program	-	-	-	-857.5	
Warrants	-	-	0.3	0.5	
Share issue	-	-	154.8	-	
Transaction costs	-		-10.8	-1.7	
Cash flow from financing activities	-	-	144.3	-858.6	
Cash flow for the period	-70.7	-90.2	-181.2	-1 230.7	
Cash and cash equivalents at beginning of period	357.2	557.8	467.8	1 698.5	
Cange in cash and cash equivalents	-	-	-	-	
Exchange rate difference, liquid assets	-0.2	0.1	-0.3		
Cash and cash equivalents at end of period	286.3	467.8	286.3	467.8	

Parent company income statement, summary	Q4		Q1 - Q4	
(SEK m)	2018	2017	2018	2017
Net turnover	14.6	6.0	24.9	38.5
Other operating income	-1.4	0.1	-3.3	1.2
Total income	13.2	6.1	21.7	39.7
Merchandise	-	-	-	-1.7
Other external expenses	-61.4	-72.1	-227.2	-273.7
Personnel costs	-45.8	-25.3	-118.4	-104.9
Depreciations and write-downs	-17.6	-11.1	-24.5	-20.3
Other operating expenses	-1.0		-2.5	-1.4
Operating profit/loss	-112.6	-102.3	-351.1	-362.2
Profit/loss from participation in Group companies	-1.1	-1.9	-1.1	-1.9
Net financial items	-0.4	0.6	0.9	3.4
Profit/loss after financial items	-114.1	-103.7	-351.2	-360.7
Тах	0.0	0.0	0.0	-0.6
Net profit/loss for the period (=comprehensive income)	-114.1	-103.7	-351.2	-361.3

Parent company balance sheet, summary	31-dec	31-dec
(SEK m)	2018	2017
Assets		
Intangible fixed assets	96.9	112.7
Tangible fixed assets	10.8	14.4
Shares in subsidiaries	0.1	0.1
Financial fixed assets	-	-1.9
Deferred tax receivable	-	-
Inventories	-	-
Receivables on Group companies	23.3	24.3
Current receivables	23.5	21.4
Short-term investments	239.1	409.2
Cash and bank balances	36.7	49.4
Total assets	430.4	629.7
Shareholders' equity and liabilities		
Shareholders' equity	301.5	509.3
Appropriations	-	-
Deferred tax liabilities	-	-
Provisions	-	7.1
Long-term liabilities	14.8	-
Liabilities to Group companies	21.3	22.8
Current liabilities	92.8	90.6
Total shareholders' equity and liabilities	430.4	629.7

Key ratios, share data, options	, share data, options Q4		Q1 - Q4	
	2018	2017	2018	2017
Return on:				
- shareholders' equity, %	-125.6	-72.9	-85.3	-32.1
- capital employed, %	-125.6	-73.0	-85.3	-32.0
- total capital, %	-99.3	-61.3	-67.7	-28.3
Number of shares at beginning of period, '000	24 288	20 319	20 319	26 966
Number of shares at period end, '000	24 288	20 319	24 288	20 319
- of which class A shares	-	475	-	475
- of which class B shares	24 288	19 833	24 288	19 833
- of which repurchased B shares	-	11	-	11
Average number of shares, '000	24 288	20 308	23 956	21 963
Outstanding warrants, '000	110	58	110	58
Share capital at period end, SEK m	188.5	157.7	188.5	157.7
Shareholders' equity at period end, SEK m	307.6	514.1	307.6	514.1
Earnings per share, SEK				
- Total operations, basic earnings	-4.72	-5.08	-14.62	-16.40
- Total operations, diluted earnings	-4.72	-5.08	-14.62	-16.40
Shareholders' equity per share, SEK	12.67	25.31	12.67	25.31
Net worth per share, SEK	12.67	25.31	12.67	25.31
Cash flow per share after investments, SEK	-2.91	-4.44	-13.59	-16.94
Equity/assets ratio, %	73.4	83.4	73.4	83.4
EBITDA	-96.6	-92.6	-326.5	-342.6
EBIT	-114.2	-103.6	-351.0	-362.8

## **Key ratio definitions**

Average number of shares. The unweighted average number of shares during the period.

**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 amortization)**. Operating profit/loss before depreciation and amortization.

**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.