

## Interim Report, January – June 2014

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## Conference call for investors, analysts and the media

The Interim Report for the second quarter of 2014 will be presented by Medivir's CEO, Maris Hartmanis, and members of the management group.

Time: Thursday, 21 August 2014 at 14.00 (CET).

### Phone numbers for participants from:

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The conference call will also be streamed via a link on the website: www.medivir.com

## **Financial calendar**

The Interim Report for January-September will be published on 20 November 2014.

## Interim Report, January – June 2014\*

#### Financial summary for the second quarter

- Net turnover totalled SEK 564.0 million (SEK 40.7 m), of which SEK 500.7 million was contributed by royalties for simeprevir. Revenues from Medivir's own pharmaceutical sales totalled SEK 62.9 million, SEK 21.7 million of which derived from sales of Olysio and SEK 41.2 million from sales of other pharmaceuticals. The profit/loss after tax was SEK 327.8 million (SEK -63.7 m).
- Basic and diluted earnings per share totalled SEK 10.49 (SEK -2.04) and SEK 10.28 (SEK -2.04), respectively.
- The cash flow from operating activities amounted to SEK 88.7 million (SEK -8.3 m), while liquid assets and short-term investments totalled SEK 430.4 million (SEK 279.9 m) at the period end.

## Financial summary for the first six months of the year

- Net turnover totalled SEK 772.2 million (SEK 218.8 m), of which SEK 662.4 million was contributed by royalties for simeprevir. Revenues from Medivir's own pharmaceutical sales totalled SEK 109.2 million, SEK 21.7 million of which derived from sales of Olysio and SEK 87.5 million from sales of other pharmaceuticals. The profit/loss after tax was SEK 611.7 million (SEK 7.5 m).
- Basic and diluted earnings per share totalled SEK 19.57 (SEK 0.24) and SEK 19.18 (SEK 0.24), respectively.
- The cash flow from operating activities amounted to SEK 31.0 million (SEK -27.2 m), while liquid assets and short-term investments totalled SEK 430.4 million (SEK 279.9 m) at the period end.

Commence of the Commence of th		Q2	Q1-Q2		Full year	
Summary of the Group's figures, continuing operations (SEK m)	2014	2013	2014	2013	2013	
Net turnover	564.0	40.7	772.2	218.8	446.1	
Gross profit	518.8	23.5	700.9	183.8	374.3	
Operating profit before depreciation and amortisation (EBITDA)	424.4	-46.9	521.2	43.6	76.4	
Operating profit (EBIT)	416.2	-62.0	504.9	14.7	25.2	
Profit/loss before tax	418.4	-62.1	508.7	14.5	27.7	
Profit/loss after tax	327.8	-63.7	611.7	7.5	16.0	
Operating margin, %	0.7	-152.3	0.7	6.7	5.6	
Basic earnings per share, SEK	10.5	-2.04	19.6	0.24	0.51	
Diluted earnings per share, SEK	10.3	-2.04	19.2	0.24	0.51	
Cash flow from operating activities	88.7	-8.3	31.0	-27.2	43.0	
Liquid assets and short-term investments at the period end	430.4	279.9	430.4	279.9	402.2	

## Significant events during Q2

- Olysio (simeprevir) was approved within the EU for the treatment of adults with hepatitis C genotype 1 and 4 infection, and was launched by Medivir in Sweden, Denmark, Norway and Finland.
- Adasuve was launched in Sweden, Norway, Finland and Denmark.
- Suscard was re-launched into the Swedish market.
- A supplemental New Drug Application for simeprevir in combination with sofosbuvir was submitted to the US FDA.
- Final phase II COSMOS study data of simeprevir in combination with sofosbuvir was presented at EASL.
- Two phase III trials evaluating combination treatment with simeprevir and sofosbuvir were initiated.
- A new Board of Directors was elected at Medivir's Annual General Meeting and Birgitta Stymne Göransson was elected Chairman of the Board.

## Significant events after the end of Q2

- U.S. FDA granted Priority Review for simeprevir in combination with sofosbuvir supplementary New Drug Application.
- Respiratory Syncytial Virus drug program was licensed from Boehringer Ingelheim.
- Medivir's Board of Directors has appointed Niklas Prager as new President and CEO of Medivir effective 1 September 2014.

<sup>\*</sup> All figures refer to the Group, unless otherwise stated. Comparisons in the Interim Report are, unless otherwise stated, with the corresponding period in 2013. Cross Pharma was divested from the Group on 30 June 2013.

## The CEO's comments on Q2 2014

# Medivir launched Olysio (simeprevir) in the Nordic region and received SEK 500.7 million in royalty income

We can now look back on a very successful quarter, both in terms of revenues and of results and activities. Medivir's royalty income for the period from the global sales of simeprevir totalled SEK 500.7 million, demonstrating the continued strong growth in Janssen's sales of simeprevir during the second quarter.

The period saw our most important market launch to date with the launch of simeprevir, which is marketed under the name of Olysio in the Nordic region. In May, the European Commission granted marketing approval for the pharmaceutical for the treatment of adult patients with chronic hepatitis C, and physicians in all of the Nordic countries have since begun prescribing Olysio, primarily as an interferon- and ribavirin-free combination treatment with Sovaldi (sofosbuvir).

The marketing authorisation in Europe is an important milestone in our history and it provides clear confirmation of Medivir's successful research and technological platform on which to base our development of protease inhibitors. It also provides proof that Medivir has the ability to collaborate successfully with global pharmaceutical partners, which is a key prerequisite if we are to achieve sustainable profitability. Revenues from our Nordic pharmaceutical sales totalled SEK 62.9 million, SEK 21.7 million of which derived from sales of Olysio and SEK 41.2 million from sales of other pharmaceuticals. Sales of other pharmaceuticals continued stable in relation to the comparison quarter.

Our partner, Janssen, initiated two interferon-free phase III trials in April, in order to continue its development of interferon-free treatments for hepatitis C. These trials will treat patients with a combination of simeprevir and sofosbuvir for 8 or 12 weeks. Janssen also submitted a supplementary New Drug Application for simeprevir in combination with sofosbuvir to the US FDA. The application is based on data from the phase II study, COSMOS, and it is an important component of the efforts to enhance simeprevir's competitiveness in the US market.

The past quarter also saw the launch in the Nordic region of the new pharmaceutical, Adasuve, for the treatment of agitation in patients with schizophrenia or bipolar disorder. Adasuve is the first inhalable treatment for agitation. We also re-launched Suscard in the Swedish market. Suscard is a pharmaceutical for the treatment of angina pectoris – one of the Western World's most common cardiac diseases. The pharmaceutical has been unavailable in Sweden for the past two years, during which time demand for the treatment from patients and physicians alike has been substantial.

The addition of innovative specialist pharmaceuticals to the Nordic product portfolio is part of Medivir's commercial strategy, and the launches of Olysio and Adasuve are important steps in this direction.

Medivir's in-house research and development projects involving cathepsin K and S and the nucleotide project are continuing to progress according to plan and we are continuously evaluating potential partnership strategies. We strengthened our R&D portfolio in August when we licensed a Respiratory Syncytial Virus drug program from Boehringer Ingelheim. Under the terms of the agreement Medivir receives an exclusive, global license to research, develop, manufacture and commercialise future RSV drugs.

On 1 September, I will be handing the baton on to Niklas Prager. I am proud of what we have achieved together at Medivir during my time as the Group's President & CEO, and I wish Niklas and all of his colleagues every success with what I am sure will be their continued successful development of the company.

Maris Hartmanis President & CEO

## Significant events during the financial period

### New clinical simeprevir data presented at EASL in London (9-13 April)

Final results from cohort 2 of the phase II COSMOS study were presented at the International Liver Congress™ 2014 of the European Association for the Study of the Liver (EASL). All patients in this cohort had genotype 1 hepatitis C and advanced liver fibrosis (METAVIR scores of F3 and F4). The results demonstrated that 93 per cent of the patients treated with simeprevir and sofosbuvir for 12 weeks were cured, i.e. were virus-free 12 weeks after the end of treatment (achieved SVR12; sustained virologic response). The addition of ribavirin did not improve SVR rates.

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COSMOS: SVR12* among patient su	ibgroups with genotype 1 HCV and ad	vanced liver fibrosis/cirrhosis
		T
	simeprevir/sofosbuvir	simeprevir/sofosbuvir + ribavirin
	% (n/N)	% (n/N)
Overall	93 (13/14)	93 (25/27)
Genotype 1a HCV without the Q80K		
polymorphism	88 (7/8)	93 (13/14)
Genotype 1a HCV with the Q80K		
polymorphism	100 (3/3)	88 (7/8)
Genotype 1b HCV	100 (3/3)	100 (5/5)
Patients with cirrhosis (METAVIR score: F4)	86 (6/7)	91 (10/11)

<sup>\*</sup>Excluding non-virologic failures.

Results from the phase III RESTORE trial of simeprevir in combination with pegylated interferon and ribavirin in HCV genotype 4 patients were also presented at EASL. 83 per cent of the treatment-naïve patients and 40-86 per cent of prior relapsers or prior null responders were cured (achieved SVR12).

## Two phase III combination trials with simeprevir and sofosbuvir initiated

Two phase III trials in which simeprevir is administered in combination with sofosbuvir for the treatment of chronic genotype 1 hepatitis C virus patients, with and without cirrhosis, were initiated in April. The trials are based on the promising results of the phase II COSMOS study.

OPTIMIST-1 is an open-label, randomised study investigating the efficacy and safety of simeprevir 150 mg in combination with sofosbuvir 400 mg. The study has enrolled approximately 300 patients with chronic genotype 1 HCV without cirrhosis. The treatment will be administered once daily for 8 or 12 weeks.

OPTIMIST-2 is an open-label, single arm study investigating the efficacy and safety of simeprevir 150 mg in combination with sofosbuvir 400 mg. The study has enrolled 103 patients with genotype 1 HCV with cirrhosis. The treatment will be administered once daily for 12 weeks.

### Supplemental New Drug Application (sNDA) for simeprevir in combination with sofosbuvir submitted to FDA

Simeprevir is currently approved in the USA as a component of a combination antiviral treatment regimen for patients with chronic HCV. The clinical antiviral activity of simeprevir has primarily been studied in combination with peginterferon alfa and ribavirin in HCV genotype 1-infected patients with compensated liver disease, including cirrhosis.

The supplemental application now submitted to the US FDA is in respect of interferon-free oral combination treatment with simeprevir and sofosbuvir and is supported by data from the phase II COSMOS study. This study showed that the combination of these two agents resulted in high SVR12 rates in treatment-naïve patients with advanced liver fibrosis (METAVIR scores of F3 to F4) and prior null responders with all stages of liver fibrosis (METAVIR scores of F0 to F4).

#### Olysio approved in the EU for the treatment of adult patients with hepatitis C

Olysio was granted marketing authorisation by the European Commission in May for the treatment of adult patients with genotype 1 and 4 chronic hepatitis C in combination with other medicinal products. The marketing authorisation also includes Olysio as part of an all oral 12-week interferon-free treatment in combination with sofosbuvir, with or without ribavirin (RBV), in genotype 1 or 4 HCV patients who are intolerant to, or ineligible for, interferon treatment.

#### Olysio made available in all Nordic countries for the treatment of adults with hepatitis C

The first patients in Sweden began to be treated with Olysio at the end of May, attracting widespread media coverage not only of Medivir, but of Olysio and of new treatment options for hepatitis C. Treatment with Olysio also began in Finland, Denmark and Norway in June, and Nordic sales of Olysio during the quarter totalled SEK 21.7 million.

## Adasuve launched in the Nordic region

April saw the launch of Adasuve in the Nordic region as a result of a license and distribution agreement for the commercialisation of Adasuve between Medivir and the Spanish pharmaceutical company, Ferrer. Adasuve is a new treatment for agitation in conjunction with schizophrenia or bipolar disorder. It is the first inhalable drug in psychiatry and is an attractive alternative to injection-based treatment, in that it is a non-invasive form of treatment and hence offers benefits for both patients and care-givers. Medivir's aim is to continue adding innovative specialist pharmaceuticals to its product portfolio.

## Significant events after the end of the financial period

## Continued strong market uptake for simeprevir on the global market

The global net sales of simeprevir in the second quarter amounted to USD 831 million, of which USD 725 million were sales in the USA. Medivir's royalties based on sales for the second quarter amounted to SEK 500.7 million (EUR 54.4 m).

# U.S. FDA has granted Priority Review for simeprevir in combination with sofosbuvir supplementary New Drug Application

The Food and Drug Administration (FDA) has assigned a Priority Review designation to the supplemental New Drug Application (sNDA) filed in May by Medivir's partner Janssen. The application relates to the use of simeprevir in combination with sofosbuvir for 12 weeks treatment of adult patients with genotype 1 chronic hepatitis C. The regulatory submission is supported by data from the phase II COSMOS study.

## Medivir licenses Respiratory Syncytial Virus drug program from Boehringer Ingelheim

Medivir entered a license agreement with Boehringer Ingelheim International GmbH for exclusive, global rights to a drug program for the treatment and prevention of Respiratory Syncytial Virus (RSV) infection. The program includes novel compounds that inhibit the RSV fusion protein, which is a target for new medicines.

## Niklas Prager appointed new President and CEO of Medivir

Medivir's Board of Directors has appointed Niklas Prager as new President and CEO of Medivir AB effective 1 September 2014. He will succeed Maris Hartmanis who, as previously announced, leaves the position of President and CEO of Medivir. Niklas Prager holds a Degree of Master of Science in Business Administration and Economics

from the Stockholm School of Economics, and has held a variety of different positions, mainly in the pharmaceutical industry, throughout his career. Niklas has long experience from both high-growth research- and technology-based companies as well as major international pharmaceutical companies. Niklas is thoroughly familiar with Medivir's operations, having earlier served as Chairman of the Board of BioPhausia, and as a member of the Board of Medivir since May 2014. As Niklas Prager takes up the position of CEO of Medivir he will be leaving the company's Board of Directors.

## **Project portfolio**

Medivir is a research-based pharmaceutical company. The research portfolio currently comprises four antiviral projects and projects in such areas as bone-related disorders and neuropathic pain. The projects are based on Medivir's expertise in the discovery and development of polymerase and protease inhibitors.

Medivir will continue to identify partners and to enter into future partnership agreements for product development, but it intends to retain commercial rights for its projects in the Nordic region. In parallel with our inhouse research projects Medivir will identify potential new opportunities for project development through acquisitions or licensing.

The company's project portfolio is summarised in the chart below. Ongoing projects in the early research phase, e.g. in the areas of cancer and antimicrobial therapy are not included here. For additional information, please visit the company's website at <a href="https://www.medivir.com">www.medivir.com</a>

	Product/Project	Partner	Preclinical phase		Clinical phase				
Therapeutic area			Research	Develop- ment	Phase I	Phase IIa	Phase IIb	Phase III	Market
Labial herpes	Xerclear®	GlaxoSmithKline							
HCV infection	Olysio® (simeprevir)	Janssen							
Bone-related disorders	MIV-711 Cathepsin K inhibitor								
HCV infection	HCV nucleotide NS5B polymerase inhibitor	Janssen							
Neuropathic pain	MIV-247 Cathepsin S inhibitor								
HCV infection	HCV nucleotide NS5B polymerase inhibitor								
RSV	RSV fusion protein inhibitor								
HIV infection	HIV protease inhibitor	Janssen							

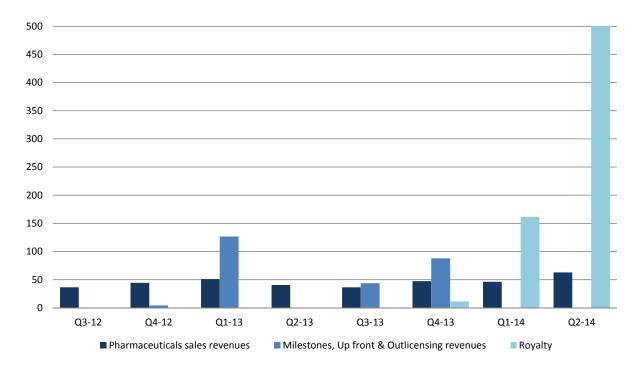
## Consolidated results and financial position\*

## Revenues and results, April – June 2014

Net turnover totalled SEK 564.0 million (SEK 40.7 m), corresponding to an increase of SEK 523.3 million. Royalty income totalled SEK 501.1 million (SEK 0.0 m), with royalties from Janssen's global sales of simeprevir amounting to SEK 500.7 million (SEK 0.0 m). Revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 62.9 million, SEK 21.7 million of which derived from sales of Olysio and SEK 41.2 million from sales of other pharmaceuticals. Sales of other pharmaceuticals remained on a par with those in the preceding period.

Descriptions of mat town over (CEV m)		Q2		Q1-Q2	
Breakdown of net turnover (SEK m)	2014	2013	2014	2013	2013
Outlicensing and partnership agreements					
Non-recurrent payments	-	-	-	126.8	258.5
Pharmaceutical sales	62.9	40.7	109.2	92	176.1
Royalties	501.1	-	662.8	-	11.5
Total	564.0	40.7	772.0	218.8	446.1

#### Net turnover, continuing operations, Q3 2012 - Q2 2014



The cost of goods sold was SEK -45.2 million (SEK -17.2 m), corresponding to an increase of SEK 28.0 million and due, primarily, to higher royalty costs for simeprevir. The gross profit amounted to SEK 518.8 million (SEK 23.5 m), corresponding to an increase of SEK 495.3 million and equating to a gross margin of 92 per cent (58%).

<sup>\*</sup>All figures refer to the Group, unless otherwise stated. Comparisons in the Interim Report are, unless otherwise stated, with the corresponding period in 2013. Cross Pharma was divested from the Group on 30 June 2013.

Selling expenses increased by SEK 8.2 million, primarily due to the establishment of a Nordic organisation to handle the market launch of Olysio and Adasuve. Administrative expenses increased by SEK 1.9 million. Research and development costs increased by SEK 7.8 million, primarily as a result of higher costs in connection with the cathepsin K and S research and development projects and the internal HCV nucleotide project. Other operating income/expenses increased by SEK 0.8 million. Overall, operating costs totalled SEK -102.6 million (SEK -85.5 m), corresponding to an increase of SEK 17.1 million.

The operating profit/loss totalled SEK 416.2 million (SEK -62.0 m), corresponding to an increase of SEK 478.2 million.

Net financial items totalled SEK 2.2 million (SEK -0.1 m), corresponding to an increase of SEK 2.3 million.

The tax cost for the period amounted to SEK -90.6 million (SEK -1.6 m). The estimated tax on the consolidated profit/loss for the period, including a reduction in the deferred tax receivable, totals SEK -92.1 million.

The profit/loss for the period from the continuing operations was SEK 327.8 million (SEK -63.7 m), corresponding to an increase of SEK 391.5 million.

Basic and diluted earnings per share from continuing operations amounted to SEK 10.49 (SEK -2.04) and SEK 10.28 (SEK -2.04), respectively.

## Revenues and results, January - June 2014

Net turnover totalled SEK 772.0 million (SEK 218.8 m), corresponding to an increase of SEK 553.2 million. Royalty income totalled SEK 662.8 million (SEK 0.0 m), with royalties from Janssen's global sales of simeprevir amounting to SEK 662.4 million (SEK 0.0 m). Revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 109.2 million, SEK 21.7 million of which derived from sales of Olysio and SEK 87.5 million from sales of other pharmaceuticals. Sales of other pharmaceuticals fell by SEK 4.5 million, primarily due to a fall in Mollipect unit sales resulting from a weak influenza and common cold season.

Non-recurrent payments from outlicensing and partnership agreements totalled SEK 126.8 million during the corresponding period last year and referred to the registration application for simeprevir in Japan (EUR 5 million) and the USA (EUR 10 million).

The cost of goods sold was SEK -71.3 million (SEK -35.1 m), corresponding to an increase of SEK 36.2 million and due, primarily, to higher royalty costs for simeprevir. The gross profit amounted to SEK 700.9 million (SEK 183.8 m), corresponding to an increase of SEK 517.1 million and equating to a gross margin of 91 per cent (84%).

Selling expenses increased by SEK 18.8 million, primarily due to the establishment of the Nordic organisation to handle the market launch of Olysio and Adasuve. Administrative expenses increased by SEK 5.2 million due to higher non-recurrent staff overheads. Research and development costs increased by SEK 4.5 million, primarily as a result of higher costs in connection with the cathepsin K and S research and development projects and the internal HCV nucleotide project. Other operating income/expenses increased by SEK 1.6 million. Overall, operating costs totalled SEK -196.0 million (SEK -169.1 m), corresponding to an increase of SEK 26.9 million.

The operating profit/loss totalled SEK 504.9 million (SEK 14.7 m), corresponding to an increase of SEK 490.2 million.

Net financial items totalled SEK 3.8 million (SEK -0.2 m), corresponding to an increase of SEK 4.0 million.

A renewed assessment of Medivir AB's fiscal loss carry forward entailed a reported tax income of SEK 213.4 million, corresponding to a capitalisation of the entire loss carry forward related to the company as of 31

December 2013. The estimated tax on the consolidated profit/loss for the period, including a reduction in the deferred tax receivable, totals SEK -110.3 million.

The profit/loss for the period from the continuing operations was SEK 611.7 million (SEK 7.5 m), corresponding to an increase of SEK 604.2 million. Basic and diluted earnings per share from continuing operations amounted to SEK 19.57 (SEK 0.24) and SEK 19.18 (SEK 0.24), respectively.

## **Discontinued operations, Parallel Imports segment**

The Parallel Imports segment was divested on 30 June 2013 and the segment has consequently reported no net turnover or profit/loss during the period. Organisationally, parallel imports had been a discrete segment prior to the sale.

For details of the divestment, see the 2013 Annual Report.

Darallal Imparts Cogmont	C	(1	Q1-0	Full year	
Parallel Imports Segment	2014	2013	2014	2013	2013
Net turnover	-	108.5	-	213	213.0
EBITDA	-	3.7	-	8.2	8.2
EBITDA %	-	3.4	-	3.8	3.8

## Cash flow and financial position, January - June 2014

Liquid assets, including short-term investments with a maximum term of 3 months, amounted to SEK 402.2 million (SEK 296.7 m) at the beginning of 2014, and to SEK 430.4 million (SEK 279.9 m) at the end of the period, corresponding to a change of SEK 28.2 million (SEK -16.8 m). Pledged assets at the end of the period totalled SEK 54.3 million (SEK 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 31.0 million (SEK -27.2 m), with changes in working capital accounting for SEK -18.7 million (SEK -24.2 m).

Cash flow from investing activities totalled SEK -2.8 million (SEK 44.2 m), of which part of the purchase price from the sale of Cross Pharma comprised SEK 5.0 million and investments in research and office equipment and in systems comprised SEK -7.8 million (SEK -0.2 m). The figure for the corresponding period last year primarily comprised the sale of Cross Pharma.

Cash flow from financing activities totalled SEK 0.0 million (SEK -33.7 m).

## Investments, depreciation and amortisation, January – June 2014

Investments in tangible fixed assets during the period amounted to SEK 5.2 million (SEK 0.8 m) and comprised research and office equipment. Investments in intangible fixed assets during the period totalled SEK 0.7 million (SEK 0.0 m) and comprised capitalised development expenses for IT-systems. Depreciation of tangible fixed assets totalling SEK -5.0 million (SEK -5.1 m) were charged to the profit/loss for the period. Write-downs of intangible fixed assets of SEK -11.3 million (SEK -10.9 m) were charged to the profit/loss for the period.

## **Employees**

Medivir had 142 (105) employees at the period end, 57 per cent (58%) of whom were women. The increase is primarily due to the establishment of the Nordic marketing and sales organisation.

## **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 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 inlicensed from other companies and for which royalty is payable. The combined royalty costs for the period were SEK 35.0 million (SEK 6.4 m).

## The Parent Company in brief, January – June 2014

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 700.9 million (SEK 126.9 m), corresponding to an increase of SEK 574.0 million. Royalty income from Janssen's global sales of simeprevir totalled SEK 662.4 million (SEK 0.0 m). Revenues from Medivir's own sales of pharmaceuticals in the Nordic region totalled SEK 21.8 million (SEK 0.0 m), SEK 21.7 million of which comprised sales of Olysio. Intra-Group sales amounted to SEK 16.2 million (SEK 18.9 m). Non-recurrent payments of SEK 126.8 million were included in the net turnover for the corresponding period last year.

The gross profit amounted to SEK 648.6 million (SEK 126.1 m), corresponding to an increase of SEK 522.5 million.

The combined operating expenses totalled SEK -168.8 million (SEK -140.5 m), corresponding to an increase of SEK 28.3 million. Selling expenses increased by SEK 20.2 million and primarily related to the establishment of a Nordic organisation to handle the market launch of Olysio and Adasuve. Other operating income/expenses fell by SEK 11.7 million. Onward invoicing of costs and services to Group companies was included under other operating income/expenses during the corresponding period last year.

The operating profit/loss was SEK 479.8 million (SEK -14.4 m), corresponding to an increase of SEK 494.2 million. Net financial items totalled SEK 3.3 million (SEK 120.7 m), corresponding to a decrease of SEK 117.4 million. Dividends of SEK 120 million from subsidiaries were included in the net financial items during the corresponding period last year.

The tax for the period totalled SEK 107 million (SEK 0.0 m). A renewed assessment of the accumulated fiscal loss carry forward entailed a reported tax income of SEK 213.2 million, corresponding to a capitalisation of the entire loss carry forward related to Medivir AB, as of 31 December 2013. The estimated tax for the period, including a reduction in the deferred tax receivable, totals SEK -106.3 million.

The profit/loss for the period was SEK 590.1 million (SEK 106.3 m), corresponding to an increase of SEK 483.8 million.

The cash flow from operating activities totalled SEK 12.7 million (SEK -5.5 m), with changes in working capital accounting for SEK -0.9 million (SEK -2.2 m).

The cash flow from investing activities totalled SEK 27.2 million (SEK 0.5 m). Investments in tangible and intangible fixed assets totalled SEK -7.8 million (SEK 0.5 m) and comprised investments in research and office equipment and in IT-systems. Recovery of loans to subsidiaries totalled SEK 35.0 million during the period.

Liquid assets, including short-term investments with a maximum term of 3 months, amounted to SEK 420.3 million (SEK 266.4 m).

Please see the section entitled "Consolidated results and financial position" for further comments on the operations.

#### **Outlook**

Medivir is a Nordic research-based pharmaceutical company. Its goal is to become a high-growth pharmaceutical company with sustainable profitability. Medivir is working resolutely and strategically to generate the best possible prospects for developing the company quickly while also balancing risks. The company has a solid financial position.

Marketing approval for simeprevir in the EU was received in May 2014, in Russia in March 2014, in Japan in September 2013, and in the USA and Canada in November 2013. A number of combination studies of simeprevir are also being conducted under the aegis of Janssen with the aim of developing interferon-free treatments for hepatitis C. Medivir has several attractive in-house projects in the development phase as well as a number of earlier discovery projects. These factors, coupled with Medivir's ambition to identify new business opportunities in the Nordic region, form the basis of our ongoing efforts to develop Medivir towards sustainable profitability.

## Share structure, earnings per share, and shareholders' equity

The total share capital at the period end was SEK 156.3 million (SEK 156.3 m) and the total shareholders' equity, SEK 1,464.7 million (SEK 843.7 m). There were a total of 31,260,027 (31,260,027) shares in Medivir AB at the period end, 660,000 (660,000) of which were class A shares and 30,600,027 (30,600,027) of which were class B shares with a nominal value of SEK 5. The average number of shares during the period was 31,260,027 (31,260,027).

## Share structure, 30 June 2014

Share class	Number of shares	Number of votes	% of capital	% of votes	Shares after full exercise of options
A, 10 votes	660 000	6 600 000	2.10%	17.70%	660 000
B, 1 vote	30 600 027	30 600 027	97.90%	82.30%	31 239 318
Total	31 260 027	37 200 027	100.00%	100.00%	31 899 318

Basic and diluted earnings per share for the continuing operations, based on a weighted average number of outstanding share warrants, amounted to SEK 19.57 (SEK 0.24) and SEK 19.18 (SEK 0.24), respectively. Shareholders' equity per share totalled SEK 46.9 (SEK 27.0). The equity/assets ratio was 90.2 per cent (85.6%).

## **Shareholders**

On 30 June 2014, Medivir AB had 12,365 shareholders. The table below shows Medivir's shareholders registered by Euroclear Sweden AB on that date.

Name	Class A shares	Class B shares	% of votes	% of capital
Bo Öberg	284 000	262 475	8.34%	1.75%
Nils Gunnar Johansson	284 000	66 575	7.81%	1.12%
Staffan Rasjö	0	1 730 516	4.65%	5.54%
AFA Försäkring	0	1 636 729	4.40%	5.24%
Catella Fondförvaltning	0	1 205 607	3.24%	3.86%
UNIONEN	0	1 204 200	3.24%	3.85%
Nordea Investment Funds	0	1 146 907	3.08%	3.67%
Avanza Pension	0	1 052 347	2.83%	3.37%
Christer Sahlberg	92 000	27 881	2.55%	0.38%
Gladiator	0	700 000	1.88%	2.24%
Skandia Fonder	0	689 210	1.85%	2.20%
Tredje AP-fonden	0	626 044	1.68%	2.00%
Danica Pension	0	601 274	1.62%	1.92%
Handelsbanken Fonder	0	547 879	1.47%	1.75%
JPM Chase NA	0	515 119	1.38%	1.65%
Total, 15 largest shareholders	660 000	12 012 763	50.04%	40.54%
Total, other shareholders		18 587 264	49.96%	59.46%
TOTAL	660 000	30 600 027	100%	100%

## Consolidated Income Statement, summary (SEK m)

	C	(2	Q1-Q2		Full year
	2014	2013	2014	2013	2013
Continuing operations					
Net turnover	564.0	40.7	772.2	218.8	446.1
Cost of goods sold	-45.2	-17.2	-71.3	-35.1	-71.8
Gross profit	518.8	23.5	700.9	183.8	374.3
Selling expenses	-26.0	-17.8	-49.4	-30.6	-70.4
Administrative expenses	-13.8	-11.9	-31.8	-26.6	-51.9
Research and development costs	-64.4	-56.6	-116.5	-112.0	-229.4
Other operating income/expenses	1.6	0.8	1.7	0.1	2.6
Operating profit/loss	416.2	-62.0	504.9	14.7	25.2
Net financial items	2.2	-0.1	3.8	-0.2	2.6
Profit/loss after financial items	418.4	-62.1	508.7	14.5	27.7
Tax	-90.6	-1.6	103.0	-7.1	-11.7
Net profit/loss for the period from continuing operations	327.8	-63.7	611.7	7.5	16.0
Net profit/loss for the period from discontinued operations	0.0	-43.3	0.0	-36.9	-37.3
Net profit/loss for the period	327.8	-107.0	611.7	-29.4	-21.3
Net profit/loss for the period attributable to:					
Parent Company shareholders	327.8	-107.0	611.7	-29.4	-21.3
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	10.49	-2.04	19.57	0.24	0.51
- Continuing operations, diluted earnings	10.28	-2.04	19.18	0.24	0.51
- Discontinued operations, basic and diluted earnings	-	-1.39	0.00	-1.18	-1.19
- Total operations, basic earnings	19.57	-3.43	19.57	-0.94	-0.68
- Total operations, diluted earnings	19.18	-3.43	19.18	-0.94	-0.68
Average number of shares, '000	31 260	31 260	31 260	31 260	31 260
Number of shares at period end, '000	31 260	31 260	31 260	31 260	31 260

## Consolidated Statement of Comprehensive Income (SEK m)

	c	Q2 Q1-		-Q2	Full year
	2014	2013	2014	2013	2013
Net profit/loss for the period	327.8	-107.0	611.7	-29.4	-21.3
Other comprehensive income Items that may be reclassified in the Income Statement					
Exchange rate differences	-0.7	-2.6	-0.7	-1.7	-2.2
Other comprehensive income for the period, net after tax	-0.7	-2.6	-0.7	-1.7	-2.2
Total comprehensive income for the period	327.1	-109.6	611.0	-31.2	-23.5
Total comprehensive income attributable to:					
Continuing operations	327.1	-64.6	611.0	6.8	14.9
Discontinued operations	0.0	-45.0	0.0	-38.0	-38.4
Total net profit/loss	327.1	-109.6	611.0	-31.2	-23.5

# Consolidated Balance Sheet, summary (SEK m)

	2014	2013	2013
	30 June	30 June	31 December
Assets			
Intangible fixed assets	421.4	442.8	431.7
Tangible fixed assets	27.6	29.7	28.3
Financial fixed assets	7.5	10.0	10.0
Deferred tax receivable	144.5	48.0	43.2
Inventories	18.8	13.9	24.0
Current receivables	572.9	161.5	56.1
Short-term investments	405.4	249.2	370.6
Cash and bank balances	25.0	30.7	31.6
Total assets	1 623.1	985.8	995.5
Shareholders' equity and liabilities			
Shareholders' equity	1 464.7	843.7	852.6
Long-term liabilities	40.0	25.0	40.0
Current liabilities	118.4	117.2	102.9
Total shareholders' equity and liabilities	1 623.1	985.8	995.5

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

	Share capital	Other paid-in capital	Exchange rate difference	Accumulated loss	Total shareholders' equity
Opening balance, 1 January 2013	156.3	1 757.9	3.6	-1 042.9	874.9
Total comprehensive income for the period	-	-	-2.2	-21.3	-23.5
Share incentive plan: value of employee service	-	1.2	-	-	1.2
Closing balance, 31 December 2013	156.3	1 759.1	1.4	-1 064.2	852.6
Opening balance, 1 January 2013	156.3	1 757.9	3.6	-1 042.9	874.9
Total comprehensive income for the period	-	-	-1.7	-29.5	-31.2
Closing balance, 30 June 2013	156.3	1 757.9	1.9	-1 072.4	843.7
Opening balance, 1 January 2014	156.3	1 759.1	1.4	-1 064.2	852.6
Total comprehensive income for the period	-	-	-0.7	611.7	611.0
Share incentive plan: value of employee service	-	1.1	-	-	1.1
Closing balance, 30 June 2014	156.3	1 760.2	0.7	-452.5	1 464.7

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

	Q2		Q1-	Full Year	
	2014	2013	2014	2013	2013
Cash flow from operating activities before changes in working capital	113.1	-94.2	49.7	-3.0	67.2
Changes in working capital	-24.4	85.9	-18.7	-24.2	-24.2
Cash flow from operating activities	88.7	-8.3	31.0	-27.2	43.0
Investing activities					
Acquisition/sale of fixed assets	-2.6	44.0	-7.8	44.2	-4.0
Sale of operations	2.5	-	5.0	-	115.0
Cash flow from investing activities	-0.1	44.0	-2.8	44.2	111.0
Financing activities					
Conversion of options	-	-	-	-	40.0
Loans amortised	-	-7.5	-	-15.0	-70.0
Other changes in liabilities	-	-13.0	-	-18.6	-18.6
Cash flow from financing activities	-	-20.6	-	-33.7	-48.6
Cash flow for the period					
Liquid assets at beginning of period	341.8	264.4	402.2	296.7	296.7
Change in liquid assets	88.6	15.5	28.2	-16.8	105.4
Exchange rate difference, liquid assets	0.0	-	0.0	-0.1	0.1
Liquid assets at period end	430.4	279.9	430.4	279.9	402.2

## Parent Company Income Statement, Summary (SEK m)

	Q2		Q1-Q2		Full Year
	2014	2013	2014	2013	2013
Net turnover	531.1	-	700.9	126.9	327.3
Cost of goods sold	-36.2	-	-52.3	-0.7	-13.6
Gross profit	494.9	-	648.6	126.1	313.7
Selling expenses	-15.1	-1.6	-26.8	-6.6	-21.6
Administrative expenses	-11.3	-17.7	-28.2	-32.8	-61.3
Research and development costs	-63.9	-58.9	-115.2	-114.2	-228.9
Other operating income/expenses	1.4	5.2	1.4	13.1	16.7
Operating profit/loss	406.0	-73.0	479.8	-14.4	18.6
Net financial items	1.5	120.1	3.3	120.7	80.2
Profit/loss after financial items	407.5	47.1	483.1	106.3	98.8
Tax	-89.8	-	107.0	-	-
Net profit/loss for the period	317.8	47.1	590.1	106.3	98.8

## Parent Company Statement of Comprehensive Income (SEK m)

	Q2		Q1-Q2		Full year	
	2014	2013	2014	2013	2013	
Net profit/loss for the period	317.8	47.1	590.1	106.3	98.8	
Other comprehensive income for the period, net after tax	317.8	47.1	590.1	106.3	98.8	
Total comprehensive income for the period	317.8	47.1	590.1	106.3	98.8	

## Parent Company Balance Sheet, Summary (SEK m)

	2014	2013	2013
	30-jun	30-jun	31 Dec
Assets			
Intangible fixed assets	7.3	6.3	6.6
Tangible fixed assets	27.1	28.8	27.6
Financial fixed assets	604.2	604.3	604.2
Deferred tax receivable	107.0	-	-
Inventories	1.8	-	-
Current receivables	555.7	156.1	84.1
Short-term investments	405.4	249.2	370.6
Cash and bank balances	14.9	17.2	9.8
Total assets	1 723.4	1 061.9	1 102.9
Shareholders' equity and liabilities			
Shareholders' equity	1 574.6	989.7	983.4
Long-term liabilities	40.0	-	40.0
Current liabilities	108.8	72.2	79.5
Total shareholders' equity and liabilities	1 723.4	1 061.9	1 102.9

## Parent Company Cash Flow Statement, Summary (SEK m)

	Q2		Q1-Q2		Full year
	2014	2013	2014	2013	2013
Cash flow from operating activities before changes in working capital	96.6	-64.4	13.6	-3.3	43.9
Changes in working capital	0.4	82.0	-0.9	-2.2	-56.9
Cash flow from operating activities	97.0	17.6	12.7	-5.5	-13.0
Investing activities					
Acquisition/sale of fixed assets	-2.6	0.2	-7.8	0.5	-4.0
Loans to subsidiary companies	35.0	-	35.0	-	-35.0
Dividend received from subsidiary companies	0.0	-	0.0	-	120.0
Cash flow from investing activities	32.4	0.2	27.2	0.5	81.0
Financing activities					
Loans raised	-	-	-	-	40.0
Cash flow from financing activities	-	-	-	-	40.0
Cash flow for the period	129.4	17.8	39.9	-5.0	108.0
Liquid assets at beginning of period	290.9	249.1	380.4	272.4	272.4
Change in liquid assets	129.4	17.4	39.9	-6.0	108.0
Liquid assets at end of period	420.3	266.4	420.3	266.4	380.4

#### Key ratios, share data, options

	2014	2013	2013
	Q1-Q2	Q1-Q2	Full year
Return on:			
- shareholders' equity, %	36.1	1.7	3.2
-capital employed, %	35.0	1.6	3.7
-total capital, %	32.1	1.4	3.3
Number of shares at beginning of period, '000	31 260	31 260	31 260
New share issues	-	-	-
Number of shares at period end, '000	31 260	31 260	31 260
-of which class A shares	660	660	660
-of which class B shares	30 600	30 600	30 600
Average number of shares, '000	31 260	31 260	31 260
Outstanding warrants, '000	639	404	249
Share capital at period end, SEK m	156.3	156.3	156.3
Shareholders' equity at period end, SEK m	1 464.7	843.7	852.6
Earnings per share, SEK			
- Continuing operations, basic earnings	19.57	0.24	0.51
- Continuing operations, diluted earnings	19.18	0.24	0.51
- Discontinued operations, basic and diluted earnings	-	-1.18	-1.19
- Total operations, basic earnings	19.57	-0.94	-0.68
- Total operations, diluted earnings	19.18	-0.94	-0.68
Shareholders' equity per share, SEK	46.9	27.0	27.3
Net worth per share, SEK	46.9	27.0	27.3
Cash flow per share after investments, SEK	2.8	0.5	4.9
Equity/assets ratio, %	90.2	85.6	85.7
EBITDA	432.5	43.6	76.4
EBIT	416.2	14.7	25.2
Operating margin, %	73.8	6.7	5.6

## **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.

Cash flow per share after investments. Cash flow after investments divided by the average number of shares.

Capital employed. Balance Sheet total less non-interest-bearing liabilities including deferred tax liabilities.

**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.

Return on capital employed. Profit/loss after financial items plus financial expenses as a percentage of average capital employed.

Return on shareholders' equity. Profit/loss after financial items as a percentage of 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.

#### **Accounting principles**

Medivir applies International Financial Reporting Standards (IFRS) as endorsed by the European Union. Significant accounting and valuation principles are presented on pages 60-67 of the 2013 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 2013 have had no significant effect on the Group's or Parent Company's financial position or results.

#### **Fiscal loss carry forwards**

Medivir AB has accumulated fiscal loss carry forwards arising from losses made in previous years. The accumulated losses at the period end, less the profit made in Q1 and Q2 of 2014, totalled SEK 486 million.

The loss carry forwards entail a latent tax benefit that can be used to offset future taxable surpluses. The reporting of deferred tax receivables from capitalisation of the loss carry forwards is subject to the provisions of the IAS 12 accounting standard. Two criteria must be fulfilled in order to report a deferred tax receivable based on loss carry forwards in accordance with IAS 12. It must be likely that future taxable surpluses will be generated against which the loss carry forwards can be offset and the company must be able to produce convincing evidence demonstrating that this will occur. Assessments are made on a rolling basis.

The launch of simeprevir has been successful and the company has reassessed the probability criterion in order to report the fiscal loss carry forwards in Medivir and has concluded that this criterion has been fulfilled and that convincing evidence exists. The combined value of deferred tax receivables within the Group attributable to Medivir AB and BioPhausia AB, at the end of the second quarter was SEK 144.5 million.

## **Segment reporting**

Medivir was, until 30 June 2013, organised into two operating segments. On 30 June, the wholly-owned subsidiary company, Cross Pharma, which conducted parallel imports of pharmaceuticals, was sold. The Group's continuing operations consist, as of the third quarter of 2013, of a single segment comprising both research and development operations and pharmaceutical sales.

#### **Discontinued operations**

On 25 June 2013, Medivir announced the sale of its parallel imports operations, Cross Pharma AB, including the Polish subsidiary company, Prodlekpol. The sale has been reported separately as a discontinued operation in the Income Statement in accordance with IFRS 5. A discontinued operation is reported separately from continuing operations in the Income Statement with retroactive effect for previous periods. For a more detailed description of the discontinued operations, see Note 24 of the 2013 Annual Report.

### **Seasonal variations**

Medivir's sales and operating profit/loss are, to some extent, dependent on external seasonal variations over which the company has no control. Sales of influenza- and common cold-related products during the first and fourth quarters are affected by the intensity and timing of the influenza and common cold season. This risk is, however, mitigated by the fact that Medivir has a growing number of pharmaceuticals in other therapeutic areas.

#### **Transactions with related parties**

Transactions with related parties are on market terms. There are agreements between companies owned by senior key employees and Medivir, conferring entitlement to royalties on products that the company may develop based on patented inventions that the company has purchased from the parties in question. Payments to senior executives of SEK 15.1 million (SEK 3.4 m) occurred during the period. Other services were purchased

from related parties for a total of SEK 0.0 million (SEK 0.0 m). Parent Company sales to Group companies totalled SEK 16.2 million (SEK 18.9 m).

#### Fair value measurement of financial assets and liabilities

IFRS 13 requires that financial instruments be classified in a 3-level hierarchy on the basis of the information used to determine their fair value. Level 1 inputs are when fair value is measured on the basis of quoted prices in active markets for identical financial assets or liabilities. Level 2 inputs are when fair value is measured on the basis of observable information other than quoted market prices included within level 1. Level 3 inputs are when the fair value is measured using valuation models in which significant inputs are based on unobservable data.

The Group has level 1 short-term investments. The short-term investments, in the form of fixed income funds, are managed as a group of financial assets and are reported at fair value in the Income Statement. The Group has saleable financial assets at level 3, the fair value of which are, as in the previous period, adjudged to be SEK 0.

#### Other financial assets and liabilities

The fair value of financial instruments such as accounts receivable, accounts payable, and other non-interest-bearing financial assets and liabilities which are reported at the accrued historical value less any depreciation, is adjudged to correspond to the reported value, due to their short anticipated terms.

#### **Share-related incentive plans**

The intention of share-related incentive plans is to promote the company's long-term interests by motivating and rewarding the company's senior executives and other members of staff. Medivir currently has two active share-related incentive plans, LTI 2014 and 2013. The cost of both plans, including social security contributions, and based on certain assumptions such as share price performance, participation, and staff turnover, was charged to the profit/loss for the period in the sum of SEK 2.6 million.

The principal rule in the event of cessation of employment prior to the end of the Vesting period is annulment of that participant's Share warrants. For a more detailed description of LTI 2013, see page 41 of the 2013 Annual Report.

48 per cent of all permanent employees have chosen to participate in LTI 2014. Other senior executives invested SEK 0.2 million (1,305 shares). 73 per cent of all permanent employees have chosen to participate in LTI 2013, with the CEO investing SEK 0.3 million (4,341 shares) and other senior executives investing SEK 0.7 million (9,909 shares).

## 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 registration. 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 CDs (candidate drugs), to enter into partnerships for its projects, to successfully develop its projects to market launch and continued sale, 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, 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.

No significant changes to the risks and uncertainty factors occurred during the period. A more detailed description of exposure to risk, and of the ways in which Medivir manages it, is provided in the 2013 Annual Report.

The Interim Report has not been subject to review by the company's auditor.

#### **Affirmation**

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

Stockholm, 21 August 2014

Björn C Andersson Susana Ayesa Alvarez

Member of the Board, employee representative

Anders Ekblom Anders Hallberg

Member of the Board Member of the Board

Anna Malm Bernsten Niklas Prager

Member of the Board Member of the Board

Bertil Samuelsson Birgitta Stymne Göransson

Member of the Board Chairman of the Board

Christian Sund Maris Hartmanis

Member of the Board, employee representative President & CEO