

Press Release, 8 May 2014



Interim Report, January – March 2014

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Conference call for investors, analysts and the media

The Interim Report for the first quarter of 2014 will be presented by Medivir's President & CEO, Maris Hartmanis, and members of Medivir's management group.
Time: Thursday, 8 May 2014, at 12.30 (CET).

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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-June will be published on 21 August 2014.

Interim Report, January – March 2014*

Financial summary for the first quarter

- Net turnover totalled SEK 208.2 million (SEK 178.1 m), SEK 161.7 million of which comprised royalties for simeprevir.
- A deferred tax receivable and a tax income of SEK 196.8 million are reported during the quarter, corresponding to a capitalisation of the entire loss carry forward related to Medivir AB, as of 31 March 2014.
- The profit/loss after tax was SEK 283.8 million (SEK 71.1 m).
- Basic and diluted earnings per share totalled SEK 9.08 (SEK 2.27) and SEK 9.01 (SEK 2.24), respectively.
- The cash flow from operating activities amounted to SEK -57.8 million (SEK -19.1 m), while liquid assets and short-term investments totalled SEK 341.8 million (SEK 264.4 m) at the period end.

Summary of the Group's figures, continuing operations (SEK m)	Q1		Full year
	2014	2013	2013
Net turnover	208.2	178.1	446.1
Gross profit	182.1	160.2	374.3
Operating profit before depreciation and amortisation (EBITDA)	96.7	90.5	76.4
Operating profit (EBIT)	88.6	76.7	25.2
Profit/loss before tax	90.3	76.6	27.7
Profit/loss after tax	283.8	71.1	16.0
Operating margin, %	42.6	43.1	5.6
Basic earnings per share, SEK	9.08	2.27	0.51
Diluted earnings per share, SEK	9.01	2.24	0.51
Cash flow from operating activities	-57.8	-19.1	43.0
Liquid assets and short-term investments at the period end	341.8	264.4	402.2

Significant events during Q1

- Simeprevir was approved in Russia and received a positive recommendation from the European Medicines Agency's advisory committee, the Committee for Medicinal Products in Human Use (CHMP), for the treatment of adults with chronic hepatitis C.
- Interim results (SVR4) presented from a phase II all-oral combination study of simeprevir and samatasvir (IDX719).
- Final results (SVR12) presented from a phase IIa study evaluating simeprevir and daclatasvir in hepatitis C patients of genotype 1.
- Final results presented from the phase III ATTAIN study (treatment with simeprevir and telaprevir).
- A renewed assessment of Medivir AB's fiscal loss carry forward resulted in Medivir reporting a deferred tax receivable in the Balance Sheet and a tax income in the Income Statement for the period.
- The Board of Directors has begun the process of recruiting a new President and CEO. Maris Hartmanis will remain in that role until his successor has taken up the position.

Significant events after the end of Q1

- Final, positive results were reported from the COSMOS study of simeprevir and sofosbuvir in cirrhotic and non-cirrhotic patients.
- Two phase III studies evaluating treatment of hepatitis C-infected patients with simeprevir and sofosbuvir have been initiated.

* 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 Q1 2014

Market uptake for Simeprevir was very good and Medivir received SEK 162 million in royalties for the quarter

The year started well and one of the most important events during the quarter was the approval of simeprevir by the Russian Ministry of Health. Russia has the world's third highest prevalence of hepatitis C, according to the World Health Organization (WHO), with approximately 3.7 million people infected. In January alone, 4,858 new cases of hepatitis C were diagnosed in Russia and there is a substantial need for a safe and effective treatment alternative like simeprevir.

We were also delighted when the European Medicines Agency's advisory committee, the Committee for Medicinal Products for Human Use (CHMP), recommended Marketing Authorisation in the EU for the use of simeprevir in combination with other antiviral medicinal products. The recommendation applies to the treatment of chronic hepatitis C in adult patients. We anticipate receiving European approval before the summer in what will be the next important step forward for Medivir, in that the company holds the sales rights for the Nordic market. The sales development in the markets in which simeprevir has already been launched by our partner, Janssen – Japan, the USA and Canada – was strong during the first quarter of the year. Royalties from Janssen's global sales during the first quarter totalled SEK 161.7 million, demonstrating very good market uptake.

The development of a completely interferon- and ribavirin-free treatment is one of the important goals for the future in the hepatitis C area. Our partner, Janssen, is currently conducting a number of studies, both internally and in partnership with other companies, in order to achieve this goal. Two new phase III studies were recently initiated: the first is OPTIMIST, which entails an interferon- and ribavirin-free combination treatment with simeprevir and sofosbuvir over an eight- or twelve-week period. Janssen also presented positive and unique results from the phase II COSMOS study at the EASL conference. Strong data on European patients, based on subgroup analyses from the earlier phase III studies, and final efficacy data for patients infected with genotype 4 HCV, were also presented.

Our own in-house research projects are proceeding according to plan towards their goals for 2014. Our strategic work has a strong focus on the growing requirement to ensure, at an early stage in the research process, that we can demonstrate both the medicinal benefits and cost-effectiveness of a potential new pharmaceutical product in comparison with existing treatments.

Our pharmaceutical portfolio comprises 16 prescription pharmaceuticals that are marketed in the Nordic region. Our own pharmaceutical sales experienced a slight downturn during the first quarter, primarily due to fewer unit sales for Mollipect as a result of a weak influenza and common cold season. The pharmaceutical portfolio as a whole generated a turnover of SEK 46.4 million. April saw the market relaunch of Suscard – an established pharmaceutical for the treatment of angina pectoris.

We have a strong focus on specialist pharmaceuticals in the growth phase. Our innovation and launch competence in the specialist care sector are both important components of our endeavours to generate sustainable profitability. One step towards this goal was taken in April with the Nordic market launch of Adasuve – a new specialist pharmaceutical for the treatment of agitation associated with bipolar disorder and schizophrenia.

Medivir has strengthened the company's marketing and sales organisation during the quarter, and the organisation, which now has a presence in Norway, Denmark and Finland, as well as Sweden, has been working intensively on the product launch of Adasuve. The organisation is also well-prepared for the launch of simeprevir in the Nordic region, which we expect to take place towards the end of the second quarter.

*Maris Hartmanis,
President & CEO*

Significant events during the reporting period

Simeprevir receives positive CHMP opinion for the treatment of adults with chronic hepatitis C

At the end of March, the European Medicines Agency's advisory committee, the Committee for Medicinal Products for Human Use (CHMP), issued a positive opinion, recommending Marketing Authorisation in the EU for the use of simeprevir in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adult patients.

The recommendation was based on positive and consistent results from three pivotal phase III studies in patients with GT1 HCV; QUEST-1 and QUEST-2 in treatment-naïve patients, and PROMISE in patients who have relapsed after previous interferon-based therapy.

Subgroup analyses of European patients from phase III studies with simeprevir

Analyses of pooled efficacy data in respect of European patients from the QUEST-1 and QUEST-2 studies (treatment-naïve patients) were presented at the annual congress of the European Association for the Study of the Liver (EASL). These data showed that 87 per cent of European patients treated with simeprevir in combination with pegylated interferon and ribavirin achieved SVR12, compared to 80 per cent in the overall study population. In an analysis of the results from the PROMISE study (patients who have relapsed after previous treatment), 88 per cent of European patients treated with simeprevir in combination with pegylated interferon and ribavirin achieved SVR12, compared to 79 per cent in the overall study population.

Marketing Authorisation for simeprevir in Russia

At the end of March, the Russian Ministry of Health approved simeprevir in combination with peginterferon alfa and ribavirin. The approval is for the treatment of chronic hepatitis C genotype 1 infection in adults with compensated liver disease, including those with cirrhosis. The patients covered by the approval must either be treatment-naïve or have failed to respond to previous interferon-based therapy.

Through the approval, Russia became the first country within the EMEA to gain access to simeprevir. According to the World Health Organization's statistics for 2011, Russia has the world's third highest prevalence of hepatitis C, with an estimated 3.7 million people infected.

Positive interim results (SVR4) from a phase II all-oral combination study of simeprevir and samatasvir (IDX719)

Idenix Pharmaceuticals released interim data from the ongoing phase II HELIX-1 clinical trial evaluating an all-oral, direct-acting antiviral (DAA) HCV combination regimen of simeprevir (150 mg) and samatasvir (50, 100 or 150 mg), and ribavirin for 12 weeks in treatment-naïve patients infected with genotype 1b or 4 HCV. Simeprevir is a protease inhibitor, while samatasvir (which is being developed by Idenix) is a pan-genotypic HCV NS5A inhibitor that is taken once-daily. The results show that the combination treatment was well-tolerated. 85 per cent (n=17/20) of the patients in the cohort group treated with 50 mg achieved SVR4. The 50 mg dose of samatasvir is the selected dose in the ongoing 3-DAA HELIX-2 clinical trial, in which a combination regimen of simeprevir, samatasvir and TMC647055 (a non-nucleoside HCV NS5B polymerase inhibitor) is being evaluated.

Significant events during the reporting period

Final SVR12 results from a phase IIa study evaluating simeprevir and daclatasvir in hepatitis C patients of genotype 1

Bristol-Myers Squibb (BMS) presented final results from a phase IIa trial evaluating 12- and 24-week treatment with simeprevir in combination with daclatasvir, an investigational HCV NS5A inhibitor developed by BMS, with and without ribavirin, in patients with hepatitis C genotype 1 infection.

In HCV genotype 1b patients, SVR12 was achieved by between 75 per cent and 85 per cent of treatment-naïve patients and by between 65 per cent and 95 per cent of the patient group that comprised prior null responders.

New phase III data from simeprevir trials, including the ATTAIN study

New phase III data from simeprevir trials were presented in March at the conference of the Asian Pacific Association for the Study of the Liver held in Brisbane, Australia:

- > The phase III ATTAIN study enrolls treatment-experienced adult patients with chronic hepatitis C virus (HCV). The primary efficacy endpoint in this study was achieved, i.e. simeprevir was demonstrated to be non-inferior compared to telaprevir when both are given in combination with pegylated interferon and ribavirin for 12 weeks, followed by 36 weeks of treatment with pegylated interferon and ribavirin only. Simeprevir (150 mg once-daily) demonstrated a superior safety profile, including a lower adverse event frequency, fewer serious adverse events, and a lower incidence of anaemia versus telaprevir (750 mg three times per day).
- > Pooled analysis of the data from the phase III QUEST-1 and QUEST-2 studies confirmed efficacy in treatment-naïve genotype 1b HCV patients. 85 per cent (ITT analysis) of treatment-naïve patients achieved SVR12 when treated with simeprevir in combination with pegylated interferon and ribavirin, compared to 53 per cent of patients treated with placebo in combination with pegylated interferon and ribavirin.
- > A similar subgroup analysis of the PROMISE phase III trial, which enrolled hepatitis C patients who had relapsed after previous interferon-based treatment, demonstrated that 86 per cent (ITT analysis) of the genotype 1b patients achieved SVR12 when treated with simeprevir in combination with pegylated interferon and ribavirin, compared to 43 per cent of the patient group treated with placebo in combination with pegylated interferon and ribavirin.

Decision to recruit a new CEO

The anticipated launch of simeprevir in the Nordic region will see the company enter a new commercialisation phase, with new opportunities and challenges. The Board of Directors has, in consultation with Maris Hartmanis, and in order to generate the best possible preconditions for Medivir to exploit these opportunities, initiated a process aimed at recruiting a new CEO for the company. Maris Hartmanis will remain as the CEO of Medivir until his successor is appointed.

Significant events after the end of the financial period

Two phase III trials evaluating once-daily simeprevir and sofosbuvir in hepatitis C infected patients have been initiated

Two phase III trials of simeprevir in combination with the nucleotide inhibitor, sofosbuvir, for the treatment of chronic genotype 1 hepatitis C virus (HCV) infection in treatment-naïve and treatment-experienced patients, with and without cirrhosis, were initiated in April. This combination therapy has demonstrated positive safety and efficacy results in the earlier phase II study, COSMOS.

OPTIMIST-1 is a phase III, open-label, randomised study investigating the efficacy and safety of simeprevir 150 mg in combination with sofosbuvir 400 mg. The combination will be administered once-daily for 8 or 12 weeks in chronic HCV genotype 1 infected patients without cirrhosis who are HCV treatment-naïve or treatment-experienced. The study will enrol approximately 300 patients in the USA and Canada.

OPTIMIST-2 is a phase III, open-label, single-arm study investigating the efficacy and safety of simeprevir 150 mg in combination with sofosbuvir 400 mg. The combination will be administered once-daily for 12 weeks in HCV genotype 1 infected patients with cirrhosis who are HCV treatment-naïve or treatment-experienced. The study will enrol approximately 100 patients in the USA and Canada.

Final data from Cohort 2 of the phase II interferon-free COSMOS study and the phase III RESTORE study of genotype 4 HCV patients presented at EASL

COSMOS

Final results from cohort 2 of the phase II COSMOS study, which enrolled prior null responder and treatment-naïve patients with genotype 1 HCV with advanced liver fibrosis (METAVIR scores F3 and F4), demonstrated that 93 per cent of the patients who were treated with simeprevir and sofosbuvir for 12 weeks achieved SVR12. The addition of ribavirin did not improve SVR rates and consistent responses for both treatment arms were seen across HCV genotype subgroups after 12 weeks.

SVR12 among patient subgroups with genotype 1 HCV and advanced liver disease (METAVIR scores F3-F4) in cohort 2 the COSMOS study		
12 weeks of treatment		
	Simeprevir/Sofosbuvir % (n/N)	Simeprevir/Sofosbuvir + Ribavirin % (n/N)
All patients	93 (13/14)	93 (25/27)
HCV genotype 1a without the Q80K polymorphism	88 (7/8)	93 (13/14)
HCV genotype 1a with the Q80K polymorphism	100 (3/3)	88 (7/8)
HCV genotype 1b	100 (3/3)	100 (5/5)
Patients with METAVIR F4 scores	86 (6/7)	91 (10/11)

*Excluding non-virologic failures.

The most common adverse events reported during the study were fatigue, headache, nausea, anaemia, pruritus, dizziness, rashes and photosensitivity.

Significant events after the end of the financial period

RESTORE

Results from the phase III RESTORE trial of simeprevir in combination with pegylated interferon and ribavirin in HCV genotype 4 treatment-naïve and treatment-experienced patients demonstrated that overall, 65 per cent of patients achieved SVR12. In the respective patient groups, SVR12 was achieved by 83 per cent of treatment-naïve patients, 86 per cent of prior relapsers, 60 per cent of prior partial responders, and 40 per cent of prior null responders. Genotype 4 HCV is considered particularly difficult to cure and currently, only limited treatment options are available.

Project portfolio

Medivir is a research-based pharmaceutical company. The research portfolio currently comprises three projects that focus on the development of antiviral pharmaceuticals. We also conduct research projects in other disease areas, such 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 in-house 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 www.medivir.com

Therapeutic area	Product/Project	Partner	Preclinical phase		Clinical phase				Market	
			Research	Development	Phase I	Phase IIa	Phase IIb	Phase III		
Antivirals										
Labial herpes	Xerclear® (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)								
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals								
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals								
Hepatitis C	NS5B nucleotide-based polymerase inhibitor									
HIV	Protease inhibitor	Janssen Pharmaceuticals								

Other indications

Bone related disorders	Cathepsin K inhibitor								
Neuropathic pain	Cathepsin S inhibitor								

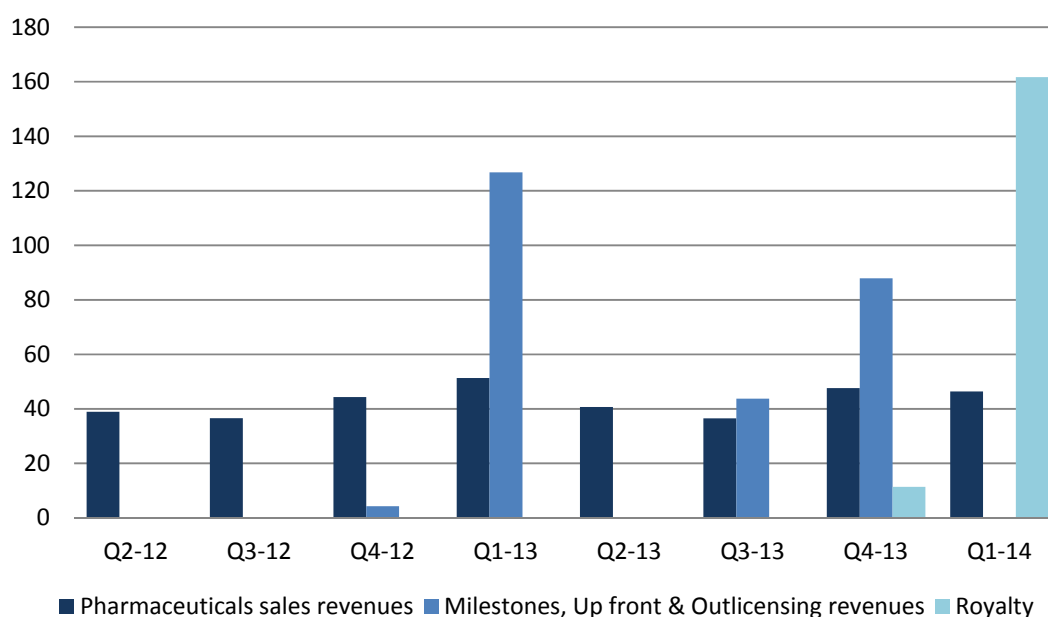
Consolidated results and financial position*

Revenues and results, January – March 2014

Net turnover totalled SEK 208.2 million (SEK 178.1 m), corresponding to an increase of SEK 30.1 million. Royalty income from Janssen's global sales of simeprevir amounted to SEK 161.7 million (SEK 0). Revenues from Medivir's own pharmaceutical sales totalled SEK 46.4 million, corresponding to a decrease of SEK 4.9 million, primarily due to a fall in Mollipect unit sales resulting from a weak influenza and common cold season. No non-recurrent payments from outlicensing and partnership agreements were received during the period. Outlicensing and partnership agreement-related non-recurrent payments during the corresponding period of the previous year totalled SEK 126.8 million and referred to the registration application for simeprevir in Japan (EUR 5 million) and the USA (EUR 10 million).

Breakdown of net turnover (SEK m)	Q1		Full year
	2014	2013	2013
Outlicensing and partnership agreements			
Non-recurrent payments	-	126.8	258.5
Pharmaceutical sales	46.4	51.3	176.1
Royalties	161.7	-	11.5
Other services	-	-	-
Total	208.2	178.1	446.1

Net turnover, continuing operations, Q2 2012 – Q1 2014



The cost of goods sold was SEK -26.1 million (SEK -17.9 m), corresponding to an increase of SEK 8.2 million and due, primarily, to higher royalty costs for simeprevir. The gross profit amounted to SEK 182.1 million (SEK 160.2 m), corresponding to an increase of SEK 21.9 million and equating to a gross margin of 87 per cent (90%).

* 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.

Consolidated results and financial position

Selling expenses increased by SEK 10.8 million, primarily due to the establishment of a Nordic organisation and to preparations ahead of an anticipated Nordic market introduction of simeprevir, and to the costs associated with the market introduction of Adasuve in April. Administrative expenses increased by SEK 3.3 million and referred to higher, non-recurrent staff overheads. Research and development costs fell by SEK 3.3 million, primarily as a result of lower royalty costs. Other operating income and expenses increased by SEK 0.8 million. Overall, operating costs totalled SEK -93.5 million (SEK -83.5 m), corresponding to an increase of SEK 10.0 million.

The operating profit/loss totalled SEK 88.6 million (SEK 76.7 m), corresponding to an increase of SEK 11.9 million.

Net financial items totalled SEK 1.7 million (SEK -0.1 m), corresponding to an increase of SEK 1.8 million.

The tax cost for the period amounted to SEK 193.5 million (SEK -5.5 m). A renewed assessment of Medivir AB's fiscal loss carry forward entailed a reported tax income of SEK 196.8 million, corresponding to a capitalisation of the entire loss carry forward related to the company as of 31 March 2014. The period's additional tax cost of SEK 3.3 million comprises a reduction in the Group's deferred tax receivable due to the utilisation of fiscal loss carry forwards.

The profit/loss for the period from the continuing operations was SEK 283.8 million (SEK 71.1 m), corresponding to an increase of SEK 212.7 million. Basic and diluted earnings per share from continuing operations amounted to SEK 9.08 (SEK 2.27) and SEK 9.01 (SEK 2.24), 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 first quarter. Organisationally, parallel imports had been a discrete segment prior to the sale. For details of the divestment, see the 2013 Annual Report.

Parallel Imports Segment	Q1		Full year
	2014	2013	2013
Net turnover	-	104.5	213.0
EBITDA	-	4.5	8.2
EBITDA %	-	4.3	3.8

Cash flow and financial position, January – March 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 341.8 million (SEK 264.4 m) at the end of the period, corresponding to a change of SEK -60.4 million (SEK -32.3 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. The company's current financial assets are, in Medivir's opinion, sufficient to ensure operational financing.

Cash flow from operating activities totalled SEK -57.8 million (SEK -19.1 m), with changes in working capital accounting for SEK 5.7 million (SEK -110.4 m).

Cash flow from investing activities totalled SEK -2.7 million (SEK -0.2 m), of which SEK 2.5 million (SEK 0) comprised part of the purchase price from the sale of Cross Pharma and SEK -5.2 million (SEK -0.2 m) comprised investments in research equipment and other fixed assets.

Cash flow from financing activities totalled SEK 0.0 million (SEK -13.1 m).

Consolidated results and financial position

Investments, depreciation and amortisation, January – March 2014

Investments in tangible fixed assets during the period amounted to SEK 2.6 million (SEK 0.3 m) and comprised research and office equipment. Depreciation of tangible fixed assets totalling SEK -2.4 million (SEK -2.7 m) were charged to the profit/loss for the period. Write-downs of intangible fixed assets of SEK -5.7 million (SEK -6.0 m) were charged to the profit/loss for the period.

Employees

Medivir had 129 (101) employees at the period end, 56 per cent (50%) of whom were women.

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 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. The combined royalty costs for the period were SEK 8.0 million (SEK 6.3 m).

The Parent Company in brief, January – March 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 169.8 million (SEK 126.9 m), corresponding to an increase of SEK 42.9 million. Royalty income from Janssen's global sales of simeprevir totalled SEK 161.7 million (SEK 0). 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 153.7 million (SEK 126.2 m), corresponding to an increase of SEK 27.5 million.

Selling expenses increased by SEK 6.7 million and primarily related to the establishment of a Nordic organisation and to preparations ahead of an anticipated Nordic market introduction of simeprevir, and to the costs associated with the market introduction of Adasuve in April. Administrative expenses increased by SEK 1.7 million, while research and development costs fell by SEK 4.0 million, primarily as a result of lower own royalty costs. Other operating income and expenses fell by SEK 7.8 million. Overall, operating costs totalled SEK -79.9 million (SEK -67.7 m), corresponding to an increase of SEK 12.2 million.

The operating profit/loss was SEK 73.7 million (SEK 58.6 m), corresponding to an increase of SEK 15.1 million. Net financial items totalled SEK 1.8 million (SEK 0.7 m), corresponding to an increase of SEK 1.1 million.

The tax for the period totalled SEK 196.8 million (SEK -5.5 m). A renewed assessment of the fiscal loss carry forward entailed a reported tax income of SEK 196.8 million, corresponding to a capitalisation of the entire loss carry forward related to Medivir AB, as of 31 March 2014.

The profit/loss for the period was SEK 272.3 million (SEK 59.3 m), corresponding to an increase of SEK 213.0 million.

The cash flow from operating activities totalled SEK -84.3 million (SEK -23.1 m), with changes in working capital accounting for SEK -1.2 million (SEK 84.2 m). Investments in tangible and intangible fixed assets totalled SEK -5.2 million (SEK -0.3 m) and comprised investments in research and office equipment.

Consolidated results and financial position

Liquid assets, including short-term investments with a maximum term of 3 months, amounted to SEK 290.9 million (SEK 249.1 m). Please see the section entitled "Consolidated results and financial position" for further comments on the operations.

Outlook

Medivir is a research-based pharmaceutical company whose focus is on infectious diseases. 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 was received in Japan in September 2013, in the USA and Canada in November 2013, and in Russia in March 2014, while European approval is expected during the first half of 2014. Medivir has early discovery projects and several attractive projects in the development phase. A number of combination studies of simeprevir are also being conducted under the aegis of Janssen with the aim of developing additional interferon-free treatments for hepatitis C. 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 1,136.9 million (SEK 953.4 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, 31 March 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%	31 004 401
Total	31 260 027	37 200 027	100.00%	100.00%	31 664 401

Basic and diluted earnings per share for the continuing operations, based on a weighted average number of outstanding shares, were SEK 9.08 (SEK 2.27) and SEK 9.01 (SEK 2.24), respectively. Shareholders' equity per share totalled SEK 36.4 (SEK 30.5). The equity/assets ratio was 89.7 per cent (83.2%).

Consolidated results and financial position

Shareholders

On 31 March 2014, Medivir AB had 13,021 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	1 940 226	5.22%	6.21%
AFA Försäkring	0	1 629 229	4.38%	5.21%
Gladiator	0	1 585 000	4.26%	5.07%
Skandia Fonder	0	1 545 618	4.15%	4.94%
UNIONEN	0	1 204 200	3.24%	3.85%
Catella Fondförvaltning	0	957 385	2.57%	3.06%
Christer Sahlberg	92 000	27 881	2.55%	0.38%
DnB Carlson Fonder	0	898 599	2.42%	2.87%
Avanza Pension	0	829 424	2.23%	2.65%
Tredje AP-fonden	0	627 713	1.69%	2.01%
Alecta Pensionsförsäkring	0	615 000	1.65%	1.97%
Banque Carnegie Luxembourg SA	0	521 178	1.40%	1.67%
JPM Chase NA	0	515 252	1.39%	1.65%
Total, 15 largest shareholders	660 000	13 225 755	53.30%	44.42%
Total, other shareholders		17 374 272	46.70%	55.58%
TOTAL	660 000	30 600 027	100%	100%

Consolidated results and financial position

Consolidated Income Statement, summary (SEK m)

	Q1		Full year
	2014	2013	2013
Continuing operations			
Net turnover	208.2	178.1	446.1
Cost of goods sold	-26.1	-17.9	-71.8
Gross profit	182.1	160.2	374.3
Selling expenses	-23.5	-12.7	-70.4
Administrative expenses	-18.0	-14.7	-51.9
Research and development costs	-52.1	-55.4	-229.4
Other operating income/expenses	0.1	-0.7	2.6
Operating profit/loss	88.6	76.7	25.2
Net financial items	1.7	-0.1	2.6
Profit/loss after financial items	90.3	76.6	27.7
Tax	193.5	-5.5	-11.7
Net profit/loss for the period from continuing operations	283.8	71.1	16.0
Net profit/loss for the period from discontinued operations	-	6.4	-37.3
Net profit/loss for the period	283.8	77.5	-21.3
Net profit/loss for the period attributable to:			
Parent Company shareholders	283.8	77.5	-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	9.08	2.27	0.51
- Continuing operations, diluted earnings	9.01	2.24	0.51
- Discontinued operations, basic and diluted earnings	-	0.20	-1.19
- Total operations, basic earnings	9.08	2.48	-0.68
- Total operations, diluted earnings	9.01	2.45	-0.68
Average number of shares, '000	31 260	31 260	31 260
Number of shares at period end, '000	31 260	31 260	31 260

Consolidated results and financial position

Consolidated Statement of Comprehensive Income (SEK m)

	Q1		Full year
	2014	2013	2013
Net profit/loss for the period	283.8	77.5	-21.3
Other comprehensive income			
<i>Items that may be reclassified in the Income Statement</i>			
Exchange rate differences	0.0	0.9	-2.2
Other comprehensive income for the period, net after tax	0.0	0.9	-2.2
Total comprehensive income for the period	283.8	78.4	-23.5
Total comprehensive income attributable to:			
Continuing operations	283.8	71.4	14.9
Discontinued operations	-	7.0	-38.4
Total net profit/loss	283.8	78.4	-23.5

Consolidated Balance Sheet, summary (SEK m)

	2014	2013	2013
	31 mar	31 mar	31 dec
Assets			
Intangible fixed assets	426.1	508.1	431.7
Tangible fixed assets	28.5	33.8	28.3
Financial fixed assets	7.5	0.0	10.0
Deferred tax receivable	236.7	44.0	43.2
Inventories	17.4	100.1	24.0
Current receivables	209.7	195.0	56.1
Short-term investments	272.5	198.0	370.6
Cash and bank balances	69.3	66.4	31.6
Total assets	1 267.7	1 145.4	995.5
Shareholders' equity and liabilities			
Shareholders' equity	1 136.9	953.4	852.6
Long-term liabilities	40.0	32.9	40.0
Current liabilities	90.8	159.1	102.9
Total shareholders' equity and liabilities	1 267.7	1 145.4	995.5

Consolidated results and financial position

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	-	-	0.9	77.6	78.5
Closing balance, 31 March 2013	156.3	1 759.1	4.5	-965.3	953.4
Opening balance, 1 January 2014	156.3	1 759.1	1.4	-1 064.2	852.6
Total comprehensive income for the period	-	-	0.0	283.8	283.8
Share incentive plan: value of employee service	-	0.5	-	-	0.5
Closing balance, 31 March 2014	156.3	1 759.6	1.4	-780.4	1 136.9

Consolidated Cash Flow Statement, summary (SEK m)

	Q1		Full Year
	2014	2013	2013
Cash flow from operating activities before changes in working capital	-63.4	91.3	67.2
Changes in working capital	5.7	-110.4	-24.2
Cash flow from operating activities	-57.8	-19.1	43.0
Investing activities			
Acquisition/sale of fixed assets	-5.2	-0.2	-4.0
Sale of operations	2.5	-	115.0
Cash flow from investing activities	-2.7	-0.2	111.0
Financing activities			
Conversion of options	-	-	40.0
Loans amortised	-	-7.5	-70.0
Other changes in liabilities	-	-5.6	-18.6
Cash flow from financing activities	-	-13.1	-48.6
Cash flow for the period			
Liquid assets at beginning of period	402.2	296.7	296.7
Change in liquid assets	-60.5	-32.3	105.4
Exchange rate difference, liquid assets	0.1	-	0.1
Liquid assets at period end	341.8	264.4	402.2

Consolidated results and financial position

Parent company income statement, summary (SEK m)

	Q1		Full Year
	2014	2013	2013
Net turnover	169.8	126.9	327.3
Cost of goods sold	-16.1	-0.7	-13.6
Gross profit	153.7	126.2	313.7
Selling expenses	-11.7	-5.0	-21.6
Administrative expenses	-16.9	-15.2	-61.3
Research and development costs	-51.3	-55.3	-228.9
Other operating income/expenses	0.0	7.8	16.7
Operating profit/loss	73.7	58.6	18.6
Net financial items	1.8	0.7	80.2
Profit/loss after financial items	75.5	59.3	98.8
Tax	196.8	-	-
Net profit/loss for the period	272.3	59.3	98.8

Parent company statement of comprehensive income (SEK m)

	Q1		Full year
	2014	2013	2013
Net profit/loss for the period	272.3	59.3	98.8
Other comprehensive income for the period, net after tax	272.3	59.3	98.8
Total comprehensive income for the period	272.3	59.3	98.8

Consolidated results and financial position

Parent company balance sheet, summary (SEK m)

	Q1		Full year
	2014	2013	2013
Assets			
Intangible fixed assets	6.5	13.1	6.6
Tangible fixed assets	27.9	30.9	27.6
Financial fixed assets	604.2	604.3	604.2
Deferred tax receivable	196.8	-	-
Inventories	0.0	0.0	0.0
Current receivables	247.2	106.9	84.1
Short-term investments	272.5	198.0	370.6
Cash and bank balances	18.4	51.1	9.8
Total assets	1 373.5	1 004.4	1 102.9
Shareholders' equity and liabilities			
Shareholders' equity	1 256.3	942.7	983.4
Long-term liabilities	40.0	-	40.0
Current liabilities	77.2	61.7	79.5
Total shareholders' equity and liabilities	1 373.5	1 004.4	1 102.9

Consolidated results and financial position

Parent company cash flow statement , summary (SEK m)

	Q1		Full year
	2014	2013	2013
Cash flow from operating activities before changes in working capital	-83.1	61.1	43.9
Changes in working capital	-1.2	-84.2	-56.9
Cash flow from operating activities	-84.3	-23.1	-13.0
Investing activities			
Acquisition/sale of fixed assets	-5,2	-0.3	-4.0
Loans to subsidiary companies	-	-	-35.0
Dividend received from subsidiary companies	-	-	120.0
Cash flow from investing activities	-5.2	-0.3	81.0
Financing activities			
Loans raised	-	-	40.0
Cash flow from financing activities	-	-	40.0
Cash flow for the period	-89.5	-23.3	108.0
Liquid assets at beginning of period	380.4	272.4	272.4
Change in liquid assets	-89.5	-23.3	108.0
Liquid assets at end of period	290.9	249.1	380.4

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Key ratios, share data, options

	2014	2013	2013
	Q1	Q1	Full year
Return on:			
- shareholders' equity, %	9.1	8.4	3.2
- capital employed, %	8.8	7.6	3.7
- total capital, %	8.1	7.0	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	249	394	249
- entitlement to class B shares upon conversion, '000	249	430	249
Share capital at period end, SEK m	156.3	156.3	156.3
Shareholders' equity at period end, SEK m	1 136.6	953.3	852.6
Earnings per share, SEK			
- Continuing operations, basic earnings	9.1	2.3	0.5
- Continuing operations, diluted earnings	9.0	2.2	0.5
- Discontinued operations, basic and diluted earnings	-	0.2	-1.2
- Total operations, basic earnings	9.1	2.5	-0.7
- Total operations, diluted earnings	9.0	2.4	-0.7
Shareholders' equity per share, SEK	36.4	30.5	27.3
Net worth per share, SEK	36.4	30.5	27.3
Cash flow per share after investments, SEK	-1.9	-0.6	4.9
Equity/assets ratio, %	87.8	83.2	85.7
EBITDA	96.7	90.5	76.4
EBIT	88.6	76.7	25.2
Operating margin, %	42.6	43.1	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.

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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. On 31 March 2014, the accumulated losses, less the profit made in Q1 of 2014, totalled SEK 895 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. The first criterion is that it must be likely that future taxable surpluses will be generated against which the loss carry forwards can be offset. The second criterion is that a company that has not previously reported taxable surpluses 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 royalty income for the first quarter totalled SEK 162 million. The company has consequently reassessed the probability criterion related to the reporting of the fiscal loss carry forwards in Medivir AB and has concluded that this criterion has been fulfilled and that convincing evidence exists.

The previous decision not to report any part of Medivir AB's fiscal loss carry forward in the Balance Sheet has, therefore, been reviewed. The new assessment has resulted in Medivir AB reporting a deferred tax receivable in its Balance Sheet and a tax income in its Income Statement for the first quarter. The tax income of SEK 197 million corresponds to a capitalisation of the entire loss carry forward in relation to Medivir AB, as of 31 March 2014.

The Medivir Group has previously reported a deferred tax receivable corresponding to the fiscal loss carry forwards in BioPhausia AB. These loss carry forwards are not affected by the new assessment. The combined value of deferred tax receivables attributable to Medivir AB and BioPhausia AB at the end of the first quarter was SEK 237 million.

Segment reporting

Medivir was, until 30 June 2013, organised into two operating segments. On 30 June, the wholly-owned subsidiary company, Cross Pharma AB, which conducted parallel imports of pharmaceuticals, was sold. The Group's continuing operations consist, as of the third quarter of 2013, of one 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, Prodlekpól. 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.

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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 seasons' influenza and common cold intensity and timing. This risk is, however, mitigated by the fact that Medivir has a number of other products 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 these parties of SEK 1.1 million (SEK 3.3 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 8.1 million (SEK 0.0 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 and which are not adjudged to have any value.

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 one active share-related incentive plan, LTI 2013. 73 per cent of all permanent employees have chosen to participate in the plan, with the CEO investing SEK 0.3 million (4,341 shares) and other senior executives investing SEK 0.7 million (9,909 shares). The cost of LTI 2013, including social security contributions, and based on assumptions such as share price performance, participation, and staff turnover, was charged to the profit/loss for the period in the sum of SEK 1.3 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.

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

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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 patient 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.

Stockholm, 8 May 2014

Maris Hartmanis
President & CEO