



**Press Release, 9 July 2009**

## **Medivir, Half-year Interim Report, 1 January – 30 June 2009**

- Consolidated net sales were SEK 24.5 (14.7) m.
- The loss after tax was SEK -62.9 (-77.3) m.
- Earnings per share were SEK -3.02 (-3.71).
- Cash flow from operating activities was SEK -72.9 (1.2) m.
- Liquid assets and short-term investments as of 30 June were SEK 210.9 (329.2) m.

### **Second quarter in brief**

Several significant corporate and project events were reported in the quarter.

The highlights can be summarized as follows:

- New, positive phase IIa data for TMC435 were presented during the quarter. A phase IIb trial involving 400 treatment-naïve patients is now underway; patient recruitment started in May.
- The reduction of the company's cost structure that started in February has now concluded and the savings measures are progressing as planned with a full year effect starting 2010.

*Ron Long  
CEO*

*Huddinge, Sweden, 9 July 2009*

### **For more information, please contact:**

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### **Forthcoming financial information**

The Nine-month Interim Report will be published on 21 October 2009.

The Report will be available at Medivir's Website, [www.medivir.se](http://www.medivir.se) from this date under the 'Investor/Media' heading.

## Highlights in the second quarter 2009

### **TMC435 (hepatitis C) now in phase I Ib trials**

TMC435 is a protease inhibitor under development by Tibotec in partnership with Medivir for treating hepatitis C virus infections (HCV).

TMC435 is currently in clinical phase I Ib trials (C-205); the recruitment of treatment-naïve patients started in May. Another phase I Ib trial will start in the autumn, in treatment experienced patients that previously failed Standard of Care (SoC).

The design of the phase I Ib trial is based on factors including results from the phase IIa trials. In these trials, TMC435 was administered once daily, at differing doses, for four weeks, and demonstrated highly potent antiviral efficacy, was well tolerated and safe. These results have been reported at various medical conferences over the past half-year.

The recently started phase I Ib trial (C-205) is a double-blind, placebo-controlled trial involving 400 treatment-naïve patients.

All patients will receive current standard of care (SoC), which consists of interferon (PegIFNalpha-2a) and ribavirin. SoC will continue for 48 weeks. The therapy arms consist of: SoC plus TMC435, 75 mg for 12 weeks; SoC plus TMC435, 150 mg for 12 weeks; SoC plus TMC435, 75 mg for 24 weeks; SoC plus TMC435, 150 mg for 24 weeks; SoC plus placebo for 24 weeks.

### **Cathepsin K in bone disorders**

In the cathepsin K project, a CD (MIV-710) was designated in February 2009. Work during the quarter focused on evaluating several potential candidate drugs (CDs) with different profiles. One additional CD will be designated in the third quarter.

### **Lipsovir<sup>®</sup>**

Lipsovir<sup>®</sup> is a patented combination of hydrocortisone (anti-inflammatory agent) and acyclovir (antiviral agent) in a proprietary cream base developed by Medivir.

Medivir filed a NDA with the US (FDA) and EU regulatory authorities for Lipsovir during the fourth quarter 2008. The regulatory process is progressing according to plan and we expect to receive the outcome of this process in the later part of 2009.

### **Reducing cost structure**

In February, Medivir initiated reduction of its cost structure involving savings in three areas: personnel, external research costs and project costs.

The process of reducing staffing concluded in April, and a total of over 20 staff have now left the company, contractually this will be materialized during the coming quarters.

Restructuring costs amount to SEK 8 m, of which SEK 7.2 m relate to staff reductions, largely charged to profits for the first quarter. Other savings measures are progressing as planned and will achieve their full-year effect starting in 2010.

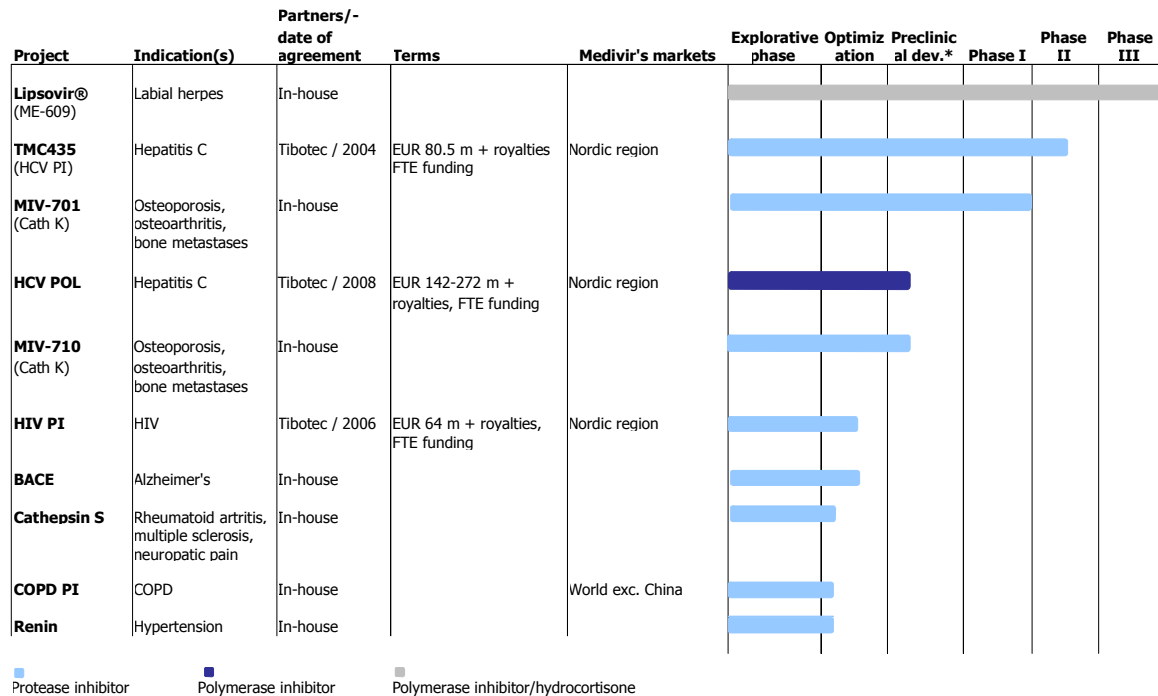
## **Project portfolio**

Two preclinical projects, HCV-POL and HIV-PI, are being conducted in partnership with Tibotec. In the HCV-POL partnership, Medivir has received research funding until mid-May this year. This project designated a CD in December 2008. Work in 2009 is focusing on identifying further

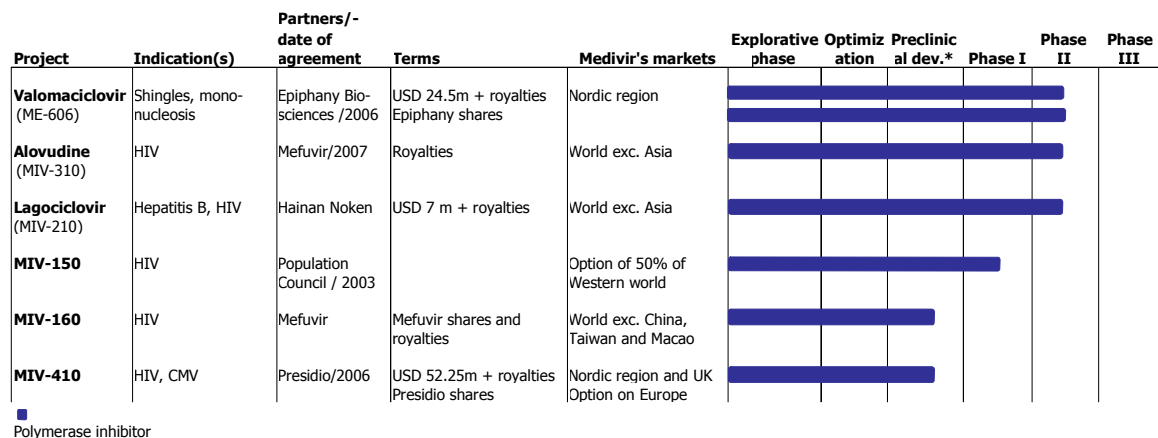
druglike compounds. The HIV-PI project has been conducted fully funded by Tibotec since year-end 2008. Its next goal is to designate CDs.

The cathepsin K project is targeting several different disease areas related to bone disorders.

Medivirs project addressing Alzheimer's disease (BACE) is ongoing in preclinical optimization phase.



Medivir HIV Franchise AB administers the polymerase-based projects against HIV, HBV, shingles and glandular fever.



For a detailed description of all projects, please see Medivir's website [www.medivir.se](http://www.medivir.se) under Research & Development.

## **Consolidated earnings and financial position**

### **Turnover and earnings, 1 January - 30 June 2009**

Net sales were SEK 24.5 (14.7) m for the period. Net sales included remuneration for research collaboration on hepatitis C of SEK 8.9 m and an allocated one-off payment of SEK 15.4 m from Tibotec Pharmaceuticals Ltd. In the corresponding period of the previous year, net sales consisted of SEK 8.2 m for research collaboration funding on HIV protease inhibitors, SEK 2.5 m for research collaboration funding on hepatitis C and an allocated one-off payment of SEK 3.9 m from Tibotec Pharmaceuticals Ltd.

Operating costs were SEK -93.1 (-100.1) m, comprising external costs of SEK -38.6 (-46.1) m, personnel costs of SEK -49.2 (-48.9) m and depreciation and amortization of SEK -5.3 (-5.1) m. The reduced external costs are mainly due to lower project costs. Restructuring costs of SEK 8.0 m were charged to profit in the first half-year 2009. SEK 7.2 m of these costs relate to staff reductions.

The operating loss was SEK -66.0 (-84.4) m. in the corresponding period of the previous year, net sales were SEK 9.8 m lower and operating costs SEK 7.0 m higher. Profit from financial investments was SEK 3.1 (7.1) m. The net loss for the period was SEK -62.9 (-77.3) m.

### **Cash flow and financial position**

As of 1 January, liquid assets including short-term investments with a maximum maturity of three months were SEK 284.4 (329.3) m and were SEK 210.9 (329.2) m at the end of the period, a change of SEK -73.5 (-0.1) m in the period. The company's current financial assets are judged to assure funding of operations including the third quarter of 2010 according to current plans. In accordance with its finance policy, Medivir invests its financial assets in fixed-income securities with low risk.

### **Investments, depreciation, amortization and impairment losses**

Gross investments in tangible fixed assets were SEK 1.0 (1.2) m in the period. Sales of fixed assets were SEK 0.2 (0.2) m. Depreciation and amortization in the year of SEK -5.3 (-5.1) m was charged to profit.

### **Shareholders' equity, share data and stock options**

The share capital at the end of the period was SEK 104.2 (104.2) m and shareholders' equity was SEK 220.5 (308.3) m. The number of shares was 20,843,547 (20,843,547), of which 660,000 (660,000) were class A and 20,183,547 (20,183,547) class B shares with a nominal value of SEK 5. There were 970,000 outstanding options at the beginning of the year. 210,000 options were forfeited in the 2004-2009 option plans in the period, due to their subscription period expiring. No options were converted in the period. The number of outstanding options was 760,000 at the end of the period, corresponding to 835,600 class B shares. The number of outstanding options could increase shareholders' equity by SEK 56.4 m, and upon full conversion, the total number of shares could amount to 21,679,147.

The equity ratio was 82.7 (77.9)%. Earnings per share, based on a weighted average number of outstanding shares, was SEK -3.02 (-3.71) and shareholders' equity per share was SEK 10.58 (14.79).

### **Financial assets held for sale**

Holdings of shares in Medivir's license partner Presidio Pharmaceuticals Inc. have been classified as financial assets held for sale. Because these shares are not quoted, and accordingly, not registered on an active marketplace, no ongoing value changes have been recognized. Due to the

operations of Presidio Pharmaceuticals Inc. being dependent on financing, the value of the holding was adjusted by SEK -4.6 m in the second quarter 2009.

### **Employees**

Medivir had 97 (100) employees at the end of the period, 49 (46)% of which were women.

### **Parent company**

Medivir AB (publ), corporate identity no. 556238-4361, is the parent company of the group. The group's operations are mainly conducted in the parent company, and consist of research operations and administrative functions. Parent company net sales for the period were SEK 24.5 (14.7) m. Operating costs were SEK -92.0 (-98.6) m, divided between external costs of SEK -37.6 (-44.6) m, personnel costs of SEK -49.1 (-48.9) m and depreciation and amortization of SEK -5.3 (-5.1) m. The operating loss was SEK -65.9 (-83.9) m and the loss after financial items was SEK -62.9 (-77.3) m. The net loss for the period was SEK -62.9 (-77.3) m. No intra-group purchases or sales occurred in the period.

Gross investments in tangible fixed assets were SEK 1.0 (1.2) m. Liquid assets including short-term investments with a maximum maturity of three months amounted to SEK 209.7 (326.1) m. For comments on operations, please refer to the section on consolidated earnings and financial position.

### **Outlook including significant risks and uncertainty factors**

Developing new pharmaceuticals to regulatory approval and launch is a highly risky and capital intensive process. Medivir's business model is characterized by high risk and the majority of projects never reach market authorization. There are primarily two types of risk to manage in operations, operational, i.e. project specific, and financial. In recent years, Medivir has taken a goal-oriented and strategic approach to create the best possible prospects of running projects quickly and with balanced risks, but despite continued work on this, there are still factors the company cannot influence.

Medivir's ability to produce new CDs, to enter partnerships on its projects and to develop its projects successfully to market launch and sale, is decisive to its future. The progress of existing partnerships and securing new partnerships will exert a major influence on Medivir's revenues and cash position. However, it is not possible to specify the exact timing of revenue flows. We will continue to take great care in prioritizing new business opportunities for our projects and managing our existing partnerships.

The company's current financial assets are judged to assure funding of operations including the third quarter of 2010 according to current plans. The recent deterioration of the global economy has created increased general uncertainty, which may affect Medivir's access to funding.

For a more detailed review of the future outlook, including significant risks and uncertainty factors, the reader is referred to the Report of the Directors in the Annual Report 2008.

## **Accounting policies**

Medivir applies International Financial Reporting Standards (IFRS) as endorsed by the European Union. The significant accounting and valuation principles are stated on pages 48-51 of the Annual Report 2008. The group's Interim Reports are prepared according to IAS 34. The parent company uses the terminology recommended in RFR 2.2 issued by RFR, the Swedish Financial Reporting Board.

The amendment of IAS 1, *Presentation of Financial Statements*, is applied from 1 January 2009. This amendment has affected Medivir's reporting retroactively from 31 December 2007. The amendment has implications including revenue and costs previously reported directly in shareholders' equity now being reported in a separate statement directly after the Income Statement. Another change is that new terminology in financial statements can be used, although this is not mandatory. Medivir has chosen to retain its previous terminology.

Other new or revised IFRS and interpretation statements from IFRIC that came into effect after 31 December 2008 did not have any material effect on the group's or parent company's financial position or results of operations.

<b>CONSOLIDATED INCOME STATEMENT</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
<b>SUMMARY (SEK m)</b>	<b>Jan-Jun</b>	<b>Jan-Jun</b>	<b>Jan-Dec</b>
<b>Turnover, etc.</b>			
Net sales	24.5	14.7	97.2
Other revenue	2.6	1.0	4.8
<b>Total</b>	<b>27.1</b>	<b>15.7</b>	<b>102.0</b>
<b>Operating costs</b>			
Other external costs	-38.6	-46.1	-101.6
Personnel costs	-49.2	-48.9	-103.8
Depreciation and amortization	-5.3	-5.1	-10.3
<b>Total</b>	<b>-93.1</b>	<b>-100.1</b>	<b>-215.7</b>
<b>Operating profit/loss</b>	<b>-66.0</b>	<b>-84.4</b>	<b>-113.7</b>
Profit/loss from financial investments	3.1	7.1	13.7
<b>Profit/loss after financial items</b>	<b>-62.9</b>	<b>-77.3</b>	<b>-100.0</b>
Tax	0.0	0.0	0.8
<b>Net profit/loss</b>	<b>-62.9</b>	<b>-77.3</b>	<b>-99.2</b>
Net profit/loss attributable to:			
<b>Equity holders of the parent</b>	<b>-62.9</b>	<b>-77.3</b>	<b>-99.2</b>
<b>Earnings per share, calculated on profit/loss attributable to equity holders of the parent in the period</b>			
Basic and diluted earnings per share, SEK	-3.02	-3.71	-4.76
Average number of shares, 000	20,844	20,844	20,844
Number of shares at end of period, 000	20,844	20,844	20,844

<b>CONSOLIDATED STATEMENT OF TOTAL RECOGNIZED GAINS AND LOSSES</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
<b>(SEK m)</b>	<b>Jan-Jun</b>	<b>Jan-Jun</b>	<b>Jan-Dec</b>
<b>Net profit/loss</b>	<b>-62.9</b>	<b>-77.3</b>	<b>-99.2</b>
<b>Other total gains and losses</b>			
Financial assets held for sale	-4.6	0.0	0.0
Exchange rate differences	-0.4	0.2	0.6
<b>Other total gains and losses for the period, net after tax</b>	<b>-5.0</b>	<b>0.2</b>	<b>0.6</b>
<b>Total gains and losses for the period</b>	<b>-67.9</b>	<b>-77.1</b>	<b>-98.6</b>
Total gains and losses attributable to:			
<b>Equity holders of the parent</b>	<b>-67.9</b>	<b>-77.1</b>	<b>-98.6</b>

<b>CONSOLIDATED INCOME STATEMENT</b>	<b>2009</b>	<b>2008</b>
<b>SUMMARY (SEK m)</b>	<b>Apr-Jun</b>	<b>Apr-Jun</b>
<b>Turnover, etc.</b>		
Net sales	7.0	10.5
Other revenue	2.2	0.5
<b>Total</b>	<b>9.2</b>	<b>11.0</b>
<b>Operating costs</b>		
Other external costs	-18.1	-22.7
Personnel costs	-21.9	-25.3
Depreciation and amortization	-2.6	-2.5
<b>Total</b>	<b>-42.6</b>	<b>-50.5</b>
<b>Operating profit/loss</b>	<b>-33.4</b>	<b>-39.5</b>
Profit/loss from financial investments	0.9	3.4
<b>Profit/loss after financial items</b>	<b>-32.5</b>	<b>-36.1</b>
<b>Net profit/loss</b>	<b>-32.5</b>	<b>-36.1</b>
Net profit/loss attributable to:		
<b>Equity holders of the parent</b>	<b>-32.5</b>	<b>-36.1</b>
<b>Earnings per share, calculated on profit/loss attributable to equity holders of the parent in the period</b>		
Basic and diluted earnings per share, SEK	-1.56	-1.73
Average number of shares, 000	20,844	20,844
Number of shares at end of period, 000	20,844	20,844

<b>CONSOLIDATED STATEMENT OF TOTAL RECOGNIZED GAINS AND LOSSES</b>	<b>2009</b>	<b>2008</b>
<b>(SEK m)</b>	<b>Apr-Jun</b>	<b>Apr-Jun</b>
<b>Net profit/loss</b>	<b>-32.5</b>	<b>-36.1</b>
<b>Other total gains and losses</b>		
Financial assets held for sale	-4.6	0.0
Exchange rate differences	-0.3	0.0
<b>Other total gains and losses for the period, net after tax</b>	<b>-4.9</b>	<b>0.0</b>
<b>Total gains and losses for the period</b>	<b>-37.4</b>	<b>-36.1</b>
Total gains and losses attributable to:		
<b>Equity holders of the parent</b>	<b>-37.4</b>	<b>-36.1</b>



<b>CONSOLIDATED BALANCE SHEET</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
<b>SUMMARY (SEK m)</b>	<b>30 Jun</b>	<b>30 Jun</b>	<b>31 Dec</b>
<b>Assets</b>			
Intangible fixed assets	0.3	0.7	0.5
Tangible fixed assets	31.3	32.4	35.8
Financial fixed assets	14.2	18.8	18.8
Current receivables	10.0	14.8	32.0
Short-term investments	199.1	263.7	227.8
Cash and bank balances	11.8	65.5	56.6
<b>Total assets</b>	<b>266.7</b>	<b>395.8</b>	<b>371.5</b>
<b>Liabilities and shareholders' equity</b>			
Shareholders' equity	220.5	308.3	287.6
Current liabilities, non interest-bearing	46.2	87.5	83.9
<b>Total liabilities and shareholders' equity</b>	<b>266.7</b>	<b>395.8</b>	<b>371.5</b>

<b>STATEMENT OF CHANGES TO SHAREHOLDERS' EQUITY</b>	<b>Share capital</b>	<b>Other paid-up capital</b>	<b>Exchange rate difference</b>	<b>Deficit brought forward</b>	<b>Total shareholders' equity</b>
(SEK m)					
<b>Opening balance, 1 January 2008</b>	<b>104.2</b>	<b>844.8</b>	<b>3.7</b>	<b>-568.8</b>	<b>384.0</b>
Total gains and losses for the period			0.6	-99.2	-98.6
Staff stock option plans: value of employee service		2.2			2.2
<b>Closing balance, 31 December 2008</b>	<b>104.2</b>	<b>847.0</b>	<b>4.3</b>	<b>-668.0</b>	<b>287.6</b>
<b>Opening balance, 1 January 2008</b>	<b>104.2</b>	<b>844.8</b>	<b>3.7</b>	<b>-568.8</b>	<b>384.0</b>
Total gains and losses for the period			0.2	-77.3	-77.1
Staff stock option plans: value of employee service		1.4			1.4
<b>Closing balance, 30 June 2008</b>	<b>104.2</b>	<b>846.2</b>	<b>3.9</b>	<b>-646.0</b>	<b>308.3</b>
<b>Opening balance, 1 January 2009</b>	<b>104.2</b>	<b>847.0</b>	<b>4.3</b>	<b>-668.0</b>	<b>287.6</b>
Total gains and losses for the period			-5.0	-62.9	-67.9
Staff stock option plans: value of employee service		0.8			0.8
<b>Closing balance, 30 June 2009</b>	<b>104.2</b>	<b>847.8</b>	<b>-0.7</b>	<b>-730.9</b>	<b>220.5</b>

<b>CONSOLIDATED CASH FLOW STATEMENT</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
<b>SUMMARY (SEK m)</b>	<b>Jan-Jun</b>	<b>Jan-Jun</b>	<b>Jan-Dec</b>
<b>Cash flow from operating activities before changes in working capital</b>	<b>-57.1</b>	<b>-70.7</b>	<b>-85.8</b>
Changes in working capital	-15.8	71.9	51.0
<b>Cash flow from operating activities</b>	<b>-72.9</b>	<b>1.2</b>	<b>-34.8</b>
<b>Investment activity</b>			
Acquisition/divestment of fixed assets	-0.8	-1.0	-9.7
<b>Cash flow from investment activity</b>	<b>-0.8</b>	<b>-1.0</b>	<b>-9.7</b>
<b>Cash flow for the period</b>			
Liquid assets, at beginning of period	284.4	329.3	329.3
Change in liquid assets	-73.6	0.2	-44.7
Exchange rate difference in liquid assets	0.1	-0.3	-0.3
<b>Liquid assets, at end of period</b>	<b>210.9</b>	<b>329.2</b>	<b>284.4</b>

<b>KEY FIGURES, SHARE DATA, OPTIONS</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
	<b>Jan-Jun</b>	<b>Jan-Jun</b>	<b>Jan-Dec</b>
Return on:			
- equity, %	-24.8	-22.3	-29.5
- capital employed, %	-24.8	-22.3	-29.6
- total capital, %	-19.7	-18.1	-23.9
Number of shares at beginning of period, 000	20,844	20,844	20,844
Issues	0	0	0
Number of shares at end of period, 000	20,844	20,844	20,844
- of which class A shares	660	660	660
- of which class B shares	20,184	20,184	20,184
Average number of shares, 000	20,844	20,844	20,844
Outstanding warrants, 000	760	970	970
- entitlement to class B shares at conversion, 000	836	1,102	1,102
Share capital at end of period, SEK m	104.2	104.2	104.2
Shareholders' equity at end of period, SEK m	220.5	308.3	287.6
Basic and diluted earnings per share, SEK	-3.02	-3.71	-4.76
Shareholders' equity per share, SEK	10.58	14.79	13.80
Net worth per share, SEK	10.58	14.79	13.80
Cash flow per share after investments, SEK	-3.53	0.01	-2.14
Equity ratio, %	82.7	77.9	77.4

<b>PARENT COMPANY INCOME STATEMENT</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
(SEK m)	Jan-Jun	Jan-Jun	Jan-Dec
<b>Turnover, etc.</b>			
Net sales	24.5	14.7	104.0
Other revenue	1.6	0.0	2.8
<b>Total</b>	<b>26.1</b>	<b>14.7</b>	<b>106.8</b>
<b>Operating costs</b>			
Other external costs	-37.6	-44.6	-100.4
Personnel costs	-49.1	-48.9	-103.8
Depreciation and amortization	-5.3	-5.1	-10.3
<b>Total</b>	<b>-92.0</b>	<b>-98.6</b>	<b>-214.5</b>
<b>Operating profit/loss</b>	<b>-65.9</b>	<b>-83.9</b>	<b>-107.7</b>
Profit/loss from financial investments	3.0	6.6	8.9
<b>Profit/loss after financial items</b>	<b>-62.9</b>	<b>-77.3</b>	<b>-98.8</b>
<b>Net profit/loss</b>	<b>-62.9</b>	<b>-77.3</b>	<b>-98.8</b>

<b>PARENT COMPANY BALANCE SHEET</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
SUMMARY (SEK m)	30 Jun	30 Jun	31 Dec
<b>Assets</b>			
Intangible fixed assets	0.3	0.7	0.5
Tangible fixed assets	31.3	32.4	35.8
Financial fixed assets	14.4	19.4	19.0
Current receivables	6.0	12.7	28.7
Short-term investments	199.1	263.7	227.8
Cash and bank balances	10.6	62.4	55.4
<b>Total assets</b>	<b>261.7</b>	<b>391.4</b>	<b>367.2</b>
<b>Liabilities and shareholders' equity</b>			
Shareholders' equity	220.8	308.3	287.6
Long-term liabilities, non interest-bearing	1.6	0.0	1.7
Current liabilities, non interest-bearing	39.3	83.1	77.9
<b>Total liabilities and shareholders' equity</b>	<b>261.7</b>	<b>391.4</b>	<b>367.2</b>

## **Certification**

The Board of Directors and Chief Executive Officer hereby certify that the Half-year Interim Report gives a true and fair view of the company's and group's operations, financial position and results of operations and reviews the significant risks and uncertainty factors facing the company and group companies.

Göran Pettersson  
*Chairman*

Björn C Andersson  
*Board member*

Anna Malm Bernsten  
*Board member*

Ingemar Kihlström  
*Board member*

Ron Long  
*CEO/Board member*

Huddinge, Sweden, 9 July 2009

## **Review report**

We have conducted a limited review of the financial statement for Medivir AB (publ) for the period 1 January – 30 June 2009. The preparation and presentation of these interim financial statements pursuant to IAS 34 and the Swedish Annual Accounts Act are the responsibility of the Board of Directors and Chief Executive Officer. Our responsibility is to report our conclusions concerning these interim financial statements on the basis of our limited review.

We have conducted our limited review pursuant to the Standard for Limited Review (SÖG) 2410 "Limited review of interim financial information conducted by the company's appointed auditor". A limited review consists of making inquiries, primarily to individuals responsible for financial and accounting matters, as well as performing analytical procedures and taking other limited review measures. A limited review has a different focus and significantly less scope than an audit according to RS Auditing Standards in Sweden and generally accepted auditing practice. The review procedures undertaken in a limited review do not enable us to obtain a level of assurance where we would be aware of all important circumstances that would have been identified had an audit been conducted. Therefore, a conclusion reported on the basis of a limited review does not have the level of certainty of a conclusion reported on the basis of an audit.

Based on our limited review, no circumstances have come to our attention that would give us reason to believe that the interim financial statements have not been prepared pursuant to IAS 34 and the Swedish Annual Accounts Act for the group, and pursuant to the Swedish Annual Accounts Act for the parent company, in all material respects.

PricewaterhouseCoopers AB

Claes Dahlén  
*Authorized Public Accountant*

Stockholm, Sweden, 9 July 2009