

### Press Release, 21 October 2009

# **Medivir, Interim Report, 1 January – 30 September 2009**

- Consolidated net sales were SEK 24.5 (31.9) m.
- The loss after tax was SEK -93.0 (-102.4) m.
- Earnings per share were SEK -4.46 (-4.91).
- Cash flow from operating activities was SEK -104.8 (-30.4) m.
- Liquid assets and short-term investments as of 30 September were SEK 176.1 (295.7) m.

# Third quarter in brief

Several significant project events were reported in the quarter.

The highlights can be summarized as follows:

- FDA approved Lipsovir<sup>®</sup> with a competitive label for marketing and sales in the US.
- At present, two phase IIb trials involving a total of 855 patients are ongoing on TMC435 against hepatitis C. The latter of these trials (C-206) started in September and involves 455 patients that previously did not respond to standard of care (SoC).
- Medivir designated another candidate drug (CD), MIV-711 in its osteoporosis portfolio, thus enhancing its commercial opportunities.

Ron Long CEO

Huddinge, Sweden, 21 October 2009

#### For more information, please contact:

Rein Piir, CFO and VP, Investor Relations: +46 (0)70 853 7292 or +46 (0)8 546 83123.

#### FORTHCOMING FINANCIAL INFORMATION

The Financial Statement for 12 months will be published on 18 February 2010.

The Three-month Interim Report will be published on 29 April 2010. The Annual General Meeting (AGM) will be held on 29 April 2010.

The Reports will be available at Medivir's Website, <u>www.medivir.se</u> from this date under the 'Investor/Media' heading.

# Highlights in the third quarter 2009

# The US regulatory authority, the Food & Drug Administration (FDA), approved Lipsovir® with a competitive label for marketing and sales in the US

On 31 July, the FDA approved Lipsovir® for topical treatment of recurrent oral herpes. Lipsovir® reduces the risk of the incidence of cold sores and the therapy is approved for adults and children aged 12 or over.

The approved label is: "Acyclovir and Hydrocortisone Cream is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time".

None of the products treating oral herpes available presently on the US market have the corresponding label or have been demonstrated the ability to prevent the incidence of cold sores with early treatment onset in clinical trials. For those patients that still get cold sores despite treatment, Lipsovir® reduces healing times. Accordingly, Medivir's product enjoys a clear competitive edge on the US market which is the most important, and in value terms the single largest geographic, market. Like other anti-herpes compounds, Lipsovir® will be sold on prescription in the US.

The objective is to enter a commercial partnership for the launch of Lipsovir<sup>®</sup>, which is scheduled for summer 2010. Partnership discussions are progressing well.

### TMC435 (hepatitis C)—phase IIb trials progressing positively

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

TMC435 is currently in two clinical phase IIb trials, whose design has been based on factors including positive partial results obtained in two phase IIa trials which have been presented at various medical congresses over the past half-year. They show that TMC435 administered with only a single daily dose and for four weeks has very potent antiviral efficacy, is well tolerated and safe at the doses studied.

#### Phase IIb trial C-205

Recruitment for the clinical phase IIb trial (C-205) of treatment-naïve patients began in May 2009. C-205 is a double-blind, placebo-controlled trial involving 400 patients; patient recruitment is progressing very well.

All 400 patients will receive current standard of care (SoC), which consists of interferon (PegIFNalpha-2a) and ribavirin. SoC will continue for 48 weeks.

The five 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.

#### Phase IIb trial C-206

Recruitment for the clinical phase IIb trial (C-206) of patients that have not previously responded to SoC started at the end of September 2009. This trial is also a double-blind, placebo-controlled trial involving 455 patients.

All 455 patients will receive current SoC, which will continue for 48 weeks.

The seven therapy arms consist of:

SoC plus TMC435, 100 mg for 12 weeks; SoC plus TMC435, 150 mg for 12 weeks; SoC plus TMC435, 100 mg for 24 weeks; SoC plus TMC435, 150 mg for 24 weeks; SoC plus TMC435, 100 mg for 48 weeks; SoC plus TMC435, 150 mg for 48 weeks; SoC plus placebo for 48 weeks.

### Medivir expands cathepsin K portfolio by designating another CD

Medivir deepened its commitment and extended its commercial interest in bone disorders by designating another CD against the target enzyme cathepsin K, a well-established drug target. This enhances the company's current interests in bone disorders, which already includes a previously designated CD. Potential indications for selected CD's include osteoporosis, osteoarthritis (OA), rheumatoid arthritis (RA) and bone metastases.

This new CD, MIV-711, is a highly active small molecule inhibitor whose profile differs from MIV-710, which was designated as a CD in February 2009. MIV-711 and MIV-710 are both expected to be dosed in tablet form at low dosages once daily.

The decision to designate another CD from Medivir's broad-based cathepsin K program was taken to capture further indications with substantial market potential. Due to their favorable efficacy and pharmacokinetic qualities these new compounds will be prioritized for onward clinical development, with the consequence that the development of MIV-701 has been discontinued.

# Highlights after the end of the reporting period

# Lipsovir® approved in Europe with a competitive label

In mid-October, the European regulatory authorities approved Medivir's marketing authorization application in 14 European countries. The trademark for the product in Europe will be  $\mathbf{Xerclear}^{\mathsf{TM}}$ .

The approved label for Xerclear<sup>TM</sup> "Treatment of early signs and symptoms of recurrent herpes labialis (cold sores) to reduce the progression of cold sore episodes to ulcerative lesions in immunocompetent adults and adolescents (12 years of age and older)" is unique for a topical cold sore product in Europe.

Xerclear<sup>™</sup> thus has a distinct competitive edge in Europe as well as US, where the product was approved on 31 July 2009 with a similarly strong label.

The remaining step in the process towards product launch in the 14 European countries takes place at the national level, and includes determination of the local packaging and  $OTC/R_X$  status. This process is expected to be completed by year-end.

# **Project portfolio**

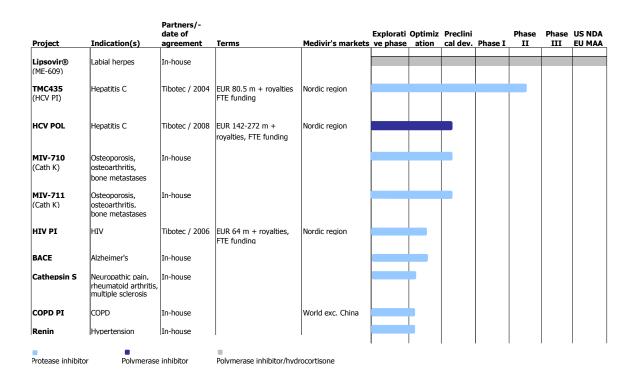
Two preclinical projects, HCV-POL and HIV-PI, are being conducted in partnership with Tibotec.

In the HCV-POL partnership, entered in May 2008, pharmaceuticals are being developed against hepatitis C with polymerase as their target enzyme. This project designated a CD in December 2008, which Tibotec is taking onwards towards phase I clinical trials. In 2009, the research partnership focused on identifying additional druglike compounds, which was completed in May. The HIV-PI project has continued, and been fully funded by Tibotec since year-end 2008. Its next goal is to designate CDs.

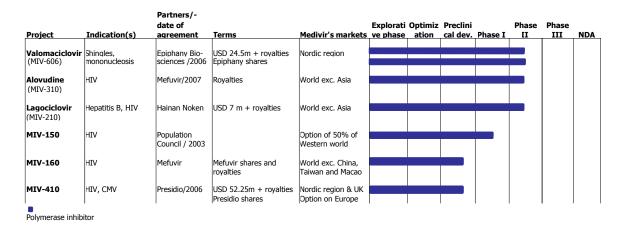
The cathepsin K project addresses a wide range of indications in bone disorders.

Medivir's protease-based project in Alzheimer's disease (BACE) is in preclinical optimization.

The cathepsin S project primarily addresses neuralgia, and is in early preclinical optimization.



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 <u>www.medivir.se</u> under Research & Development.

# Consolidated earnings and financial position

### Turnover and earnings, 1 January - 30 September 2009

Net sales were SEK 24.5 (31.9) m. Net sales in the period 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 12.3 m for research collaboration funding on HIV protease inhibitors, SEK 7.6 m for research collaboration funding on hepatitis C and an allocated one-off payment of SEK 9.6 m from Tibotec Pharmaceuticals Ltd.

Operating costs were SEK -128.4 (-147.9) m, comprising external costs of SEK -54.9 (-68.0) m, personnel costs of SEK -65.6 (-72.2) m and depreciation and amortization of SEK -7.9 (-7.7) m. The reduced external costs are mainly due to lower project costs. Restructuring costs of SEK 8.5 m were charged to profit in the period. SEK 7.5 m of these costs relate to staff reductions.

The operating loss was SEK -97.3 (-113.7) m. in the corresponding period of the previous year, net sales were SEK 7.4 m higher and operating costs SEK 19.5 m higher. Profit from financial investments was SEK 4.3 (10.4) m. The net loss for the period was SEK -93.0 (-102.4) 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 176.1 (295.7) m at the end of the period, a change of SEK -108.3 (-33.6) m in the period. The company's current financial assets are judged to assure funding of operations until the end of the third quarter of 2010 inclusive. 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 in the period were SEK 1.0 (3.1) m; gross investments in intangible fixed assets were SEK 2.8 (0.0) m. Primarily, investments in tangible fixed assets are for research equipment. Investments in intangible fixed assets relate to capitalization of external costs and personnel costs for completion of Lipsovir $^{(8)}$  after FDA approval of the product for marketing and sale in the US. Capitalized costs for the product will be amortized over its assessed useful life. No amortization for the product was charged to operating profit/loss during the period as amortization is scheduled to start in 2010. Sales of fixed assets were SEK 0.3 (0.2) m. Depreciation and amortization in the year of SEK -7.9 (-7.7) m was charged to profit.

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

Share capital at the end of the period was SEK 104.2 (104.2) m and shareholders' equity was SEK 195.6 (283.4) 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 83.8 (74.2)%. Earnings per share, based on a weighted average number of outstanding shares, was SEK -4.46 (-4.91) and shareholders' equity per share was SEK 9.38 (13.60).

#### 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 Presidio Pharmaceuticals Inc. having refinanced operations in the third quarter 2009, the value of this holding has been restated with SEK 4.6 m.

#### **Employees**

Medivir had 86 (103) employees at the end of the period, 49 (48)% 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 (31.9) m. Operating costs were SEK -126.8 (-145.5) m, divided between external costs of SEK -53.4 (-65.7) m, personnel costs of SEK -65.5 (-72.1) m and depreciation and amortization of SEK -7.9 (-7.7) m. The operating loss was SEK -97.2 (-112.8) m and the loss after financial items was SEK -92.9 (-102.9) m. The net loss for the period was SEK -92.9 (-102.9) m. No intragroup purchases or sales occurred in the period.

Gross investments in tangible fixed assets were SEK 1.0 (3.1) m and gross investments in intangible fixed assets were SEK 2.8 (0.0) m. Liquid assets including short-term investments with a maximum maturity of three months amounted to SEK 172.8 (294.8) m. For comments on operations, please refer to the section on consolidated earnings and financial position.

#### **Nomination committee 2009-2010**

Pursuant to an AGM resolution, the Nomination Committee for 2009-2010 shall consist of representatives of at least the three largest shareholders as of the end of the third quarter 2009, and the Chairman of the Board. A new committee was appointed in October consisting of; Bo Öberg, representing A shareholders, Eva Gottfridsdotter-Nilsson, Länsförsäkringar Fonder AB, Frank Larsson, Handelsbanken Fonder AB and Göran Pettersson, Chairman of the Board.

### **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 registration. 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 previously entered partnerships and future 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 expected 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 until the end of the third quarter of 2010. 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.

CONSOLIDATED INCOME STATEMENT	2009	2008	2008
SUMMARY (SEK m)	Jan-Sep	Jan-Sep	Jan-Dec
Turnover, etc.			
Net sales	24.5	31.9	97.2
Other revenue	6.6	2.3	4.8
Total	31.1	34.2	102.0
Operating costs			
Other external costs	-54.9	-68.0	-101.6
Personnel costs	-65.6	-72.2	-103.8
Depreciation and amortization	-7.9	-7.7	-10.3
Total	-128.4	-147.9	-215.7
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Operating profit/loss	-97.3	-113.7	-113.7
Profit/loss from financial investments	4.3	10.4	13.7
Profit/loss after financial items	-93.0	-103.3	-100.0
Tax	0.0	0.8	0.8
I di	0.0	0.0	0.0
Net profit/loss	-93.0	-102.4	-99.2
Net profitioss	-33.0	-102.4	-33.2
Not profit/loop attributable to			
Net profit/loss attributable to:	00.0	400.4	00.0
Equity holders of the parent	-93.0	-102.4	-99.2
Earnings per share, calculated on profit/loss			
attributable to equity holders of the parent in the			
period			
Basic and diluted earnings per share, SEK	-4.46	-4.91	-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
CONSOLIDATED STATEMENT OF TOTAL			
RECOGNIZED GAINS AND LOSSES	2009	2008	2008
(SEK m)	Jan-Sep	Jan-Sep	Jan-Dec
Net profit/loss	-93.0	-102.4	-99.2
Other total gains and losses			
Financial assets held for sale	0.0	0.0	0.0
Exchange rate differences	-0.1	0.1	0.6
Other total gains and losses for the period,			
net after tax	-0.1	0.1	0.6
Total materials and the control of the control of		400.0	
Total gains and losses for the period	-93.0	-102.3	-98.6
Total gains and losses attributable to:			
Equity holders of the parent	-93.0	-102.3	-98.6

CONSOLIDATED INCOME STATEMENT SUMMARY (SEK m)	2009 Jul-Sep	2008 Jul-Sep
SOMMAN (SER III)	our ocp	our ocp
Turnover, etc.		47.0
Net sales Other revenue	0.0 4.0	17.2 1.3
Total	4.0	18.5
Operating costs		
Other external costs	-16.3	-22.0
Personnel costs	-16.4	-23.3
Depreciation and amortization	<u>-2.6</u>	<u>-2.5</u>
Total	-35.3	-47.8
Operating profit/loss	-31.3	-29.3
Profit/loss from financial investments	1.2	3.3
Profit/loss after financial items	-30.1	-26.0
Tax	0.0	0.8
Net profit/loss	-30.1	-25.2
Net profit/loss attributable to:  Equity holders of the parent	-30.1	-25.2
Earnings per share, calculated on profit/loss attributable to equity holders of the parent in the period		
Basic and diluted earnings per share, SEK	-1.44	-1.21
Average number of shares, 000	20,844	20,844
Number of shares at end of period, 000	20,844	20,844
CONSOLIDATED STATEMENT OF TOTAL RECOGNIZED GAINS AND LOSSES (SEK m)	2009 Jul-Sep	2008 Jul-Sep
Net profit/loss	-30.1	-25.2
Other total gains and losses Financial assets held for sale	4.6	0.0
Exchange rate differences	0.3	-0.1
Other total gains and losses for the period, net after tax	4.9	-0.1
Total gains and losses for the period	-25.2	-25.3
Total gains and losses attributable to:		
Equity holders of the parent	-25.2	-25.3

CONSOLIDATED BALANCE SHEET	2009	2008	2008
SUMMARY (SEK m)	30 Sep	30 Sep	31 Dec
Assets			
Intangible fixed assets	2.9	0.6	0.5
Tangible fixed assets	28.9	31.6	35.8
Financial fixed assets	18.8	18.8	18.8
Current receivables	6.8	35.4	32.0
Short-term investments	156.4	224.8	227.8
Cash and bank balances	19.7	70.9	56.6
Total assets	233.4	382.1	371.5
Liabilities and shareholders' equity			
Shareholders' equity	195.6	283.4	287.6
Current liabilities, non interest-bearing	37.8	98.7	83.9
Total liabilities and shareholders' equity	233.4	382.1	371.5

STATEMENT OF CHANGES TO SHAREHOLDERS' EQUITY (SEK m)	Share capital	Other paid-up capital	Exchange rate difference	Deficit brought forward	Total sharehold ers' equity
Opening balance, 1 January 2008	104.2	844.8	3.7	-568.8	384.0
Total gains and losses for the period Staff stock option plans: value of			0.6	-99.2	-98.6
employee service		2.2			2.2
Closing balance, 31 December 2008	104.2	847.0	4.3	-668.0	287.6
Opening balance, 1 January 2008	104.2	844.8	3.7	-568.8	384.0
Total gains and losses for the period Staff stock option plans: value of			0.1	-102.4	-102.3
employee service		1.7			1.7
Closing balance, 30 September 2008	104.2	846.5	3.8	-671.2	283.4
Opening balance, 1 January 2009	104.2	847.0	4.3	-668.0	287.6
Total gains and losses for the period			-0.1	-93.0	-93.0
Staff stock option plans: value of					
employee service		1.0			1.0
Closing balance, 30 September 2009	104.2	848.0	4.2	-761.0	195.6

CONSOLIDATED CASH FLOW STATEMENT	2009	2008	2008
SUMMARY (SEK m)	Jan-Sep	Jan-Sep	Jan-Dec
Cash flow from operating activities before			
changes in working capital	-83.9	-92.7	-85.8
Changes in working capital	-20.9	62.3	51.0
Cash flow from operating activities	-104.8	-30.4	-34.8
Investment activity			
Acquisition/divestment of fixed assets	-3.5	-2.9	-9.7
Cash flow from investment activity	-3.5	-2.9	-9.7
Cash flow for the period			
Liquid assets, at beginning of period	284.4	329.3	329.3
Change in liquid assets	-108.2	-33.4	-44.7
Exchange rate difference in liquid assets	-0.1	-0.2	-0.3
Liquid assets, at end of period	176.1	295.7	284.4

KEY FIGURES, SHARE DATA, OPTIONS	2009	2008	2008
	Jan-Sep	Jan-Sep	Jan-Dec
Return on:			
- equity, %	-38.5	-30.7	-29.5
- capital employed, %	-38.4	-30.9	-29.6
- total capital, %	-30.7	-24.5	-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	195.6	283.4	287.6
Basic and diluted earnings per share, SEK	-4.46	-4.91	-4.76
Shareholders' equity per share, SEK	9.38	13.60	13.80
Net worth per share, SEK	9.38	13.60	13.80
Cash flow per share after investments, SEK	-5.20	-1.61	-2.14
Equity ratio, %	83.8	74.2	77.4

PARENT COMPANY INCOME STATEMENT	2009	2008	2008
SUMMARY (SEK m)	Jan-Sep	Jan-Sep	Jan-Dec
Turnover, etc.			
Net sales	24.5	31.9	104.0
Other revenue	5.1	0.8	2.8
Total	29.6	32.7	106.8
Operating costs			
Other external costs	-53.4	-65.7	-100.4
Personnel costs	-65.5	-72.1	-103.8
Depreciation and amortization	-7.9	-7.7	-10.3
Total	-126.8	-145.5	-214.5
Operating profit/loss	-97.2	-112.8	-107.7
Profit/loss from financial investments	4.3	9.9	8.9
Profit/loss after financial items	-92.9	-102.9	-98.8
Net profit/loss	-92.9	-102.9	-98.8

PARENT COMPANY BALANCE SHEET	2009	2008	2008
SUMMARY (SEK m)	30 Sep	30 Sep	31 Dec
Assets			
Intangible fixed assets	2.9	0.6	0.5
Tangible fixed assets	28.9	31.5	35.8
Financial fixed assets	19.0	19.0	19.0
Current receivables	5.4	30.5	28.7
Short-term investments	156.4	224.8	227.8
Cash and bank balances	16.4	70.0	55.4
Total assets	228.9	376.4	367.2
Liabilities and shareholders' equity			
Shareholders' equity	195.7	283.1	287.6
Long-term liabilities, non interest-bearing	1.5	1.3	1.7
Current liabilities, non interest-bearing	31.7	92.0	77.9
Total liabilities and shareholders' equity	228.9	376.4	367.2

Ron Long CEO/Board member

Huddinge, Sweden, 21 October 2009

## **Review report**

We have conducted a limited review of the financial statement for Medivir AB (publ) for the period 1 January – 30 September 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, 21 October 2009