



Stockholm 21 of February 2005

## Biolipox – Year-end report 2004

### Full-year 2004

- Biolipox secure additional funding – international venture capital firms invest EUR 30 million
- NLA Nasal Spray for the treatment of rhinitis shows good efficacy in phase II study
- Progress in projects leads to several patent applications
- Early drug development organisation further expanded
- Net sales amounted to SEK 0 (0)
- Results after tax amounted to a loss of SEK 96.7 million (loss: 63.3)
- Earnings per share amounted to a loss of SEK 112.25 (loss: 72.46)

Biolipox's year-end report for 2004 is presented on the following pages.

For further information, please contact:

Torbjörn Bjerke, President & CEO, Tel: +46 70 66 19 90,

e-mail: [torbjorn.bjerke@biolipox.com](mailto:torbjorn.bjerke@biolipox.com)

Peter Hein, CFO, Tel: +46 8 545 28 153, Cellular phone: +46 733 70 73 43,

e-mail: [peter.hein@biolipox.com](mailto:peter.hein@biolipox.com)

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Biolipox AB, Box 6280, SE-102 34 Stockholm, Sweden.

Tel: +46-8-545 28 140, Fax: +46-8-545 28 141, E-mail: [torbjorn.bjerke@biolipox.com](mailto:torbjorn.bjerke@biolipox.com)

[www.biolipox.com](http://www.biolipox.com)



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### **Fourth quarter**

- Net sales amounted to SEK 0 (0)
- Results after tax amounted to a loss of SEK 24.7 million (loss: 18.5)
- Earnings per share amounted to a loss of SEK 28.70 (loss: 20.84)

### **Biolipox secures additional funding – international venture capital firms invest EUR 30 million**

At year-end 2004, Biolipox successfully completed a EUR 30 million private placement. The Series C round was led by Scandinavian Life Science Venture (SLSV), and included existing investors HealthCap, Apax Partners, Sofinnova Partners, Auriga Partners and Crédit Lyonnais Private Equity. The funds provided will enable Biolipox to take bring its projects to human studies and to implement introductory studies phase I and II on humans.

### **NLA Nasal Spray for the treatment of rhinitis shows good efficacy in phase II study**

Biolipox's Phase II study with the new NLA Nasal Spray for the treatment of allergic and non-allergic rhinitis was concluded during the year. Results were encouraging showing significant relief of rhinitis symptoms after treatment with NLA Nasal Spray compared with placebo. Furthermore, NLA proved to have a more sustained antihistamine effect than cetirizine tablets. The low plasma concentrations seen with NLA Nasal Spray suggest that this type of administration will result in less systemic adverse events.

*Rhinitis gives rise to an inflamed swelling in the mucous membranes of the nose, which can result in nasal congestion, itching, and sneezing. Rhinitis can be allergic or non-allergic, and has an incidence that has increased sharply during the past 20 years. It is estimated that approximately 25 percent of the global population is afflicted. Sales of the largest drugs prescribed for rhinitis amounted to USD 5 billion in 2003.*



### **Progress in projects leads to several patent applications**

Research activities during 2004 were successful and strengthened the patent situation. Patent applications were filed in all the projects during the year.

#### Selective PGE2 synthase inhibitor – an effective anti-inflammatory drug with few side effects

The project is aimed at the development of a new, effective medicine for inhibiting pain, inflammation and fever, with fewer side effects than existing drugs. It is based on the discovery of a new mechanism of action, permitting selective blocking of a specific enzyme that is central to various inflammatory processes. The project is in early pre-clinical phase.

The non-steroidal anti-inflammatory drugs currently available (NSAIDs) and the cyclooxygenase-2-inhibitors (COX-2-inhibitor) block the first step in the formation of prostaglandins. This broader-based effect gives rise to side effects, since all prostaglandins are blocked, including those necessary for the body's proper functioning. Selective blocking of the formation of prostaglandin E2, which is the main inducer of pain and inflammation, is expected to markedly reduce the risk of side effects.

*One out of three adults in the US suffers from arthritis, resulting in pain and impaired mobility. Rheumatoid arthritis (RA), inflammation in several joints simultaneously, is somewhat less common, but often more disabling. It may also affect young people in their active years, leading to great suffering and a high cost to society at large. NSAIDs represented USD 12.4 bn or 3 percent of global pharmaceutical sales in 2003, with a year-over-year growth of 6 percent.*

#### Eoxin inhibitors – a new class of drugs for the treatment of asthma and Chronic Obstructive Pulmonary Disease

The eoxin inhibitor project is aimed at the development of a new generation of drugs for asthma, Chronic Obstructive Pulmonary Disease (COPD) and other inflammatory diseases. Biolipox collaborates closely with the Karolinska Institutet in Stockholm, which has long experience of research in the field of arachidonic acid and its transformation into biologically active substances, including prostaglandins and leukotrienes. Continuing research by the company has resulted in the discovery of a group of substances - the eoxins - derived from arachidonic acid, which have been shown to play an important role in various inflammatory processes. The project is in early preclinical phase.

#### Dual effect respiratory drug project – a new treatment principle for the treatment of asthma and COPD

The project, intended for the development of a respiratory drug with potentially both bronchodilatory and anti-inflammatory properties, was initiated during the year and has already moved into the phase of lead identification/optimisation.

*Asthma affects 6 to 8 percent of the adult population and about 10 percent of the children. COPD is a permanent pulmonary inflammation (chronic bronchitis), combined with shortness of breath and impaired lung function. Inflammation brings about increased mucous production, lesions in the airway wall and lung tissue, which combined cause obstruction, thereby restricting air flow. COPD is usually caused by smoking and is a serious and incurable disease for which effective treatment is lacking.*



*COPD affects 6 to 8 percent of the adult population. Sales of drugs for respiratory diseases, mainly asthma, amounted to USD 28 billion in 2003.*

### **Early drug development organisation expands further**

During the second quarter of 2004, the company established a new pre-clinical pharmacological unit. The new unit will facilitate the company's potential to quickly and effectively complete pharmacological studies that represent a key step in the development of a drug. During the year, Biolipox has strengthened its organisation further through the recruitment of key employees within research and project management, as well as through expansion of the chemistry out-sourcing organisation.

## **Revenues and costs 1 January – 31 December 2004**

### **Costs and earnings**

#### *Research and development*

During the period 1 January – 31 December 2004, R&D costs totalled SEK 68.5 million (54.7), corresponding to an increase of 25 percent. Of the total R&D costs, SEK 35.0 million (31.5) are related to external researchers and subcontractors. Project activities comprise preclinical studies, pharmaceutical and chemical development and clinical trials. The company has several joint research ventures, both project-related and early research within the field of arachidonic acid. During 2004 compared with previous year, the internal R&D expenses have increased faster than costs for external scientific collaborations etc. mainly due to increased internal resources. In April 2003 Biolipox set up its own research unit at the Karolinska Institutet and in 2004 the company established an internal in vivo pharmacology research group.

The costs for research and development amounted during the fourth quarter to SEK 19.5 million (15.4).

#### *Administration*

Administrative expenses amounted to SEK 29.7 million (10.3), of which the costs during the fourth quarter amounted to SEK 5.5 million, an increase of SEK 2.1 million compared to the fourth quarter previous year. Administrative expenses include costs for functions such as accounts and finance, legal, HR, business development, external communications, the President & CEO and fees for Board members. The increased cost in 2004 is mainly due to costs associated with the financing of the company's operations and was primarily incurred during the second and third quarter 2004.

#### *Personnel*

During the year personnel costs increased by 54 percent to SEK 35.8 million (23.2). The number of employees at the end of the year was 39 (24). The average number of employees was 33 (17), an increase by 94 percent.



#### *Other*

Other operating income and operating expenses mainly comprise exchange gains and losses arising on accounts payable in foreign currency. Only minor other operating income and expenses incurred during the year.

#### *Depreciation*

Depreciation in an amount of SEK 1.8 million (1.3) was charged against earnings for the year. Depreciation relates to tangible fixed assets mainly instruments and equipment, and to a lesser extent on costs for improvement of facilities in property owned by others.

#### *Net financial income*

Biolipox's net financial income amounted to SEK 1.3 million (1.7). The lower income is due to lower interest income than previous year on the company's cash and short-term investments.

#### *Earnings*

Net loss amounted to SEK 96.7 million (loss: 63.3), which corresponds to an increased deficit by 53 percent. The increased deficit is caused by cost increases pertaining to external project-related activities, internal costs primarily personnel related, other operative expenses and costs associated with the financing of the company's activities. Activities within all areas have increased compared to the previous year.

#### **Investments and cash flow**

The cash flow for January - December was positive in an amount of SEK 0.5 million (negative: 67.5). Cash-flow from operating activities was negative in an amount of SEK 93.3 million (negative: 65.5), mainly due to the company's negative operating result primarily caused by its significant R&D expenditures. Changes in working capital reduced the negative cash flow from operating activities by SEK 1.6 million (negative: 3.5).

Investing activities pertaining to capital investments in machinery and equipment (mainly instruments, computers and office equipment) used cash of SEK 2.4 million (2.0).

Financing activities during the year provided cash of SEK 96.1 million (0.0) due to net proceeds from a new share issue in the first quarter 2004.

Biolipox's liquid funds at December 31, 2004 amounted to SEK 30.5 million (30.0).

#### **New share issues and stock options**

At an extra ordinary general meeting with the shareholders of Biolipox on 22 January 2004 it was resolved on a directed new share issue comprising 1,999,997 preferential shares (series P5 shares) at nominal value of SEK 0.10 per share, increasing the share capital by TSEK 200. The shares were issued at SEK 48.07 per share and the net proceeds from the issuance amounted to SEK 96.1 million which was paid to the company in February 2004.

In December 2004 the shareholders agreed to further share issues to provide another EUR 30 million to Biolipox. At an extra ordinary general meeting with the shareholders of Biolipox on



21 December 2004 it was resolved on a directed new share issue comprising 2,670,895 preferential shares (series P6 shares) at nominal value of SEK 0.10 per share, increasing the share capital by TSEK 267. The shares were issued at SEK 50.70 per share and the proceeds from the issuance amounted to SEK 135.4 million which was paid to the company in January 2005. This represents a first tranche of EUR 15 million which was agreed among the shareholders.

During the first quarter 2004 a total of 125,800 stock options were issued to employees and directors in accordance with an allocation made by the board in December 2003. The stock options entitle the holder a right to acquire the same amount of newly issued ordinary shares in the company at a price of SEK 0.10 per share, during a period up to and including 31 December 2010.

In February and May 2004 additional 53,500 and 25,000 stock options respectively at the same conditions were issued and allocated to employees of the company. To cover future delivery of shares and social security costs associated with these stock options Biolipox issued a total of 111,000 warrants to its subsidiary Pyrinox. At the annual general meeting of the shareholders on 7 May 2004 it was resolved to issue 470,000 subscription options to be used in a new incentive plan for the employees. At an extra ordinary meeting on 12 November 2004 it was decided to rescind the resolution taken at the ordinary meeting on 7 May and it was instead resolved to issue 300,000 subscription options to be used in an incentive program for the employees.

### **Personnel**

As of December 31, 2004, Biolipox had 39 employees, of whom 36 were employed on a full-time and 3 employees were employed part time. Out of those 39 employees, 33 employees were engaged with the company's R & D projects and 6 employees were engaged in accounts and finance, business development and management.

### **Business segments**

The operations of Biolipox consist of research and development within certain development stages of pharmaceutical projects. These development projects are in several respects of similar nature and any future products would address similar therapeutic areas and utilize similar distribution channels. Since the Company currently has no sales, the Company's operations are currently not divided into lines of business or geographic segments. In these circumstances the Company's operations are presented in one segment.

### **Contingent assets and liabilities**

Biolipox has no contingent assets or liabilities, which is no change from the financial year opening.



### **Post-statement events**

The Company has no significant post-statement events to report.

### **Accounting principles**

This report has been prepared in accordance with RR20 Interim Reports.

In 2004 Biolipox has adopted RR29 Employee benefits in accounting for its pension commitments. Since the insurer is not able to provide sufficient information for defined benefit accounting, post-retirement benefits have been accounted for as a defined contribution plan, as prescribed by RR29 section 30. Accounting according to RR29 section 30 has had no effect on the Company's reported pension costs.

All other accounting principles remain unchanged compared to the preceding year.

### **Annual General Meeting and dividend**

The Annual General Meeting of shareholders in Biolipox will be held on Thursday, April 28, 2005, at 2:00 p.m., at the Company's premises, Västmannagatan 15, Stockholm. Registration for the Annual General Meeting will commence at 1:30 p.m. Registration of participation must be addressed to Biolipox not later than Monday, 25 April 2005, at 4:00 p.m.

The board of directors will propose to the Annual General Meeting that no dividend is paid for the financial year 2004. In regard to the Company's early stage of development, the Company is not expected to pay a dividend for the next few years.

### **Annual Report**

The Annual Report for the 2004 financial year will be available at Biolipox' head office, Västmannagatan 15, Stockholm, two weeks prior to the Annual General Meeting. The Annual Report and other future reports will be available at [www.biolipox.com](http://www.biolipox.com).

#### **Future reports:**

Interim report, January-March 2005	April 28, 2005
Interim report, January-June 2005	August 31, 2005
Interim report, January-September 2005	October 26, 2005



## Income statement

Amount in SEK millions	Jan-Dec 2004	Jan-Dec 2003	Okt-Dec 2004	Okt-Dec 2003
Net sales	-	-	-	-
Administrative costs	-29.7	-10.3	-5.5	-3.4
Research and development costs	-68.5	-54.7	-19.5	-15.4
Other operating revenues	0.3	0.1	0.2	0.0
Other operating costs	-0.1	0.0	0.0	0.0
<b>Operating loss</b>	<b>-98.0</b>	<b>-65.0</b>	<b>-24.8</b>	<b>-18.8</b>
Profit from net financial items				
Interest income and similar items	1.3	1.7	0.2	0.2
Interest expense and similar items	0.0	0.0	0.0	0.0
<b>Profit after net financial item</b>	<b>-96.7</b>	<b>-63.3</b>	<b>-24.7</b>	<b>-18.5</b>
Tax on earnings for the year	-	-	-	-
<b>Loss for the period</b>	<b>-96.7</b>	<b>-63.3</b>	<b>-24.7</b>	<b>-18.5</b>
Earnings per share, SEK <sup>1</sup>	-112.25	-72.46	-28.70	-20.84
Earnings per share after full dilution, SEK <sup>2</sup>	-112.25	-72.46	-28.70	-20.84
Number of shares at end of period	1,000,000	1,000,000	1,000,000	1,000,000
Average number of shares outstanding	1,000,000	1,000,000	1,000,000	1,000,000

<sup>1</sup> Earnings per share are based on the average number of ordinary shares outstanding during the period. In calculating the earnings per share for the period, the dividend to which the preferential shares are entitled was taken into consideration, which reduced the period's earnings by SEK -15.6 million (-9.2). As per December 31 2004, 8,047,306 (3,376,414) preferential shares were entitled to a cumulative dividend of SEK 27.0 million (11.5).

<sup>2</sup> The number of potential ordinary shares (preferential shares and warrants) amounted to 11,464,135 at December 31, 2004 (3,711,353). Since earnings per share increase on the conversion of potential ordinary shares to ordinary shares, no dilution effect occurs, in accordance with recommendation RR18 of the Swedish Financial Accounting Standards Council.

## Key figures

	Dec 31 2004	Dec 31 2003
Number of employees at end of period	39	24
Number of employees, average	33	17
Equity/assets ratio, %	91.5%	68.4%
Net cash/equity ratio, %	19.1%	115.5%
Shareholders' equity per share, SEK	159.76	25.96
Shareholders' equity per share after full dilution, SEK <sup>3</sup>	12.82	5.51

<sup>3</sup> Shareholders' equity per share after full dilution has been calculated under assumption that all potential ordinary shares has been converted into ordinary shares. No consideration has been taken in regards to change of shareholders' equity at conversion of warrants to ordinary shares.





## Balance sheet

Amount in SEK millions	Dec 31, 2004	Dec 31, 2003
<i>Fixed assets</i>		
Tangible fixed assets	4.9	4.3
Participations in Group companies	0.1	0.1
<i>Total fixed assets</i>	<u>5.0</u>	<u>4.4</u>
<i>Current assets</i>		
Other receivables	138.2	1.7
Deferred costs and accrued income	0.9	1.8
Liquid assets and short-term investments	30.5	30.0
<i>Total current assets</i>	<u>169.6</u>	<u>33.5</u>
<b>Total assets</b>	<b>174.6</b>	<b>37.9</b>
Shareholders' equity	159.8	26.0
<i>Current liabilities</i>		
Accounts payable, trade	5.4	7.2
Liabilities, Group companies	0.0	0.0
Other short-term liabilities	1.4	1.0
Accrued costs and deferred income	8.1	3.7
<i>Total current liabilities</i>	<u>14.9</u>	<u>12.0</u>
<b>Total shareholders' equity and liabilities</b>	<b>174.6</b>	<b>37.9</b>

## Shareholders' equity

	Share Capital	Premium Reserve	Loss carried forward	Loss for the year	Total equity
<b>2002-12-31</b>	<b>0.4</b>	<b>144.5</b>	<b>-19.9</b>	<b>-35.7</b>	<b>89.3</b>
Loss, preceding year			-35.7	35.7	0.0
Loss for the year				-63.3	-63.3
<b>2003-12-31</b>	<b>0.4</b>	<b>144.5</b>	<b>-55.6</b>	<b>-63.3</b>	<b>26.0</b>
Loss, preceding year			-63.3	63.3	0.0
New share issue	0.5	231.1			231.6
New share issue costs		-1.1			-1.1
Loss for the year				-96.7	-96.7
<b>2004-12-31</b>	<b>0.9</b>	<b>374.5</b>	<b>-118.9</b>	<b>-96.7</b>	<b>159.8</b>



# **Cash-flow statement**

Amount in SEK millions	Jan-Dec 2004	Jan-Dec 2003	Oct-Dec 2004	Oct-Dec 2003
Cash flow from operating activities <sup>1</sup>	-93.3	-65.5	-24.9	-17.0
Cash flow from investing activities	-2.4	-2.0	-0.5	-0.2
Cash flow from financing activities	96.1	0.0	0.0	0.0
<b>Cash flow for the period</b>	<b>0.5</b>	<b>-67.5</b>	<b>-25.4</b>	<b>-17.2</b>
Liquid funds, opening balance	30.0	97.5	55.9	47.2
Liquid funds, closing balance	30.5	30.0	30.5	30.0
<sup>1</sup> Of which, changes in working capital	1.6	-3.5	-1.1	1.2

## **Additional information to the cash-flow statement**

Amount in SEK millions	Jan-Dec 2004	Jan-Dec 2003	Oct-Dec 2004	Oct-Dec 2003
Interest paid and received				
Interest received	1.3	1.7	0.2	0.2
Interest paid	0.0	0.0	0.0	0.0
Depreciation and write-down of assets	1.8	1.3	0.5	0.4

This report is based on audited annual accounts.

Stockholm, 21 February 2005

Biolipox AB (publ)

Torbjörn Bjerke, President & CEO

For further information, please contact:

Torbjörn Bjerke, President & CEO, Tel: +46-708-66 19 90

e-mail: [torbjorn.bjerke@biolipox.com](mailto:torbjorn.bjerke@biolipox.com)

Peter Hein, VP & CFO, Tel: +46-8-545-28 153, or +46-733 -70 73 43

e-mail: [peter.hein@biolipox.com](mailto:peter.hein@biolipox.com)

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Biolipox AB (publ) (Corporate registration no. 556588-3658)

Box 6280

SE-102 34 Stockholm

Tel: +46 (0)8-545 281 40

Fax: +46 (0)8-545 281 41

E-mail: [info@biolipox.com](mailto:info@biolipox.com)

Internet: [www.biolipox.com](http://www.biolipox.com)