

# INTERIM REPORT

## January 1 - September 30 1998

# Biora AB (publ)

November 5, 1998

- **Sales: January 1 – September 30, SEK 35.4 million (compared to SEK 9.1 million for the same period in 1997).**
- **Sales: July 1 – September 30, SEK 12.5 million. (compared to SEK 3.4 million for the same period in 1997).**
- **Operating loss: SEK –41.5 million (compared to SEK –67.5 million for the same period in 1997) (*operating loss for the nine months ended September 30, includes nonrecurring revenue from Biora's Japanese partner in an amount of SEK 39.4 million*).**
- **Loss after tax: SEK –32.2 million (compared to SEK –53.8 million for the same period in 1997)**
- **Biora's principal product, Emdogain<sup>®</sup>, was approved and launched in Japan.**
- **Biora's second product, PrefGel<sup>™</sup>, was launched in the Nordic countries, Germany and the United States.**

*Biora develops, manufactures and sells products for the treatment of periodontal disease and for use in oral surgery. Using its proprietary technology and expertise, Biora aims to become a world leader in biology-based products for specialized dental therapy. Biora's American Depositary Shares are listed on the Nasdaq National Market in the US and Biora's ordinary shares are listed on the "O-list" of the Stockholm Stock Exchange in Sweden.*

## The first nine months of 1998

Biora's sales during January 1- September 30 1998, amounted to SEK 35.4 million, as compared to SEK 9.1 million during the first nine months of 1997. The improvement in sales is attributable to a general sales increase in all key markets as well as sales to Biora's distributor in Japan, which equaled SEK 3.1 million, including an initial order of SEK 2.2 million.

Sales in the third quarter of 1998 were SEK 12.5 million, which is slightly higher than both the first quarter, SEK 11.7 million, and the second quarter, SEK 11.2 million, of 1998. Compared to the third quarter of 1997, SEK 3.4 million, sales during third quarter of 1998 were almost four times better.

The number of periodontists (specialists in periodontitis –the primary target group so far for Emdogain) who purchased the product continued to increase during the first nine months of 1998. Approximately 520 periodontists and general practitioners in Sweden have purchased Emdogain and of those 325 have made more than one purchase. In Germany approximately 4,500 periodontists and general practitioners have purchased Emdogain, of which almost 1,400 have made more than one purchase.

In the U.S. market, potentially the largest single market for Emdogain, the product has been available for about a year and a half. The number of U.S. periodontists is estimated to be 4,000. The number of periodontists who have purchased Emdogain increased during the first nine months to 1,560 of which approximately 610 have made more than one purchase.

During September the annual conference for periodontists arranged by AAP, American Academy of Periodontology, was held in Boston and approximately 7,000 periodontists world wide attended. The results of treatment and extended follow-up of U.S. patients who were treated with Emdogain were presented at the conference. This first presentation of U.S.-data is one of several important components in the continuing marketing activities.

### ***Good penetration of the Japanese market***

At the end of January, Emdogain was approved for sale in Japan and launched in April. There has been a strong interest for the product and the Japanese association of periodontists has selected the product as "Theme of the year 1998".

There are approximately 80 000 dentists in Japan and Biora's distributor Seikagaku has initially chosen to concentrate its marketing efforts on 1 500 specialists. According to Seikagaku 620 specialists and dentists have bought Emdogain and 120 of those have purchased the product more than once.

### ***The goal is to make Emdogain a preferred treatment***

Emdogain has now been approved and launched in all initial key markets. The long-term goal is to make Emdogain a preferred treatment of severe periodontitis. Biora will focus the marketing activities in order to achieve this goal.

According to Biora's statistics, about five percent of the total number of periodontal operations performed in Sweden and Germany during the report period involved the use of Emdogain. In the U.S. the corresponding market share was approximately one percent.

### ***New product approved and launched***

During the first half of 1998, Biora was granted approval for its second product, PrefGel, for sale in Europe as well as the US. The product can replace the strong acids dentists have used to clean the dental root surface in periodontal operations. PrefGel is primarily for use in treatments involving Biora's main product, Emdogain, but can also be used in other treatments.

PrefGel was launched in the Nordic countries during the summer and in September in the U.S. and Germany during the conferences for periodontists in these countries. Biora's goal is to launch PrefGel in Europe and Canada during the fourth quarter.

### ***New markets established***

During the beginning of 1998, Biora commenced sales in France and Israel, via well-established companies in specialized dentistry to establish Emdogain in these markets. During the summer Biora

has entered into a distribution-agreement in Canada, where Emdogain previously was marketed via its U.S. subsidiary Biora, Inc. During the third quarter Biora entered into distribution-agreements in Spain and Mexico, where Emdogain was launched in September/October.

### ***Intensified focus on Research and Development***

To strengthen Biora's standing in the long term Research- and Development-projects are in process to broaden the number of products and applications. Development work is conducted on three fronts:

1. New indications for Emdogain, basically in clinical studies
2. Better knowledge about the Emdogain mechanism.
3. Development of new products based on biological principles.

The main areas for new indications are impacted wisdom teeth, recession type defects, non-surgical treatment of periodontitis and endodontics. New knowledge has led to a patent application pertaining to new, positive biological effects of Emdogain-related proteins (the XP 11-project) was submitted. The project XP 20 is proceeding involving pre-clinical trials and the preparation of a patent based on studies of effects of new proteins and protein combinations.

To further strengthen its research and development efforts, Biora entered into two new research agreements in the second quarter of 1998, one with the University of Texas, Health Science Centre at San Antonio, US, and a second with the Department of Conservative Dentistry, Periodontology and Pedodontics of the University Hospital of Ulm, Germany.

### ***The Year 2000-problem***

A year 2000 review of Biora's production equipment as well as the computer systems of its subsidiaries and principal suppliers is scheduled to be completed by the end of 1998. Biora does not expect that the year 2000 issue will have a material effect on either its sales or supplies of raw material.

### ***Net Sales***

The Group's net sales during January – September 1998 period amounted to SEK 35.4 million (1997: SEK 9.1 million). The increase is attributable to increased sales in all markets.

### ***Profit loss***

Gross profit amounted to SEK 27.6 million (1997: SEK 5.8 million). The improvement can be explained mainly by the increase in sales and increased production volumes, which had a positive effect on the unit cost of goods sold.

Operating income amounted to loss of SEK 41.5 million (1997: SEK - 67.5 million). The improvement was due primarily to the advance payment of SEK 39.4 million which Biora received in 1996 from the Seikagaku Corporation for the right to represent Biora in the Japanese market. The advance was conditional and contingent on a sales approval not later than June 1999. Since the approval was obtained in January 1998, the amount was booked as other operating income in the first quarter. At the same time, costs have increased due primarily to the work involved in building the market organizations in North America and Europe and the increased focus on research and development. Net financial items were SEK 8.7 million (1997: SEK 13.3 million), comprising mainly interest income from the Group's liquid funds. The amount for the corresponding period of the proceeding year includes exchange gains on the Group's liquid funds in USD, in an amount of SEK 4,3 million.

Net income amounted to a loss of SEK 32.2 million (1997: loss SEK 53.8 million), corresponding to a SEK loss of 1.52 (1997: SEK - 2.64) per share based on the average of number of shares.

### ***Investments***

Capital expenditures during the period totalled SEK 4.8 million (1997: SEK 11.3 million).

### ***Financial position***

Cash flow after investments during the period was negative, in an amount of SEK 73.4 million (1997: SEK 290.9 million). The cash flow for the same period last year includes SEK 372.3 million as a result of the new share issue in February 1997.

At the end of the report period (figures for December 31, 1997, for comparison, are given below in parentheses), the Group's liquid funds amounted to SEK 212.9 million (286.3), the equity/assets ratio was 88.0 percent (81.9) and Group equity amounted to SEK 244.1 million (277.9).

### ***Employees***

As of September 30, 1998, Biora had 82 employees as compared to 71 employees as of December 31, 1997.

### ***Parent Company***

Biora's net sales for the period increased to SEK 26.4 million (1997: SEK 9.4 million) and its income after financial items was loss SEK 1.6 million (SEK - 19.0 million). This includes the nonrecurring revenue of SEK 39.4 million received from the Japanese distributor. Capital expenditure during the period totalled SEK 3.2 million (1997: SEK 7.2 million). Cash flow after investment totalled SEK - 77.0 million (1997: SEK 288.5 million). Cash flow for the corresponding period in 1997 includes SEK 372.3 million as a result of the new share issue in February 1997. As of September 31, 1998, (figures for December 31, 1997, for comparison, are given below in parentheses) the parent company's liquid funds amounted to SEK 204.8 million (281.8), the equity/assets ratio was 94.3 % (85.2) and its equity to SEK 325.3 million (326.3).

### ***Future outlook***

Biora does not make earnings projections. Emdogain is believed to have considerable potential, but to establish the product in new markets takes time and additional marketing activities are required.

### ***Coming financial information***

During 1999, Biora will publish financial information on the following dates::

Year end report on 1998 operations	February 18
Interim report January – March	April 29
Shareholder's meeting	April 29
Interim report January – June	August 18
Interim report January – September	October 28
Investor's Day	March 25

Malmö, November 5 1998

*Tomas Hammargren*  
*President and CEO*

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*Biora's auditors have not audited this interim report.*

This report may contain certain forward-looking statements that relate to future events or future business and financial performance. Such statements can only be predictions and the actual events or results may differ from those discussed. The Company cautions that these statements are subject to important factors that could cause actual results to differ materially from those expressed or implied in such forward-looking statements and are more fully discussed in periodic reports filed with Securities and Exchange Commission.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(Swedish GAAP, unaudited)	1998 Jan-Sep (TUSD) 1)	1998 Jul-Sep (TSEK)	1997 Jul-Sep (TSEK)	1998 Jan-Sep (TSEK)	1997 Jan-Sep (TSEK)	1997 Jan-Dec (TSEK)
Net sales	4 459	12 493	3 400	35 422	9 068	16 499
Costs of goods sold 2)	-986	-2 912	-852	-7 835	-3 265	-5 533
<b>Gross margin</b>	<b>3 473</b>	<b>9 581</b>	<b>2 548</b>	<b>27 587</b>	<b>5 803</b>	<b>10 966</b>
Selling expenses	-7 955	-20 632	-14 868	-63 194	-43 833	-64 830
Administrative expenses	-2 071	-4 095	-3 911	-16 453	-12 346	-18 173
Research and development costs 2)	-3 802	-9 473	-6 770	-30 206	-14 336	-20 293
Other operating income and expenses 3)	5 127	1 884	-1 900	40 727	-2 764	-475
<b>Loss from operations</b>	<b>-5 229</b>	<b>-22 735</b>	<b>-24 901</b>	<b>-41 539</b>	<b>-67 476</b>	<b>-92 805</b>
Financial net	1 095	2 309	3 070	8 698	13 324	17 399
<b>Loss after financial items</b>	<b>-4 134</b>	<b>-20 426</b>	<b>-21 831</b>	<b>-32 841</b>	<b>-54 152</b>	<b>-75 406</b>
Income tax 4)	75	592	238	594	241	-101
Minority interest	-	-	5	-	153	149
<b>Loss for the period</b>	<b>-4 059</b>	<b>-19 834</b>	<b>-21 588</b>	<b>-32 247</b>	<b>-53 758</b>	<b>-75 358</b>

## CONSOLIDATED BALANCE SHEETS

(Swedish GAAP, unaudited)	Sep 30, 1998 (TUSD) 1)	Sep 30, 1998 (TSEK)	Sep 30, 1997 (TSEK)	Dec 31, 1997 (TSEK)
Intangible long term assets	3 257	25 876	27 754	27 974
Tangible long term assets	1 562	12 411	11 243	11 568
Financial long term assets	316	2 511	2 396	2 554
<b>Total long term assets</b>	<b>5 136</b>	<b>40 798</b>	<b>41 393</b>	<b>42 096</b>
Inventories	395	3 140	2 314	2 410
Current receivables	2 596	20 625	16 453	8 518
Bank deposits	24 747	196 587	-	175 000
Cash and bank	2 054	16 317	296 275	111 310

<b>Total current assets</b>	29 792	<b>236 669</b>	315 042	297 238
<b>Total assets</b>	34 928	<b>277 467</b>	356 435	339 334
Shareholders' equity	30 731	<b>244 128</b>	300 697	277 935
Provisions	32	<b>254</b>	93	199
Long term liabilities 5)	-	-	36 774	123
Current liabilities 5)	4 165	<b>33 085</b>	18 871	61 077
<b>Total shareholders' equity and liabilities</b>	34 928	<b>277 467</b>	356 435	339 334

1) Average exchange rate Jan-Sep , 1998, USD 1 = 7,944

2) 2.5% royalty to Astra on sales of Emdogain has been reclassified from research and development costs to costs of goods sold.

The comparative figures have been adjusted accordingly.

3) In the first quarter 1998 a nonrecurring revenue from Seikagaku Corporation of 39,4 MSEK is included in other operating income and royalty expense to Astra of 1,0 MSEK on this revenue is included in other operating expenses.

4) The nine month tax income consists of reduction of deferred tax liability due to decrease in foreign-exchange reserve and deferred tax regarding increase in inter-company profit in inventory.

5) Biora did not have any interest bearing liabilities neither on September 30, 1998, September 30, 1997 nor December 31, 1997.

## KEY RATIOS

	1998 Jan-Sep 1)	1997	1996	1995	1994
(Swedish GAAP, unaudited)					
Net sales (TSEK)	<b>35 422</b>	16 499	4 561	936	--
R & D costs (TSEK) 2)	<b>30 206</b>	21 207	10 884	9 347	8 924
Return on capital employed, % 3)	<b>-36.3</b>	-53.2	-266.2	-46.1	-15.8
Return on equity,% 4)	<b>-36.0</b>	-58.1	neg	-128.8	-30.7
Equity / assets ratio, % 5)	<b>88.0</b>	81.9	-34.2	28.8	52.2
Net debt / equity ratio, % 6)	<b>-87.2</b>	-103.0	-84.3	163.3	50.6
Total equity (TSEK)	<b>244 128</b>	277 935	-18 437	7 986	8 983
Average number of shares outstanding, (000s) 7)	<b>21 204</b>	20 571	14 207	10 819	8 988
Equity per share, SEK 7)	<b>11.51</b>	13.51	-1.30	0.74	1.00
Loss per share, SEK 7)	<b>-2.02</b>	-3.66	-2.61	-1.01	-0.24

1) Return on capital employed, return on equity and loss per share have been calculated by

multiplying the nine month operating loss

and net loss respectively by 1.33 to obtain

comparability to the other presented twelve

months key ratios. Return on capital employed and return on equity have been adjusted for the effect of the nonrecurring revenue from Seikagaku.

2) R&D-costs are shown gross, including capitalized costs. During Jan-Sep 1998 no R&D costs have been capitalized under intangible long term assets, why the net and gross costs were equal, 30,206, while the net costs for Jan-Dec were 20,293.

3) Operating loss plus financial income divided

by average total assets (total assets less non-interest-bearing operating liabilities including deferred taxes).

4) Net loss divided by average equity.

5) Shareholders' equity divided by total assets.

6) Interest-bearing liabilities less cash and bank deposits divided by shareholders' equity.

7) The number of ordinary shares outstanding used

in determination of loss and equity per ordinary

share is calculated on a proforma basis by giving

effect to a 25:1 share split and the 3:1 bonus issue

completed by the Company during 1996. The dilution effects

of outstanding convertible loans and options have not been

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(2.5% royalty to Astra on sales of Emdogain has been reclassified to costs of goods sold.)

considered when calculating equity and loss per share for the years 1994-1998 as this would reduce the loss per share.