Biolight International AB (publ)

Press release of annual earnings figures for the financial year 2000

- **Studies have been carried out within all the three business areas, Wound Care, Dental Care and Physiotherapeutic Care, and the results have been good.**

- **In the completed phase III study, BL-034, on the healing of decubitus ulcers, grade 2, the last patient finished treatment on January 16, 2001. A statistical report is expected to be ready in March 2001.**

- **A phase III study on patients with gingivitis (inflammation of the gums) was presented in June. The study shows a statistically significant difference in reduction of gingivitis in the patients treated with Biolight®(87 %), in comparison to placebo-treated patients.**

- **The German sports centres that have been trying Biolight® for the rehabilitation of acute sports injuries since February 2000, report very good treatment results. The company is currently examining the possibilities for distribution in Germany.**

- **The company was quality certified according to ISO 9001 on June 28, 2000.**

- **Biolight® WCD (Wound Care Device) and Biolight® DCD (Dental Care Device) were approved according to the medical device directive on June 28, 2000. This means that the company has a CE marked product, ready for sale.**

- **Biolight® PCD (Physiotherapeutic Care Device) – a new device for the treatment and rehabilitation of sports injuries – is currently passing the final tests for CE marking. This work is expected to be completed in March 2001.**

- **The company filed a 510(k) application with the FDA in February 2001 for the business area dental care. An approval from FDA is a basic requirement for selling products in the American market. 510(k) is a simplified registration procedure.**

- **The patent situation of the company has been reinforced through further approvals in several countries, and more patent applications have been submitted.**

- **Discussions are ongoing with international companies regarding commercialization and distribution within the wound care sector.**

- **The new issue, authorized by the annual general meeting, was floated in June. The issue, amounting to SEK 40 million, was directed to international and Swedish institutional investors.**

Company focus in 2000

During the year, the company focused on developing and verifying the treatment programs within its core areas, as well as preparing for the commercialization of Biolight® within these areas. Development of treatment equipment, quality certification of the company and CE marking of the treatment equipment have been important milestones. Discussions conducted with potential partners for marketing and distribution have also been given high priority.

New issue

To fund the commercialization, and simultaneously accelerate the development speed, a directed new issue was floated in June, in accordance with the authorization of the annual general meeting held on May 4, 2000. The total liquidity of the issue amounted to SEK 40 million. The issue was directed to international and Swedish institutional investors.

Important events after 2000

In January 2001, a Technical Director was employed. His responsibilities include production, logistics and maintaining the quality of the Company's products and systems.
In January 2001, the Company was granted another two patents in the USA.
The company filed a 510(k) application with the FDA in February 2001 for the business area "Dental Care".

Scientific results and research programs

BL-032, Gingivitis

During the second quarter 2000, a double-blind, randomized, placebo-controlled phase III study on patients with gingivitis (inflammation of the gums) was completed. The study included 86 patients. The object of the study was to examine the effects of treatment with Biolight® on gingivitis. The study showed a very good result.
The inflammation of the gum was reduced by 87 % more *(p£0,035)* in patients treated with Biolight®, than in placebo-treated patients.
The study also showed that the more pronounced the inflammation, the greater the amelioration achieved after treatment with Biolight®. The results are statistically significant.
The clinical report is completed.

BL-034, Decubitus ulcers

In the ongoing phase III study, BL 034, on the healing of decubitus ulcers, grade 2, all the patients have been included (n=87; "intention to treat"). The last patient completed treatment on January 16, 2001. A statistical report is expected to be ready in March 2001.

Quality certification

The process of quality certification according to ISO 9001, which started in the beginning of 1999, is now completed. LRQA – Lloyd's Register Quality Assurance, our notified body – has carried out the last part of the audit. The outcome of the audit was most satisfactory, and the company was approved for certification on June 28, 2000. LRQA carried out a "Routine Surveillance" on January 17, 2001.

Market approval

Through the quality certification, and as the new device was approved according to MDD 93/42/EEC, the company now has a CE marked product, ready for sale in the EU countries.
The company filed a 510(k) application with the FDA in February 2001 for the business area dental care. An approval from the FDA is a basic requirement for sales and marketing in the American market. 510(k) is a simplified registration procedure.

Biolight® Physiotherapeutic Care

The German sports centres which have been trying Biolight® since February for the rehabilitation of acute sports injuries, report very good treatment results. The company is currently examining the possibilities for distribution in Germany.
Biolight® PCD (Physiotherapeutic Care Device) – a new device for the treatment and rehabilitation of sports injuries – is currently passing the final tests for CE marking. This work is expected to be completed in March 2001.

Patents

During the financial year 2000, the patent protection was reinforced through four new patents, two of them in China and two in Canada. The company also had another two patents approved in the USA in January 2001. In addition to these, the company holds four patents in Sweden and two in the USA. The approved patents are valid until 2014-2016. The patents relate to the technology for generating and pulsating light, to get the wanted effect during treatment.
International applications regarding these patents have been submitted, primarily for the EU countries, the USA, Japan and China.
Based on the new treatment system, five new patent applications have been prepared and submitted to the patent authorities (Q1:99).
A new patent application was filed in Sweden in the third quarter 2000.

Production of Biolight® WCD and Biolight® DCD

The production of Biolight® WCD (Wound Care Device) and Biolight® DCD (Dental Care Device) at Amersham Pharmacia Biotech AB in Umeå runs according to plan. The machines have passed the final tests at Semco and were approved according to MDD 93/42/EEC on June 28, 2000.

Future Partners

Discussions are under way with international companies regarding commercialization and distribution within the wound care sector.

Result, cash flow and liquidity

In 2000, sales amounted to SEK 0.5 M (0.9). The operating costs amounted to SEK 18.2 M (15.2). The Group's result after taxes showed a loss of SEK 19.7 M in 2000 (-13.6). The result was encumbered by costs of stock issue of SEK 3.0 M (-).

The group's investments amounted to SEK 22.8 M during the year (0.7), including SEK 9.0 M for clinical trials and SEK 11.7 M for development of new treatment equipment. The investments of the parent company amounted to SEK 22.8 M (0.7).

Liquid assets as of December 31, 2000, amounted to SEK 30.4 M (16.9). For the parent company, liquid assets as of December 31, 2000, amounted to SEK 30.3 M (16.8).

The income statement, balance sheet, cash flow analysis, etc. presented below, refer to the group.

Future reports

Quarterly report for the 1st quarter, 2001	April 23, 2001
Semi-annual report 2001	August 21, 2001
Quarterly report for the 3rd quarter, 2001	November 1, 2001

Other information

The annual general meeting for the financial year 2001, will be held on April 25, 2001, at 4 p.m. at Biolight International AB's headquarters in Danderyd. The annual report will be made available for the shareholders from April 9, 2001. It will also be published on the company's web site: www.biolight.se

Danderyd, February 23, 2000

Board of Directors, Biolight International AB

Biolight International AB is a medical technology company with products based on the biological effects of pulsating, monochromatic light. Biolight develops a system for effective, painless and safe treatment, primarily of chronic wounds and inflammatory conditions. The Biolight share is quoted on the SBI-list (SBI Marknadsplats AB).

Income statement

Amounts in SEK thousands	*2000*	*1999*
Operating income	526	936
Operating expenses		
Goods for resale	-182	-139
Other external costs	-10,435	-9,324
Personnel costs	-6,008	-4,719
Depreciation of intangible and tangible assets	-1,539	-1,018
Other operating expenses	-11	-9
Operating loss	**-17,649**	**-14,273**
Financial items	981	704
Issue expenses	-2,997	-
Loss before taxes	**-19,665**	**-13,569**
Taxes	2	2
Net loss of the year	**-19,663**	**-13,567**

Balance sheet

Amounts in SEK thousands	*Dec. 31, 2000*	*Dec. 31, 1999*
Intangible assets	21,679	1,710
Tangible assets	2,094	781
Projects in progress	2,660	16,916
Other current assets	1,859	1,849
Liquid assets	30,456	16,935
Total assets	**58,748**	**38,191**
Shareholders' equity	55,723	35,337
Provisions	2	4
Current liabilities	3,023	2,850
Total shareholders' equity and liabilities	**58,748**	**38,191**

Cash flow analysis

Amounts in SEK thousands	*2000*	*1999*
Current operations		
Loss after financial items	-19,663	-13,569
Adjustments for items not included in the cash flow	1,550	1,029
	-18,113	**-12,540**
Taxes paid	-	-
Cash flow from current operations before changes of working capital	**-18,113**	**-12,540**
Cash flow from changes of working capital	14,419	-8,193
Cash flow from current operations	**-3,694**	**-20,733**
Investment activities		
Acquisitions of tangible and intangible assets	-22,832	-669
Cash flow from investment activities	**-22,832**	**-669**
Financing activities		
New issue	40,000	-
Issue of debenture with detachable subscription warrants	49	212
Repayment of debts	-2	-2
Cash flow from financing activities	**40,047**	**210**
Period's cash flow	**13,521**	**-21,192**
Liquid assets at beginning of year	**16,935**	**38,127**
Liquid assets at year-end	**30,456**	**16,935**

Key ratios

No. of shares at year-end (thousands)	59,346	52,073
No. of outstanding subscription warrants (thousands)	450	400
Earnings per share	-0.35	-0.26
Return on equity	neg.	neg.
Return on capital employed	neg.	neg.
Equity ratio in %	94.9%	92.6%
Shareholders' equity per share, SEK	0.94	0.68