

Biolight International AB (publ)

Semi-annual report January 1 - June 30, 2001

- **The company has signed a blanket agreement with TryCare Limited regarding the distribution within Dental Care in the UK. Discussions are also ongoing with distributors in other markets within the business area Dental Care.**
- **A controlled study on decubitus ulcers has been finalised during this period. The effect shown is considerable and statistically significant. The result is a decisive breakthrough for Biolight® Wound Care.**
- **A market test has been conducted by a group of private dentists and dental hygienists and the result is positive. 10 participants out of 11 decided to buy the equipment.**
- **During the period the company has filed two 510(k) applications with the FDA regarding the areas Physiotherapeutic Care and Dental Care.**
- **A manager for the business area Dental Care and a technical manager have been employed during the period.**
- **A study on tooth extraction is starting up at the dental college in Göteborg.**
- **Biolight® PCD (Physiotherapeutic Care Device) - a new device for the treatment and rehabilitation of sports injuries - was approved for CE marking in March, 2001.**
- **In January, the Company was granted another two patents in the USA.**

Company focus in 2001

The company is focusing its resources on starting commercialisation within its core areas - Biolight® Wound Care, Biolight® Dental Care and Biolight® Physiotherapeutic Care.

Biolight® Wound Care

BL-030 and BL-034, Decubitus ulcers

The analysis of data from two randomised, double-blind and placebo-controlled phase III studies on the effect on the healing of decubitus ulcers, grade 2, after treatment with Biolight®, finalised in March, shows a statistically significant difference in effect - 61 % ($p=0.0394$) - between patients treated with Biolight® as compared to placebo-treated patients. The study has been carried out at 9 centres in Sweden and Denmark. The healing of the wounds involves the same pattern and speed characteristics as in the earlier studies. The results show that the time to healing after treatment with Biolight® was reduced by 36 %. 163 patients (79 Biolight®, 84 placebo) are included in the analysis.

A clinical report on the study on wound healing regarding decubitus ulcers, presented in March, is being compiled.

Ove Dehlin, professor of geriatrics in Malmö, Sweden, Sölve Elmståhl, professor of geriatrics, Malmö, Sweden, and Finn Gottrup, professor of wound healing in Copenhagen, Denmark, who have jointly headed the execution of the clinical phase III studies on decubitus ulcers, make the following statement:

”Decubitus ulcers is a big problem in medical care, and primarily affects older patients, who, in many cases, are already suffering from other complicated illnesses. In recent years, there hasn’t been anything principally new in the treatment of decubitus ulcers, until now. Biolight® involves pulsating, monochromatic light, which in pre-human studies has shown interesting biological effects in relation to wound healing. In two double-blind, placebo-controlled studies, we have examined the effects of Biolight® on decubitus ulcers, grade 2, in older patients. In the first study, promising but not altogether significant results ($p=0.06$) were achieved, which is the reason why that study has now been supplemented with another study, and the studies have been pooled. The results are satisfactory. Treatment with Biolight® made the wounds heal significantly faster compared to placebo ($p=0.04$). No serious side effects have been observed.

Professor Jan-Åke Gustafsson of the Department of Medical Nutrition and the Department of Biosciences, Novum, the Karolinska Institute, and chairman of Biolight’s scientific council, says:

”The healing effect of Biolight® in the treatment of decubitus ulcers, is now clearly established through the same stringent criteria as apply to the trial of drugs. Thus, Biolight® has taken a definite step from being an alternative medical method into being an allopathic treatment method.”

Discussions are currently in progress with international companies regarding commercialization and distribution within the wound care sector.

Biolight® Dental Care

The company has signed a blanket agreement with TryCare Limited regarding the distribution within Dental Care in the UK. Discussions are also ongoing with distributors in other markets.

A market test has been conducted by a group of private dentists and dental hygienists and the result is positive. 10 participants out of 11 decided to buy the equipment.

In June, Thomas Ericsson, 50, was employed as head of the business area. Ericsson has a degree in economics and many years’ experience in the dental market. He has worked for the Swedish dental company SDI for 17 years, including 7 years as President. Before joining SDI, he worked for Johnson & Johnson Dental for 6 years. Ericsson has good, well established contacts with national and, in particular, international distributors.

The company filed a 510(k) application with the FDA in February 2001.

The company is preparing a study on tooth extraction at the dental college in Göteborg.

During the autumn of 2001 and spring of 2002, the company will take part in several national and international dental exhibitions.

Biolight® Physiotherapeutic Care

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.

Biolight® PCD (Physiotherapeutic Care Device) - a new device for the treatment and rehabilitation of

sportsinjuries - was approved for CE marking in March, 2001.

The company filed a 510(k) application with the FDA in May. FDA has asked for clarification of a number of technical specifications.

Patents

The company was granted another two patents in the USA in January 2001. In 2000 the patent protection was strengthened through four new patents, two of them in China and two in Canada. The company now holds a total of four patents in Sweden, four in the USA, two in Canada and two in China. The patents granted are valid until 2014-2016 and relate to the technology for generating and pulsating light to achieve the desired treatment effect.

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.

Result, cash flow and liquidity

Sales amounted to SEK 325 T (300) during the period. Operating expenses during the first six months 2001 amounted to SEK -13,395 T (-7,133). The loss for the period amounted to SEK -12,664 T (-9,407). The result of the first six months 2000 was encumbered by costs of stock issue of SEK 2,800 T.

Investments during the first six months amounted to SEK 805 T (630).

Liquid assets as of June 30, 2001, amounted to SEK 17,322 T (42,630). As of December 31, 2000, liquid assets amounted to SEK 30,456 T.

This interim report has not been subjected to audit by the company auditors.

Future reports

Quarterly report for the 3rd quarter, 2001 November 1, 2001

Accounting principles

This semi-annual report applies the same accounting principles and basis of calculation as the last annual report and complies with the interim report recommendations of the Swedish Financial Accounting Council.

Danderyd, August 23, 2001

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 the effective, painless and safe treatment, primarily of chronic wounds and inflammatory conditions. The Biolight share is listed on the NGM Equity (Nordic Growth Market NGM AB).

Income statement

Amounts in SEK thousands	Jan- june		Apr-june		Whole year
	2001	2000	2001	2000	2000
Operating income	325	300	211	118	526
Operating expenses					
Goods for resale	-150	-89	-119	-40	-182
Other external costs	-6,684	-3,644	-3,356	-2,051	-10,435
Personnel costs	-4,033	-2,930	-2,279	-1,542	-6,008
Depreciation of assets	-2,516	-470	-1,259	-250	-1,539
Other operating expenses	-12	0	-8	0	-11
Operating loss	-13,070	-6,833	-6,810	-3,765	-17,649
Financial items	406	226	122	125	981
Issue expenses	0	-2,800	0	-2,800	-2,997
Loss before taxes	-12,664	-9,407	-6,688	-6,440	-19,665
Taxes					2
Net loss for the period	-12,664	-9,407	-6,688	-6,440	-19,663

Balance sheet

Amounts in SEK thousands	June 30, 2001	June 30, 2000	December 31,2000
Intangible assets	19,514	1,829	21,679
Tangible assets	2,550	822	2,094
Projects in progress	4,003	21,098	2,660
Other current assets	3,730	1,453	1,859
Liquid assets	17,322	42,630	30,456
Total assets	47,119	67,832	58,748
Shareholders' equity	43,692	65,979	55,723
Provisions	2	4	2
Current liabilities	3,425	1,849	3,023
Total shareholders' equity and liabilities	47,119	67,832	58,748

Cash flow analysis

	2001	Jan- june 2000	Whole year 2000
Current operations			
Loss after financial items	-12,664	-9,407	-19,663
Adjustments for items not included in the cash flow	2,513	470	1,550
	-10,151	-8,937	-18,113
Taxes paid	-	-	-
Cash flow from current operations before changes of working capital	-10,151	-8,937	-18,113
Cash flow from changes in working capital	-2,812	-4,788	14,419
Cash flow from current operations	-12,963	-13,725	-3,694
Investment activities			
Acquisition of assetsr	-805	-630	-22,832
Cash flow from investment activities	-805	-630	-22,832
Financing activities			
New issue	-	40,000	40,000
Issue of debenture with detachable subscription warrants	634	49	49
Raising loans / Repayment of debts	-	1	-2
Cash flow from financing activities	634	40,050	40,047
Period's cash flow	-13,134	25,695	13,521
Liquid assets at beginning of year	30,456	16,935	16,935
Liquid assets at end of period	17,322	42,630	30,456

Changes in share capital

	Jan-june 2001		
	Share capital	Restricted reserves	Accumulated losses
At beginning of year	1,780	113,682	-59,739
Debenture issued with right of warrants		634	
Translation differences			-1
Net loss for the period			-12,664
At end of period	1,780	114,316	-72,404

	Jan-june 2000		
	Share capital	Restricted reserves	Accumulated losses
At beginning of year	1,562	73,851	-40,076
Debenture issued with right of warrants		49	
New issue	218	39,782	
Net loss for the period			-9,407
At end of period	1,780	113,682	-49,483

Key ratios

	Jan- June	Whole year
	2001	2000
No. of shares at end of period (thousands)	59,346	59,346
No. of outstanding subscription warrants (thousands)	916	450
Earnings per share	-0.21	-0.18
Return on equity	neg.	neg.
Return on capital employed	neg.	neg.
Equity ratio in %	92.7%	97.3%
Shareholders' equity per share, SEK	0.74	1.11