

# **Biolight International AB (publ)**

## **Quarterly report January 1 – March 31, 2001**

- **The wound healing study finalised during the first quarter is a decisive breakthrough for Biolight®. The established effect is considerable and statistically significant.**
- **Biolight® PCD (Physiotherapeutic Care Device) – a new device for the treatment and rehabilitation of sports injuries – was approved for CE-marking in March, 2001.**
- **The company filed a 510(k) application with the FDA in February 2001 for the area dental care. FDA desires to study the clinical documentation.**
- **In January, a Technical Director, whose responsibilities include production, logistics and quality, was employed.**
- **In January, the Company was granted another two patents in the USA.**

### **Company focus in 2001**

In 2001, the Company will focus its resources on implementing a commercialisation within its core areas – Biolight® Wound Care, Biolight® Dental Care and Biolight® Physiotherapeutic Care.

### **Scientific results and research programs**

#### ***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 of treatment with Biolight® on the healing of decubitus ulcers, grade 2, is finalised. Regarding effect, the results show a statistically significant difference of 61 %<sup>1</sup> ( $p=0.0394$ ) between patients treated with Biolight® compared to placebo-treated patients. The study has been carried out at 9 centres in Sweden and Denmark. The healing of the wounds has the same pattern and speed 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.

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<sup>1</sup> The effect is expressed as the difference in reduction of normalised wound area between the groups in the 12<sup>th</sup> week.

**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 affect older patients, who already suffer from other complicated illnesses. In recent years, there hasn’t been anything principally new in the treatment of decubitus ulcers, until now. Biolight® is 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 complemented with another one, and these 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.”

### ***BL-032, Gingivitis***

A scientific article is under way concerning the study which was carried out and presented during the second quarter, 2000. The study was a double-blind, randomised, placebo-controlled phase III study on patients with gingivitis (inflammation of the gums). 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®, in comparison to 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.

### **Biolight® Physiotherapeutic Care**

The German sports centres which have been trying Biolight® for the rehabilitation of acute sports injuries since February 2000, have reported very good treatment results, which has induced the Company to examine the possibilities for distribution in Germany.

Biolight® PCD (Physiotherapeutic Care Device) – a new device for the treatment and rehabilitation of sports injuries – was approved for CE-marking in March.

### **Biolight® Dental Care**

In January, the Company started a market test for Biolight® with dentists and dental hygienists in Sweden. The goal of this test is to get indications regarding acceptance, price intervals for the treatment, and the actual handling of the equipment. The results of the test will form the basis of a marketing effort for the indication Gingivitis, which is expected to begin in the third quarter, 2001.

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

The FDA desires to study the clinical documentation before starting its assessment. The time available for an assessment at the FDA is 90 days. All clinical documents have been sent to FDA.

### **Biolight® Wound Care**

Discussions are ongoing with international companies regarding commercialisation and distribution within the wound care sector.

### **Patents**

The Company was granted another two patents in the USA in January 2001. In 2000, the patent protection was reinforced through four new patents, two of them in China and two in Canada. The company now has a total of four patents in Sweden, four in the USA, two in Canada and two in China. 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. 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 during the first quarter amounted to SEK 114 T (182). Operating expenses during the first quarter amounted to SEK -6,374 T (-3,250). The result of the period amounted to a loss of SEK -5,976 T (-2,967).

Investments during the first quarter amounted to SEK 512 T (223).

Liquid assets as of March 31, 2001, amounted to SEK 24,693 T (11,648). As of December 31, 2000, liquid assets amounted to SEK 30,456 T.

This quarterly report has not been subjected to audit by the company's auditors.

## **Future reports**

Semi-annual report 2001  
Quarterly report for the 3<sup>rd</sup> quarter, 2001

August 23, 2001  
November 1, 2001

**Danderyd, April 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 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	Group		
	Jan. - March 2001	2000	Whole year 2000
Operating income	114	182	526
<i>Operating expenses</i>			
Goods for resale	-31	-49	-182
Other external costs	-3,328	-1,593	-10,435
Personnel costs	-1,754	-1,388	-6,008
Depreciation of assets	-1,257	-220	-1,539
Other operating expenses	-4	-	-11
<b>Operating loss</b>	<b>-6,260</b>	<b>-3,068</b>	<b>-17,649</b>
Financial items	284	101	981
Issue expenses	-	-	-2,997
<b>Loss before taxes</b>	<b>-5,976</b>	<b>-2,967</b>	<b>-19,665</b>
Taxes	-	-	2
<b>Net loss of the period</b>	<b>-5,976</b>	<b>-2,967</b>	<b>-19,663</b>

## Balance sheet

Amounts in SEK thousands	March 31, 2001	March 31, 2000	Dec.31, 2000
Intangible assets	20,583	1,686	21,679
Tangible assets	2,445	808	2,094
Projects in progress	3,530	18,743	2,660
Other current assets	1,527	1,027	1,859
Liquid assets	24,693	11,648	30,456
<b>Total assets</b>	<b>52,778</b>	<b>33,912</b>	<b>58,748</b>
Shareholders' equity	49,746	32,370	55,723
Provisions	2	4	2
Current liabilities	3,030	1,538	3,023
<b>Total shareholders' equity and liabilities</b>	<b>52,778</b>	<b>33,912</b>	<b>58,748</b>

## Cash flow analysis

	<i>Group</i>		
	<i>Jan. - March</i>		<i>Whole year</i>
	<i>2001</i>	<i>2000</i>	<i>2000</i>
<b>Current operations</b>			
Loss after financial items	-5,976	-2,967	-19,663
Adjustments for items not included in the cash flow	1,257	220	1,550
	<b>-4,719</b>	<b>-2,747</b>	<b>-18,113</b>
Taxes paid	-	-	-
<b>Cash flow from current operations before changes of working capital</b>	<b>-4,719</b>	<b>-2,747</b>	<b>-18,113</b>
Cash flow from changes in working capital	-532	-2,317	14,419
<b>Cash flow from current operations</b>	<b>-5,251</b>	<b>-5,064</b>	<b>-3,694</b>
<b>Investment activities</b>			
Acquisitions of tangible and intangible assets	-512	-223	-22,832
<b>Cash flow from investment activities</b>	<b>-512</b>	<b>-223</b>	<b>-22,832</b>
<b>Financing activities</b>			
New issue	-	-	40,000
Issue of debenture with detachable subscription warrants	-	-	49
Repayment of debts	-	-	-2
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>	<b>40,047</b>
<b>Period's cash flow</b>	<b>-5,763</b>	<b>-5,287</b>	<b>13,521</b>
<b>Liquid assets at beginning of year</b>	<b>30,456</b>	<b>16,935</b>	<b>16,935</b>
<b>Liquid assets at end of period</b>	<b>24,693</b>	<b>11,648</b>	<b>30,456</b>

## Key ratios

No. of shares at end of period (thousands)	59,346	52,073	59,346
No. of outstanding subscription warrants (thousands)	450	400	450
Earnings per share	-0.10	-0.06	-0.35
Return on equity	neg.	neg.	neg.
Return on capital employed	neg.	neg.	neg.
Equity ratio in %	94.3%	95.5%	94.9%
Shareholders' equity per share, SEK	0.84	0.62	0.94