

# **Biolight International AB (publ)**

## **Financial report, September 30, 2001**

### *Third quarter*

- **New research results from the Karolinska Institutet show that effects of treatment with Biolight<sup>®</sup> can now be measured using molecular biology technology. The results indicate that six hours after treatment there is a significant increase in the activities of a number of genes, including genes coding for growth factors and collagen.**
- **The new Biolight WCD, DCD and PCD equipments, which have all gained CE approval, have been tested in the market during the year. Test sales have begun and have aroused great interest during the third quarter.**
- **Invoiced sales amounted to SEK 365 T (SEK 97 T).**
- **During the third quarter, Biolight has signed distribution agreements for the business area Dental Care with the following companies:**
  - **TryCare Limited in the UK**
  - **Praktikertjänst in Sweden**
  - **Zuchowski Dental in Poland**
  - **Excal in Colombia**
- **A study on tooth extraction has started up at the dental college in Göteborg. To date, 20 patients have been included.**

### *First six months*

- **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<sup>®</sup> Wound Care.**
- **A market test has been conducted by a group of dentists and dental hygienists in private practice, and the result is positive. 10 participants out of 11 decided on buying 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.**
- **Biolight<sup>®</sup> PCD (Physiotherapeutic Care Device) - a new device for the treatment and rehabilitation of sports injuries - gained CE approval 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 commercialisation within its core areas - Biolight® Wound Care, Biolight® Dental Care and Biolight® Physiotherapeutic Care.

### ***Biolight® Wound Care***

***New research results from the Karolinska Institutet show that effects of treatment with Biolight® can now be measured using molecular biology technology. The results indicate that six hours after treatment there is a significant increase in the activities of a number of genes, including genes coding for growth factors and collagen.***

After several years of clinical studies, Biolight International AB is able to provide significant results on the healing of decubitus ulcers and oral inflammations. Aiming to gain knowledge about what it is that makes treatment using monochromatic light a successful healing agent, Biolight® has linked with Dr. Gunnar Kratz at the Karolinska Institutet, KI, in Stockholm to carry out in vitro studies of the effects of Biolight® on fibroblasts, a cell type that is vital to healing ulcerations. The results of these studies indicated significant increases in the number of fibroblasts after treatment with Biolight®

These effects have now also been studied by Professor Jan-Åke Gustafsson at Novum, KI, and Dr. Gunnar Kratz, KI, using a so-called Affymetrix method. This method enables measurement at a molecular biology level of differences in expression of various genes before and after treatment.

### **Professor Jan-Åke Gustafsson at the Institution for Nutritional Studies and for Biological Sciences at Novum KI, and chairman of Biolight's Scientific Council, states that:**

”The effects on fibroblasts treated with Biolight® have been studied using the so-called AFFYMETRIX methodology, a process that allows for measuring differences in expression of different genes before and after treatment. Six hours after treatment, a significant increase in the activities of a number of genes was observed, including genes coding for growth factors and collagen. That the first group of genes, growth factors, is activated after light treatment can help explain the treatment's growth enhancing effects on fibroblasts, while an increase in the amount of collagen is in agreement with the method's healing effects on chronic wounds.”

”These new findings are very interesting since they indicate that the effects of treatment with Biolight® can now be measured using molecular biology technology, at the same time as they open particularly exciting possibilities for research on potential, but still hardly known, cellular photoreceptors,” concludes Professor Gustafsson.

### ***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 result shows that the time to healing was reduced by 36 % after treatment with Biolight®. 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® 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 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, 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 ongoing with international companies regarding commercialisation and distribution within the wound care sector.

## ***Biolight® Dental Care***

Biolight International AB has entered into distribution agreements for the business area Dental Care with the following companies:

- TryCare Limited in the UK
- Praktikertjänst in Sweden
- Zuchowski Dental in Poland
- Excal in Colombia

TryCare Limited has:

- Sent out information about Biolight to 17,000 dentists twice
- Participated at the dental exhibition in Birmingham, the biggest one in the UK

A market test has been conducted by a group of dentists and dental hygienists in private practice and the result is positive. 10 participants out of 11 decided on buying 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 has initiated a study on tooth extraction at the dental college in Göteborg. To date, 20 patients have been included.

During the autumn of 2001 and spring 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, have reported 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 - gained CE approval 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**

The new Biolight WCD, DCD and PCD equipments have gained CE approval, and have afterwards been tested in the market. Sales have begun during the third quarter and agreements have been signed with various distributors. Sales in the third quarter amounted to SEK 365 T (97). Operating expenses during the third quarter amounted to SEK -6,936 T (-4,035). The loss for the third quarter amounted to SEK -6,363 T (-3,633). The result for the first nine months of 2001 amounted to SEK -19,027 T (-13,040). The result for 2000 was encumbered by costs of stock issue of SEK 2,890 T.

Investments during the third quarter amounted to SEK 912 T (8,959). Accumulated investments for the first nine months of 2001 amounted to SEK 1,717 T (9,589). Investments in 2000 consist mainly of balanced costs for clinical trials.

Liquid assets as of September 30, 2001, amounted to SEK 10,721 T (38,541). As of December 31, 2000, liquid assets amounted to SEK 30,456 T.

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

## **Future reports**

Press release of audited annual earnings figures etc. for 2001

February 18, 2002

## **Accounting principles**

This financial report applies the same accounting principles and basis of calculation as the latest annual report, and complies with the interim report recommendations of the Swedish Financial Accounting Council.

**Danderyd, November 1, 2001**

## **Board of Directors, Biolight International AB**

Biolight International AB is a medical technology company offering products based on the biological effects of pulsating, monochromatic light. Biolight is developing 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.- Sep.		July-Sep.		Whole year 2000
	2001	2000	2001	2000	
Operating income	690	397	365	97	526
Operating expenses					
Goods for resale	-272	-118	-122	-29	-182
Other external costs	-10,355	-5,913	-3,671	-2,269	-10,435
Personnel costs	-5,918	-4,282	-1,885	-1,352	-6,008
Depreciation of assets	-3,773	-855	-1,257	-385	-1,539
Other operating expenses	-13	-	-1	-	-11
<b>Operating loss</b>	<b>-19,641</b>	<b>-10,771</b>	<b>-6,571</b>	<b>-3,938</b>	<b>-17,649</b>
Financial items	614	621	208	395	981
Issue expenses	-	-2,890	-	-90	-2,997
<b>Loss before taxes</b>	<b>-19,027</b>	<b>-13,040</b>	<b>-6,363</b>	<b>-3,633</b>	<b>-19,665</b>
Taxes	-	-	-	-	2
<b>Net loss for the period</b>	<b>-19,027</b>	<b>-13,040</b>	<b>-6,363</b>	<b>-3,633</b>	<b>-19,663</b>

## Balance sheet

Amounts in SEK thousands	Sep. 30, 2001	Sep. 30, 2001	Dec. 31, 2000
Intangible assets	19,172	10,457	21,679
Tangible assets	2,543	768	2,094
Projects in progress	4,396	13,238	2,660
Other current assets	3,486	1,194	1,859
Liquid assets	10,721	38,541	30,456
<b>Total assets</b>	<b>40,318</b>	<b>64,198</b>	<b>58,748</b>
Shareholders' equity	37,329	62,346	55,723
Provisions	2	4	2
Current liabilities	2,987	1,848	3,023
<b>Total shareholders' equity and liabilities</b>	<b>40,318</b>	<b>64,198</b>	<b>58,748</b>

## Cash flow analysis

	Jan.- Sep.		Whole year
	2001	2000	2000
<b>Current operations</b>			
Loss after financial items	-19,027	-13,040	-19,663
Adjustments for items not included in the cash flow	3,773	855	1,550
	<b>-15,254</b>	<b>-12,185</b>	<b>-18,113</b>
Taxes paid	-	-	-
<b>Cash flow from current operations before changes of working capital</b>	<b>-15,254</b>	<b>-12,185</b>	<b>-18,113</b>
Cash flow from changes in working capital	-3,398	3,331	14,419
<b>Cash flow from current operations</b>	<b>-18,652</b>	<b>-8,854</b>	<b>-3,694</b>
Investment activities			
Acquisition of assets	-1,717	-9,589	-22,832
<b>Cash flow from investment activities</b>	<b>-1,717</b>	<b>-9,589</b>	<b>-22,832</b>
Financing activities			
New issue	-	40,000	40,000
Issue of debenture with detachable subscription warrants	634	49	49
Raising loans / Repayment of debts	-	-	-2
<b>Cash flow from financing activities</b>	<b>634</b>	<b>40,049</b>	<b>40,047</b>
<b>Period's cash flow</b>	<b>-19,735</b>	<b>21,606</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>10,721</b>	<b>38,541</b>	<b>30,456</b>

## Changes in share capital

### Jan.-Sep. 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 of differences			-1
Net loss for the period			-19,027
At end of period	1,780	114,316	-78,767

### Jan.-Sep. 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			-13,040
At end of period	1,780	113,682	-53,116

## Key ratios

	Jan.- Sep.		Whole year
	2001	2000	2000
No. of shares at end of period (thousands)	59,346	59,346	59,346
No. of outstanding subscription warrants (thousands)	916	450	450
Earnings per share	-0.32	-0.24	-0.35
Return on equity	neg.	neg.	neg.
Return on capital employed	neg.	neg.	neg.
Equity ratio in %	92.6%	97.1%	94.9%
Shareholders' equity per share, SEK	0.63	1.05	0.94