

PhotoCure ASA – Results 3rd Quarter 2001

Oslo, 7th of November 2001

HIGHLIGHTS

- **The commercialisation of Metvix[®] Photodynamic Therapy (PDT) is on track:**
 - **The Metvix[®] PDT “World Launch Symposium” was held in Stockholm, Sweden on the 18th of October.**
 - **The new drug application for Metvix[®] PDT was filed with the FDA in the USA on 26th of September.**
 - **Marketing Authorisation Applications are also pending in 16 EU / EEA countries, Australia and New Zealand.**
 - **Metvix[®] licensing negotiations outside of the Nordic countries are ongoing.**
- **Development of Hexvix[®] for the photodiagnosis (PD) of bladder cancer progresses as planned:**
 - **Based on the very promising results in phase II, patient enrollment started in early October for the Phase III programme.**
 - **The Phase III trials program is expected to end in approximately 1 year.**
- **PCI Biotech continues commercial development of its first products for an international research market.**
- **Total expenses of NOK 30.8 million and a net loss of NOK 22.5 million for the 3 months ending 30th of September 2001 were according to plan. Liquid funds totalled NOK 342.4 million as of 30th of September 2001.**

Metvix[®] Launched in Sweden

On the 18th of October, PhotoCure hosted a "World Launch Symposium" for Metvix[®] in Stockholm, Sweden. Metvix[®] is the first topical photodynamic therapy (PDT) drug to be approved for the treatment of skin cancer. The launch showed that there is a large interest for Metvix[®] amongst the Swedish dermatologist.

The launch in Sweden followed the Marketing Authorisation for Metvix[®] PDT which the company received on the 15th of June 2001. Furthermore, on the 4th of October, the Swedish authorities (Riksförsäkringsverket) approved a reimbursement price for the Metvix[®] cream, thus making the product available to patients under the Swedish reimbursement scheme ("högkostnadsskydd"). Following the launch, the focus in Sweden is now on training dermatologists in the use of Metvix[®] PDT.

On 26th of September, PhotoCure submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for Metvix[®] cream in combination with the CureLight

lamp in PDT for the treatment of actinic keratosis. In addition, Marketing Authorisation Applications for Metvix[®] PDT are pending in Australia, New Zealand and the EU / EEA for both actinic keratosis and basal cell carcinoma unsuitable for traditional therapy.

Recently, PhotoCure presented clinical data for Metvix[®] PDT at the European Academy of Dermatology and Venereology Congress in München, Germany. Clinical data were also presented at the congress in a separate “Metvix[®] satellite symposium” with more than 150 participating dermatologists. During the congress, the company received very positive feedback from many leading international dermatologists.

PhotoCure has conducted clinical studies in Europe, US and Australia on a total of 3000 patients with either basal cell carcinoma (BCC) or actinic keratosis (AK).

PhotoCure is already marketing Metvix[®] PDT in Sweden through its own marketing and sales force. The approval in Sweden has created an increased interest for Metvix[®] PDT. Six centres of excellence have been established to train 45 Swedish dermatology centres in performing PDT. Approximately 20 centres have already been trained. The company is also about to recruit Product Specialists in the other Nordic countries.

Outside of the Nordic region, licensing negotiations are ongoing.

Patient Enrollment Started for the Phase III Programme for Hexvix[®] Photodiagnosis (PD) for the Diagnosis of Bladder Cancer

Patient enrollment has now started for a phase III programme of Hexvix[®]. The programme is designed to document the safety and efficacy of Hexvix[®] PD for the diagnosis of bladder cancer. The first part of this programme is a European multi-center trial involving around 300 patients at 20 centres. A similar trial will start in the US within a few months.

The phase III programme follows positive phase II results in which a total of 52 patients with known or suspected bladder cancer underwent both standard cystoscopy and Hexvix[®] photodiagnostic fluorescence cystoscopy (PD) examination. Biopsies were taken from all visible tumours and suspicious areas to confirm the findings. Results showed that Hexvix[®] PD detects four times as many patients with serious malignant tumours than standard cystoscopy. In addition, ten times as many lesions of these tumours were detected with Hexvix[®] PD compared to standard cystoscopy.

Bladder cancer is the sixth most common malignant disease worldwide, and in 1990 more than 50,000 new cases were reported in the US and 66,500 in Europe. Every year more than 2.5 million cystoscopies (bladder inspections) are performed in Europe and North America in order to diagnose or rule-out bladder cancer. The main problem with conventional cystoscopy is that a significant number of early cancers cannot be accurately detected and hence the recurrence rate after treatment is reported to be as high as 70%. Patients with these recurrent tumours also have a high risk of progression (30%) and often necessitates the surgical removal of the entire bladder. Earlier and more accurate detection of these tumours will contribute to improved patient management and outcomes. The commercial potential for Hexvix[®] fluorescence cystoscopy is therefore very promising.

PCI Biotech AS – Product Development on Track for Launch

PCI Biotech continues its commercial development of the first products for the world preclinical research market. The company's products consist of a transfection agent, LumiTrans™, and a lightsource, LumiSource™. Used in combination, the two products enable a more effective, direct intracellular delivery of molecules, such as genes and proteins, and will also enable the transfer of molecules into cells where other known transfer technologies cannot be used. The technology also enables researchers to achieve the required level of transfection whilst using less and / or cheaper vectors than can currently be used. PCI Biotech plans to introduce its first product in 2002. With millions of transfection experiments carried out by researchers every year, the market potential for the PCI Biotech's products is substantial.

PCI Biotech AS was established to ensure focus and optimal development of products based on the group's new patented transfection technologies. This technology platform will generate products aimed at both the preclinical research market and the clinical market.

Strong Equity and Cash Position

Total operating expenses for the group amounted to NOK 30.8 million for the three months ending 30th of September of 2001 compared to NOK 17.3 million in the same period of 2000. The increase is associated with development activities relating to the Metvix® PDT and Hexvix® PD products as well as an increase in marketing activities related to Metvix® PDT. Net loss for the group totalled NOK 22.5 million for the three months ending 30th of September of 2001 compared to NOK 9.1 million in the same period in 2000.

Shareholders equity totalled NOK 304.7 million as of 30th of September 2001 compared to NOK 357.4 as of 31st of December 2000. Total liquidity amounted to NOK 342.4 million as of 30th of September 2001 and is mainly invested in money market funds. The number of outstanding shares was 17,260,000 as of 30th of September 2001.

Profit & Loss (Group)

(all amounts in NOK 1,000 except per share data)

Three month ended			Nine month ended		2000
30.09.01	30.09.00		30.09.01	30.09.00	1.1-31.12
750	967	Sales	1 682	1 643	2 131
86	824	Other operating revenues	2 772	2 248	2 558
836	1 792	Operating revenues	4 453	3 891	4 689
3 980	3 502	Salaries & other pers. costs	14 620	15 939	17 440
21 029	9 660	External R&D	48 580	26 125	42 299
213	113	Ordinary depreciation	554	267	410
5 587	3 992	Other operating costs	16 792	9 310	11 322
30 808	17 266	Total operating expenses	80 546	51 641	71 471
-29 972	-15 474	Operating loss	-76 092	-47 749	-66 782
		Financial income and expenses			
7 170	6 926	Interests income	21 243	10 978	5 259 689
58	509	Interests expense	830	1 097	721 944
7 112	6 417	Net financial income	20 413	9 881	16 794
-22 860	-9 057	Loss before tax	-55 680	-37 868	-49 988
320	0	Minority interests	422	0	0
0	0	Taxes	0	0	0
-22 540	-9 057	Net loss	-55 258	-37 868	-49 988
-1.32	-0.57	Net loss per share (1)	-3.23	-2.40	-3.11

(1) Calculation based on average weighted number of shares outstanding

Balance sheet (all amounts in NOK 1,000)

	2001	2000	2000
	30.09	30.09	31.12
Fixed assets	2 598	1 710	2 563
Receivables	6 411	2 707	2 604
Securities	314 132	374 356	366 009
Cash & cash equivalents	28 266	31 173	33 674
Total assets	351 407	409 946	404 850
Shareholders' equity	304 754	367 638	357 360
Long term liabilities	17 071	16 620	17 155
Current liabilities	29 582	25 689	30 335
Total equity and liabilities	351 407	409 946	404 850

The Board of Directors of PhotoCure ASA

PhotoCure ASA is a Norwegian listed company with the mission to develop and sell pharmaceuticals and medical devices based on proprietary photodynamic technologies. The company develops products for skin cancer and other skin diseases, internal cancer, gene therapy and cancer vaccines. Its Metvix[®] and Curelight products were developed for the treatment of basal cell carcinoma (skin cancer) and actinic keratosis (pre-cancerous skin lesions). PhotoCure's second pharmaceutical product, Hexvix[®], is currently undergoing clinical phase III trials for bladder cancer detection.

PCI Biotech AS was established as a subsidiary of PhotoCure ASA in order to develop and commercialise new transfection technologies for the research market as well as products for oncology and gene therapy.

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