PhotoCure ASA – Results 2nd quarter 2001

Oslo 21st of August 2001

HIGHLIGHTS

- **The planned commercialisation of Metvix® Photodynamic Therapy (PDT) is on track:**
  - **Marketing Authorisation was obtained for Metvix® PDT in Sweden on the 15th of June for the treatment of pre-malignant actinic keratosis (pre-cancerous skin lesions, AK) and basal cell carcinoma (skin cancer, BCC).**
  - **The launch of Metvix® PDT in Sweden is scheduled for 4th quarter 2001.**
  - **Marketing Authorisation Applications are pending in 16 EU / EEA countries, Australia and New Zealand.**
  - **Licensing of Metvix® outside the Nordic countries progresses according to plans**
  - **A New Drug Application (NDA) for Metvix® PDT will be filed with the US FDA during the latter part of 2001.**
- **Development of Hexvix® for the photodiagnosis (PD) of bladder cancer is progressing as planned:**
  - **Phase II results have shown that Hexvix® improved the detection rate of cancer lesions significantly.**
  - **Phase III studies are to begin later this year.**
  - **Regulatory filing is scheduled for the 1st half of 2003.**
- **Total expenses of NOK 49.7 million and a net loss of NOK 32.7 million for the first 6 months of 2001 were according to plan. Liquid funds totalled NOK 363 million as of 30th of June 2001.**

Metvix® Photodynamic Therapy (PDT) Approved in Sweden

PhotoCure received Marketing Authorisation in Sweden for Metvix® PDT on the 15th of June 2001 for the treatment of actinic keratosis (AK) and basal cell carcinoma (BCC) in patients where traditional therapies are considered less suitable. The approval confirms that Metvix® PDT is an effectiv treatment regime that is well tolerated by patients.

Achieving the first European approval of Metvix® is the most important milestone that PhotoCure has accomplished to date. The strength of PhotoCure's development capabilities is evidenced by the fact that it has taken just four and half years, since the company began its development of Metvix® PDT, to gain its first approval.

In addition, Marketing Authorisation Applications for Metvix® PDT are pending in Australia,

New Zealand and the EU / EEA for both AK and BCC unsuitable for traditional therapy. PhotoCure also plans to file a New Drug Application (NDA) in the U.S. during the second half of 2001.

Positive data from the phase II and phase III Metvix® PDT clinical studies has been presented at a number of scientific conferences this year and recently, PhotoCure participated in the Nordic Dermatology meeting in Sweden. At this meeting, the company also received very positive feed-back from leading international dermatologists to a presentation of two new light sources, Curelight 16 and Curelight 128, which are used for the activation of Metvix®.

PhotoCure intends to market Metvix® and Curelight in the Nordic region through its own marketing and sales force who have now been recruited and are currently being trained. PhotoCure has filed for price and reimbursement for Metvix® PDT to the Swedish Authorities and plans to launch Metvix® in Sweden in the 4th quarter of 2001. Outside the Nordic region, the company is evaluating licensing arrangements, and a licensing deal for markets outside the Nordic area is expected to be finalised later this year.

Basal cell carcinoma (BCC), the most frequent non-melanoma skin cancer, and actinic keratosis (AK), a pre-cancerous skin condition, are both sun induced skin diseases. Worldwide it is estimated that there are more than 2 million cases of BCC and 20 million cases of AK newly reported each year.

Positive Phase II Results Achieved for Hexvix® Photodiagnosis (PD) for the Diagnosis of Bladder Cancer

In a multi-centre phase II clinical trial, a total of 52 patients with known or suspected bladder cancer underwent both standard cystoscopy and Hexvix® photodiagnostic fluorescence cystoscopy examination. Biopsies were taken from all visible tumours and suspicious areas to confirm the findings. Results showed that of 45 patients with bladder cancer, 29% had CIS (carcinoma *in situ*) tumours. Of these CIS tumour patients, 92% were diagnosed through Hexvix® fluorescence cystoscopy compared to 23% by standard cystoscopy. When assessing the results in terms of all other bladder tumour types, 98% of patients with tumours were detected with Hexvix® compared to 80% by standard cystoscopy.

The diagnosis of bladder cancer is a major clinical problem globally. There are estimated more than 2.5 million cystoscopic procedures performed for diagnostic purposes on bladder cancer patients annually. 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 frequently need to remove the bladder. Earlier and more accurate detection of these tumours will contribute to a much better patient management.

Based on the positive phase II results, phase III studies are planned to start later this year in upwards of 30 centres in Europe and the U.S. These studies will again compare the

detection rate of bladder tumours using Hexvix® cystoscopy with standard cystoscopy in patients with bladder cancer. The clinical programme will document the efficacy and safety of this diagnostic procedure and further studies will also evaluate the effect of Hexvix® cystoscopy on the recurrence of this disease.

PCI Biotech AS – First product to be introduced in 2002

PhotoCure's subsidiary, PCI Biotech AS, was established to ensure the optimal development of products based on the groups new patented transfection technologies. This technology platform is the basis for products aimed at both the pre-clinical research market and the clinical market.

PCI Biotech continues with the commercial development of its first products for the world research market. The products consist of a reagent, 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 same levels of transfection using less or cheaper vectors than currently used. PCI Biotech plans to introduce its first product in 2002. The market potential for the products is large as there are millions of transfection experiments carried out by researchers every year.

Expenses as Planned

Total operating expenses for the group amounted to NOK 49.7 million for the first six months of 2001 compared to NOK 34.4 million in the first six months 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 prior to launch of Metvix® PDT. Net loss for the group totalled NOK 32.7 million for the first six months of 2001 compared to NOK 28.8 million in the same period in 2000.

Shareholders equity totalled NOK 325.8 million as of 30th of June 2001 compared to NOK 357.4 as of 31.12.2000. Total liquidity amounted to NOK 362.6 million as of 30th of June 2001 and is mainly invested in money market funds. The number of outstanding shares was 17,115,000 as of 30th of June 2001 and at the same timepoint, the number of outstanding share options to employees totalled 647,000.

Profit & Loss (Group)
(all amounts in NOK 1,000 except per share data)

Three month ended			Six month ended		2000
30.06.01	**30.06.00**		**30.06.01**	**30.06.00**	**1.1-31.12**
529	111	Sales	931	676	2 131
2 061	799	Other operating revenues	2 686	1 424	2 558
2 590	**910**	**Operating revenues**	**3 617**	**2 100**	**4 689**
5 545	4 942	Salaries & other pers. costs	10 640	12 437	17 440
14 731	9 295	External R&D	27 551	16 466	42 299
182	85	Ordinary depreciation	341	154	410
6 712	2 401	Other operating costs	11 205	5 318	11 322
27 170	**16 723**	**Total operating expenses**	**49 738**	**34 375**	**71 471**
-24 580	**-15 813**	**Operating loss**	**-46 121**	**-32 275**	**-66 782**
6 204	**2 458**	**Net financial income**	**13 301**	**3 464**	**16 794**
-18 376	**-13 355**	**Loss before tax**	**-32 820**	**-28 811**	**-49 988**
96	0	Minority interests	102	0	0
0	0	Taxes	0	0	0
-18 281	**-13 355**	**Net loss**	**-32 718**	**-28 811**	**-49 988**
-1.07	-0.88	Net loss per share (1)	-1.91	-1.91	-3.11

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

Balance sheet (all amounts in NOK 1,000)

	2001	**2000**	**2000**
	30.06	**30.06**	**31.12**
Fixed assets	2 479	900	2 563
Receivables	3 093	612	2 604
Securities	330 698	377 975	366 009
Cash & cash equivalents	31 901	39 062	33 674
Total assets	**368 171**	**418 550**	**404 850**
Shareholders' equity	325 836	375 189	357 360
Long term liabilities	17 152	16 539	17 155
Current liabilities	25 183	26 821	30 335
Total equity and liabilities	**368 171**	**418 550**	**404 850**

The Board of Directors of PhotoCure ASA

PhotoCure ASA is a Norwegian listed company with the mission is 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 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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