METVIX® PDT APPROVABLE IN THE US

PhotoCure ASA
Third Quarter Report 2002

Highlights:

- **New Drug Application for Metvix® PDT Approvable in the US**
- **Increase in Metvix® PDT Revenues**
- **Positive Phase III Clinical Results for Hexvix®**

Metvix® PDT Approvable in the US

In September 2001, PhotoCure ASA filed a New Drug Application (NDA) regarding Metvix® PDT (Photodynamic Therapy) for the treatment of Actinic Keratosis (pre-malignant skin disorder), with the Food and Drug Administration (FDA) in the US. Twelve months later, in September 2002, PhotoCure received a letter from the FDA stating that the review of the NDA is completed and that the application is approvable.

The FDA has requested that certain items be resolved before a final marketing approval can be granted. These items mostly relate to completion of the Metvix® PDT labelling and written information to clinicians and patients. In addition, PhotoCure has to commit itself to perform limited phase IV clinical studies after final marketing approval.

The US market is the largest pharmaceutical market in the world, and the Approvable Letter from the FDA is an important milestone for PhotoCure. PhotoCure is planning to file a second NDA for Metvix® PDT in the US later this year for the treatment of basal cell carcinoma (skin cancer).

Increase in Metvix® PDT Revenues

Revenues in the third quarter of 2002 totalled NOK 7.7 million, compared to NOK 0.8 million in the same period in 2001 and NOK 4.6 million in the second quarter of 2002.

Marketing of Metvix® PDT in the Nordic countries is progressing as planned. Metvix® PDT is launched in Sweden, while launch activities are ongoing in Norway, Denmark and Finland. The acceptance among dermatologists is high, and at present, a total of 161 light sources have been installed at 107 clinical centres. PhotoCure is targeting to have 150 centres established in the Nordic countries by May 2003.

Galderma S.A., which is responsible for sales and marketing of Metvix® PDT in countries outside of the Nordic region, is now finalising its preparations for the launch of Metvix® PDT in Germany, the first country in their market area. The launch is scheduled to take place in February 2003, and will be followed by the launch of Metvix® PDT in the UK.

Metvix® PDT is, as of today, approved in 14 European countries and in New Zealand.

Positive Phase III Clinical Results for Hexvix®

PhotoCure's first multi-centre phase III study of Hexvix® for the detection of bladder cancer is now completed. This study, which involved 211 patients with a known high risk for bladder cancer, took place at 19 leading university clinics throughout Europe. The aim of the phase III study was to confirm that the main patient benefit of Hexvix® fluorescence cystoscopy is to detect more patients with flat cancer lesions (carcinoma in situ, CIS). If this is the case, these patients would benefit from an earlier and more aggressive treatment.

In the phase III study, Hexvix® fluorescence cystoscopy detected almost 30% additional patients with CIS lesions compared to standard white light cystoscopy. In addition, in a majority of patients with this type of cancer, more cancer lesions were found with Hexvix® than with standard white light cystoscopy. Using Hexvix® fluorescence cystoscopy, 97% of the CIS lesions

were detected, compared to 59% with standard white light cystoscopy. Regardless of lesion type, Hexvix® identified 97% of all tumours, compared to 78% for white light. The investigators reported that in more than 60% of the patients, Hexvix® cystoscopy gave valuable information for the diagnosis and treatment of the patient. The safety profile of Hexvix® was excellent, with no major side effects reported.

PhotoCure's development programme for Hexvix® fluorescence cystoscopy is progressing as planned, and the phase III trial results are important for the planned market authorisation applications. The first application is scheduled to be filed in Europe during the first half of 2003.

Patient Enrolment Ongoing in Pilot Study with Benzvix®

Benzvix® is being developed as a product for photodiagnostics and photodynamic therapy for cancerous and pre-cancerous lesions in the gastro-intestinal tract. Patient enrolment in the pilot study is progressing as planned.

PCI Biotech AS

PCI Biotech continues, in co-operation with leading academic institutions, to focus its business on the opportunities for photochemical internalisation (PCI) in drug discovery, development and delivery of novel cancer therapeutics.

Financial Position

Operating revenues, including accrued signing fees from Galderma, totalled NOK 7.7 million for the third quarter of 2002, compared to NOK 0.8 million in the same period of 2001. Cost of products sold in the third quarter of 2002 was negatively influenced by scale-up production costs and by margins on product sale in the initial launch phase with the partners. Total operating expenses for the group amounted to NOK 25.5 million for the three months ending 30 September 2002, compared to NOK 30.8 million during the same period of 2001. The decrease is due to fewer Metvix® PDT development activities and a strong NOK currency. Net loss for the group totalled NOK 17.2 million for the three months ending 30 September 2002, compared to NOK 22.9 million in the same period in 2001.

Shareholders' equity totalled NOK 190.2 million as of 30 September 2002 compared to NOK 259.4 million as of 31 December 2001. Total liquidity amounted to NOK 271.9 million as of 30 September 2002, compared to NOK 305.2 million as of 30 June 2001. The funds are mainly invested in money market funds. The number of outstanding shares was 17,445,000 as of 30 September 2002.

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

Three month ended			Nine month ended		2001
30.09.02	30.09.01		30.09.02	30.09.01	1.1-31.12
7 700	750	Sales revenues	15 991	1 682	2 330
0	86	Other operating revenues	130	2 772	3 022
7 700	**836**	**Operating revenues**	**16 121**	**4 453**	**5 352**
3 009	0	Cost of products sold	3 615	0	0
4 691	**836**	**Gross Profit**	**12 506**	**4 453**	**5 352**
6 526	3 980	Labour costs	11 400	14 620	25 737
12 320	21 029	External R&D	57 677	48 580	78 036
473	213	Ordinary depreciation	1 018	554	758
6 150	5 587	Other operating expenses	25 399	16 792	28 687
25 469	**30 808**	**Total operating expenses**	**95 494**	**80 546**	**133 218**
-20 778	**-29 972**	**Operating loss**	**-82 988**	**-76 092**	**-127 866**
4 843	7 170	Financial income	15 290	21 243	27 486
1 254	58	Financial expense	6 171	830	1 308
3 589	**7 112**	**Net financial income**	**9 119**	**20 413**	**26 178**
-17 189	**-22 860**	**Loss before tax**	**-73 869**	**-55 680**	**-101 688**
0	0	Taxes	0	0	0
-17 189	**-22 860**	**Net loss**	**-73 869**	**-55 680**	**-101 688**
-245	-320	Minority interests	-793	-422	-1 074
-0.98	-1.33	Net loss per share (1)	-4.24	-3.25	-5.93

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

Balance Sheet (all amounts in NOK 1,000)

	2002	2001	2001
	30.09	30.09	31.12
Fixed assets	11 545	2 247	3 935
Stocks	20 813	0	4 287
Receivables	12 193	6 411	6 169
Securities	218 176	314 132	283 564
Cash & cash equivalents	53 690	28 266	21 614
Total assets	**316 417**	**351 056**	**319 569**
Shareholders' equity	190 243	304 403	259 398
Long term liabilities	17 605	17 071	17 362
Current liabilities	108 569	29 582	42 809
Total equity and liabilities	**316 417**	**351 056**	**319 569**

Change in equity (all amounts in NOK 1,000)

	Nine month ended		2001
	30.09.02	30.09.01	1.1-31.12
Equity at beginning of period	**259 398**	**357 360**	**357 360**
Accrued subscription rights	576	1 661	2 215
Unpaid subscription	-	-	239
Share issue employees	4 137	991	1 201
Share increase in subsidiary	1	71	71
Net loss for the year	-73 869	-55 680	-101 688
Equity at end of period	**190 243**	**304 403**	**259 398**

Cash Flow Statement (all amounts in NOK 1,000)

	Nine month ended		2001
	30.09.02	30.09.01	1.1-31.12
Loss before taxes	-73 869	-55 680	-101 688
Other operational items	44 804	-1 146	7 068
Net Cash Flow from Operations	**-29 064**	**-56 826**	**-94 620**
Cash Flow from Investing	-8 628	-838	-1 364
Cash Flow from Financing	4 380	379	1 479
Net Change in Cash & cash equivalents	**-33 312**	**-57 285**	**-94 505**
Cash & cash equivalents at beginning of period	305 178	399 683	399 683
Cash & cash equivalents at end of period	**271 866**	**342 398**	**305 178**