PhotoCure ASA – Development on track

Oslo 2nd November 2000

HIGHLIGHTS

- **The global development of Metvix® and Curelight for the treatment of the pre-cancerous skin lesion actinic keratosis (AK) and the skin cancer basal cell carcinoma (BCC) is on track:**
  - **Marketing Authorisation Application (MAA) for Metvix® for the treatment of AK is currently under review by the Swedish authorities.**
  - **Patient recruitment for two phase III clinical studies for AK in Australia and U.S. has been completed. Analysis of the response data from these studies will take place three months after final treatment.**
  - **Two new phase III clinical studies evaluating Metvix® photodynamic therapy (PDT) for primary BCC have been initiated in Australia and U.S. A further phase III study for "high risk" BCC has also been started in Australia.**
  - **Clinical results from the Metvix® PDT clinical studies have been presented at a number of international scientific conferences.**
- **A phase III clinical study with Metvix® for Squamous cell carcinoma in situ (skin cancer) also called Bowens disease has been initiated.**
- **A phase II clinical study with Hexvixä for bladder cancer detection is now underway.**
- **Total expenses of NOK 51.6 million for the first 9 months of 2000 are according to plans. Liquid funds totalled NOK 405.6 million as of 30th September 2000.**

PhotoCure's research and product development is based on its three platform technologies:

- Photodynamic Therapy (PDT) and Photodiagnosis (PD) based on its novel ALA derivatives
- Photochemical synergism (PCS), and
- Photochemical internalisation (PCI).

The company currently has four products in development: the pharmaceutical products *Metvix®, Hexvix™ and Benzvix™* , all of which are ALA derivatives and the light source *Curelight.* Development programs are on track.

Metvix® and Curelight Development (Metvix® PDT)

Metvix® is PhotoCure's most advanced pharmaceutical product (PDT agent) and approximately 2,000 patients have been treated with Metvix® PDT during the course of 19 clinical trials in approximately 70 clinical centres in Europe, U.S. and Australia. PhotoCure's global development program has initially focused on the combination of Metvix® and Curelight (Metvix® PDT) as a topical treatment modality for non-melanoma skin cancers, including "high risk" Basal Cell Carcinoma (BCC), primary BCC and the pre-cancerous skin condition (AK). There are more than 1.7 million cases of BCC each year in Europe, the U.S. and Australia and it is estimated that there are more than 15 million cases of AK each year. The Metvix® PDT treatment regime consist of the application of Metvix® cream to the skin lesion followed by red light illumination by Curelight to the same area, three hours later.

PhotoCure has completed its phase III AK clinical studies in Europe and a Marketing Authorisation Application (MAA) was filed with the Medicines Products Agency (MPA) in Sweden in May of this year. The first response to this application from the MPA is expected during November 2000.

In order to supplement the clinical data included in the MAA for AK, the company has undertaken further clinical studies in the U.S. and Australia. Patient recruitment has been completed in two phase III clinical trials for AK: one in Australia and one in the U.S.. In these studies, which involved a total of 290 patients, Metvix® PDT was compared to placebo and/or cryotherapy. The first data from these studies are expected during first half of 2001.

The second indication which PhotoCure expects to file a MAA for Metvix® PDT is BCC (basal cell carcinoma). In order to achive this, the company is undertaking a comprehensive clinical program.

A pivotal phase II clinical trial (final decisive study) for the treatment of "high risk" BCC is ongoing and response data after 12 months follow up are expected to be released in the 1st quarter of 2001. To support this indication further, PhotoCure has initiated a clinical study on "high risk" BCC in Australia. PhotoCure plans to file its first MAA for "high risk" BCC 1st quarter 2001.

Two phase III clinical studies for primary BCC are ongoing in Europe and the response data after three months follow up are expected to be released in early 2001. A total of 220 patients have been included in these studies which compare Metvix® PDT to cryotherapy and surgical excision. Further phase III clinical studies for primary BCC in Australia and USA have also been started.

Response data after 12 months follow up in our phase II study for BCC have been evaluated. The data show more than 80% complete response rate after 12 months follow up. The recurrence rate is approximately 10%.

Clinical data for Metvix® PDT presented at international scientific conferences

Data from the phase II and III Metvix® PDT studies have been presented at a number of scientific conferences. These conferences have included the 13th International Congress on PhotoBiology and 28th Annual Meeting of the American Society for Photobiology held in San Francisco July 2000, the Annual Meeting of the Norwegian Dermatology Society, held in Tromsø September 2000 and the European Academy of Dermatology and Venerology held in Geneva in October this year.

Phase III clinical study initiated for squamous cell carcinoma in situ

The company has initiated a phase III clinical study with Metvix® PDT for the treatment of squamous cell carcinoma (SCC) in situ, also called Bowens disease. SCC is a non-melanoma skin cancer that is about 3-4 times less frequent than BCC.

Clinical phase II study with Hexvix™ for bladder cancer detection initiated

The diagnosis of bladder cancer is a major clinical problem around the world. Although there are only approximately 115.000 cases of bladder cancer reported in the U.S. and Europe each year, an estimated 2.8 million cystoscopic procedures (for diagnostic purposes) are performed on bladder cancer patients annually. However, the main problem with conventional cystoscopy is that a significant number of early cancers are not detected, and recurrence rates after treatment are approximately 70%. PhotoCure believe that Hexvix™ in combination with blue or red light, will provide an improvement in the early detection and treatment of bladder cancer.

A phase II clinical study for detection of bladder cancer using Hexvix™ and blue light to improve the cystoscopic procedure has started. A total of 50 patients will be recruited into this study, which will take place at five different clinical centres in Europe.

For the development of Hexvix™ in the diagnosis and treatment of bladder cancer, PhotoCure will be working closely with the scientists at the Swiss Federal Institute of Lausanne. The university clinic in Lausanne has already done explorative clinical

studies with Hexvix™ for bladder diagnosis in more than 100 patients. The results indicate clear clinical benefits of the methodology and minimal side effects.

Meetings with regulatory agencies in Europe and the U.S. (FDA) have been held recently in order to achieve a common understanding of the documentation required to obtain market authorisation for Hexvix™ as a diagnostic for bladder cancer.

Pre-clinical research and development with Benzvix™ progressing

Benzvix™ is being developed topically for the photodetection and photodynamic therapy of pre-malignant and malignant lesions in the gastrointestinal tract including the oesophagus, stomach and colon. Benzvix™ is in its pre-clinical phase with the chemical development program ongoing while the toxicology program has just started.

PCI Biotech AS established

PhotoCure has decided to establish a subsidiary for its new and patented transfection technologies in order to ensure the optimal development of products based on this technology platform. Dr. Andreas Grimeland has recently joined PhotoCure as the CEO of PCI Biotech AS.

Expenses as expected

Total operating expenses amounted to NOK 51.6 million for the first three quarters of 2000 compared to NOK 34.5 million in the first three quarters of 1999. The increase is mainly due to increased development activities, especially related to Metvix® PDT but also to Hexvix™ photodiagnosis.

Shareholders equity totalled NOK 367.6 million as of 30th of September 2000 compared to NOK 81.4 million as of 30th of September 1999. Total liquidity amounted to NOK 405.6 million as of 30th September 2000 and is mainly invested in money market funds. The number of outstanding shares is 17.09 million as of 30th of September 2000.

Profit & Loss (all amounts in NOK)

	01.01.00-30.09.00	01.01.99-30.09.99	1999
Operating revenues	1 642 953	717 400	1 094 560
R&D grants from NFR	2 248 446	2 133 938	2 500 001
Operating revenues	**3 891 399**	**2 851 338**	**3 594 561**
Labour cost	7 515 887	7 929 722	10 546 218
Employee options, social security tax	8 422 617	1 248 327	3 203 779
External R&D	28 373 913	21 906 392	28 335 733
Ordinary depreciation	266 762	137 393	200 967
Other operating expenses	7 061 508	3 326 473	7 352 381
Total operating expenses	**51 640 687**	**34 548 307**	**49 639 078**
Operating loss	**-47 749 288**	**-31 696 969**	**-46 044 517**
Net financial income	**9 881 051**	**3 379 030**	**4 537 745**
Loss before tax	**-37 868 237**	**-28 317 939**	**-41 506 772**
Taxes	0	0	0
Net loss	**-37 868 237**	**-28 317 939**	**-41 506 772**
Net loss per share (1)	-2.40	-2.16	-3.09

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

Balance sheet (all amounts in NOK)

	30.09.00	30.09.99	31.12.99
Fixed assets	1 710 348	366 093	523 772
Receivables	2 706 686	4 220 401	974 530
Money market funds	374 355 599	83 760 356	84 924 470
Cash & cash equivalents	31 173 317	22 668 001	14 439 253
Total assets	**409 945 950**	**111 014 851**	**100 862 025**
Shareholders' equity	**367 637 502**	**81 429 895**	**68 227 569**
Long term liabilities	16 619 865	16 674 762	16 841 499
Current liabilities	25 688 583	12 910 194	15 792 957
Total equity and liabilities	**409 945 950**	**111 014 851**	**100 862 025**

Oslo 2nd of November 2000

The Board of Directors of PhotoCure ASA

PhotoCure ASA is a Norwegian listed company founded in 1993. PhotoCure ASA mission is to develop and sell pharmaceuticals and medical devices based on proprietary photodynamic technologies. The company is developing products for skin cancer and other skin diseases, internal cancer, gene therapy and cancer vaccines. PhotoCure has completed final registration studies (phase III) with its first products, Metvix® and Curelight for actinic keratosis (pre-cancerous skin lesion), and has filed its first application for European marketing approval in May year 2000.

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