

# **PhotoCure ASA**

## **Results 1<sup>st</sup> quarter 2002**

**May 2002**



# Highlights

- Metvix<sup>®</sup>
  - Commercialisation on track
- Hexvix<sup>®</sup>
  - On track for filing of marketing authorisation first half 2003
- Strong R&D pipeline
  - Benzvix<sup>®</sup> clinical pilot studies on track



# Metvix<sup>®</sup>

## – Marketing Authorisations in many countries

- National authorisations issued in:
  - Sweden, Norway, Denmark, Iceland, Germany, UK, Ireland, Luxembourg, New Zealand
- Awaiting national authorisations in:
  - Finland, Belgium, Austria, Spain, Italy, Greece
- Application filed in Switzerland
- Additional clinical data will be submitted to the Australian Authorities from already completed studies
- Application pending for AK in USA
- Galderma
  - file new applications in several countries based on UK approval



# Marketing Metvix<sup>®</sup>

## –Commercialisation in Sweden

- Regulatory approval June 2001
- Reimbursed price of 1300 SEK per tube of Metvix<sup>®</sup> October 2001
- Procedure fee negotiations ongoing
- Target group: 120 dermatology centers
- Training personell from 78 centres
  - 46 centers completed
- Provided 41 centers with 60 lightsources
  - Placement of lightsources started in January 2002
- Revenues 1<sup>st</sup> quarter as planned



# Marketing Metvix<sup>®</sup>

## –Commercialisation in Norway

- Final regulatory approval February 2002
- Approved price of 1100 NOK per tube of Metvix<sup>®</sup>
- Reimbursement application filed for Metvix<sup>®</sup>
- Procedure fee negotiations ongoing
- Target group: 85 dermatology centers
- Focus on hospitals and opinion leaders
- Training of centres initiated



# Marketing Metvix<sup>®</sup>

## –Commercialisation in Denmark

- Final approval obtained
- Reimbursement application filed for Metvix<sup>®</sup>
- Target group: 90 dermatology centers
- Market introduction symposium this month
- Focus on hospitals and opinion leaders



# Marketing Metvix<sup>®</sup>

## –Commercialisation in Finland

- Awaiting final national approval
- Target group: 100 dermatology centers
- Market introduction symposium this month
- Focus on hospitals and opinion leaders



# Marketing Metvix®

## – Galderma pre-launch preparations ongoing

- Several meetings held between Galderma and PhotoCure executives on three continents – Co-operation established
- Steering committee established between Galderma and PhotoCure
- Galderma hired dedicated strategic marketing manager
- Galderma task forces established
  - More resources allocated than for any other product
  - Fastest progress ever since signing
- Transfer of marketing authorisation licenses to Galderma
- Presentations at important conferences





# New indications in dermatology

## – Several possible indications

- Positive data on acne
  - Pilot study completed
  - World wide acne market totals 1.7 bn USD per year
- Other areas of interest
  - Photoaging (skin rejuvenation)
  - Wound healing (pilot study planned)
  - Warts



# Hexvix® preparation

Hexyl aminolevulinate 85mg

+

Phosphate buffer saline 50 mL

↓

Hexvix® 8mM solution

- Stable for 24h in refrigerator
- Instilled 1 hour in the bladder
- Start cystoscopy within 30 minutes



# Hexvix® in bladder cancer – positive results in phase II clinical trial

## Four times more patients with CIS lesions detected

(CIS = Carcinoma in Situ)

Hexvix®		White light	
12 / 13	92%	3 / 13	23%

Patients have one or more CIS lesions



# Hexvix®

## – phase III program ongoing

- Europe
  - Enrolment in first clinical phase III study completed
  - One additional study initiated
- USA
  - Investigational New Drug status obtained
  - Phase III study initiated
- First marketing application planned 1<sup>st</sup> half 2003



# Hexvix®

## – pre-marketing activities ongoing

- Contract manufacturer selected
- Market research study completed
- Price and reimbursement preparations ongoing
- Out-licensing activities initiated
  - PhotoCure will at least retain the Nordic region



# Research and development – strong pipeline

## **ALA derivatives R&D opportunities**

(excluding dermatology and urology)

- Barrets esophagus – clinical pilot study initiated
- Colo-rectal cancer – clinical pilot study initiated
- Lesions in mouth, pharynx and larynx
- Gynegology (vulva, cervix, ovarian)
- Brain tumours
- Mammary tumours (breast conserving surgery)



# PhotoCure

## – important milestones the next twelve months

**As of May 2002**

### **Metvix<sup>®</sup>**

- Introduce the product in Norway, Denmark and Finland
- Submitt additional clinical data for AK and BCC in Australia, France, Portugal & Holland
- File new drug application for BCC in the US
- Initiate clinical study for new indication
- Launches by Galderma in up to 10 other European countries



# PhotoCure

## – important milestones the next twelve months

**As of May 2002**

### **Hexvix<sup>®</sup>**

- Complete current ongoing phase III studies for PD of bladder cancer
- File first marketing authorisation application for PD of bladder cancer

### **Benzvix<sup>®</sup>**

- Complete current ongoing clinical pilot studies

### **PCI Biotech AS**

- First product on the research market
- First clinical pilot study started





# Financial Statements

## – Profit & Loss

Three months ended		All figures in NOK 1,000	Twelve months ended
31.03.2002	31.03.2001		31.12.2002
3 697	402	Sales	2 330
124	625	Other revenues	3 022
<b>3 821</b>	<b>1 027</b>	<b>Total operating revenues</b>	<b>5 352</b>
3 845	5 095	Salaries & other pers. costs	25 737
23 536	12 820	External R&D costs	78 036
232	159	Ordinary depreciation	758
8 971	4 494	Other operating expenses	28 687
<b>36 584</b>	<b>22 568</b>	<b>Total operating expenses</b>	<b>133 218</b>
<b>-32 763</b>	<b>-21 541</b>	<b>Operating income</b>	<b>-127 866</b>
<b>3 253</b>	<b>7 097</b>	<b>Net financial income</b>	<b>26 178</b>
-29 510	-14 443	Loss before tax	-101 688
-	-	Tax	-
<b>-29 510</b>	<b>-14 443</b>	<b>Net loss for the period</b>	<b>-101 688</b>
-313	6	Minority interests	-1 074
-1.70	-0.84	Net loss per share (NOK)	-5.93



# Financial statements

## - Balance sheet

Figures in NOK 1,000	31.03.2002	31.12.2001
Fixed assets	4 075	3 935
Receivables	18 445	10 456
Securities	241 556	283 564
Cash and bank deposits	116 640	21 614
<b>Total assets</b>	<b>380 716</b>	<b>319 569</b>
Shareholders' equity	233 108	259 398
Long term liabilities	17 447	17 362
Current liabilities	130 161	42 809
<b>Total shareholders' capital &amp; liabilities</b>	<b>380 716</b>	<b>319 569</b>

