

# **PhotoCure ASA**

## **Presentation of Results 2001**

**Oslo 27<sup>th</sup> of February 2002**



# Disclaimers

- This document includes forward-looking statements. These statements are based on current expectations and projections about future events. Actual results could differ materially from those discussed in, or implied by, these forward-looking statements.
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# 2001;- The Year to be Remembered

- Metvix<sup>®</sup> is being commercialised
  - Approved in 14 European countries and New Zealand
  - Launched in Sweden
  - Marketing applications filed in Australia, US & Switzerland
  - Licensed to Galderma S.A. outside the Nordic area
  - New lightsources developed and CE mark obtained
- Hexvix<sup>®</sup> is in final clinical stage
  - Positive phase II study finalised
  - Phase III program ongoing
- R&D progress made for other indications and Benzvix<sup>®</sup>
- PCI Biotech AS established
  - First product for the research market close to launch



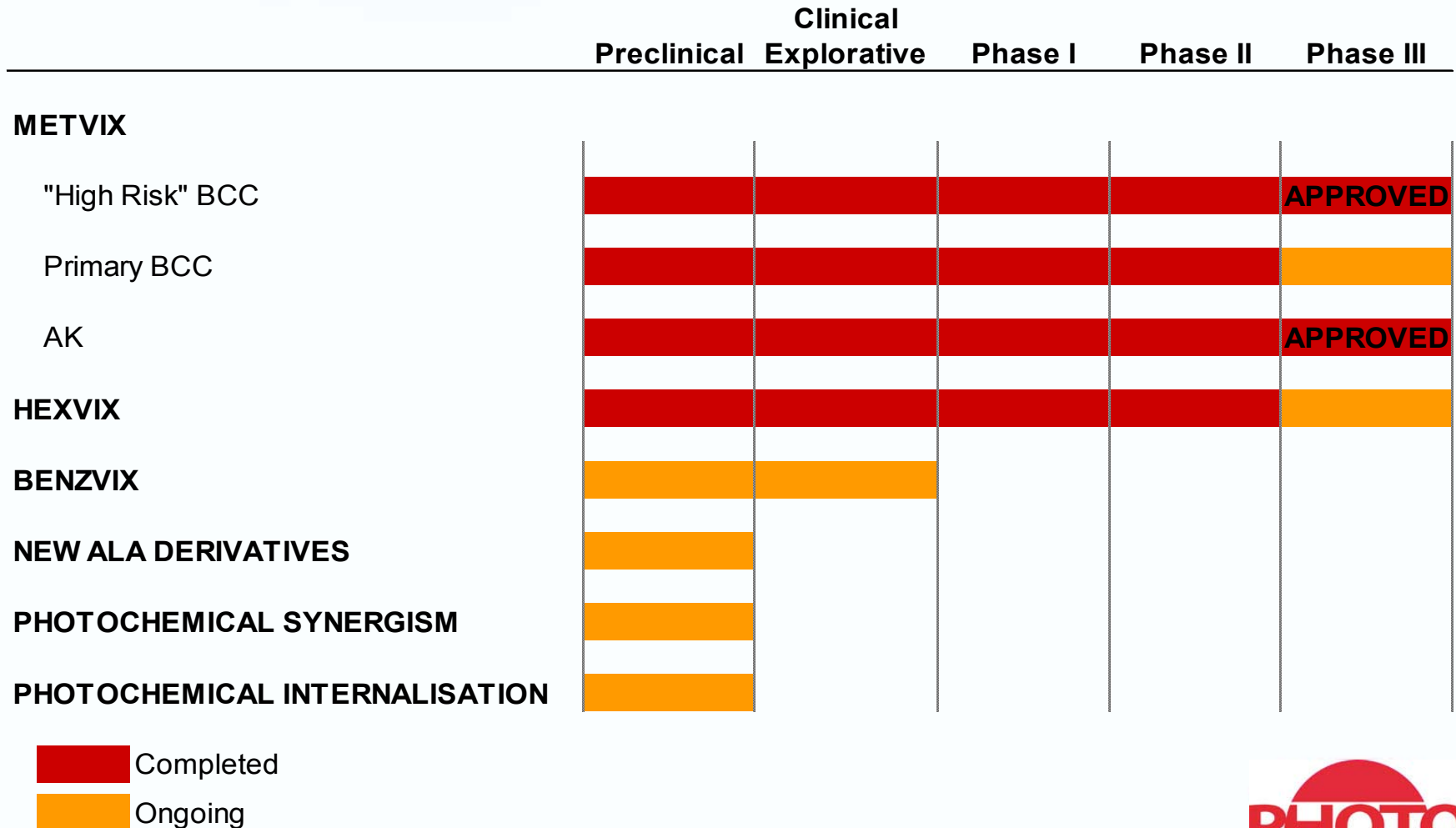
# PhotoCure ASA

## – Mission

*Develop and market novel therapeutic and diagnostic products and related medical devices based on proprietary photodynamic therapy (PDT) technologies.*



# Broad technology platforms and advanced development programmes



# Metvix<sup>®</sup>

– quick and simple treatment

*Lesion preparation*



*Metvix<sup>®</sup> application*



*Curelight illumination*



# Metvix<sup>®</sup>

– new light sources



**Curelight 128**

**Curelight 16**



**Metvix<sup>®</sup>**

**– highly effective with superior cosmetic results**





**Metvix<sup>®</sup>**

**– highly effective with superior cosmetic results**



# Metvix<sup>®</sup>

## – great market opportunities

### ■ BCC

- Appr. 2 mill. new cases per year in EU, America & AUS
- Current therapies give disfiguration / morbidity

### ■ AK

- Appr. 20 mill. new cases per year in EU, America & AUS
- Current therapies give white spots, poor patient compliance

### ■ Dermatologists view Metvix<sup>®</sup> as a real improvement

- Easy to use (fast, not time consuming)
- Additional medical indications
- Practice builder (less referrals to surgeons)



# Marketing Metvix<sup>®</sup>

## – Nordic sales force established

- Launched in Sweden
  - Reimbursed price of 1300 SEK per tube of Metvix<sup>®</sup>
  - Two product specialists promotes Metvix<sup>®</sup> in Sweden
  - Trained and provided more than 40 centers with lightsources
- Final approval obtained in Norway
  - Price application filed and two product specialists hired
- Preparations ongoing in Denmark and Finland
  - Pre-launch activities by one product specialist ongoing in each country



**Metvix®**

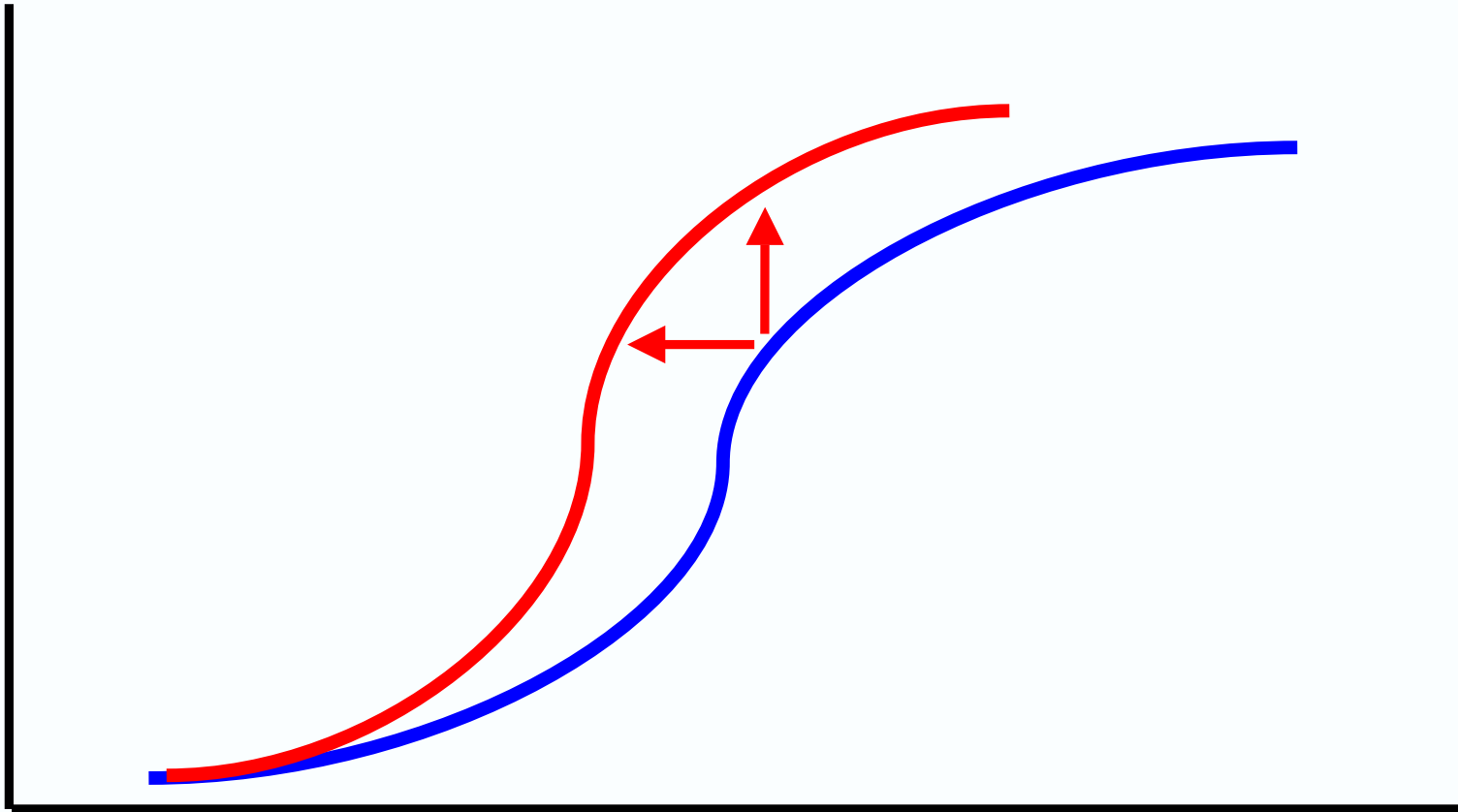
– market introduction

	Old product	New product
Old Market	Renaissance	Penetration
New Market	Market development	



# Metvix<sup>®</sup>

## – sales volume development



# Marketing Metvix®

## – licensed to Galderma outside the Nordic area

### Galderma preferred partner

- Owned 50/50 by Nestlé and L'Oréal
- World wide largest sales force
  - presence in more than 60 countries
- Exclusively dedicated to dermatology

*Galderma strategy*

*"We have chosen dermatology"*

*Galderma corporate objective*

*"Become the leading company in dermatology in the world"*



# Marketing Metvix<sup>®</sup>

## – Galderma licensing agreement

- Marketing and sales
  - Galderma will promote Metvix<sup>®</sup> & PhotoCure lightsources world wide outside the Nordic area
- Regulatory approvals
  - PhotoCure will be responsible for MAA in EU, US, AUS and NZ
  - Galderma will file MAA's in other countries
- Research & development
  - Galderma will fund 75% of costs for new projects
  - Additional milestone payments at approval of new indications
  - Both companies see several possible new indications



# Marketing Metvix<sup>®</sup>

## – significant payments from Galderma

- Up front payment of 12 mill Euro received
- Regulatory milestones: 18 mill Euro
  - Approval and launch in certain countries
- Sales milestones
  - For global sales level of 25 mill Euro per year and above
- Double digit royalty for existing and new indications
- Payments for manufacturing
  - Metvix<sup>®</sup>, active ingredient and PhotoCure lightsources
- Significant guaranteed min. payments of royalties & sales milestones





# Marketing Metvix®

## – Galderma pre-launch preparations ongoing

- Several meetings held between Galderma and PhotoCure executives on three continents – Co-operation established
- Dedicated strategic marketing manager hired
- Galderma task forces established
  - More resources allocated than for any other product
  - Fastest progress ever since signing
- 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<sup>®</sup>

## – great market opportunities

### Bladder cancer

- Significant medical problem: appr. 115,000 cases annually in the US & Europe
- > 2.5 million diagnostic cystoscopic procedures annually in Europe and the US
- On first diagnosis 70-80% of patients have superficial tumours
- Over 70% will have one or more recurrences after initial therapy
- In over 30% cases, tumour progression occurs
- Cause of the high recurrence rate generally believed to be that the lesions are *overlooked*



# Hexvix® preparation

Hexyl aminolevulinate 85mg

+

Phosphate buffer saline 50 mL

➤

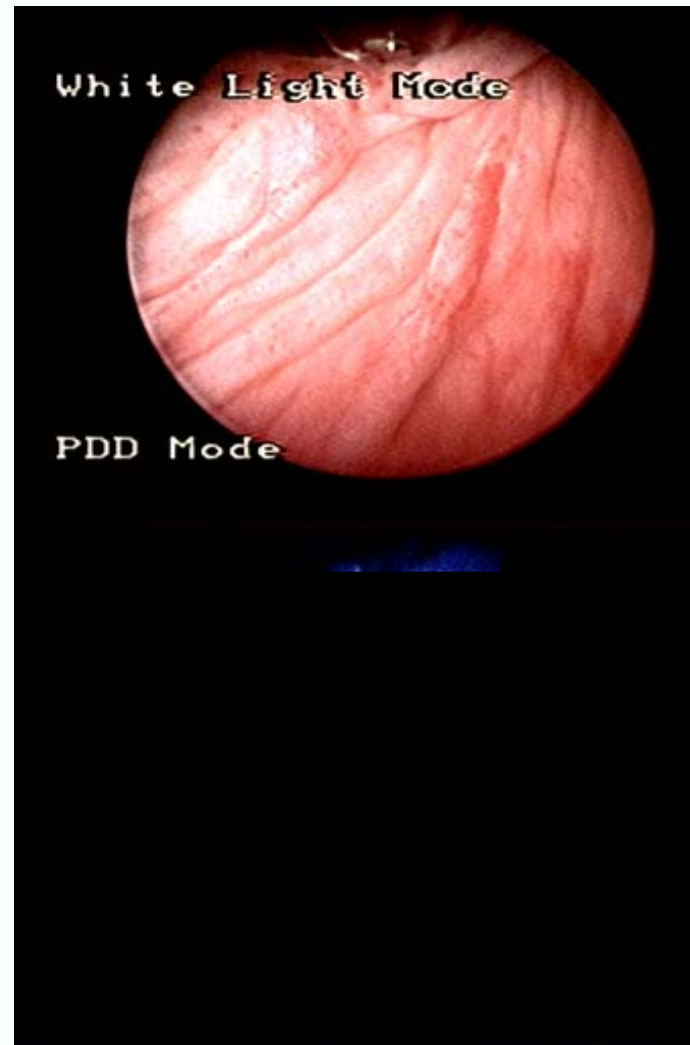
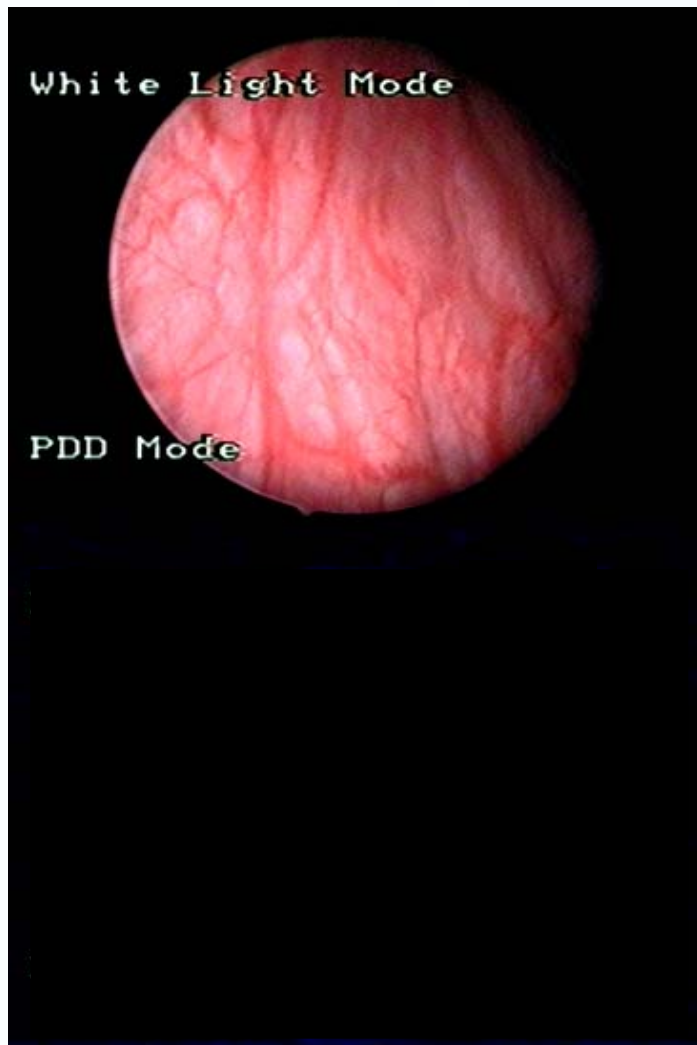
Hexvix® 8mM solution

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



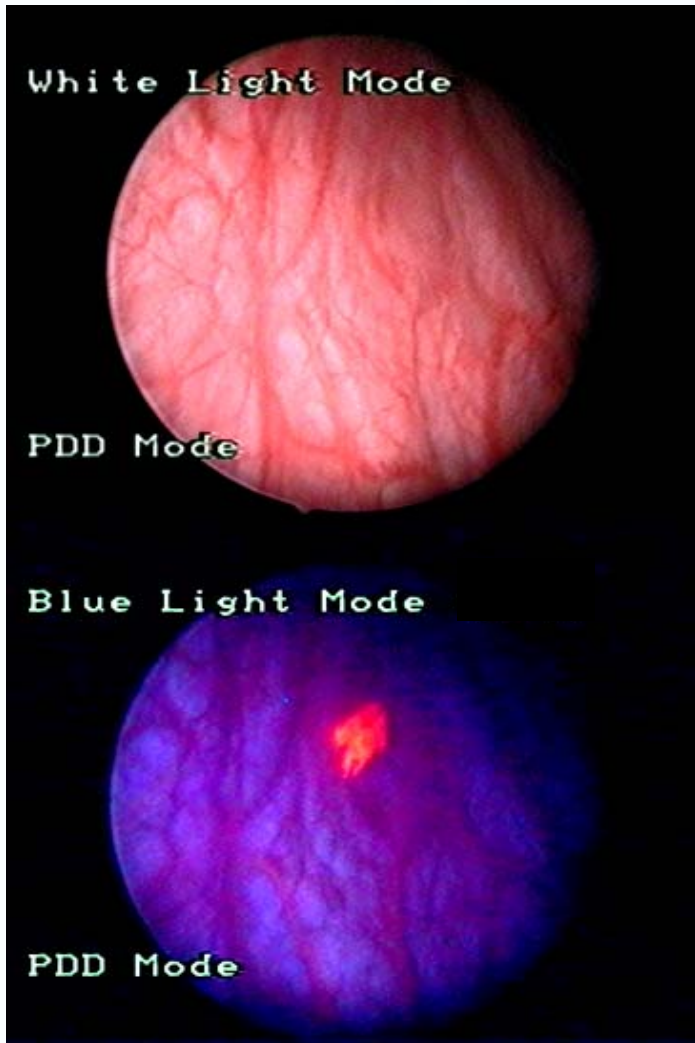
# Bladder cancer

– detection of flat lesions (CIS) difficult



# Hexvix<sup>®</sup> in bladder cancer

- detects CIS lesions with blue light



# Hexvix® in bladder cancer

– positive results in phase II clinical trial

## More patients with tumour lesions detected

Hexvix®		White light	
44 / 45	98%	36 / 45	80%

Histology positive = CIS, Ta, T1

Histology positive patients have one or more tumours



# Hexvix<sup>®</sup> in bladder cancer

– positive results in phase II clinical trial

**Four times more patients with CIS lesions detected**

(CIS = Carcinoma in Situ)

Hexvix <sup>®</sup>		White light	
12 / 13	92%	3 / 13	23%

Patients have one or more CIS lesions





# Hexvix®

## – phase III program ongoing

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



# Research and development – strong pipeline

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

(excluding dermatology and urology)

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



# PCI Biotech AS

## – focus on new transfection technologies

- Increased focus on Photchemical Internalisation (PCI)
  - PCI Biotech AS established as a subsidiary of PhotoCure ASA
- PCI Biotech's product development focuses on:
  - new transfection technology for the research market
  - improve existing technologies for clinical gene therapy
  - new concepts for light directed chemotherapy



# Financial Statements

## – Profit & Loss (Group)

Three months ended		All figures in NOK 1,000	Twelve months ended	
31.12.2001	31.12.2000		31.12.2001	31.12.2000
648	488	Sales	2 330	2 131
250	310	Other revenues	3 022	2 558
<b>898</b>	<b>797</b>	<b>Total operating revenues</b>	<b>5 352</b>	<b>4 689</b>
11 117	1 502	Labour costs	25 737	17 440
29 456	16 174	External R&D costs	78 036	42 299
204	143	Ordinary depreciation	758	410
11 895	2 011	Other operating expenses	28 687	11 322
<b>52 672</b>	<b>19 830</b>	<b>Total operating expenses</b>	<b>133 218</b>	<b>71 471</b>
<b>-51 774</b>	<b>-19 032</b>	<b>Operating income</b>	<b>-127 866</b>	<b>-66 782</b>
6 243	7 170	Interests income	27 486	18 148
478	258	Interests expense	1 308	1 355
<b>5 765</b>	<b>6 912</b>	<b>Net financial income</b>	<b>26 178</b>	<b>16 793</b>
-46 009	-12 120	Loss before tax	-101 688	-49 989
-	-	Tax	-	-
<b>-46 009</b>	<b>-12 120</b>	<b>Net loss for the period</b>	<b>-101 688</b>	<b>-49 989</b>
-652	-	Minority interests	-1 074	-
-2,69	-0,71	Net loss per share (NOK)	-5,93	-3,11



# Balance sheet (Group)

## – strong financial position

Figures in NOK 1,000	31.12.2001	31.12.2000
Fixed assets	3 935	2 563
Receivables	10 456	2 604
Securities	283 564	366 009
Cash and bank deposits	21 614	33 674
<b>Total assets</b>	<b>319 569</b>	<b>404 850</b>
Shareholders' equity	259 398	357 360
Long term liabilities	17 362	17 155
Current liabilities	42 809	30 335
<b>Total shareholders' capital &amp; liabilities</b>	<b>319 569</b>	<b>404 850</b>



# PhotoCure

## – track record for achieving milestones

### Milestones for next twelve months as of May 2001

#### Metvix<sup>®</sup>

- ✓ File MAA's for AK & "High Risk" BCC in Australia & NZ- Q1 2001
- ✓ Achieve marketing authorisation (MA) for AK in Sweden – Q2 2001
- ✓ Achieve MA for "High Risk" BCC first EU country (Sweden) – Q2 2001
- ✓ File mutual recognition procedure in other EU countries – Q3 2001
- ✓ File New Drug Application for AK in US – 2H 2001
- ✓ Marketing partner outside Nordic area
- ✓ File MAA for "High Risk" BCC & AK in Switzerland
- MAA for primary BCC ready for submission in EU



# PhotoCure

## – track record for achieving milestones

### Milestones for next twelve months as of May 2001

#### Hexvix®

- ✓ Enter Phase III trial for PD of bladder cancer in Europe
- ✓ Enter Phase III trial for PD of bladder cancer in US

#### Benzvix®

- ✓ Complete pre-clinical studies necessary for clinical trials

#### PCI Biotech AS

- Launch first product for the research market



# Key investment highlights

- Leader in photodynamic therapeutics and diagnostics
- Metvix<sup>®</sup> PDT new treatment in dermatology:
  - Launched for AK & BCC in first EU country (Sweden)
  - Approved in 14 European countries and NZ, pending in US & Australia
- Hexvix<sup>®</sup> in phase III for bladder cancer detection
  - Phase II completed with positive results
- PCI Biotech AS established – first product close to launch
- Strong cash position
- All commercial rights retained
- Targeting large markets and medical needs
- Strong pipeline of follow-on products & technologies to drive future value
- Strong and experienced management team

