

**PhotoCure ASA**

**Company Presentation**

**January 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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# What is PhotoCure ASA?

- A Norwegian pharmaceutical / biotech company
- Listed on the Oslo Stock Exchange (Ticker PHO, Reuters: PHO.OL)
- Products are based on novel Photodynamic Therapy technologies
  - Metvix<sup>®</sup>: A cream approved for treatment of skin cancer (BCC) and pre-cancerous skin lesions (AK)
  - Hexvix<sup>®</sup>: A drug for detecting bladder cancer.
  - Benzvix<sup>®</sup>: Under development for gastro-intestinal cancers
- PCI Biotech AS
  - A subsidiary of PhotoCure ASA developing new transfection technologies



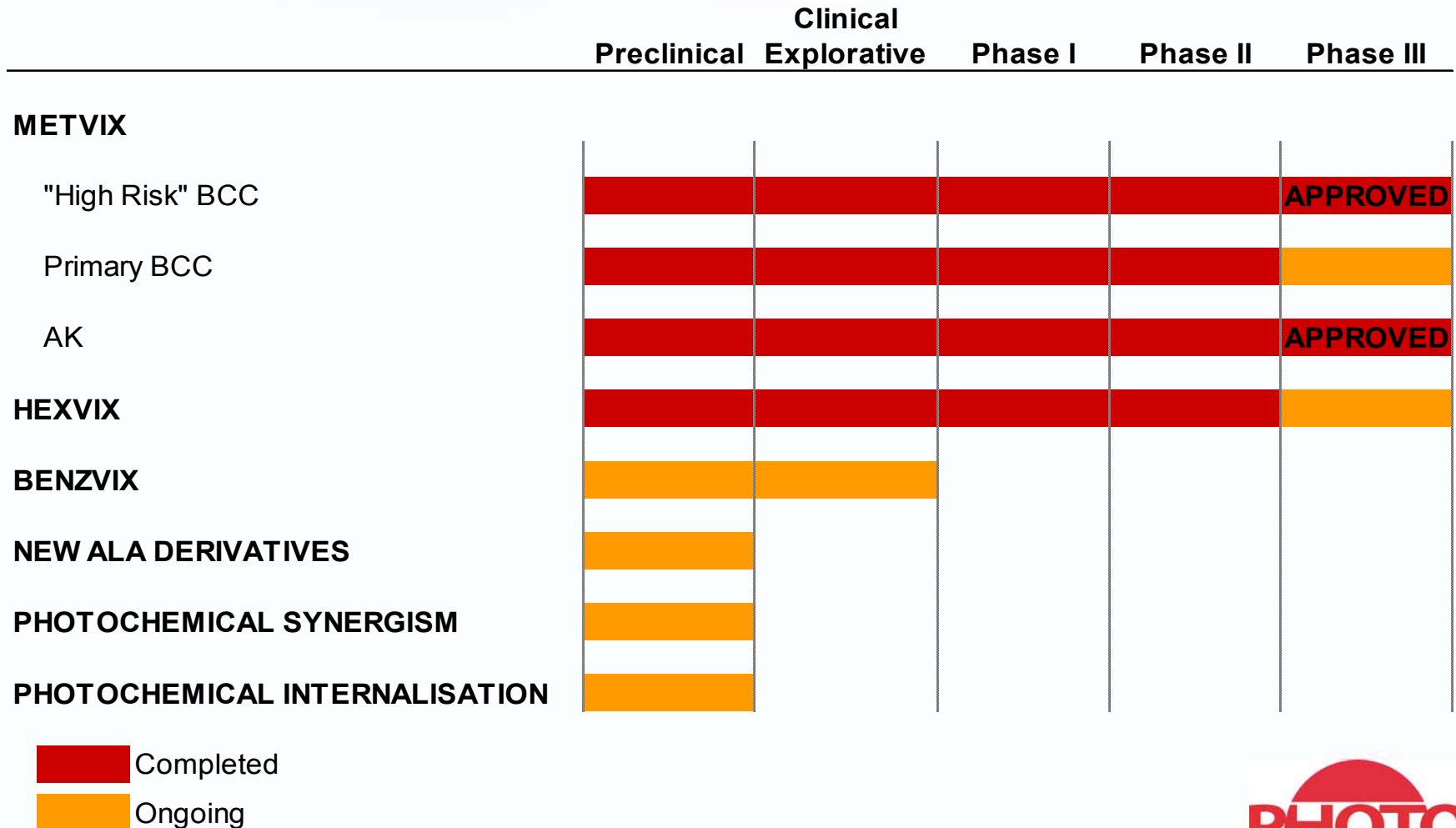
# PhotoCure ASA

## – Mission

*Our mission is to develop and market novel therapeutic and diagnostic products and related medical devices based on our 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**

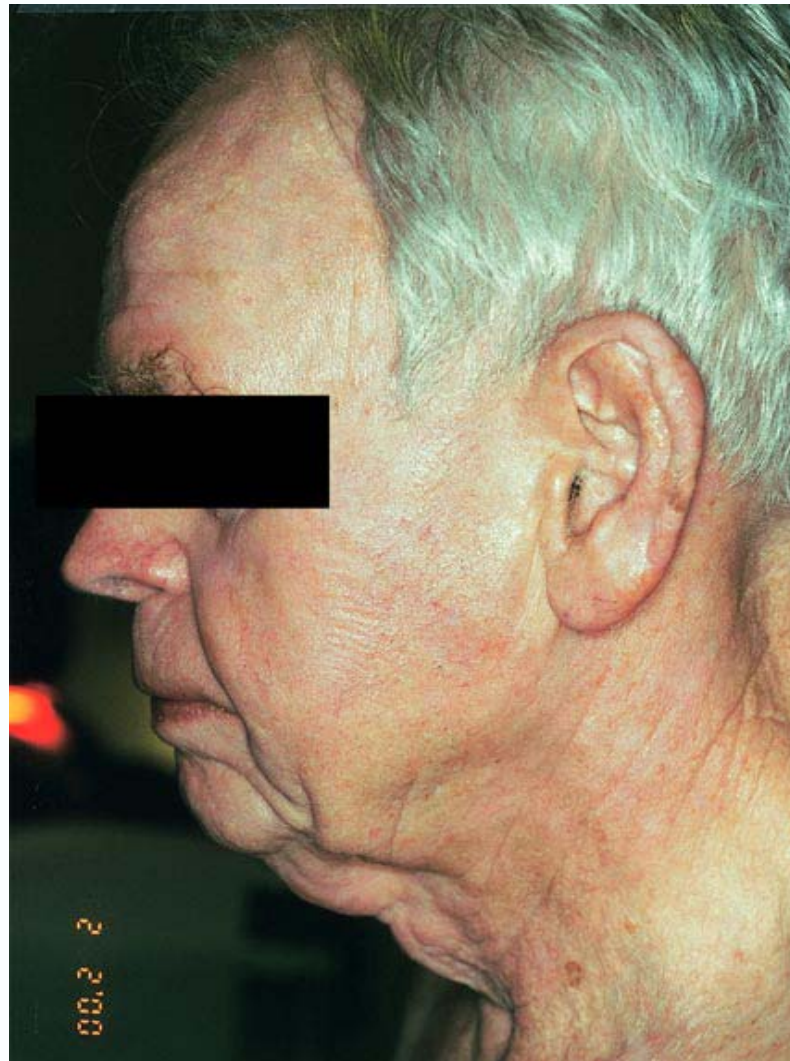
**Curelight 16**





**Metvix<sup>®</sup>**

**– highly effective with superior cosmetic results**





**Metvix<sup>®</sup>**

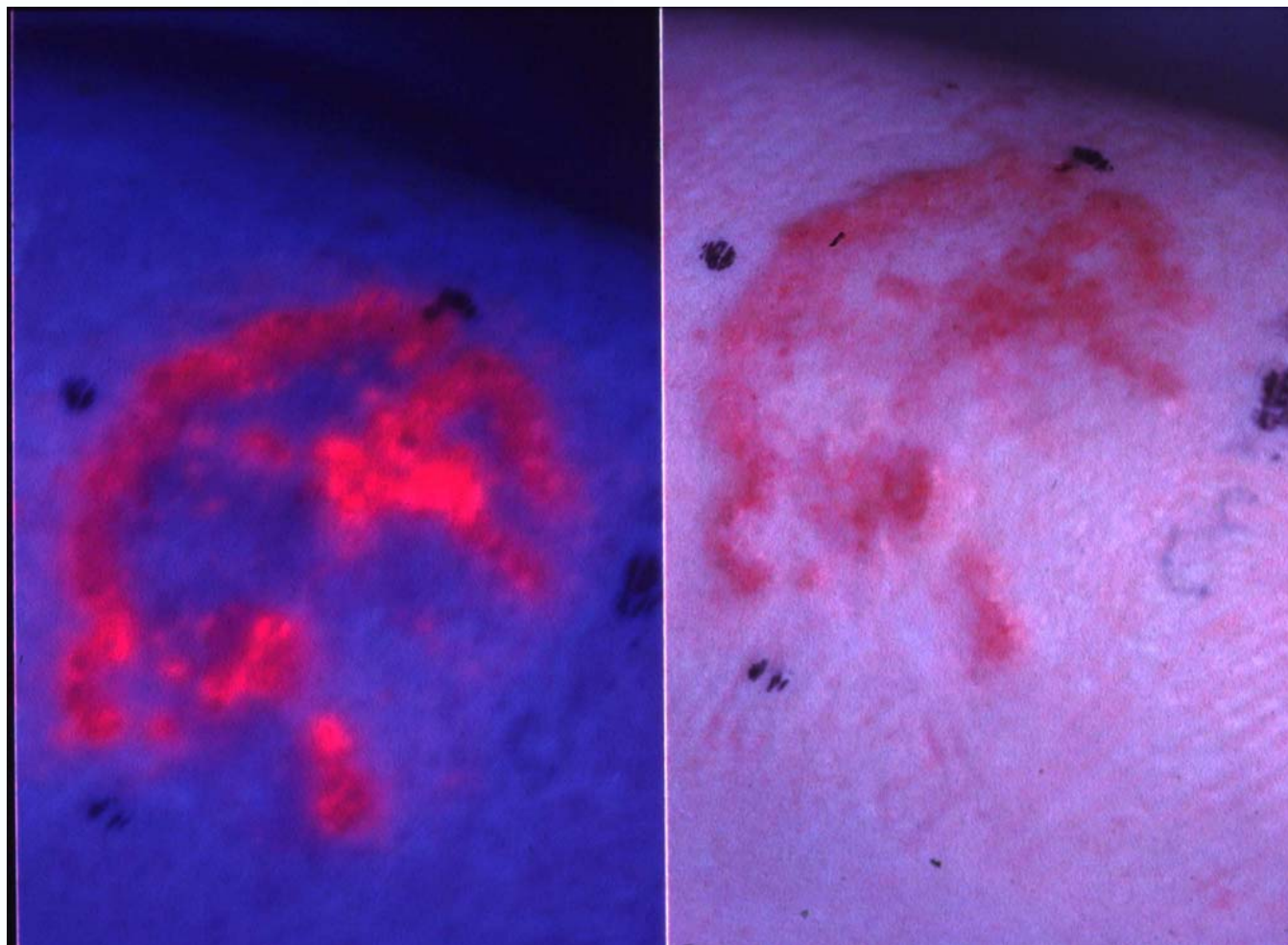
**– highly effective with superior cosmetic results**





# Metvix<sup>®</sup>

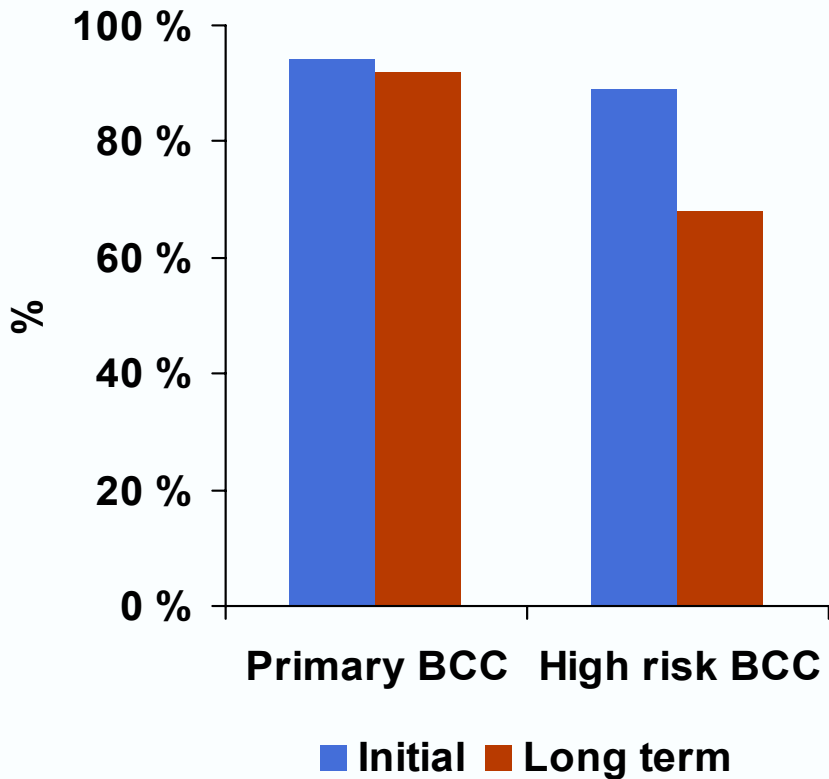
– highly selective



# Metvix®

## – excellent clinical results in BCC

### Lesion response



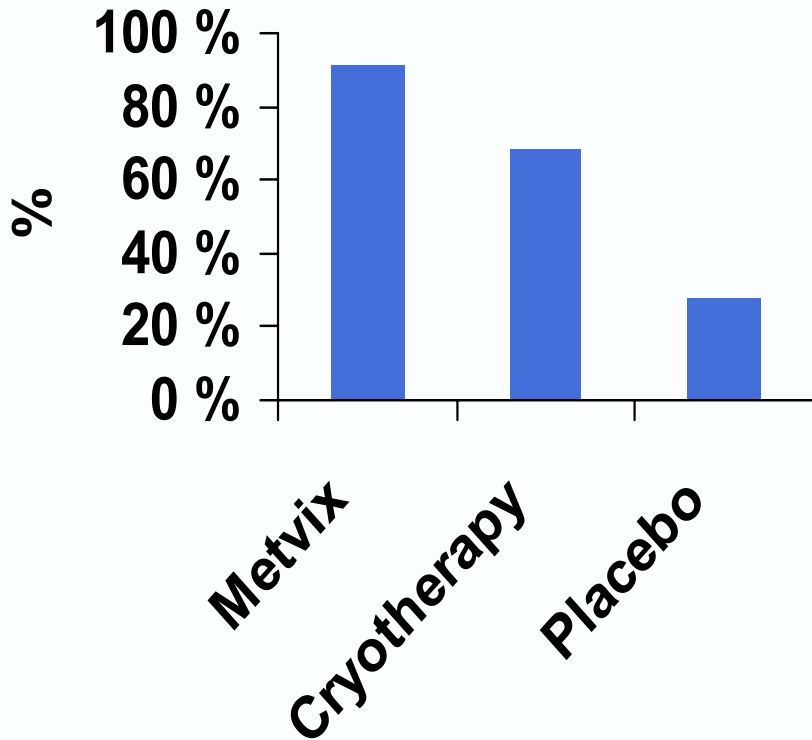
### Cosmetic outcome



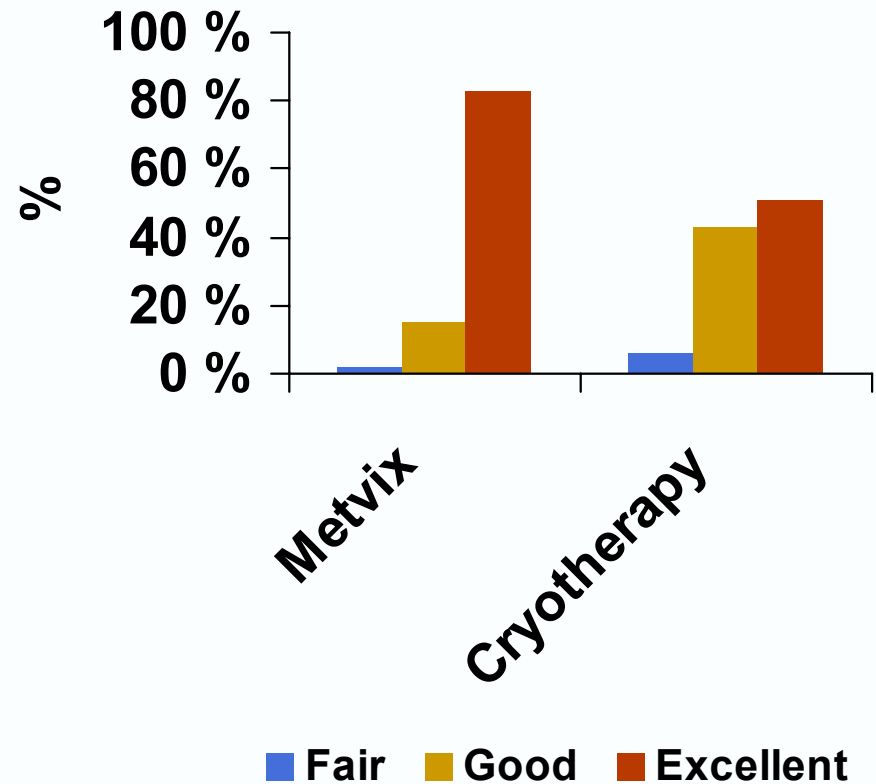
# Metvix®

## – excellent clinical results in AK

*Lesion response*

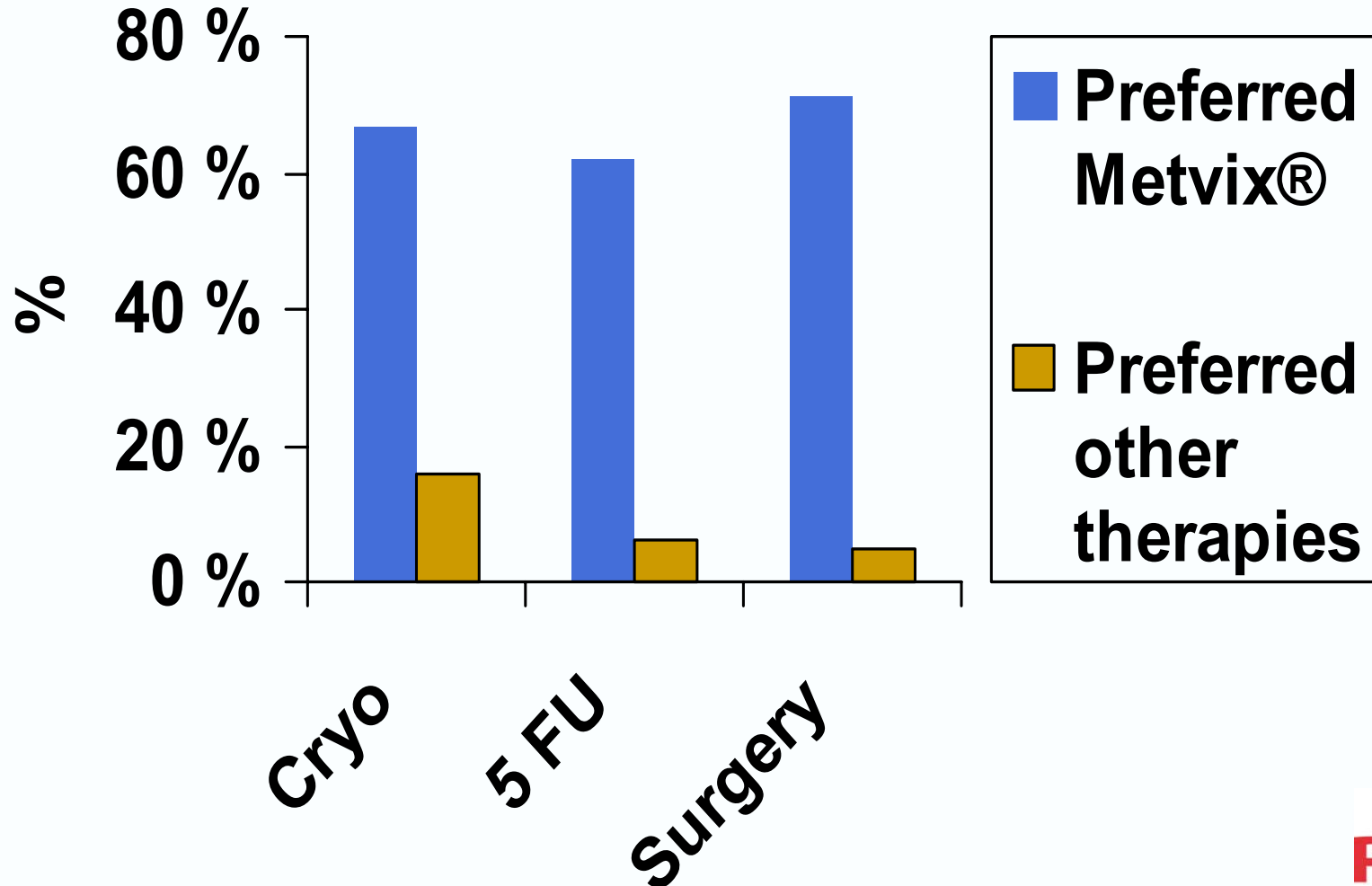


*Cosmetic outcome*



# Patient preference

– Metvix<sup>®</sup> vs. other therapies in AK



# 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®

## – on track for world wide launch

- Launched in 1<sup>st</sup> EU country (Sweden)
  - Reimbursed price of 1300 SEK per tube of Metvix®
  - Two product specialist promotes Metvix® in Sweden
- Marketing authorisation granted in Europe for AK and BCC in 14 countries
- Applications pending Australia and New Zealand for AK and BCC
- NDA filed in the US for AK September 2001



# Metvix<sup>®</sup> sales and marketing strategy

## – balanced risk and reward

### ■ Nordic region

- commercial rights retained
- small, specialised sales force established
- retain additional value
- maintain close contact with the needs of physicians

### ■ Rest of World (more than 60 countries)

- partnership with Galderma S.A.



# Marketing Metvix®

## – Galderma SA preferred partner

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



# 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



# Metvix<sup>®</sup>

## – significant payments from Galderma

- Up front payment of 12 mill Euro
- 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
- Royalties for existing and new indications
- Payments for manufacturing
  - Metvix<sup>®</sup>, active ingredient and PhotoCure lightsources
- Significant guaranteed min. payments of royalties & sales milestones



# Metvix®

## – several potential new indications

- Inhibitory effect on pilosebaceous units
  - Acne (pilot study ongoing)
  - Oily skin
- Anti-wrinkles
  - Photoaging (skin rejuvenation)
- Anti-microbial
  - Wound healing (pilot study planned)
- Anti-viral
  - 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*

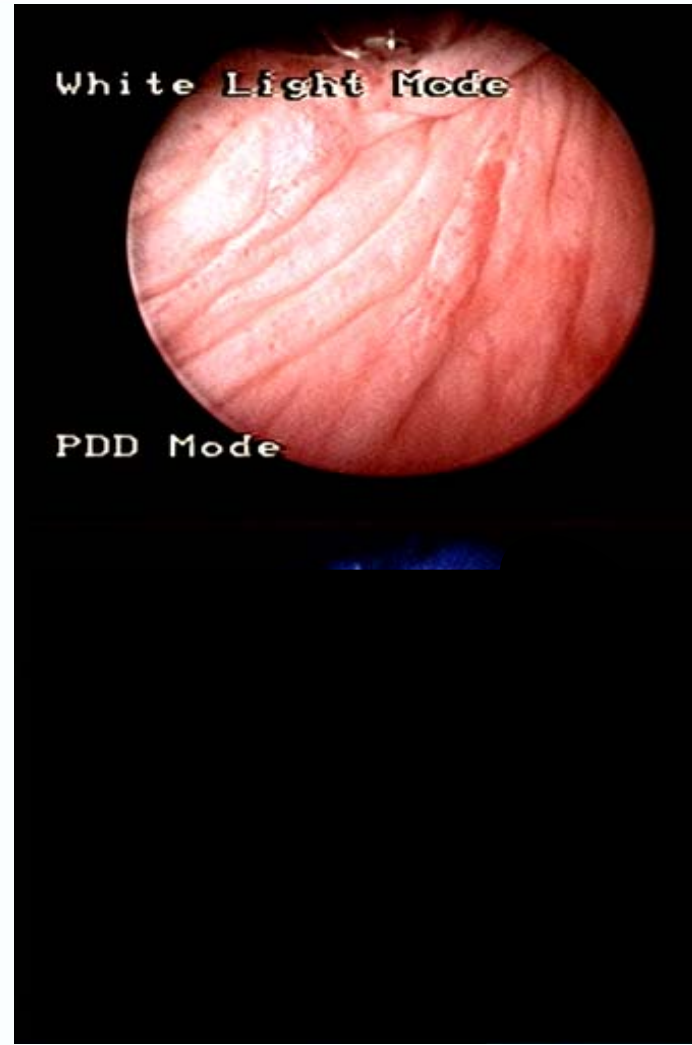
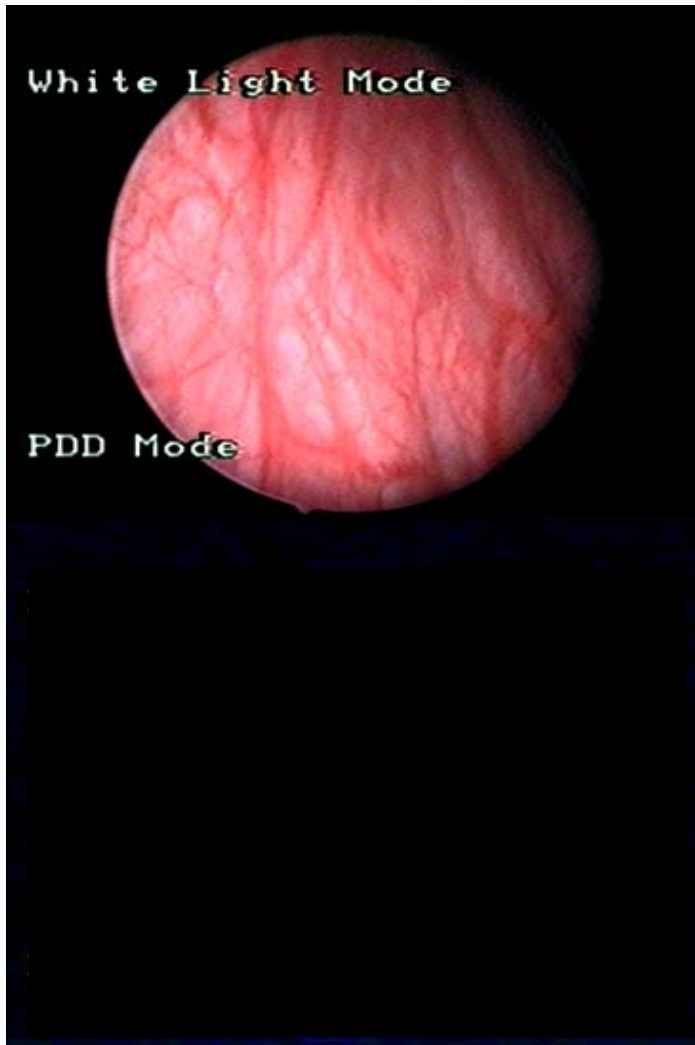
### Development status

- Phase III trial in Europe ongoing
- IND in place - phase III trial in US to be started shortly



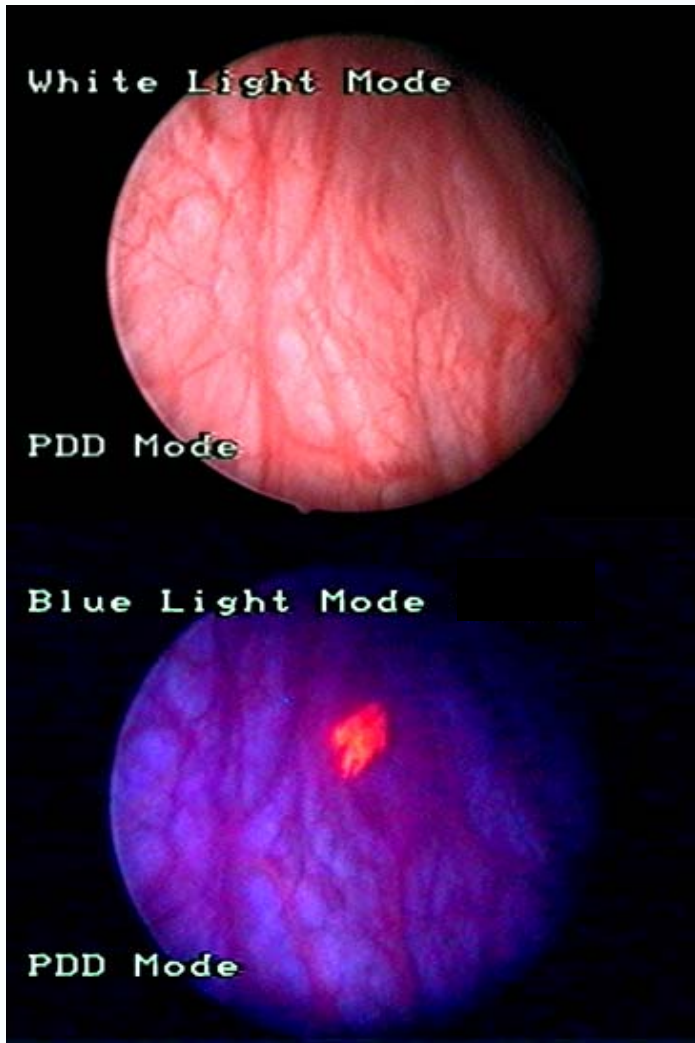
# Bladder cancer

– 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



# Research and development – strong pipeline

## **ALA derivatives R&D opportunities** (excluding dermatology)

- 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

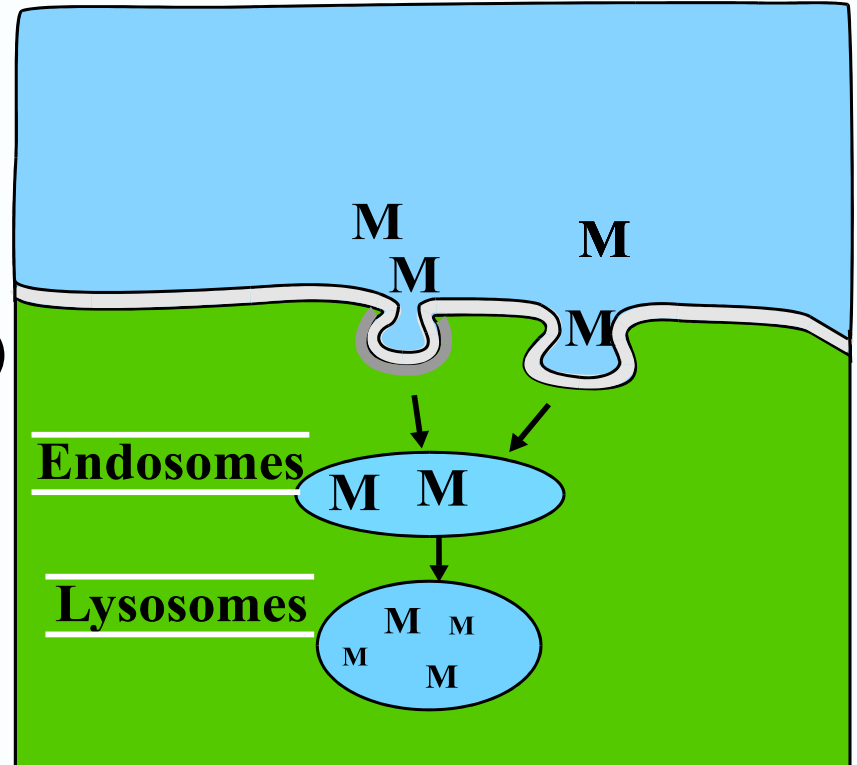
- Increased focus on Photchemical Internalisation (PCI)
  - PCI Biotech AS established as a subsidiary of PhotoCure ASA
- PCI Biotech's product development focuses on:
  - new transfection technology for the research market
  - improve existing technologies for clinical gene therapy
  - new concepts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



# PCI Biotech AS

## – PCI makes macromolecules work as drugs

- Proteins  
(e.g. protein toxins, antibodies)
- Peptides
- DNA/RNA  
(e.g. virus, plasmids, ribozymes etc.)



# PCI Biotech AS

## – PCI has important benefits

- Independent of molecule
- High specificity
- High efficacy (30-300 fold amplification of effect)
- Treatment of many diseases  
(oncology, vaccination, gene therapy)



# PCI Biotech AS

## – first product close to launch

- PCI product for the research market (pre-clinical)
  - Lumitrans™ and a Lumisource
- Market size
  - More than 5 mill. transfections per year
  - Growing market
- Benefits
  - Can use less or cheaper vectors
  - Transfer macromolecules to a larger fraction of cells with the same amount of vector
  - Transfer genes to new cell types to which gene transfer with other methods is difficult
  - Can also be used for protein internalisation (peptides, proteins, antibodies)



# PhotoCure

## – strong intellectual property position

<i>Main patent applications</i>	<i>Priority date</i>	<i>Status</i>	<i>Progress</i>
1. Transfer of molecules to cells (PCI)	Sept. 1994	Published	Granted: Norway, Australia, US, Singapore, Czech Rep. Accepted: NZ
2. Esters of ALA	March & Dec. 1995	Published	Granted in US, EU, Australia, Singapore
3. PCS	Jan. 1997	Published	National phase
4. Illumination source	May 1997	Published	Granted: Australia
5. Cancer vaccines	1999	Not published	
6. ALA derivatives I	2000	Not published	
7. ALA derivatives II	2000	Not published	
8. Formulations I	2000	Not published	
9. Formulations II	2000	Not published	
10. PDT new diseases	2000	Not published	



# PhotoCure

## – track record for achieving milestones

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

#### Metvix®

- ✓ 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



# Strategy

- Continue to develop, and obtain marketing approval for our products in all major markets
- Leverage our broad platform technologies to develop and commercialise new pharmaceutical products
- Maintain focus on oncology market
- Establish sales and marketing partnerships and infrastructure to promote our products
- Maintain and strengthen development collaborations with leading academic institutions





# 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, pending in US, Australia & NZ
- 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



# Appendix



# Financial Statements

## – Profit & Loss (Group)

Three months ended		All figures in NOK 1,000	Nine months ended	
30.09.2001	30.09.2000		30.09.2001	30.09.2000
750	967	Sales	1 682	1 643
86	824	Other revenues	2 772	2 248
<b>836</b>	<b>1 792</b>	<b>Total operating revenues</b>	<b>4 453</b>	<b>3 891</b>
3 980	3 502	Labour costs	14 620	15 939
21 029	9 660	External R&D costs	48 580	26 125
213	113	Ordinary depreciation	554	267
5 587	3 992	Other operating expenses	16 792	9 310
<b>30 808</b>	<b>17 266</b>	<b>Total operating expenses</b>	<b>80 546</b>	<b>51 641</b>
<b>-29 972</b>	<b>-15 474</b>	<b>Operating income</b>	<b>-76 092</b>	<b>-47 749</b>
7 170	6 926	Interests income	21 243	10 978
58	509	Interests expense	830	1 097
<b>7 112</b>	<b>6 417</b>	<b>Net financial income</b>	<b>20 413</b>	<b>9 881</b>
-22 860	-9 057	Loss before tax	-55 680	-37 868
320	-	Minority interests	422	-
-	-	Tax	-	-
<b>-22 540</b>	<b>-9 057</b>	<b>Net loss for the period</b>	<b>-55 258</b>	<b>-37 868</b>
-1,32	-0,57	Net loss per share (NOK)	-3,23	-2,40



# Balance sheet (Group)

## – strong financial position

Figures in NOK 1,000	30.09.2001	30.09.2000	31.12.2000
Fixed assets	2 598	1 710	2 563
Receivables	6 411	2 707	2 604
Securities	314 132	374 356	366 009
Cash and bank deposits	28 266	31 173	33 674
<b>Total assets</b>	<b>351 407</b>	<b>409 946</b>	<b>404 850</b>
Shareholders' equity	304 754	367 638	357 360
Long term liabilities	17 071	16 620	17 155
Current liabilities	29 582	25 689	30 335
<b>Total shareholders' capital &amp; liabilities</b>	<b>351 407</b>	<b>409 946</b>	<b>404 850</b>



**Metvix®**

– market introduction

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



# Metvix<sup>®</sup>

## – sales volume development

