

# PhotoCure ASA

**Presentation February 2001**



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# Highlights last twelve months

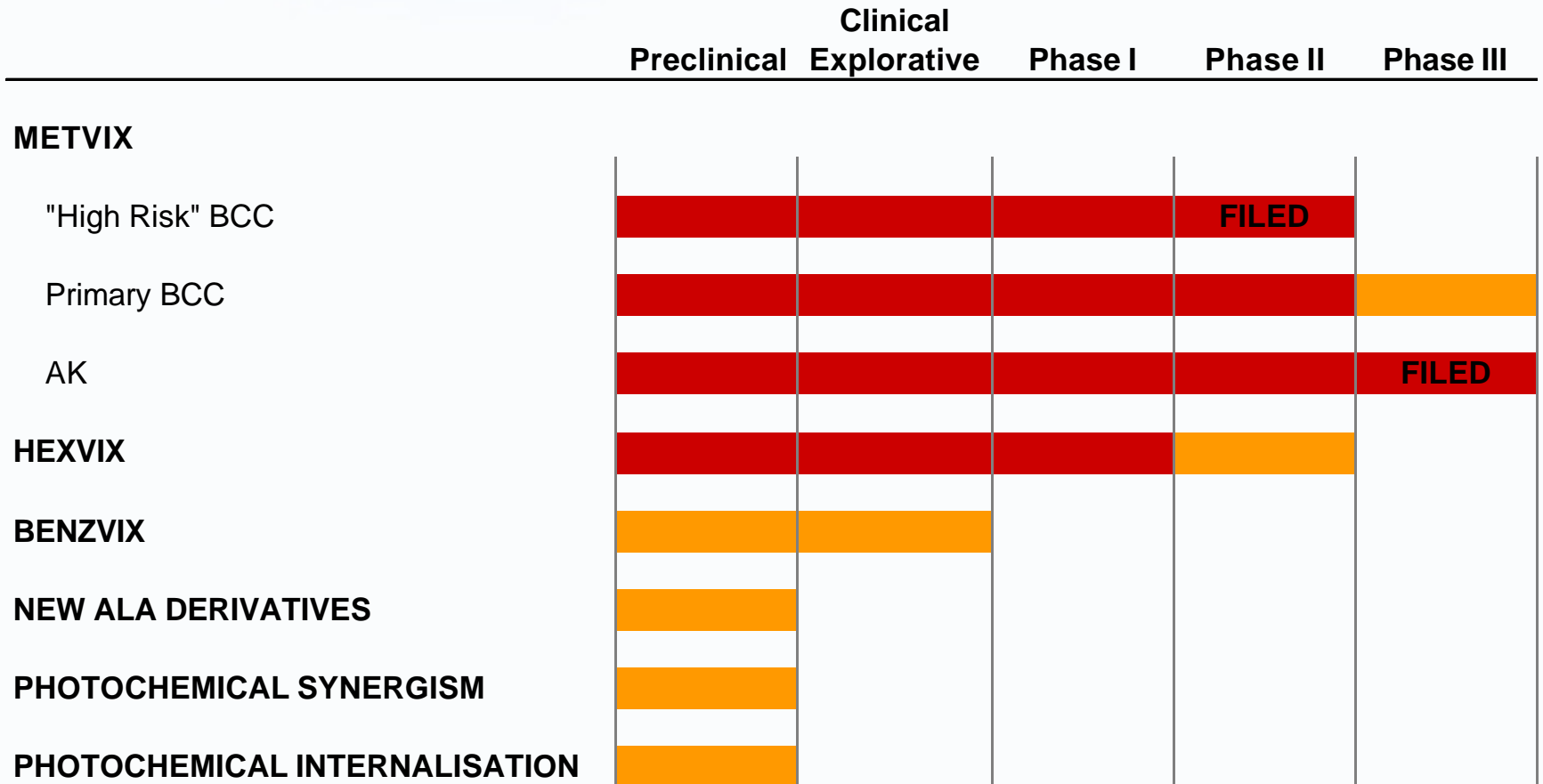
- Metvix<sup>®</sup> global development for Actinic Keratosis (AK) and Basal Cell Carcinoma (BCC) on track:
  - Marketing Authorisation Application (MAA) for "High Risk" BCC filed Jan. 2001
  - MAA for AK in EU filed May 2000
  - Metvix<sup>®</sup> clinical results presented at scientific conferences
- Hexvix<sup>™</sup> phase II study for bladder cancer detection initiated 4 Q 2000
- PCI Biotech AS established
- IPO and share issue of NOK 356.5 mill completed in May - Liquid funds totalled NOK 399.7 mill. as of 31<sup>st</sup> of December

AK: Pre-malignant skin disorder

BCC: Non melanoma skin cancer



# Broad technology platforms and advanced development programmes



 Completed  
 Ongoing



# Metvix®

## – large and growing market opportunity

### **Skin cancers and dermatological disorders**

- Basal Cell Carcinoma (BCC)
  - most common form of cancer among fair skinned people
  - accounts for approx. 40% of new cancers in the US
  - over 1.7 million cases annually in Europe, the US and Australia
- Actinic Keratosis (AK)
  - pre-malignant skin disorder
  - approximately 10 times more frequent than BCC
  - in Australia, 40% of all people above 40 years have AK
- Increasing levels of skin cancer in Europe, the US and Australia
- Other indications under evaluation
  - squamous cell carcinoma (SCC) in situ (Bowen's disease), wound healing, skin dysplasia of immuno-compromised patients & detection of BCC



# Actinic Keratosis and Basal Cell Carcinoma – existing therapies

- Basal Cell Carcinoma
  - Surgical excision
  - Curettage & cautery
  - Electrodesiccation
  - Radiotherapy
  - Cryotherapy
  - Plastic surgery
  - Moh's surgery
  
- Actinic Keratosis
  - Cryotherapy
  - 5-FU
  - Levulan® PDT (U.S. only)



# Dermatology market estimates

## Levulan sales estimates disclosed by Schering / Berlex

- AK sales in US 3rd year post launch 50 - 100 Mill. USD
  - Based on the Levulan price of 85 USD per Kerastick, this estimate corresponds to 600,000-1,200,000 units
- World wide potential in dermatology:  
200 Mill. USD per year



# Sales and marketing strategy – balancing risk and reward

## ■ Nordic region

- retain commercial rights
- establish small, specialised sales force
  - small number of high value specialised prescribers
- retain additional value
- maintain close contact with the needs of physicians

## ■ Rest of World

- partnerships with pharmaceutical companies





# Metvix®

## – marketing development

- Broad clinical program involving more than 2000 patients in more than 80 centres on three continents
- First medical indications: “high risk” BCC, primary BCC, AK
- “Top down” strategy in treatment hierarchy
  - University hospitals → regional hospitals → clinics → dermatologists
- Clinical results presented at international scientific conferences
- Establishment of marketing alliance ongoing
- Sales force Nordic countries under establishment
- Final pricing and reimbursement strategy ongoing



# Industry profit figures

## Average cost figures for pharmaceutical companies

Sales	100 %
COGS	28 %
<hr/>	
Gross margin	72 %
Sales, General & Adm.	34 %
R&D	14 %
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Profit	24 %

Source: Deutsche Bank Alex Brown and Enskilda Securities



# Metvix<sup>®</sup>

– quick and simple treatment

*Metvix application*



*Application dressing*

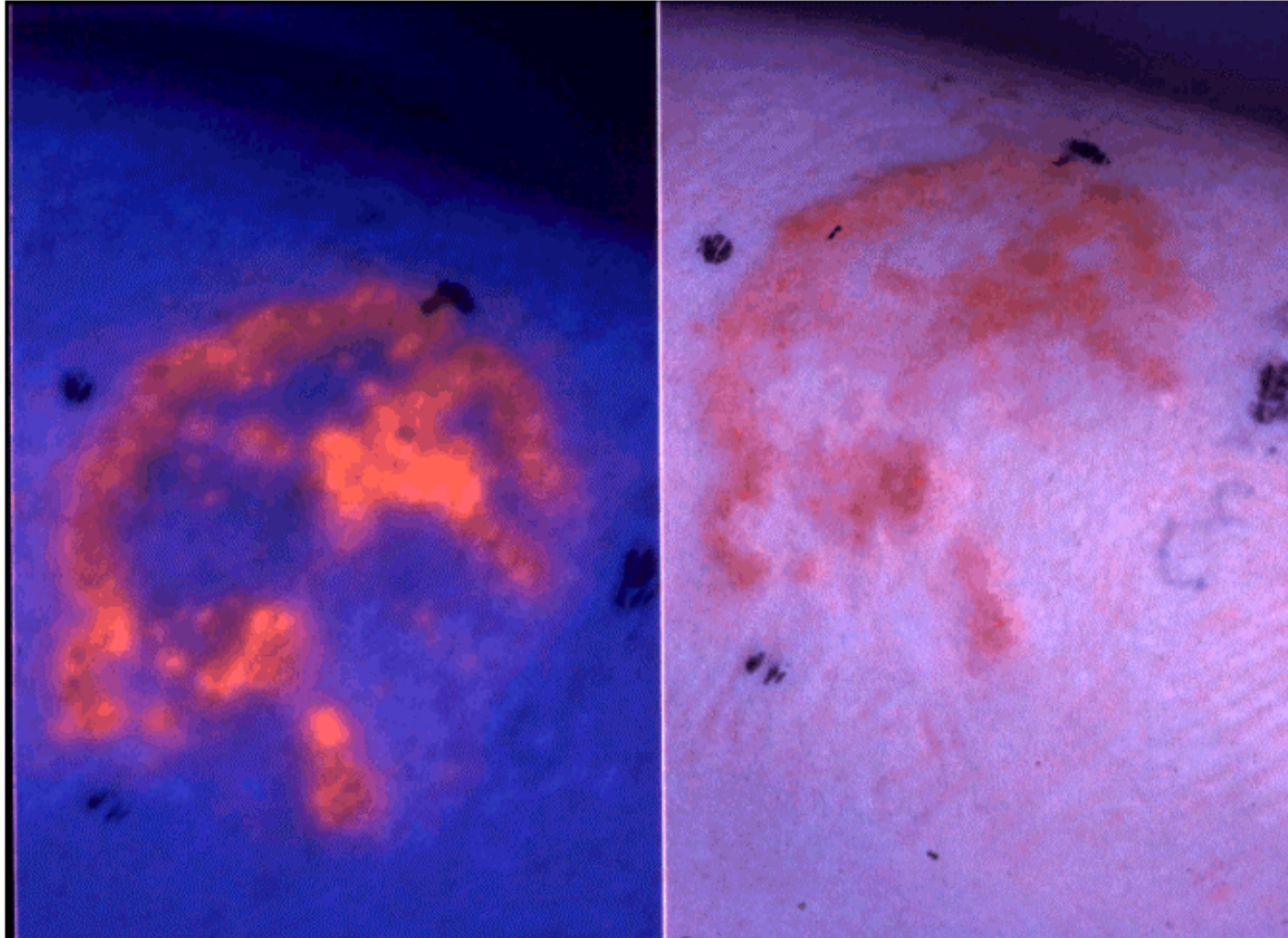


*Curelight illumination*



# Metvix<sup>®</sup>

– highly selective





**Metvix®**

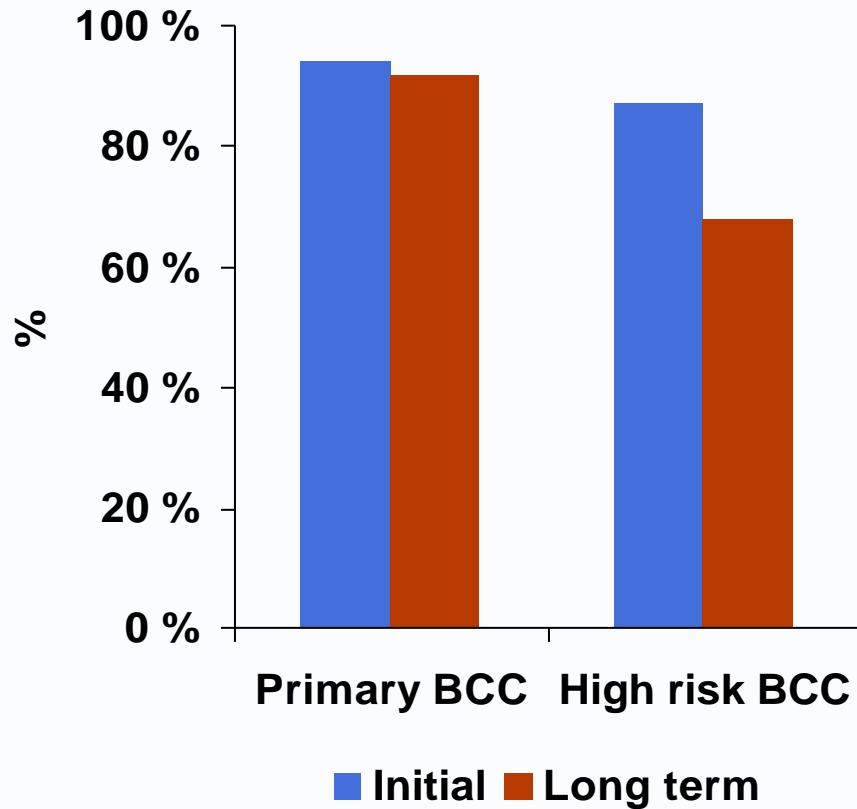
**– highly effective with superior cosmetic results**



# Metvix<sup>®</sup>

## – excellent clinical results in BCC

### *Lesion response*



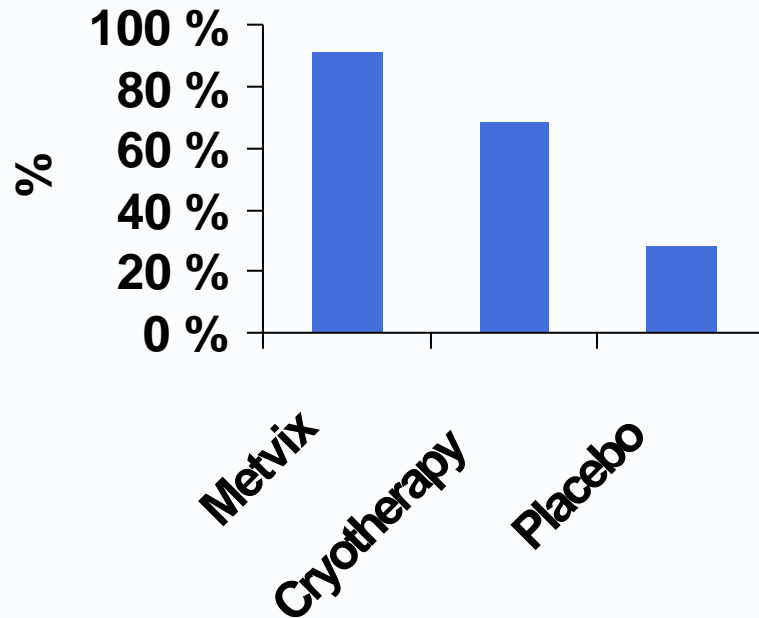
### *Cosmetic outcome*



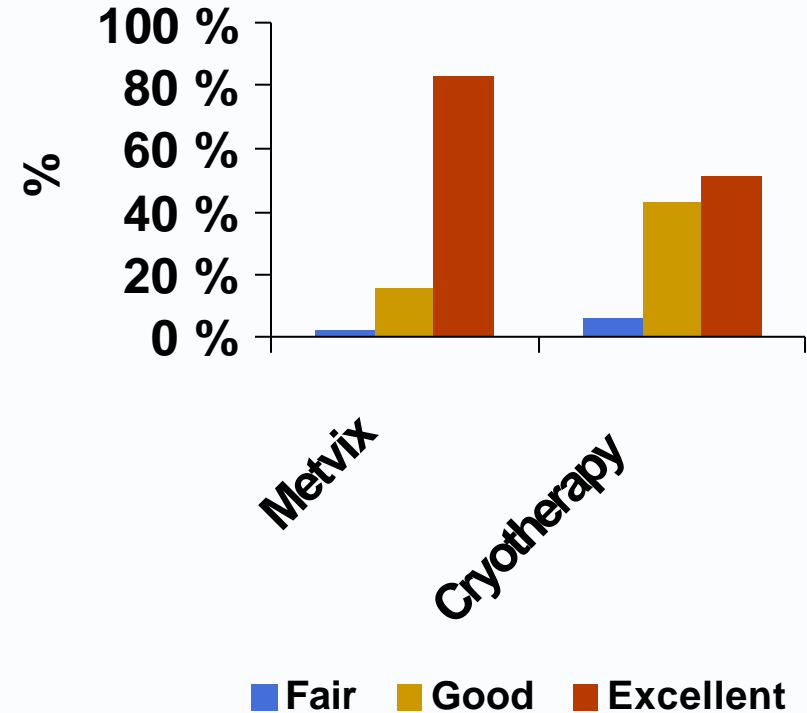
# Metvix®

– excellent clinical results in AK

*Lesion response*



*Cosmetic outcome*



# Metvix<sup>®</sup>

## – key advantages over existing therapies

- Highly effective
- Superior cosmetic outcome
- Limited side-effects
- Low systemic uptake
- Ability to repeat procedure and conduct other procedures
- Simple and cost-effective procedure





# Hexvix™

## – market opportunity

### Bladder cancer

- Significant medical problem: appr. 115,000 cases annually in the US & Europe
- 2.8 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*

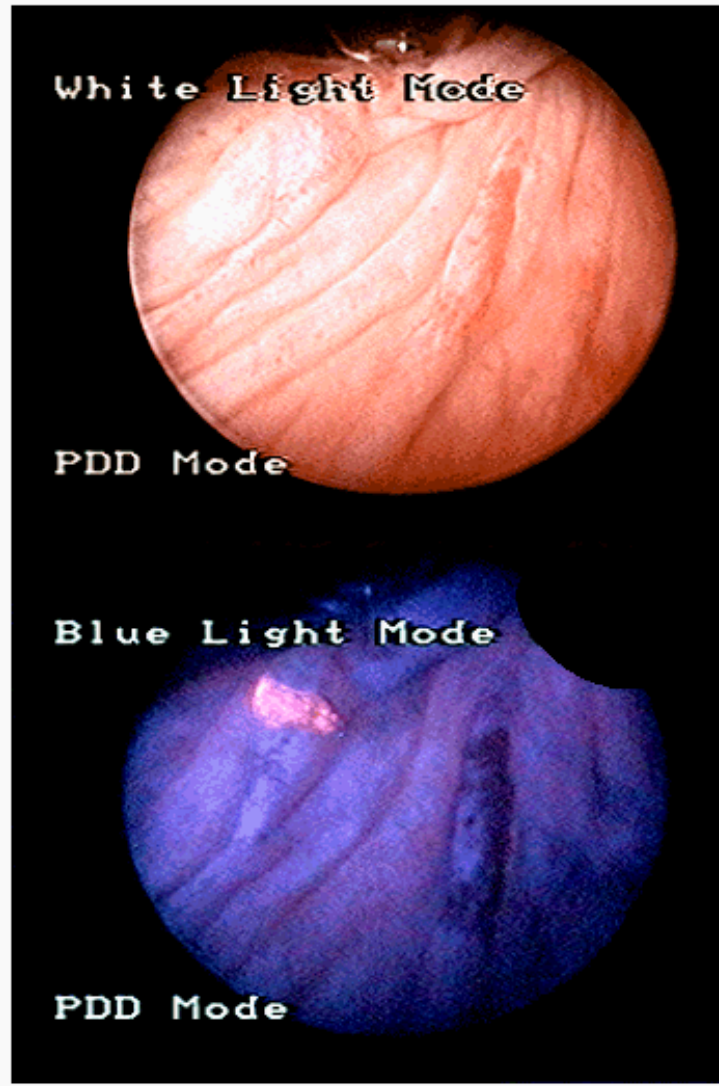
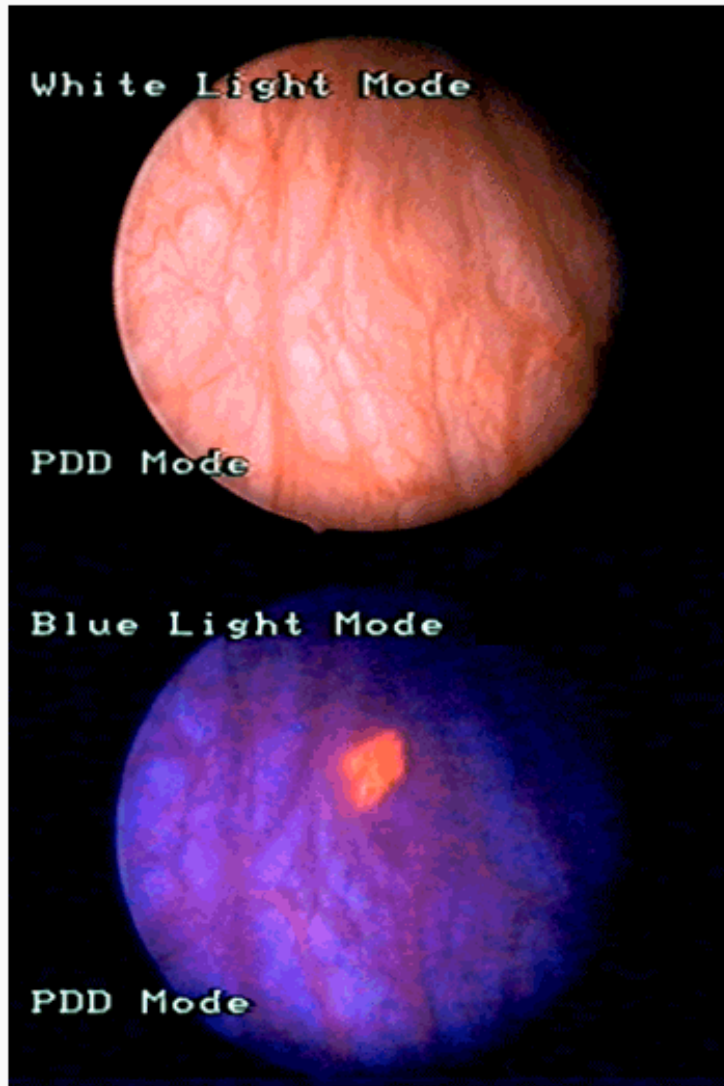
### Development status

- Exploratory research in bladder cancer diagnosis in approx. 100 patients
- Pre-clinical toxicology studies completed
- Multi-center Phase II trials started 4 Q 2000
- Phase III trials in Europe and US expected to start during 2001



# Hexvix™

– detection of flat lesions with blue light



# Hexvix™

## – important clinical benefits

- Red fluorescence makes it easier to distinguish between malignant and non malignant tissue
- High medical benefit of detecting CIS lesions
- Flat lesions (CIS) are easily overlooked in white light, but are much better seen with blue light, which induces red fluorescence
- Requires minimal changes of clinical routines



# PCI Biotech AS

- Increased focus on Photchemical Internalisation (PCI)
  - PCI Biotech AS established as a subsidiary
- 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



# Strong intellectual property position

<i>Patent application</i>	<i>Priority date</i>	<i>Status</i>	<i>Progress</i>
1. Transfer of molecules to cells	Sept. 1994	Published	Granted: Norway, Australia, US, Singapore, Czech Rep. Accepted: NZ
2. Esters of ALA	March & Dec. 1995	Published	Granted in US, 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	



# Achieved milestones

## Milestones for next twelve months as of May 2000

### ■ Metvix<sup>®</sup>

- ✓ 12 month follow-up for pivotal "High Risk" BCC trial
- ✓ MAA filing for "High risk" BCC in Europe
- ✓ 3 month follow-up for phase III primary superficial BCC trial
- ✓ Phase III AK trial in Australia completed
- ✓ Initiation of phase I/II trial for SCC in situ (phase III initiated)
- ✓ Initiation of phase I/II trial for PDD of BCC
- 3 month follow-up for phase III primary nodular BCC trial
- Initiation of phase I/II trial for wound healing
- 3 month phase III AK trial complete in the US

### ■ Hexvix<sup>™</sup>

- ✓ Enter phase I/II trials for bladder cancer

### ■ Benzvix<sup>™</sup>

- Complete pre-clinical studies necessary for clinical studies



# Milestones for next twelve months

## Metvix<sup>®</sup>

- File MAA's for AK & "High risk" BCC in Australia & NZ- Q1
- Achieve marketing authorisation for AK in Sweden – Medio 2001
- Achieve marketing authorisation for "High risk" BCC in Sweden
- File mutual recognition procedure in other EU countries
- File MAA for "High risk" BCC & AK in Switzerland
- File New Drug Application for AK in US
- MAA for primary BCC ready for submission in EU



# Milestones for next twelve months (cont'd)

## **Hexvix™**

- Enter Phase III trial for PDD of bladder cancer in Europe and USA

## **Benzvix™**

- Complete pre-clinical studies necessary for clinical trials

## **PCI Biotech AS**

- Launch first product for the research market





# Financial Statements

## - Profit & Loss (Group)

Three months ended		All figures in 1,000 NOK	Twelve months ended	
31/12/00	31/12/99		31/12/00	31/12/99
488	378	Operating revenues	2,131	1,095
310	366	Other revenues	2,558	2,500
<b>798</b>	<b>744</b>	<b>Total operating revenues</b>	<b>4,689</b>	<b>3,595</b>
1,501	4,572	Labour costs	17,440	13,750
18,422	10,765	External R&D costs	42,299	28,403
143	64	Ordinary depreciation	410	201
4,261	3,959	Other operating expenses	11,322	7,286
<b>24,327</b>	<b>19,360</b>	<b>Total operating expenses</b>	<b>71,471</b>	<b>49,640</b>
<b>-23,529</b>	<b>-18,616</b>	<b>Operating income</b>	<b>-66,782</b>	<b>-46,045</b>
7,171	1,409	Interests income	18,149	5,260
258	250	Interests expense	1,355	722
<b>6,913</b>	<b>1,159</b>	<b>Net financial income</b>	<b>16,794</b>	<b>4,538</b>
-16,616	-17,457	Loss before tax	-49,988	-41,507
-	-	Tax	-	-
<b>-16,616</b>	<b>-17,457</b>	<b>Net loss for the period</b>	<b>-49,988</b>	<b>-41,507</b>
-1.03	-1.30	Net loss per share (NOK)	-3.11	-3.09



# Financial Statements

## - Balance sheet (Group)

<b>Figures in 1,000 NOK</b>	<b>31/12/00</b>	<b>31/12/99</b>
Fixed assets	2,563	524
Receivables	2,604	975
Securities	366,009	84,924
Cash and bank deposits	33,674	14,439
<b>Total assets</b>	<b>404,850</b>	<b>100,862</b>
Shareholders' equity	357,360	68,228
Long term liabilities	17,155	16,841
Current liabilities	30,335	15,793
<b>Total shareholders' capital &amp; liabilities</b>	<b>404,850</b>	<b>100,862</b>



# Key investment highlights

- Leader in photodynamic therapeutics and diagnostics with two products in advanced clinical development
- Metvix<sup>®</sup> PDT new treatment in dermatology:
  - Market Authorisation Application for AK and “High risk” BCC filed in Europe
  - late stage clinical trials for primary BCC
  - experience from over 2,000 patients
- Hexvix<sup>™</sup> in phase II for bladder cancer detection
- All commercial rights retained
- Targeting large markets and medical needs
- Strong pipeline of follow-on products and technologies to drive future value
- Focus on oncology to achieve higher value for products
- Close relationship with the Norwegian Radium Hospital
- Strong and experienced management team

