

**PhotoCure ASA**

**Presentation**

**Enskilda Securities Seminar**

**15<sup>th</sup> of January 2003**



# 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



# Highlights

## ■ Metvix<sup>®</sup>

- Approvable letter from FDA - September 2002
- Increasing sales in the Nordic markets - 3rd quarter 2002
- Launch in Germany - February 2003

## ■ Hexvix<sup>®</sup>

- Positive phase III results - September 2002
- European Marketing Authorisation Application filed - December 2002

## ■ Benzvix<sup>®</sup>

- Clinical pilot studies on track – 3<sup>rd</sup> quarter 2002



# Metvix<sup>®</sup>

– quick and simple treatment

*Lesion preparation*



*Metvix<sup>®</sup> application*



*Red light illumination*



**Metvix<sup>®</sup>**

**– highly effective with superior cosmetic results**





**Metvix®**

**– highly effective with superior cosmetic results**



# Financial Statements

## – Profit & Loss

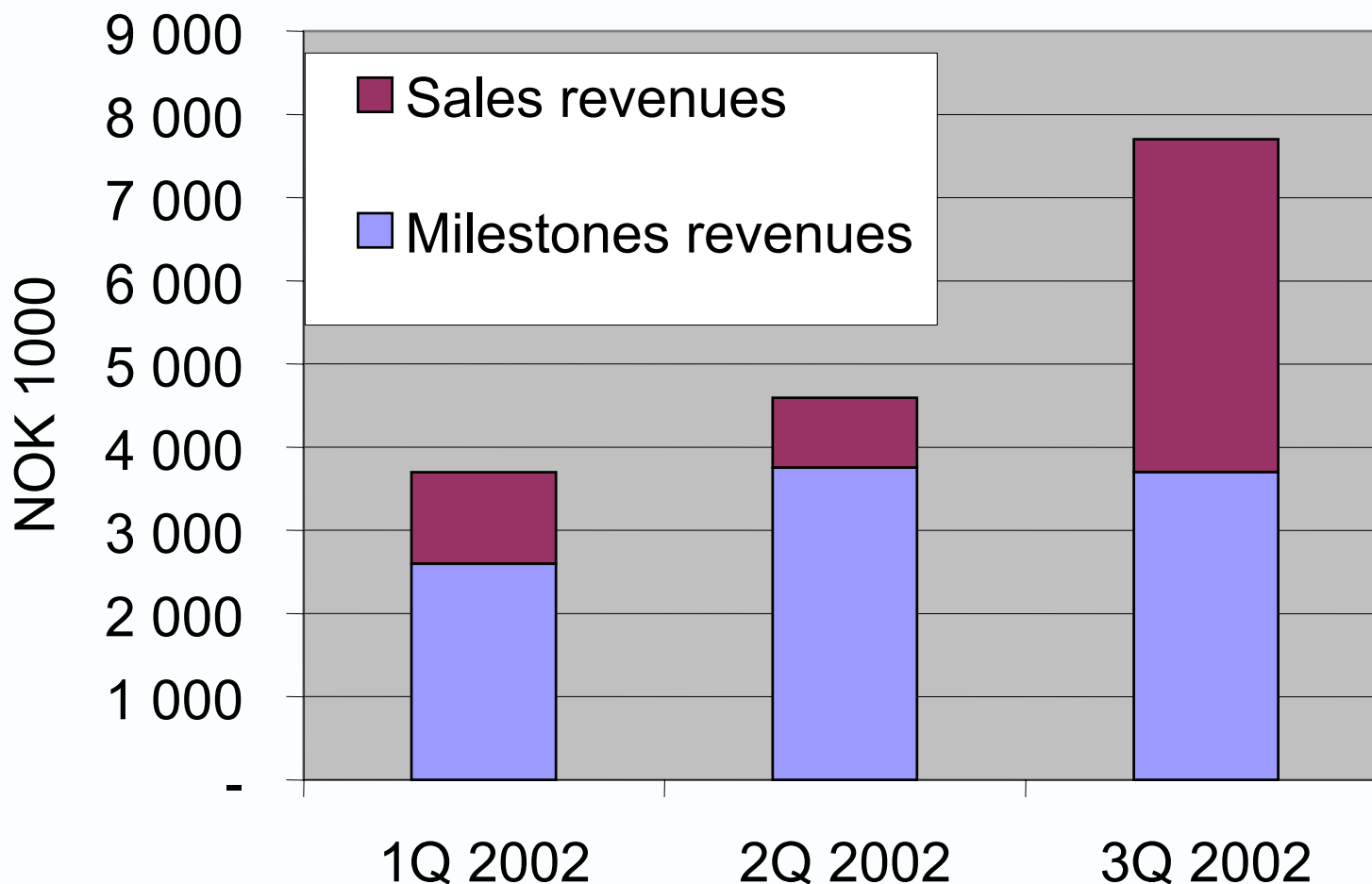
Three months ended		All figures in NOK 1,000	Nine months ended	
30.09.2002	30.09.2001		30.09.2002	30.09.2001
7 700	750	Sales revenues	15 991	1 682
-	86	Other operating revenues	130	2 772
<b>7 700</b>	<b>836</b>	<b>Total operating revenues</b>	<b>16 121</b>	<b>4 453</b>
3 009	-	Cost of products sold	3 615	-
<b>4 691</b>	<b>836</b>	<b>Gross profit</b>	<b>12 506</b>	<b>4 453</b>
6 526	3 980	Labour costs	11 400	14 620
12 320	21 029	External R&D costs	57 677	48 580
473	213	Ordinary depreciation	1 018	554
6 150	5 587	Other operating expenses	25 399	16 792
<b>25 469</b>	<b>30 808</b>	<b>Total operating expenses</b>	<b>95 494</b>	<b>80 546</b>
<b>-20 778</b>	<b>-29 972</b>	<b>Operating loss</b>	<b>-82 988</b>	<b>-76 092</b>
<b>3 589</b>	<b>7 112</b>	<b>Net financial income</b>	<b>9 119</b>	<b>20 413</b>
-17 189	-22 860	Loss before tax	-73 869	-55 680
-	-	Taxes	-	-
<b>-17 189</b>	<b>-22 860</b>	<b>Net loss for the period</b>	<b>-73 869</b>	<b>-55 680</b>
-245	-320	Of this minority interests	-793	-422
-0.98	-1.33	Net loss per share (NOK)	-4.24	-3.25



**Metvix®**

– positive development of sales revenues

## Sales revenues

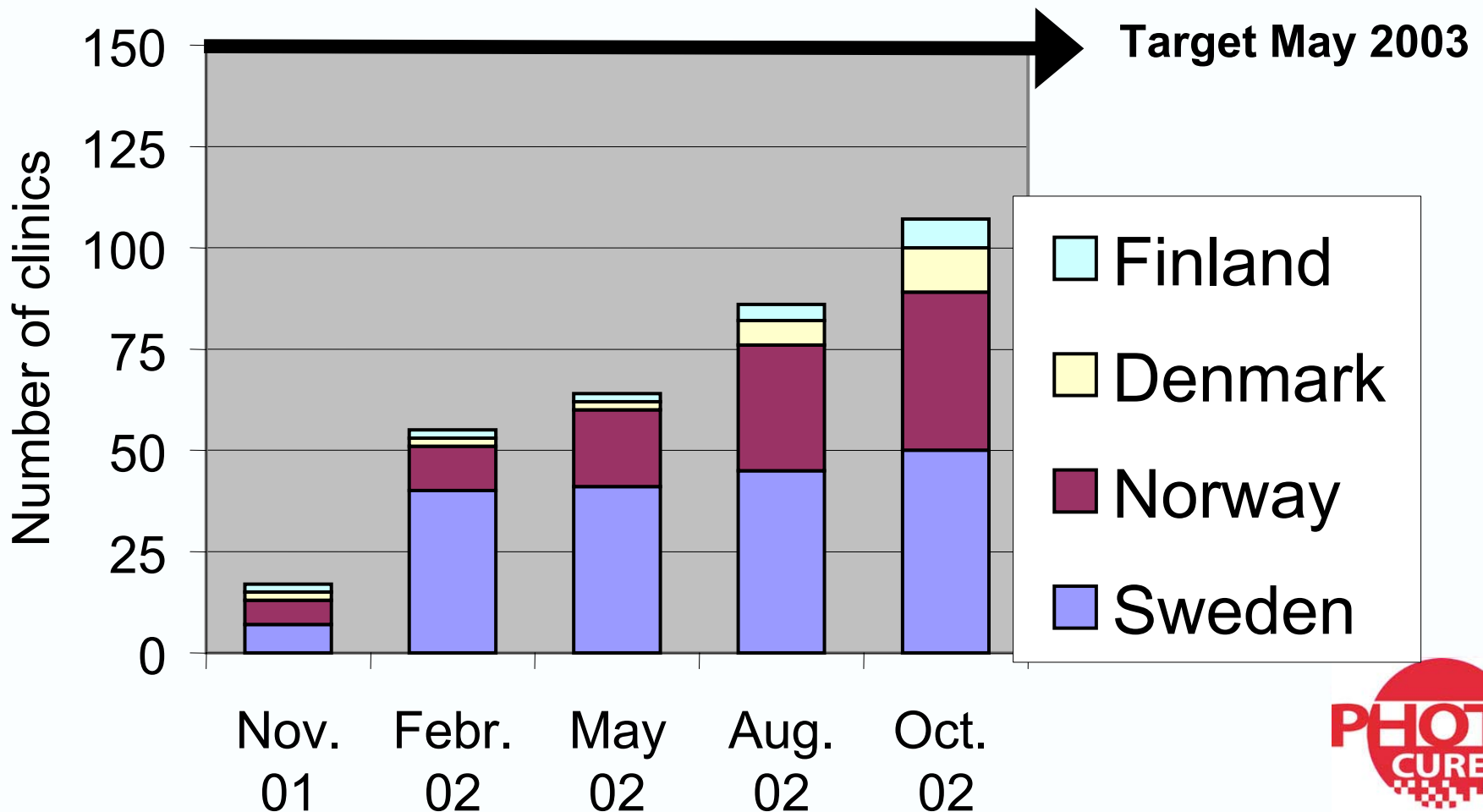




**Metvix®**

– marketing in the Nordic area on track

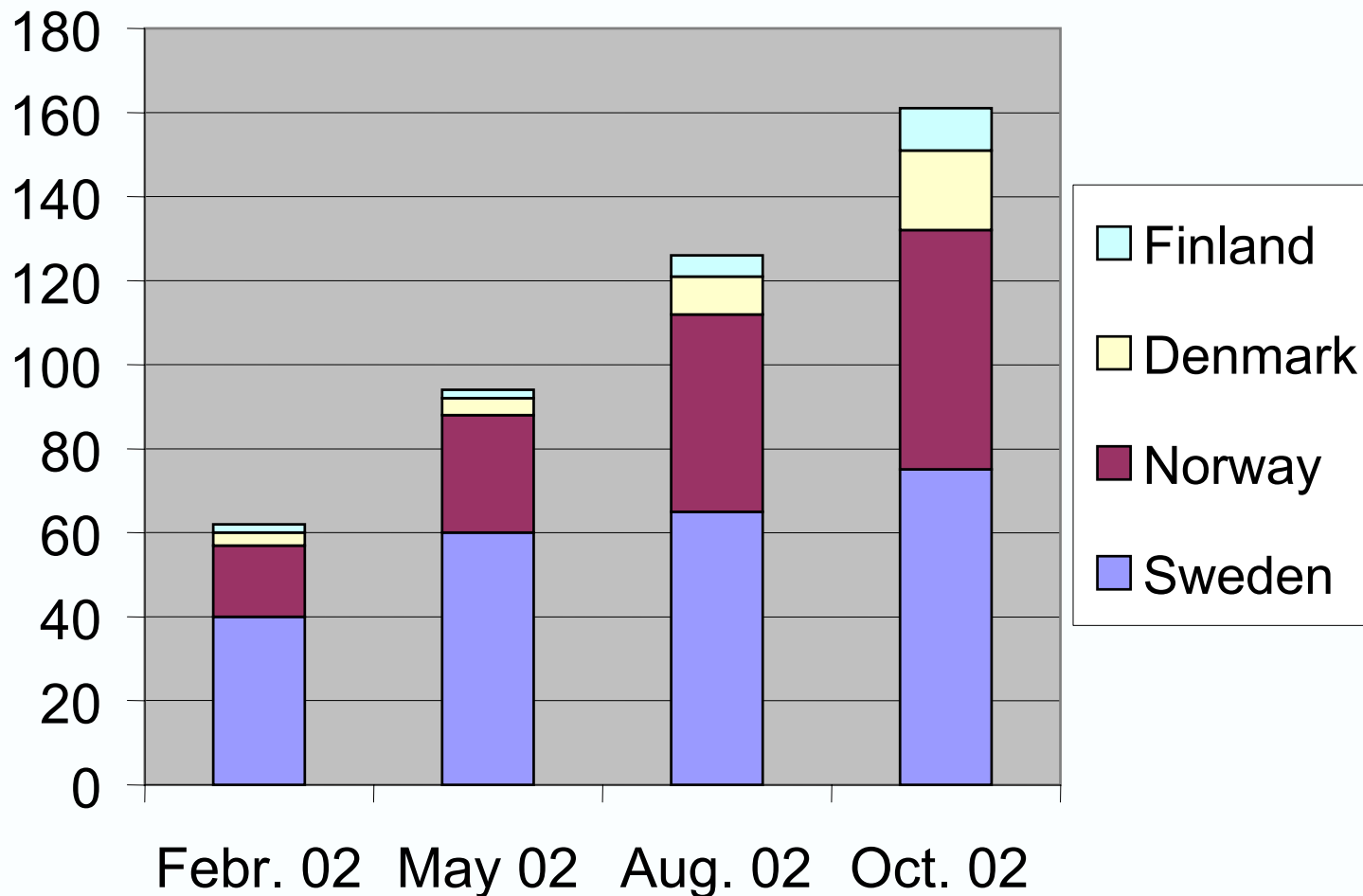
# Clinics with PhotoCure lamps



**Metvix<sup>®</sup>**

**– marketing in the Nordic area on track**

## Number of light sources



# Marketing Metvix<sup>®</sup>

## – Sweden

- Estimated market size:

	<u>New cases per year</u>	<u>Treatments per year</u>
– BCC	20 000	30 000
– AK	200 000	40 000

- Reimbursed price of 1300 SEK per tube of Metvix<sup>®</sup> October 2001

- Procedure codes private clinics

- Procedure fee negotiations ongoing



# Marketing Metvix<sup>®</sup>

## – establishing clinical centers in Sweden

Oct. 2001

Dec. 2001

Oct. 2002

N.A./N.I.	123	38	19
Interest		80	59
User	5	10	43
Big User			7

Big user:  
more than 5 treatments per week





# Marketing Metvix®

## – Norway

### ■ Estimated market size:

	<u>New cases per year</u>	<u>Treatments per year</u>
– BCC	10 000	20 000
– AK	100 000	30 000

- Approved price of 1100 NOK per tube of Metvix®
- Reimbursement application filed for Metvix®
- Procedure codes private clinics under negotiation



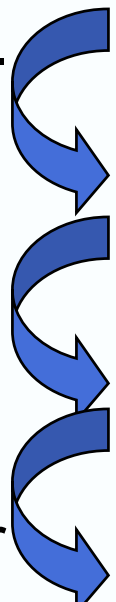
# Marketing Metvix®

## – establishing clinical centers in Norway

Dec. 2001

Oct. 2002

N.A./N.I.	99	60
Interest		10
User	9	35
Big User	1	4



# Marketing Metvix®

## – Denmark

### ■ Estimated market size:

	<u>New cases per year</u>	<u>Treatments per year</u>
– BCC	10 000	20 000
– AK	100 000	30 000

- Metvix® commercially available July 2002, priced at 1100 DKK per tube
- Drug reimbursement routinely on a named patient basis
- Procedure codes private clinics under negotiation



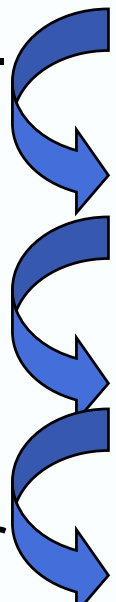
# Marketing Metvix<sup>®</sup>

## – establishing clinical centers in Denmark

July 2002

Oct. 2002

N.A./N.I.	93	26
Interest		54
User	3	15
Big User		1





# Marketing Metvix<sup>®</sup>

## – Finland

- Estimated market size:

	<u>New cases per year</u>
– BCC	5 000
– AK	50 000

- National approval May 2002
- Metvix<sup>®</sup> priced at 148 Euro per tube
- Reimbursement application filed for Metvix<sup>®</sup>



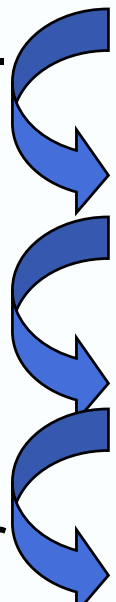
# Marketing Metvix®

## – establishing clinical centers in Finland

July 2002

Oct. 2002

N.A./N.I.	52	37
Interest		11
User	5	8
Big User		1



# Marketing Metvix®

## – Galderma launch in Germany February 2003

- Pre-launch activities ongoing
  - Largest economical effort – pre-launch activity ever
  - Ready for major launch in Germany February 2003
- Launch
  - Galderma will host launch symposium 1<sup>st</sup> of February 2003
- Price and reimbursement
  - Negotiations successfully finalised
- Supply
  - First light sources and Metvix® tubes sold to Galderma Germany
- Other European countries
  - UK first to launch after Germany
- Phase IV clinical trials
  - Galderma together with PhotoCure plan a trial in immunosuppressed patients



# Hexvix®

## – preparation finished

Hexyl aminolevulinate powder

+

Phosphate buffer saline 50 mL

➤

Hexvix® solution

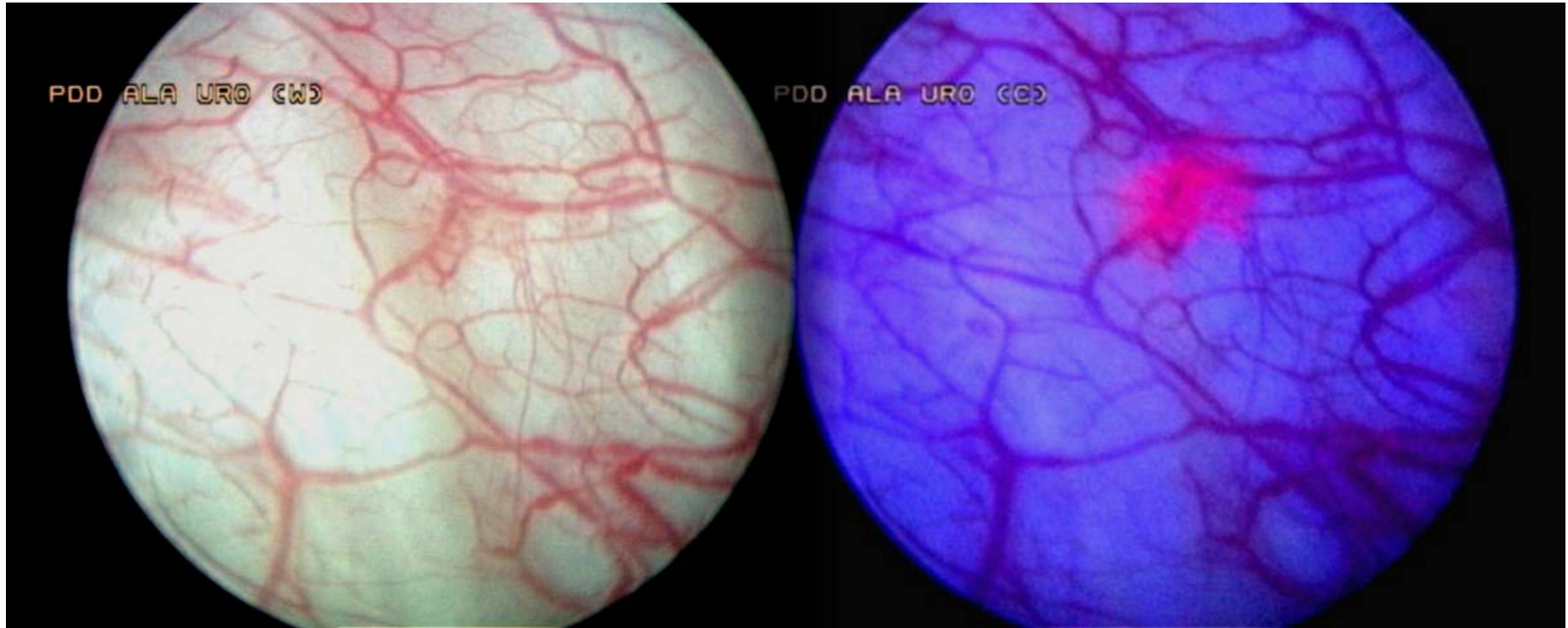
- Instilled 1 hour in the bladder
- Start cystoscopy within 30 minutes





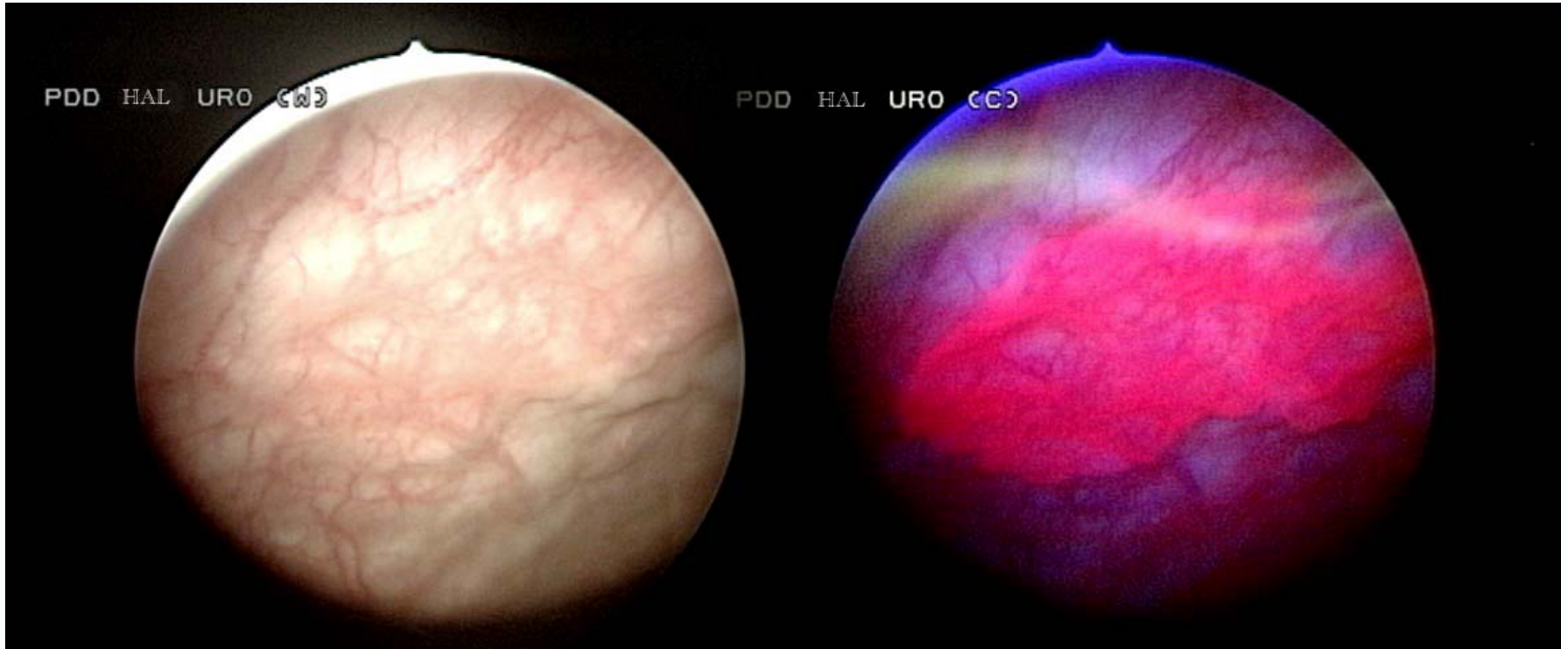
# Hexvix®

– papillary lesion detected with Hexvix only



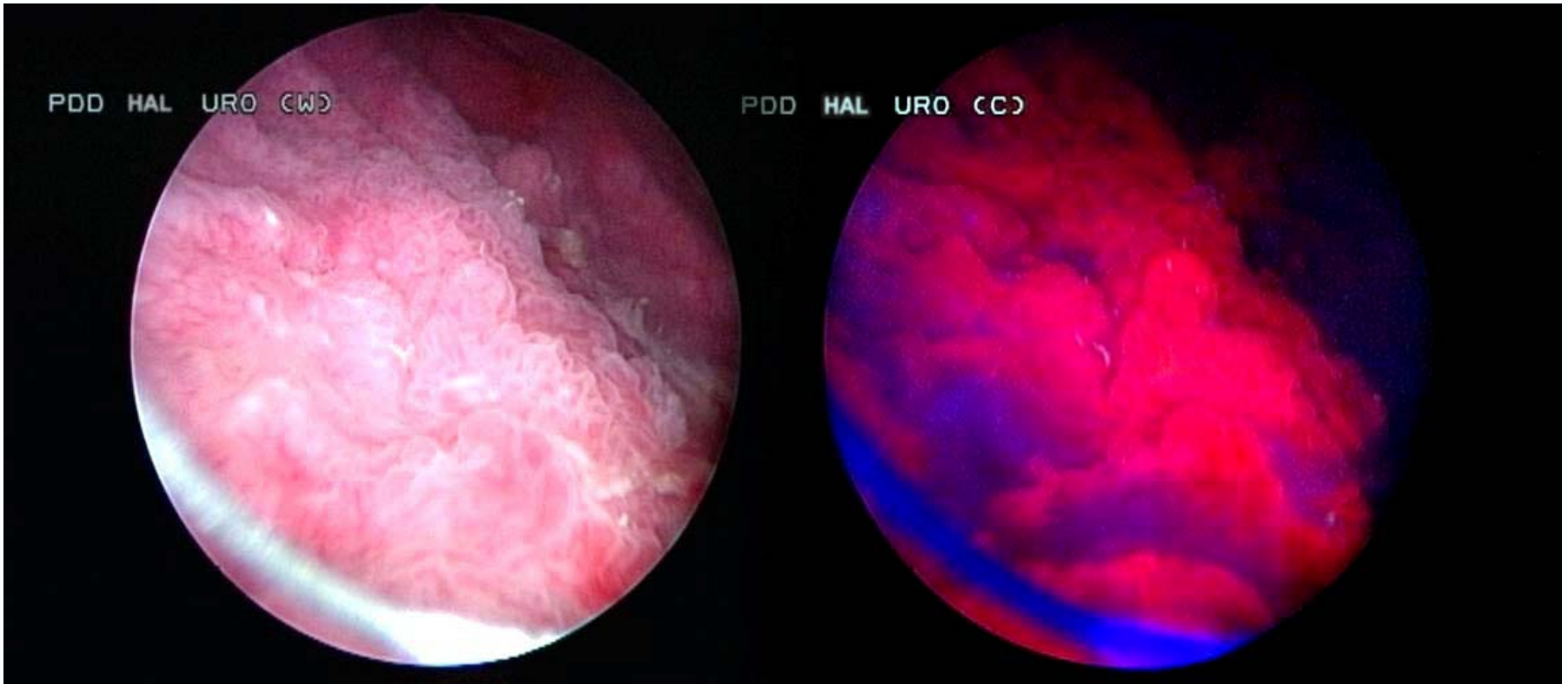
# Hexvix®

– CIS detected with Hexvix® only



# Hexvix®

– papillary tumour



# Hexvix® in bladder cancer

– positive results in phase III clinical trial

**Hexvix detected 97% of CIS lesions**  
(CIS = Carcinoma in Situ)

<b>Hexvix® cystoscopy</b>	<b>Standard white light cystoscopy</b>
<b>97%</b>	<b>59%</b>



# Hexvix<sup>®</sup>

## – first marketing authorisation application filed

### ■ Europe

- Clinical phase III study completed with positive results
- Marketing application filed December 2003

### ■ USA

- Investigational New Drug status obtained
- Phase III studies initiated



# Hexvix®

## – bladder cancer market

- Newly diagnosed patients, annually
  - Europe                    75 000
  - US                            65 000
  - ROW                    100-150 000
- Fourth leading cause of cancer in men
- Eighth leading cause in women
- Related to smoking, exposure to carcinogens





# Hexvix®

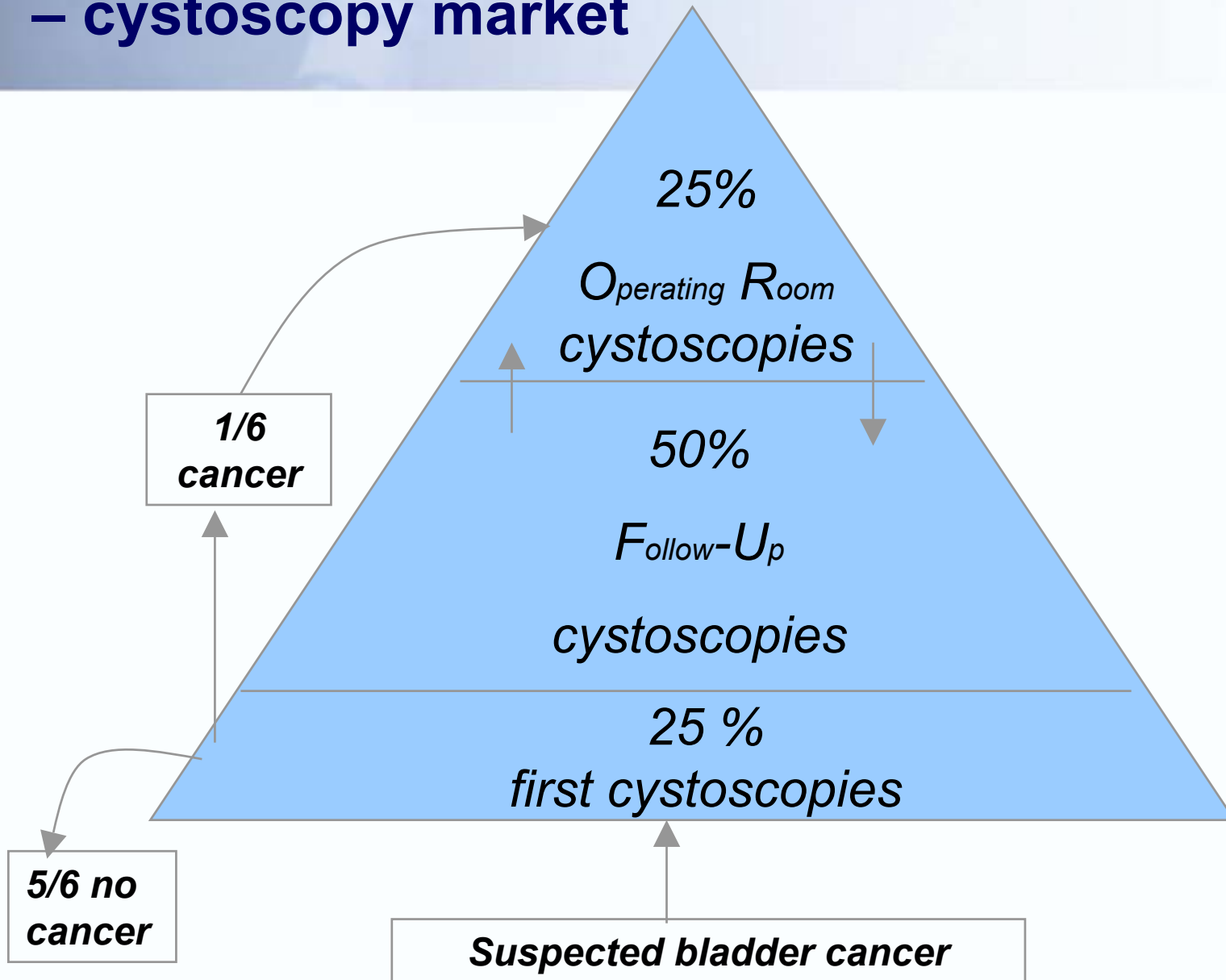
## – cystoscopy market

- Approximately 140 000 (2000) new cases of bladder cancer in Europe and the US per year (120 000 in 1990)
- At first cystoscopy only 1/6 patients are diagnosed with bladder cancer
- Patients with suspicious or diagnosed bladder cancer will go through 1-2 cystoscopies for further diagnoses and treatment
- Thereafter patients will be followed up 1-4 times annually for years
- Estimated 3 million cystoscopies performed every year in Europe and North America





# Hexvix® – cystoscopy market



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



# Financial statements

## - Balance sheet

Figures in NOK 1,000	30.09.2002	31.12.2001
Fixed assets	11 545	3 935
Stocks	20 813	4 287
Receivables	12 193	6 169
Securities	218 176	283 564
Cash and bank deposits	53 690	21 614
<b>Total assets</b>	<b>316 417</b>	<b>319 569</b>
Shareholders' equity	190 243	259 398
Long term liabilities	17 605	17 362
Current liabilities	108 569	42 809
<b>Total shareholders' capital &amp; liabilities</b>	<b>316 417</b>	<b>319 569</b>



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