

PhotoCure ASA

Results 3rd quarter 2002

November 2002



Highlights

■ Metvix®

- Approvable letter from FDA
- Increasing sales in the Nordic markets
- Launch in Germany in February 2003

■ Hexvix®

- Positive phase III results
- On track for filing of marketing authorisation first half 2003

■ Benzvix®

- Clinical pilot studies on track



Metvix[®]

– quick and simple treatment

Lesion preparation



Metvix[®] application



Red light illumination



Financial Statements

– Profit & Loss

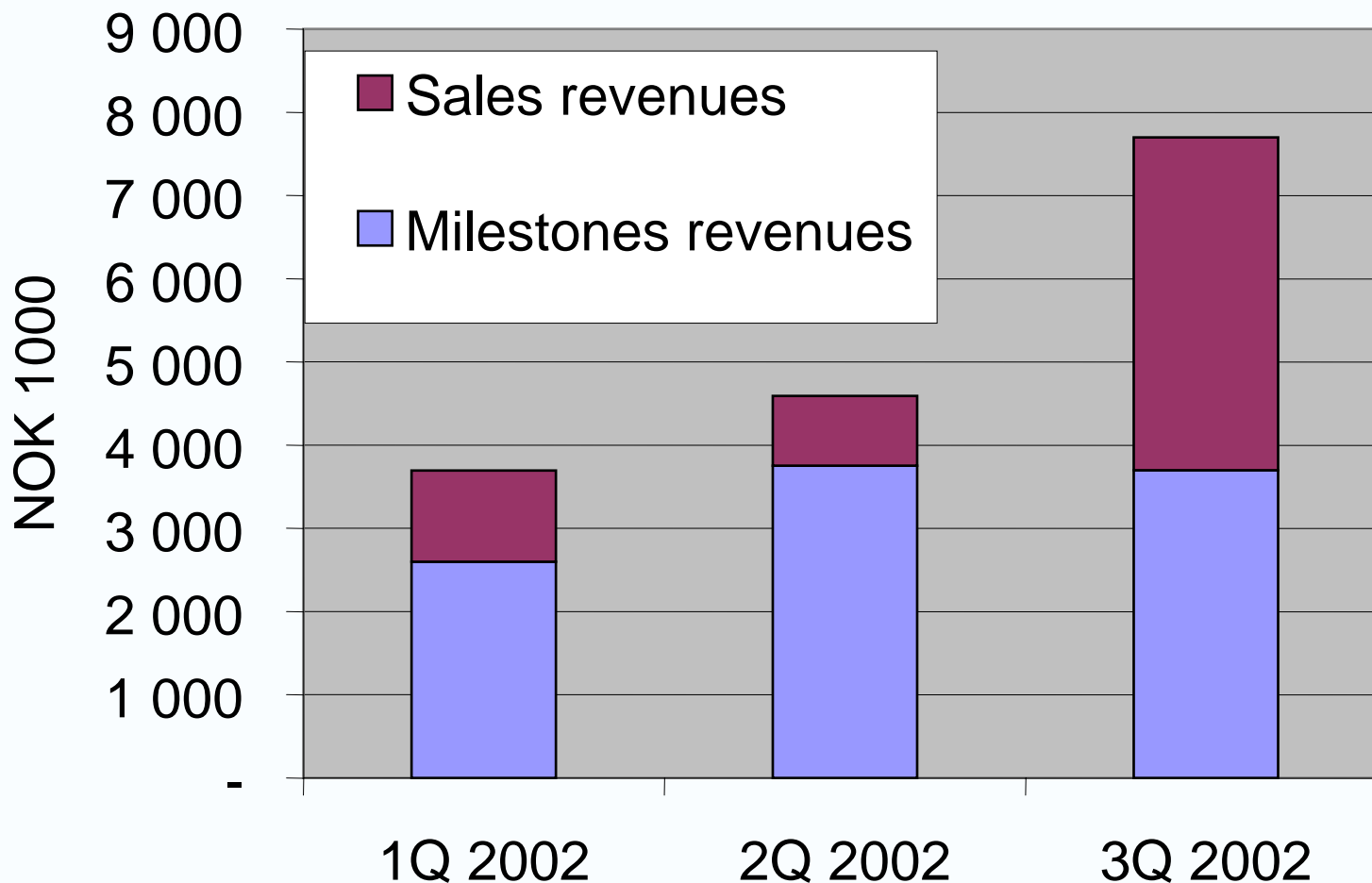
Three months ended		All figures in NOK 1,000	Nine months ended	
30.09.2002	30.09.2001		30.09.2002	30.09.2001
7 700	750	Sales revenues	15 991	1 682
-	86	Other operating revenues	130	2 772
7 700	836	Total operating revenues	16 121	4 453
3 009	-	Cost of products sold	3 615	-
4 691	836	Gross profit	12 506	4 453
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
25 469	30 808	Total operating expenses	95 494	80 546
-20 778	-29 972	Operating loss	-82 988	-76 092
3 589	7 112	Net financial income	9 119	20 413
-17 189	-22 860	Loss before tax	-73 869	-55 680
-	-	Taxes	-	-
-17 189	-22 860	Net loss for the period	-73 869	-55 680
-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

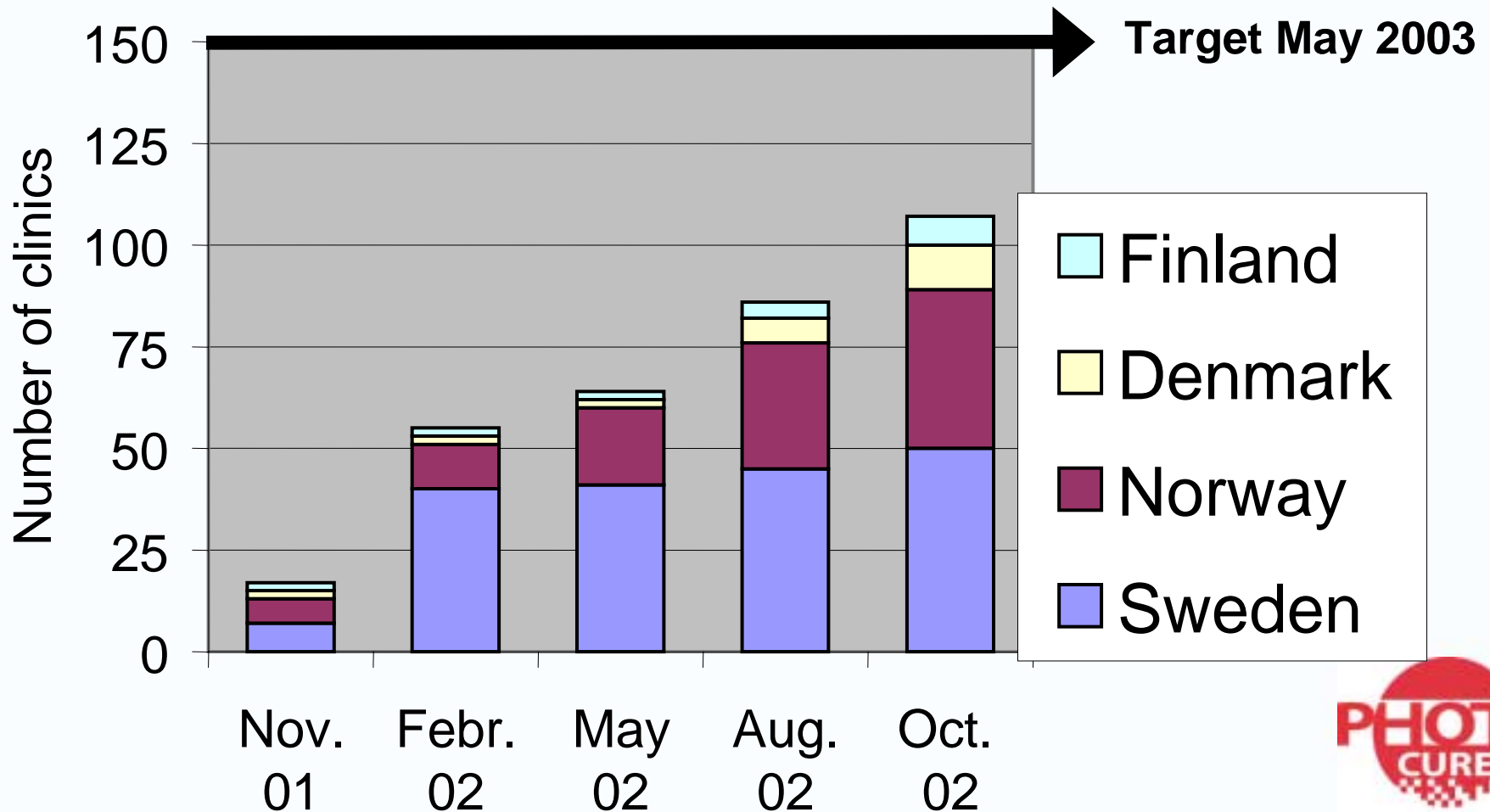
Sales revenues



Metvix®

– marketing in the Nordic area on track

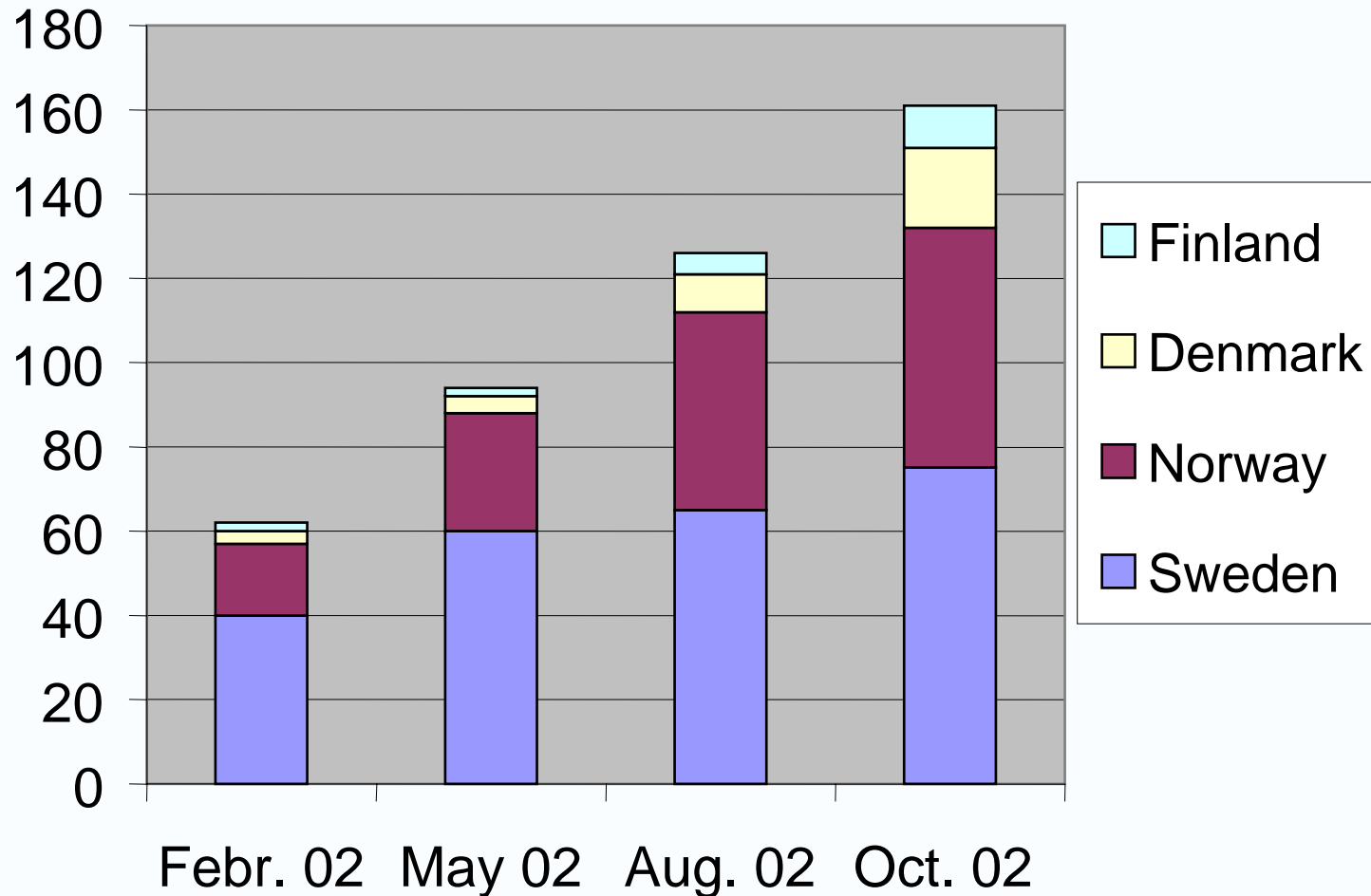
Clinics with PhotoCure lamps



Metvix[®]

– marketing in the Nordic area on track

Number of light sources



Marketing Metvix®

– 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® October 2001

- Procedure codes private clinics

- Procedure fee negotiations ongoing



Marketing Metvix[®]

– 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[®]

– 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[®]

– Finland

- Estimated market size:

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

- National approval May 2002
- Metvix[®] priced at 148 Euro per tube
- Reimbursement application filed for Metvix[®]



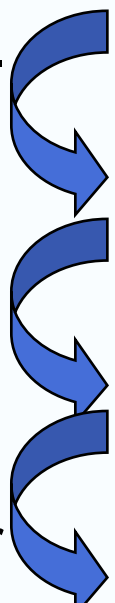
Marketing Metvix[®]

– 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 1st 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



Metvix[®]

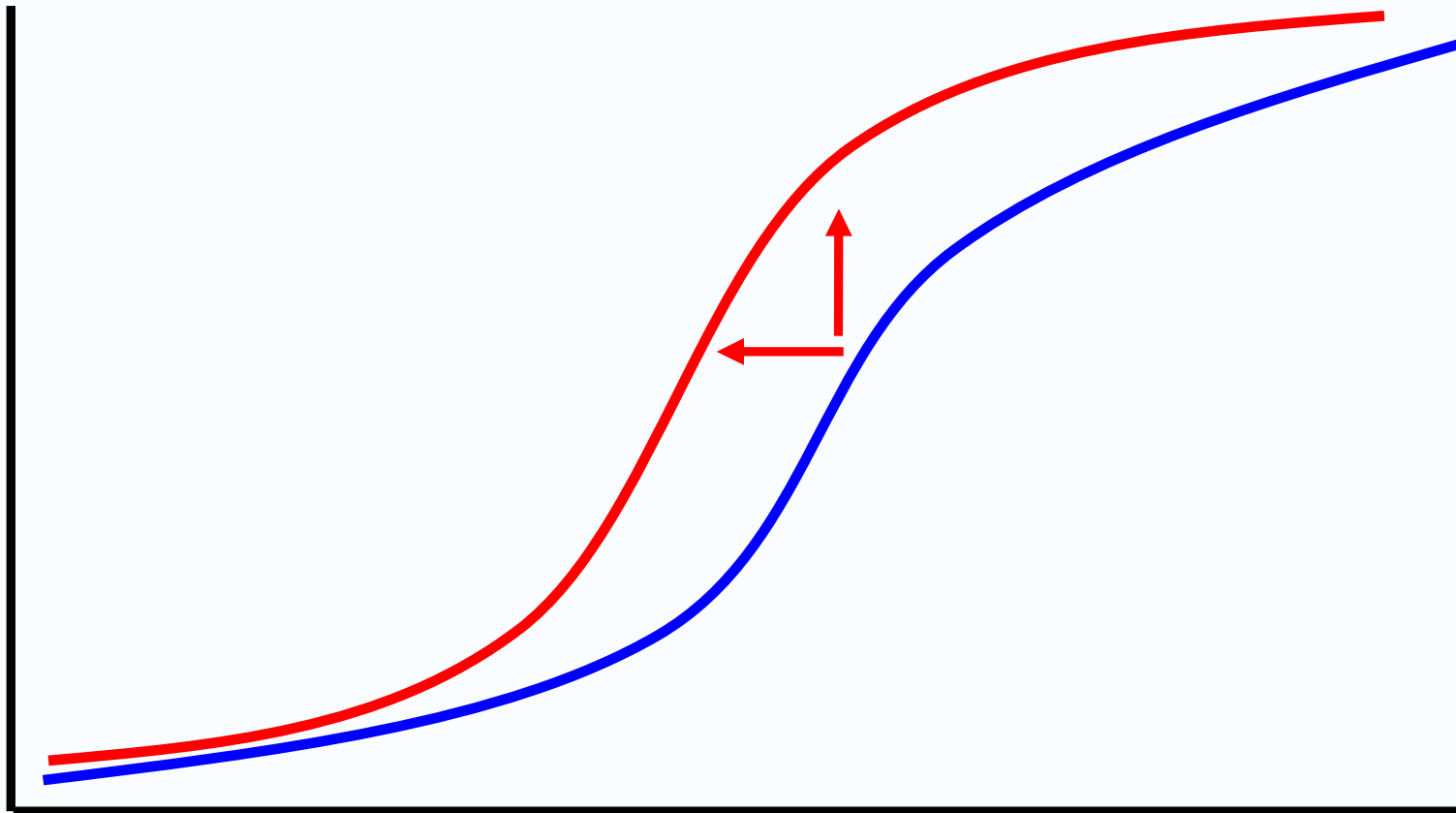
– PhotoCure top down Marketing strategy



Metvix[®]

– PhotoCure market strategy

Sales volume development



Launch

Year 5 (after launch)



Hexvix®

– preparation finished

Hexyl aminolevulinate powder

+

Phosphate buffer saline 50 mL

↓

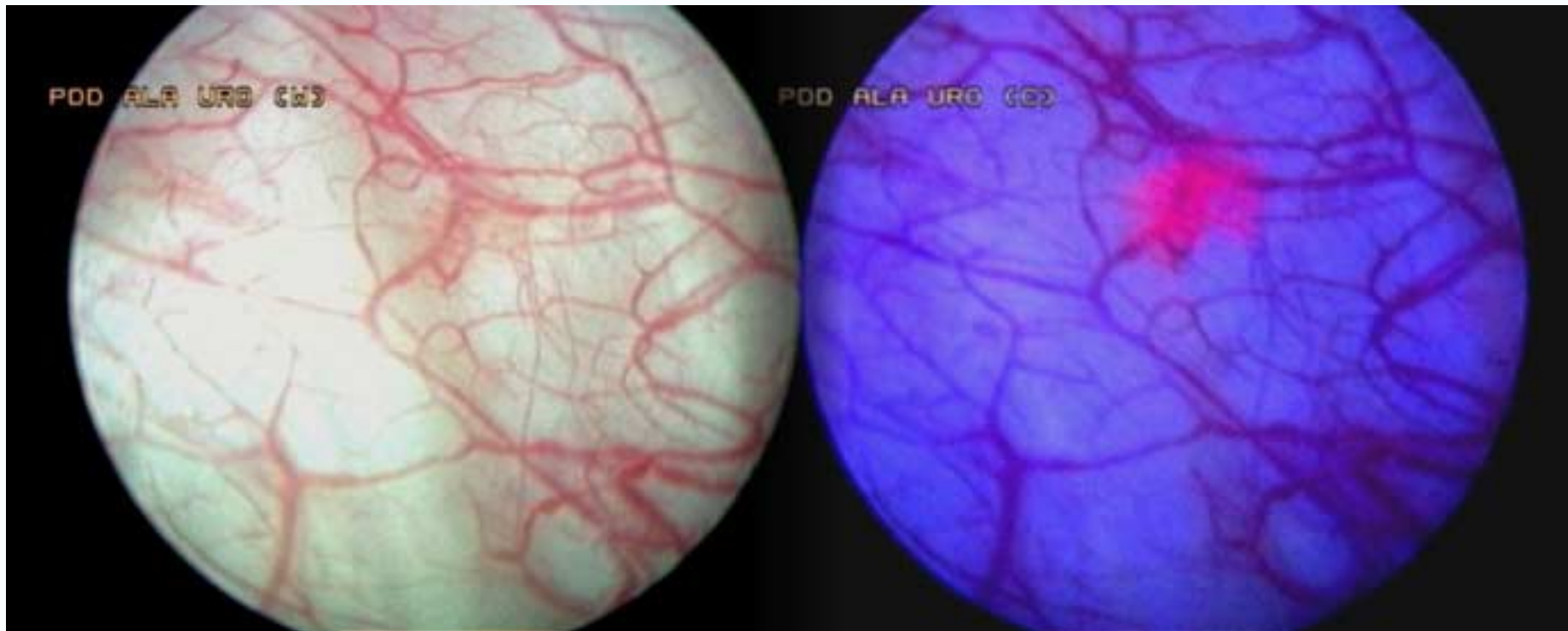
Hexvix® solution

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



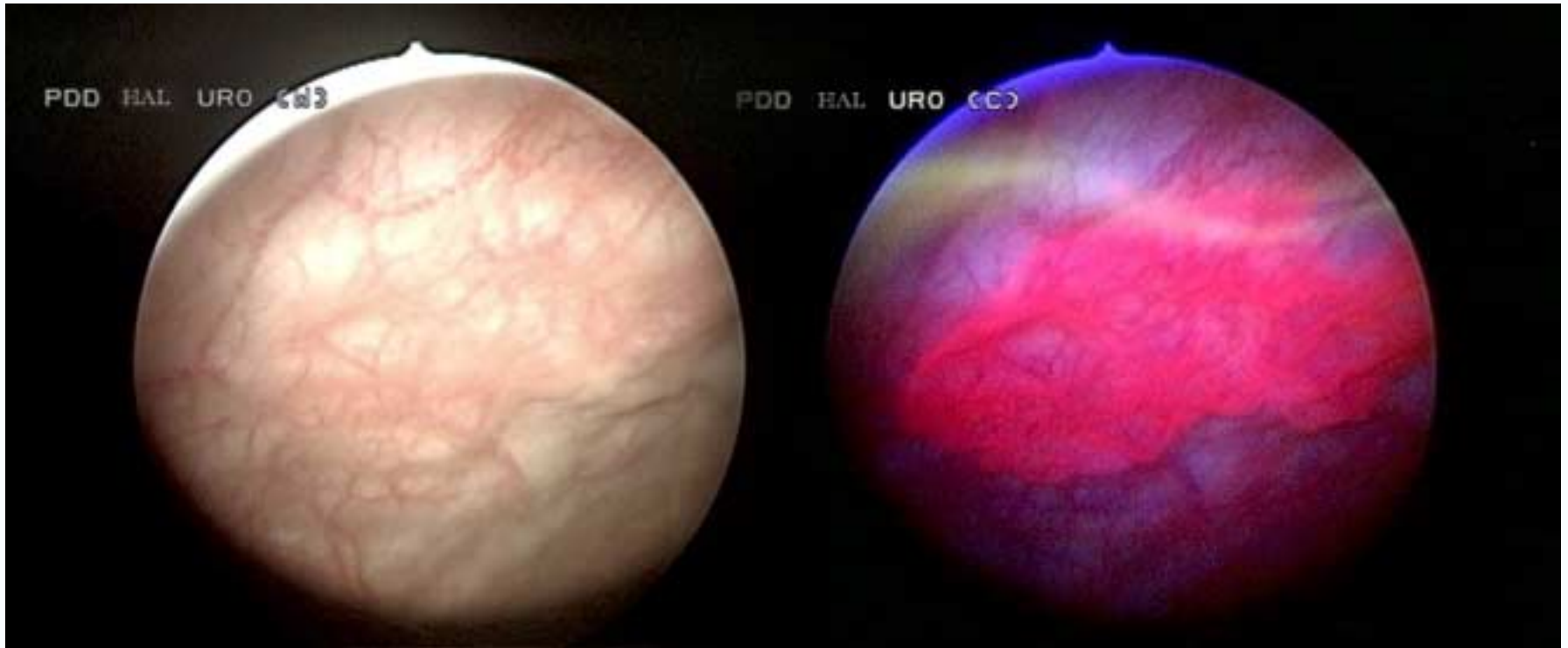
Hexvix®

– papillary lesion detected with Hexvix only



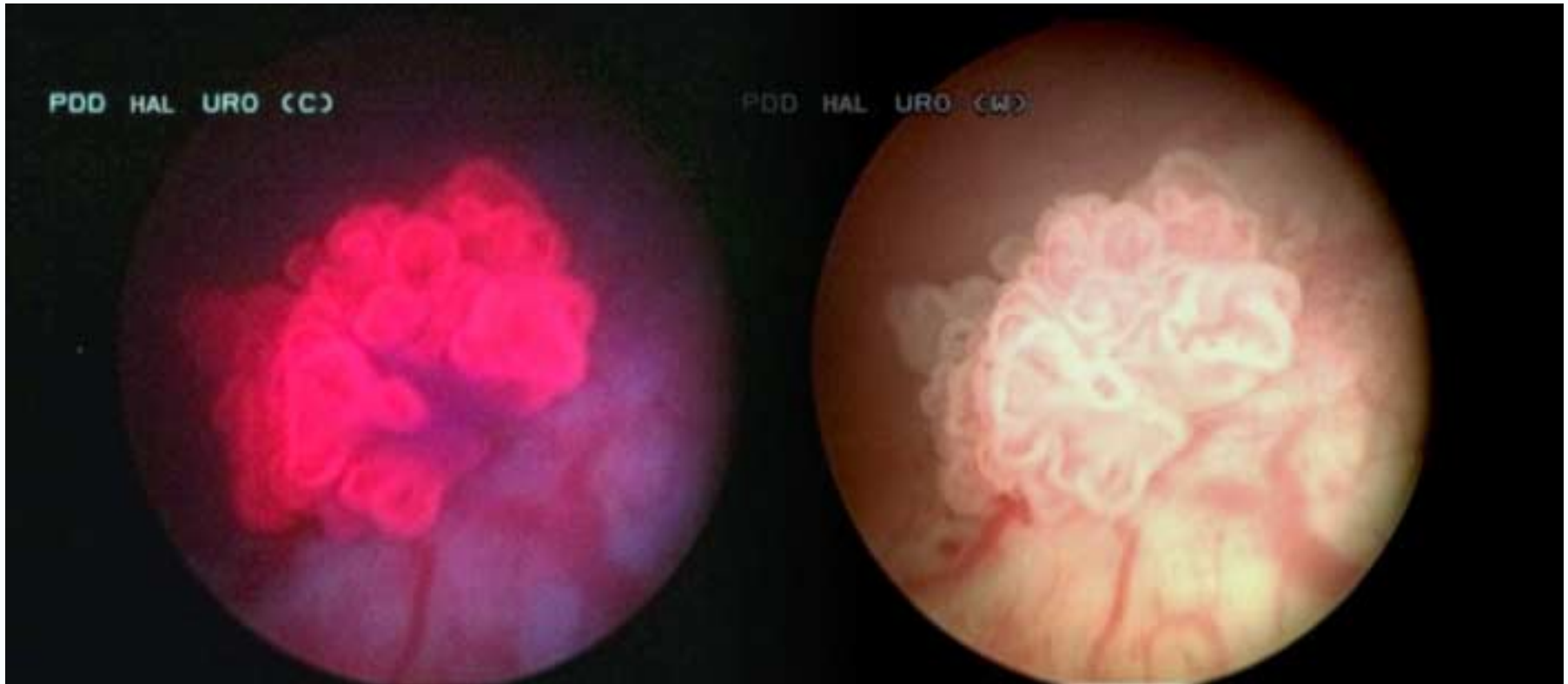
Hexvix®

– CIS detected with Hexvix® only



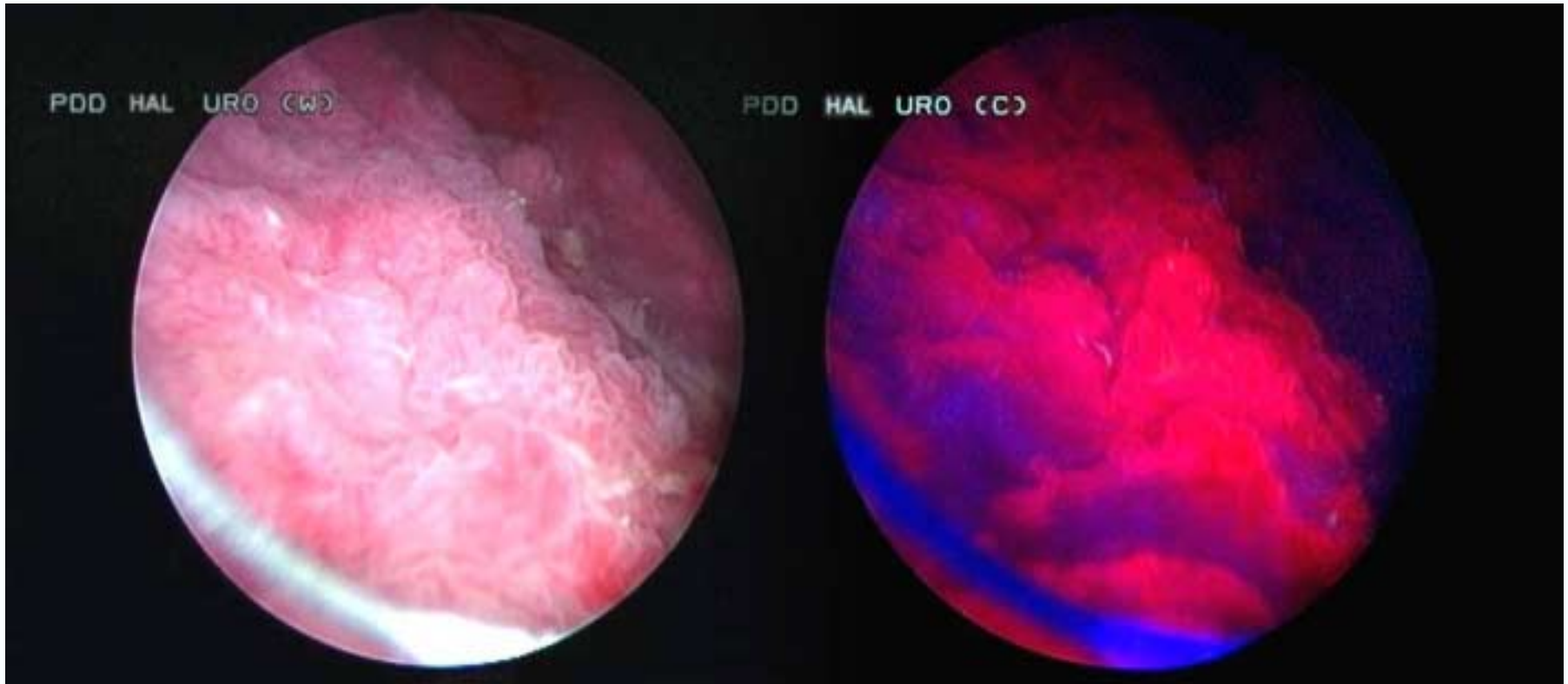
Hexvix®

– single papillary tumour



Hexvix®

– papillary tumour



Hexvix® in bladder cancer

– positive results in phase III clinical trial

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

Hexvix® cystoscopy	Standard white light cystoscopy
97%	59%



Hexvix®

– phase III program ongoing

- Europe
 - Clinical phase III study completed with positive results
 - One additional study initiated
- USA
 - Investigational New Drug status obtained
 - Phase III studies initiated
- First marketing application planned 1st half 2003
 - Preparations on track



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



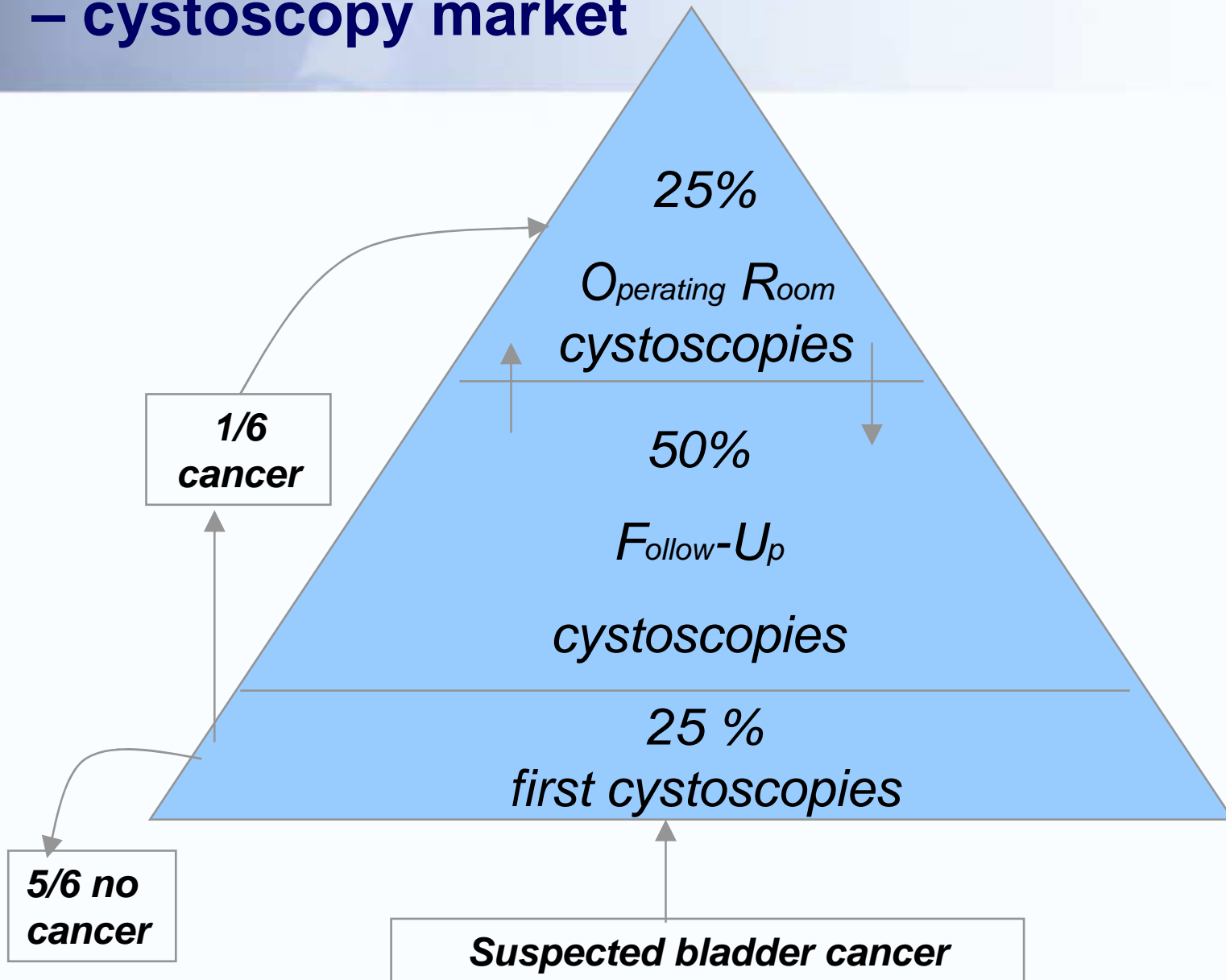
Hexvix®

– 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®

– commercial strategy

- Enter the market for patients who are in the operating room anyway – achieve high price
- Thereafter move into follow-up and confirmatory diagnostic procedures in clinics
- Eventually move into out-patient and private practice urology and early diagnosis
- Document Hexvix for both rigid and flexible scopes



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
- Gynaecology (vulva, cervix, ovarian) – clinical pilot study initiated
- Brain tumours
- Mammary tumours (breast conserving surgery)



PhotoCure

– important milestones the next twelve months

As of May 2002

Metvix[®]

- Expand the number of clinics in the Nordic countries
 - 150 clinics with light sources
- Submit additional clinical data in Australia, France, Portugal & Holland
- File new drug application for BCC in the US
- Initiate clinical study for new indication
- Launches by Galderma



PhotoCure

– important milestones the next twelve months

As of May 2002

Hexvix®

- Complete current ongoing phase III studies for bladder cancer detection
- File first marketing authorisation application for bladder cancer detection
- Start clinical pilot study on treatment of bladder cancer

Benzvix®

- Complete current ongoing clinical pilot studies

PCI Biotech AS

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



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
Total assets	316 417	319 569
Shareholders' equity	190 243	259 398
Long term liabilities	17 605	17 362
Current liabilities	108 569	42 809
Total shareholders' capital & liabilities	316 417	319 569



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