

# **PhotoCure ASA**

**Full Year Results  
Presentation  
2002**

**26th February 2003**



# Important Achievements

## ■ Metvix®

- Launch started in Germany by Galderma – February 2003
- International roll out in progress– UK launch soon
- Approvable letter from US FDA – September 2002
- NDA filed for BCC indication in the US – February 2003
- Recommended approval in Australia – February 2003
- Increasing sales in the Nordic markets – 2nd half 2002

## ■ Hexvix®

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

## ■ Benzvix®

- Clinical pilot studies on track



# The financial profile to succeed

	2002	2001	% change	Comments
Sales	25 223	2 330	983 %	Substantial increase
Cost of products sold	5 832	0		
<b>Gross Profit</b>	<b>19 392</b>	<b>2 330</b>	<b>732 %</b>	
Other operating revenues	3 486	3 022	15 %	Increase government grants
Other operating expenses	132 404	133 218	-1 %	Costs levelled out
Net financial income	13 521	26 178	-48 %	More Euro's - strong NOK
<b>Net loss</b>	<b>-96 005</b>	<b>-101 688</b>	<b>-6 %</b>	First decrease ever
<b>Cash flow operations</b>	<b>-50 906</b>	<b>-94 620</b>	<b>-46 %</b>	Substantial improvement
<b>Liquid funds (year-end)</b>	<b>249 503</b>	<b>305 178</b>	<b>-18 %</b>	



# Metvix<sup>®</sup> – The Commercial Roll Out Gathers Momentum

PhotoCure 1<sup>st</sup> Photodynamic Therapy (PDT) Agent

Rapid Growth in Revenues



# Metvix®

## – Galderma, the optimal marketing partner

- Dermatology specialist – Sales + production + research
- Strong shareholders – Owned 50/50 by Nestlé and L'Oréal
- The only global company 100% focused on dermatology
  - reaching dermatologists in more than 70 countries
  - worlds largest sales force in dermatology
  - US No1 market for Galderma
- Sales 2002 – Euro 642 million
- Organisation strongly dedicated to maximising the potential of the Metvix® franchise



# Marketing Metvix®

## – the German launch by Galderma

- Started launch 1<sup>st</sup> February 2003
- Launch symposium in Berlin attended by 150 key opinion leaders
- Educational centres in place
- Metvix® and Light Sources with Galderma
- International roll out in progress



# Marketing Metvix®

## – the Galderma commitment

- Metvix® subject to biggest launch investment ever
- Major international agency working to support product's international roll out
- Dedicated international marketing team in place
- Metvix® could in time be Galderma's biggest product



# Marketing Metvix<sup>®</sup>

## – progress in the Nordic region

- Metvix<sup>®</sup> available in all four countries
- Usage developing as planned
- Growing acceptance of benefits
- 130 centres now using technique routinely





# Metvix<sup>®</sup>

– quick and easy treatment

*Lesion preparation*



*Metvix<sup>®</sup> application*



*Red light illumination*



**Metvix<sup>®</sup>**

**– highly effective with superior cosmetic results**



**Metvix<sup>®</sup>**

**– highly effective with superior cosmetic results**



# Marketing Metvix®

– positive development of sales revenues

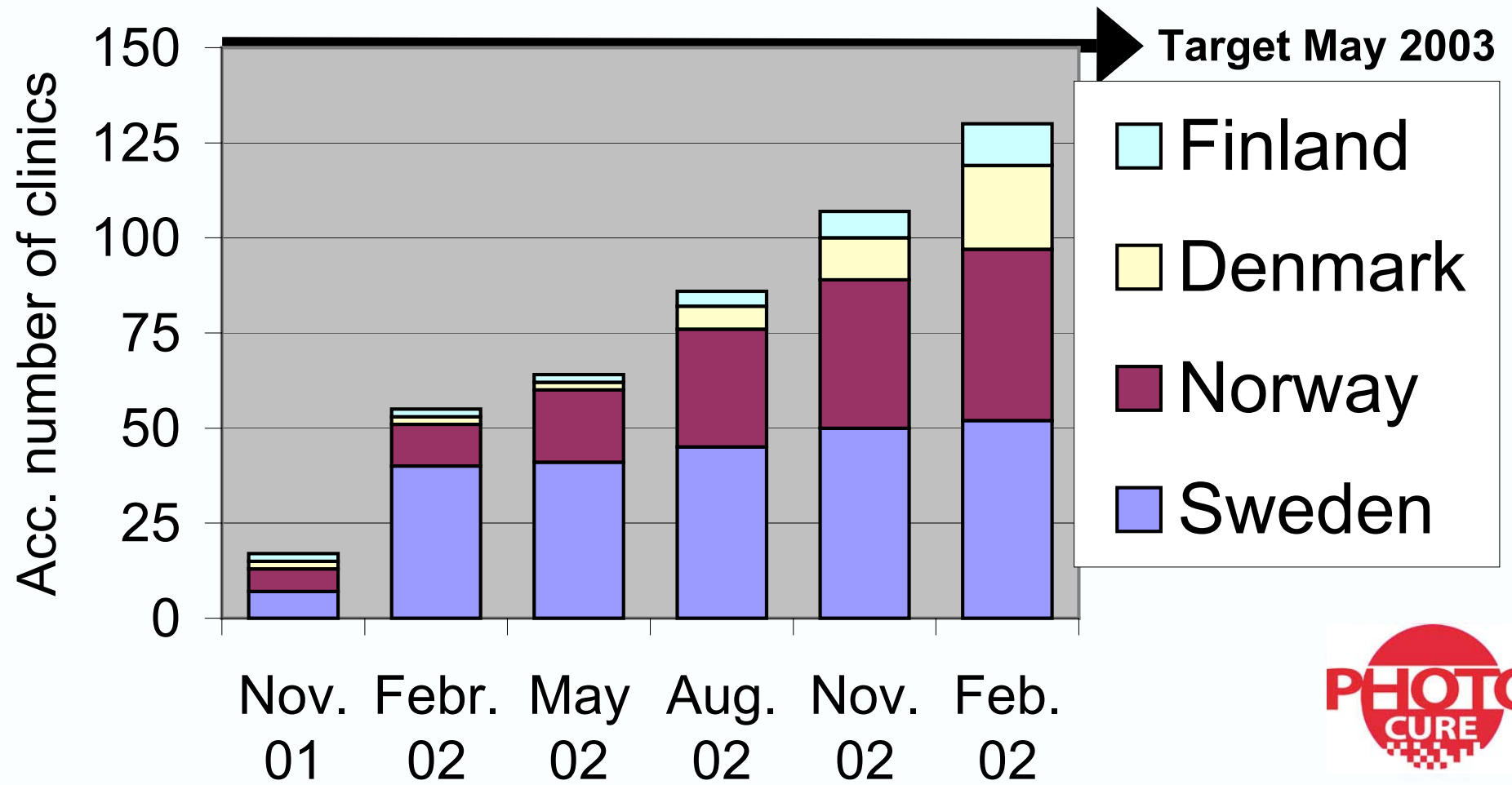
## Sales revenues



Metvix®

– marketing in the Nordic area on track

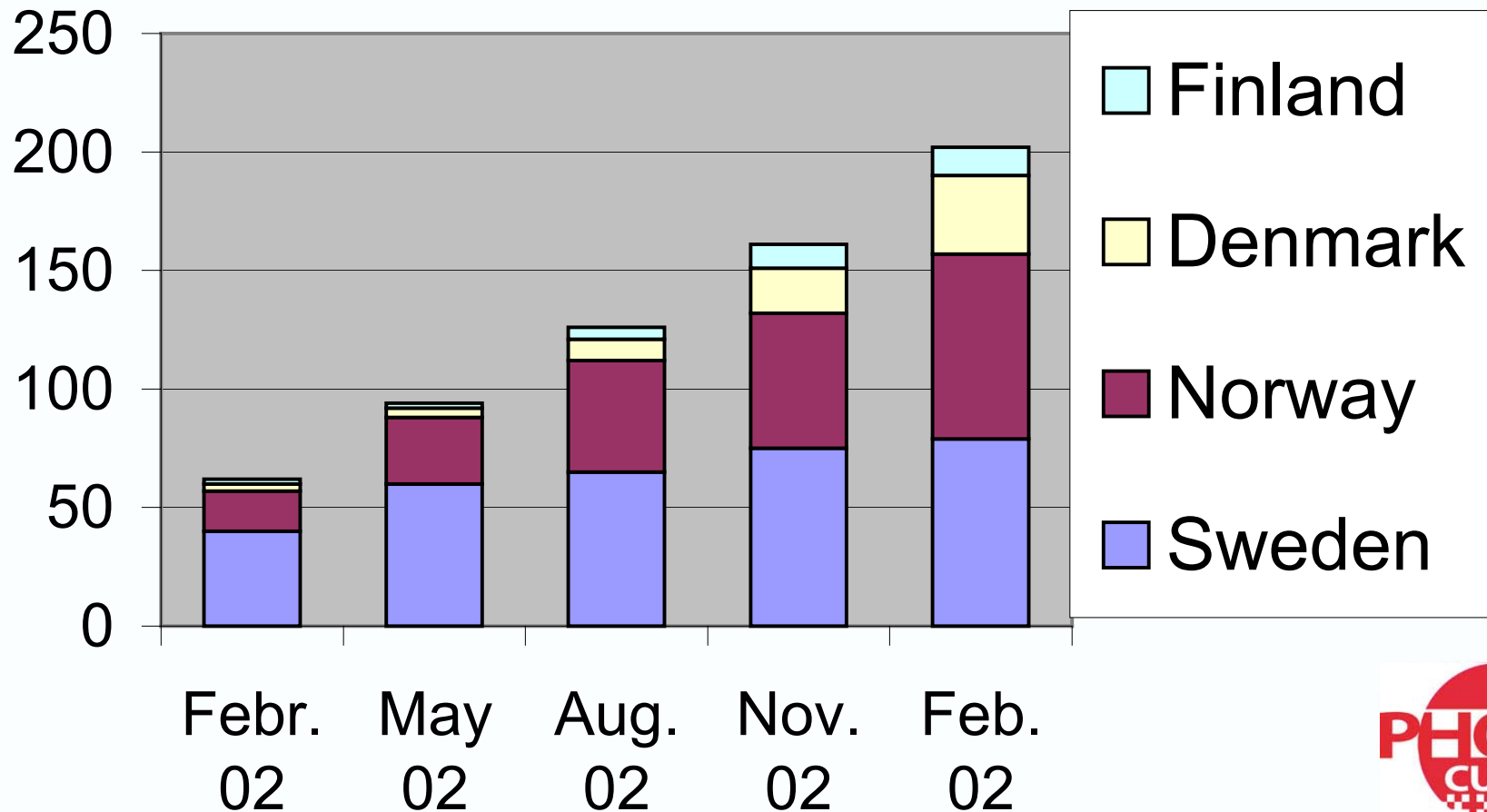
## Clinics with PhotoCure lamps



**Metvix®**

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

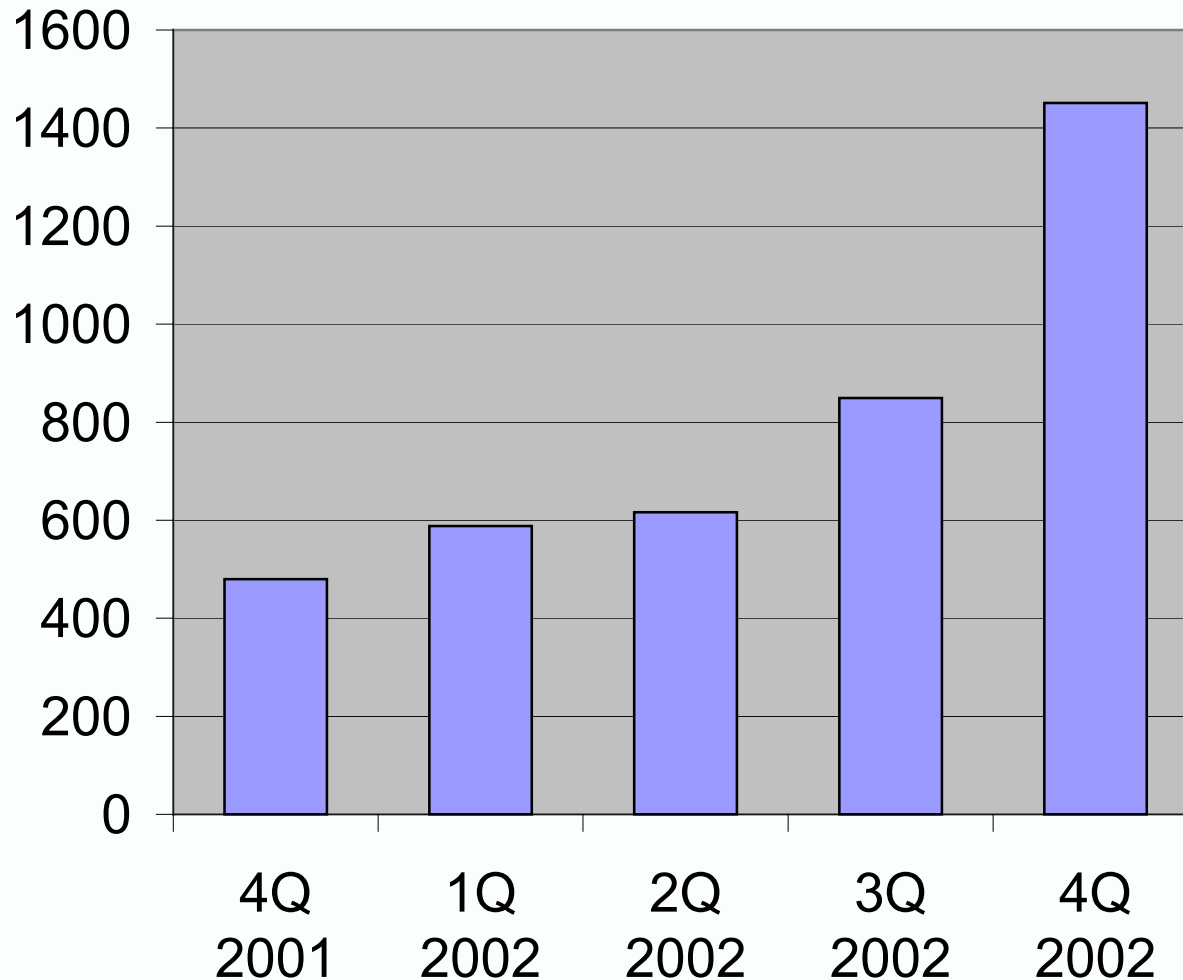
## Acc. number of light sources



**Metvix<sup>®</sup>**

**– marketing in the Nordic area**

## Number of tubes sold to pharmacies



# Marketing Metvix<sup>®</sup>

## – establishing clinical centers in Sweden

Oct. 2001

Oct. 2002

Febr. 2003

N.A./N.I.	123	19	13
Interest		59	58
User	5	43	45
Big User		7	7

Big user:  
more than 5 treatments per week





# Marketing Metvix®

## – establishing clinical centers in Norway

	Dec. 2001	Oct. 2002	Febr. 2003
N.A./N.I.	99	60	39
Interest		10	30
User	9	35	40
Big User	1	4	5



# Marketing Metvix<sup>®</sup>

## – establishing clinical centers in Denmark

	July 2002	Oct. 2002	Febr. 2003
N.A./N.I.	93	26	24
Interest		54	43
User	3	15	19
Big User		1	3



# Marketing Metvix®

## – establishing clinical centers in Finland

	July 2002	Oct. 2002	Febr. 2003
N.A./N.I.	52	37	35
Interest		11	10
User	5	8	10
Big User		1	1



# Marketing Metvix<sup>®</sup>

## – the international roll out

- Launch started in Germany
- UK next country to launch
- Launch preparations are ongoing in 4 other countries



# Germany – a significant potential

- The first major market addressed
- Enthusiastic response from opinion leaders to launch
- Dedicated product management
- Sales force consist of 50 sales representatives
  - of which 5 dedicated exclusively to Metvix®
- 6 educational centres in place
- Price and reimbursement
  - negotiations successfully finalised for privately insured patients



## Metvix<sup>®</sup> in the US

- Approvable letter for AK received
- NDA for BCC now filed
- Pre-launch activities starting
- Opinion leader education started



# Hexvix<sup>®</sup> – A Breakthrough in Bladder Cancer Diagnosis

PhotoCure's 1<sup>st</sup> Photo-Diagnostic (PD) agent close to 1<sup>st</sup> launch



# Hexvix®

– preparation finished



**Hexvix 85 mg Powder  
for solution  
for intravesical use**

+

**50 ml Solvent for Hexvix  
for intravesical use**

Hexvix® solution

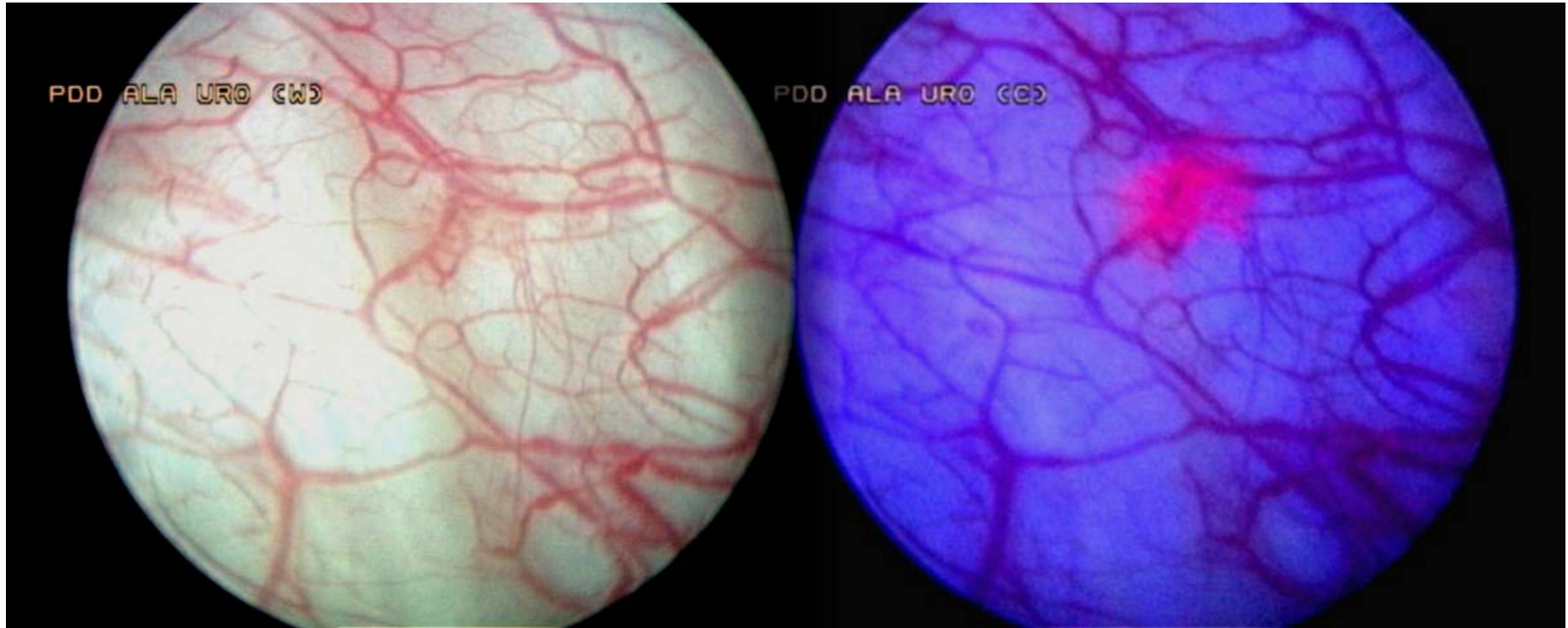
- Instilled 1 hour in the bladder
- Start cystoscopy within 30 minutes





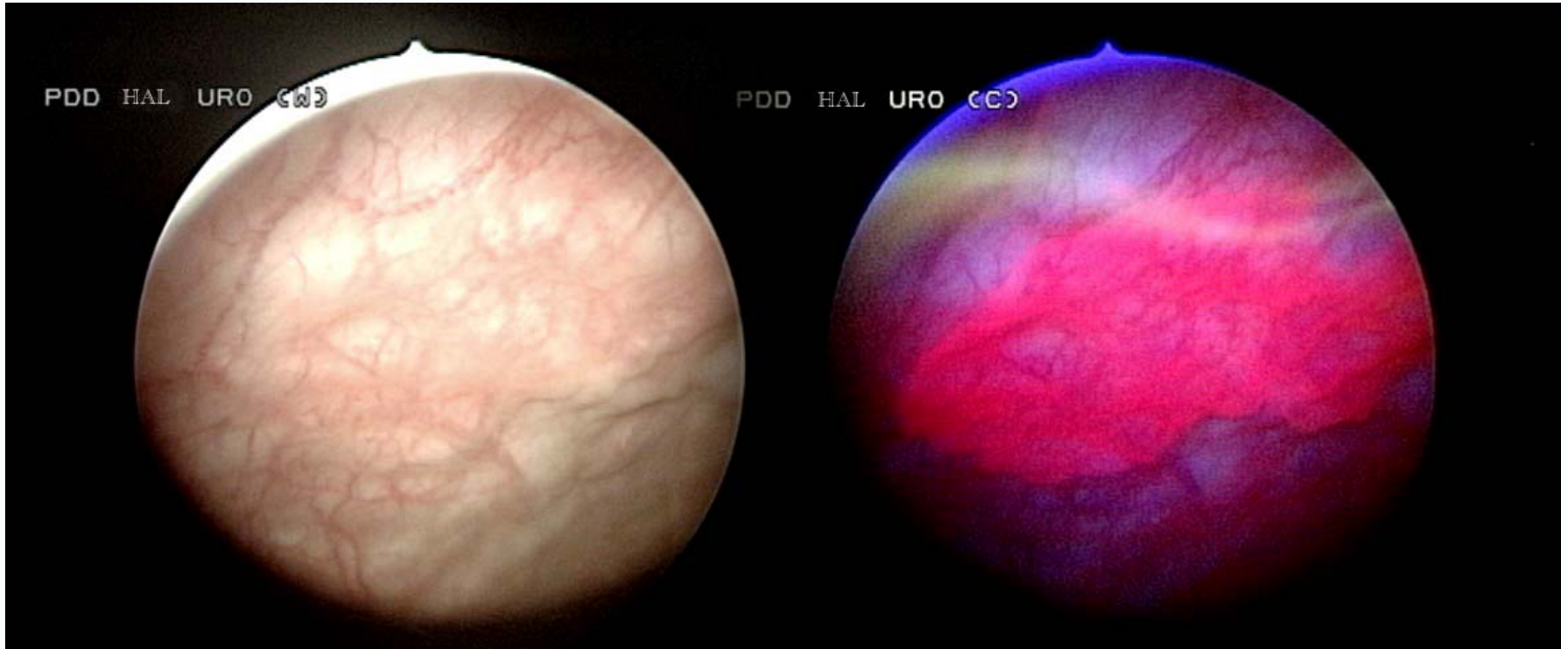
# Hexvix®

– papillary lesion detected with Hexvix only



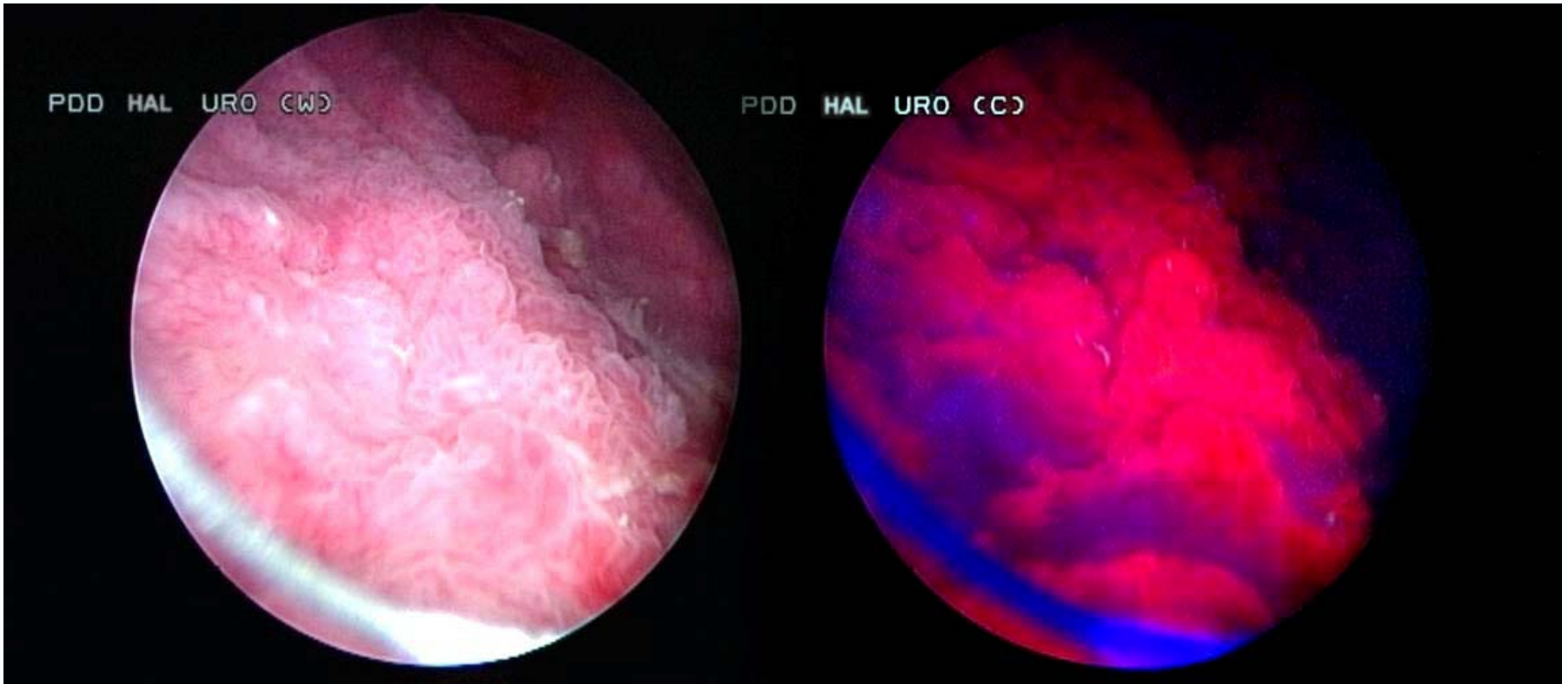
# Hexvix®

– CIS detected with Hexvix® only

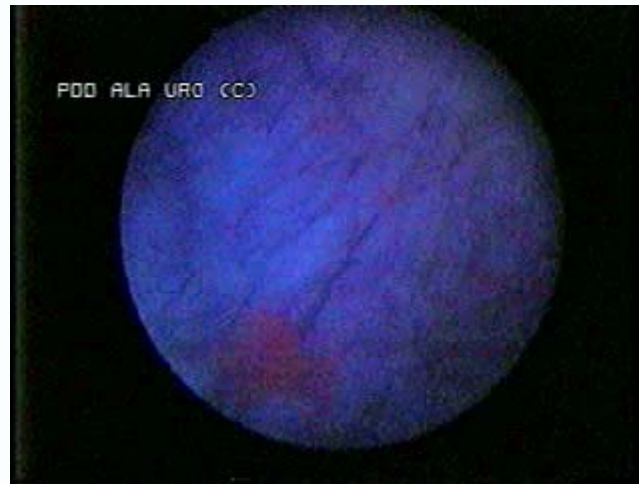


# Hexvix®

– papillary tumour



# How Hexvix® is used



# Hexvix®

– excellent phase III results

**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®

## – 1<sup>st</sup> MAA already filed in Europe

### ■ Europe

- Clinical phase III study completed with positive results
- Marketing application for EU filed in Sweden - December 2003

### ■ USA

- Investigational New Drug status obtained
- Phase III studies on-going



# Hexvix®

## – the commercial opportunity

- Newly diagnosed patients, annually
  - Europe and North America: 200 000
- **Fourth leading cause of cancer in men**
- Eighth leading cause in women
- Related to smoking, exposure to carcinogens



# Hexvix®

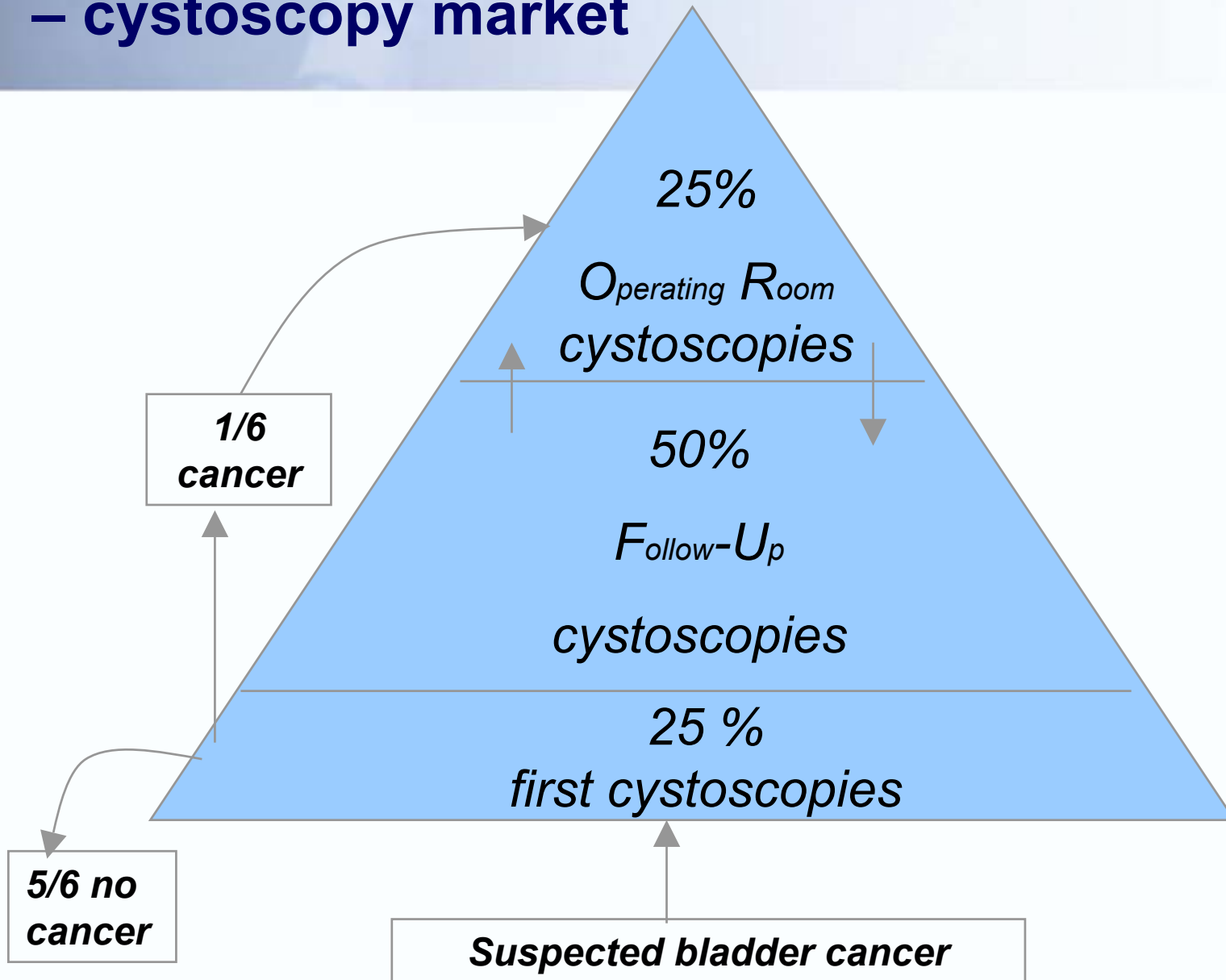
## – the cystoscopy market explained

- 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
- More than 4 million cystoscopies performed every year in Europe and North America





# Hexvix® – cystoscopy market



# Hexvix<sup>®</sup>

## – pre-Launch activities underway

- Contract manufacturer selected
- Market research study completed
- Price and reimbursement preparations ongoing
- Out-licensing activities initiated
  - PhotoCure will retain the Nordic region as with Metvix<sup>®</sup>



# Strong pipeline progressing well

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

- Barrets oesophagus – clinical pilot study initiated
- Colorectal 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)



# We will continue to deliver

## – milestones for the next twelve months

### ■ Metvix<sup>®</sup>

- UK launch and further global roll out
- 150 clinical centres established in the Nordic area
- Final approval in the US and in Australia
- Update regulatory dossier for remaining EU countries
- Initiate clinical study for new indication

### ■ Hexvix<sup>®</sup>

- Start clinical studies for treatment of bladder cancer

### ■ Benzvix<sup>®</sup>

- Complete ongoing clinical studies – initiate new studies

### ■ PCI Biotech AS

- First product on the research market



# Highlights

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