

# **PhotoCure ASA**

**Results  
2nd quarter 2003**

**19th of August 2003**



# Progress towards sustained profitability

## ■ Increased revenues and reduced costs

### ■ Metvix<sup>®</sup>

- European roll out continues
- Regulatory approvals expands the commercial potential

### ■ Hexvix<sup>®</sup>

- Closer to commercialisation

### ■ Exploratory projects

- Encouraging clinical pilot data



# The financial profile to succeed – first quarter with profit

	<b>Q2 2003</b>	<b>Q2 2002</b>
Sales revenues	24,285	4,594
Other operating revenues	1,045	6
<b>Operating revenues</b>	<b>25,330</b>	<b>4,601</b>
Operating expenses	21,478	34,045
Net financial income	3,710	2,275
<b>Net income / net loss</b>	<b>7,561</b>	<b>-27,169</b>
<b>Cash flow from operations</b>	<b>-7,405</b>	<b>-45,467</b>
<b>Liquid funds, end of period</b>	<b>213,227</b>	<b>305,158</b>



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

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

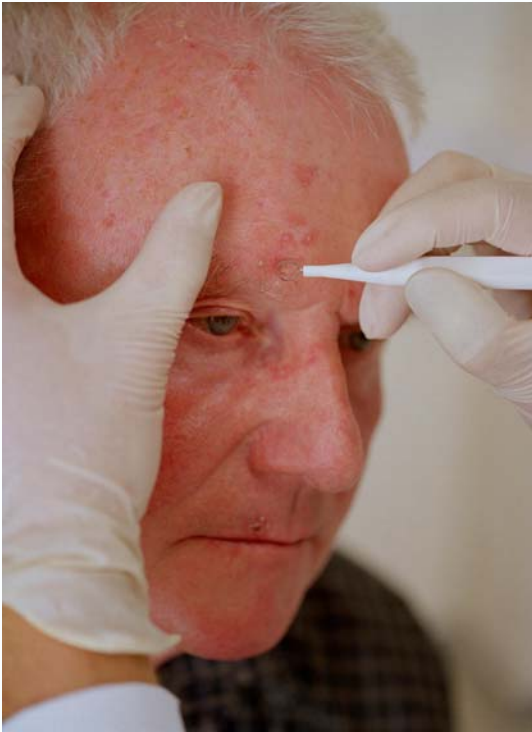
Rapid Growth in Revenues



# Metvix<sup>®</sup>

– quick and easy treatment

*Lesion preparation*



*Metvix<sup>®</sup> application*



*Red light illumination*



# 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



# Metvix®

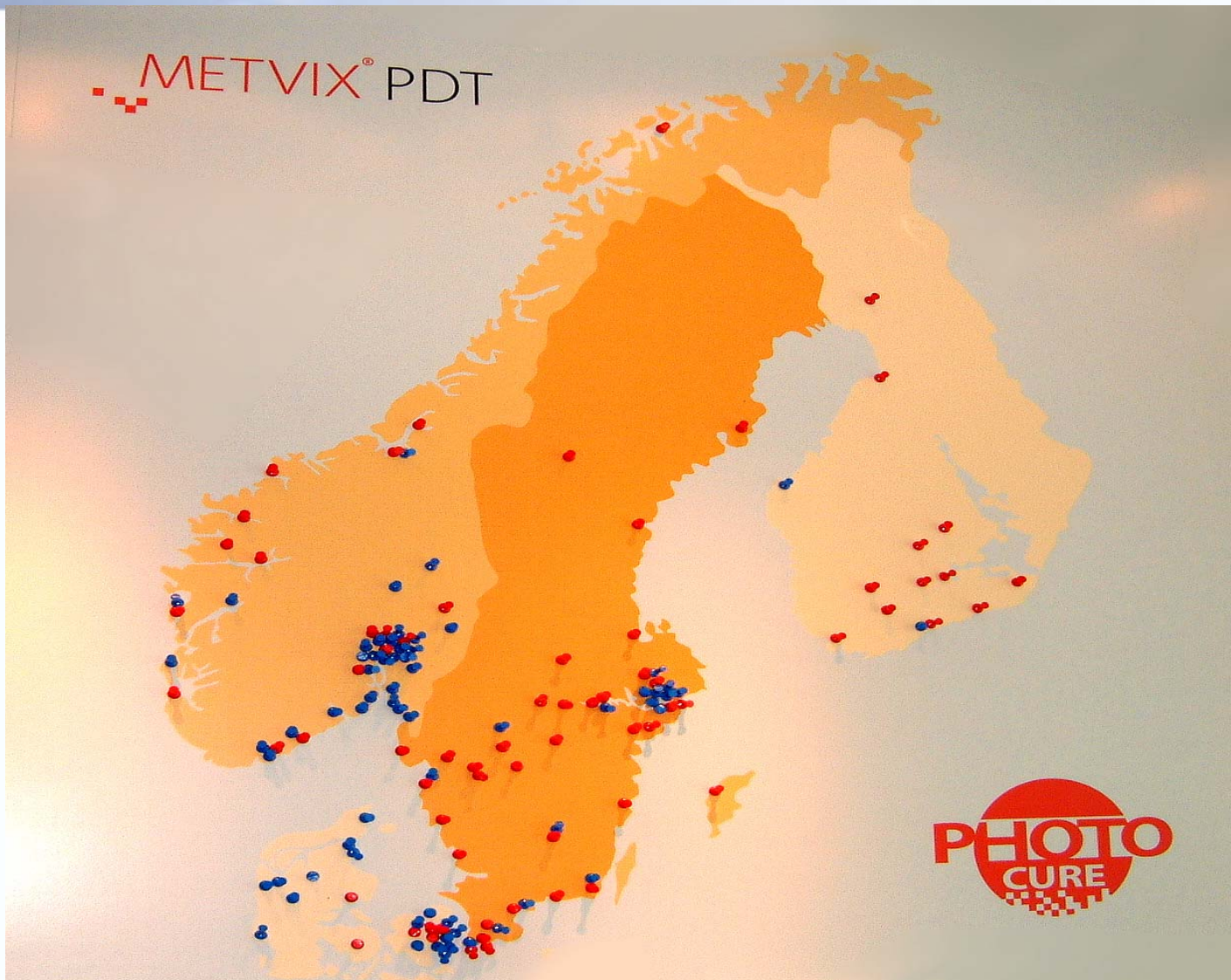
## – international roll out

- Launched in Germany by Galderma – February 2003
- Launched in UK by Galderma – May 2003
- Milestone payment of 2 mill. Euro from Galderma – May 2003
- Launch preparations ongoing in 4 other countries



# Metvix®

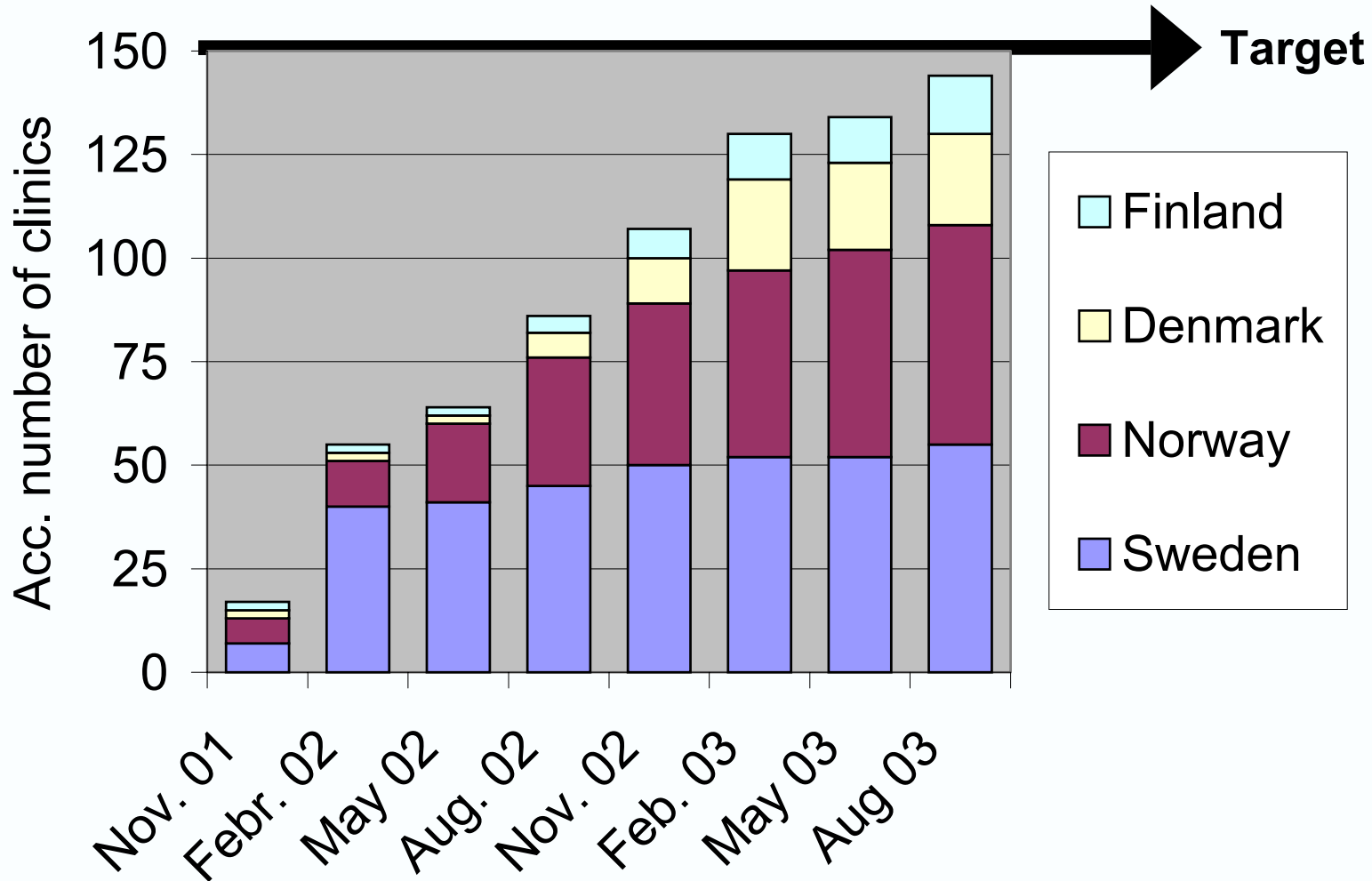
– high penetration in the Nordic area



Metvix®

– marketing in the Nordic area

## Clinics with PhotoCure lamps



# Marketing Metvix®

## – reimbursement progresses in the Nordic area

### ■ Sweden

- Drug reimbursement – October 2001

### ■ Norway

- Procedure reimbursement including drug – July 2003

### ■ Denmark

- Drug reimbursement routinely on a named patient basis
- Procedure codes established in certain regions

### ■ Finland

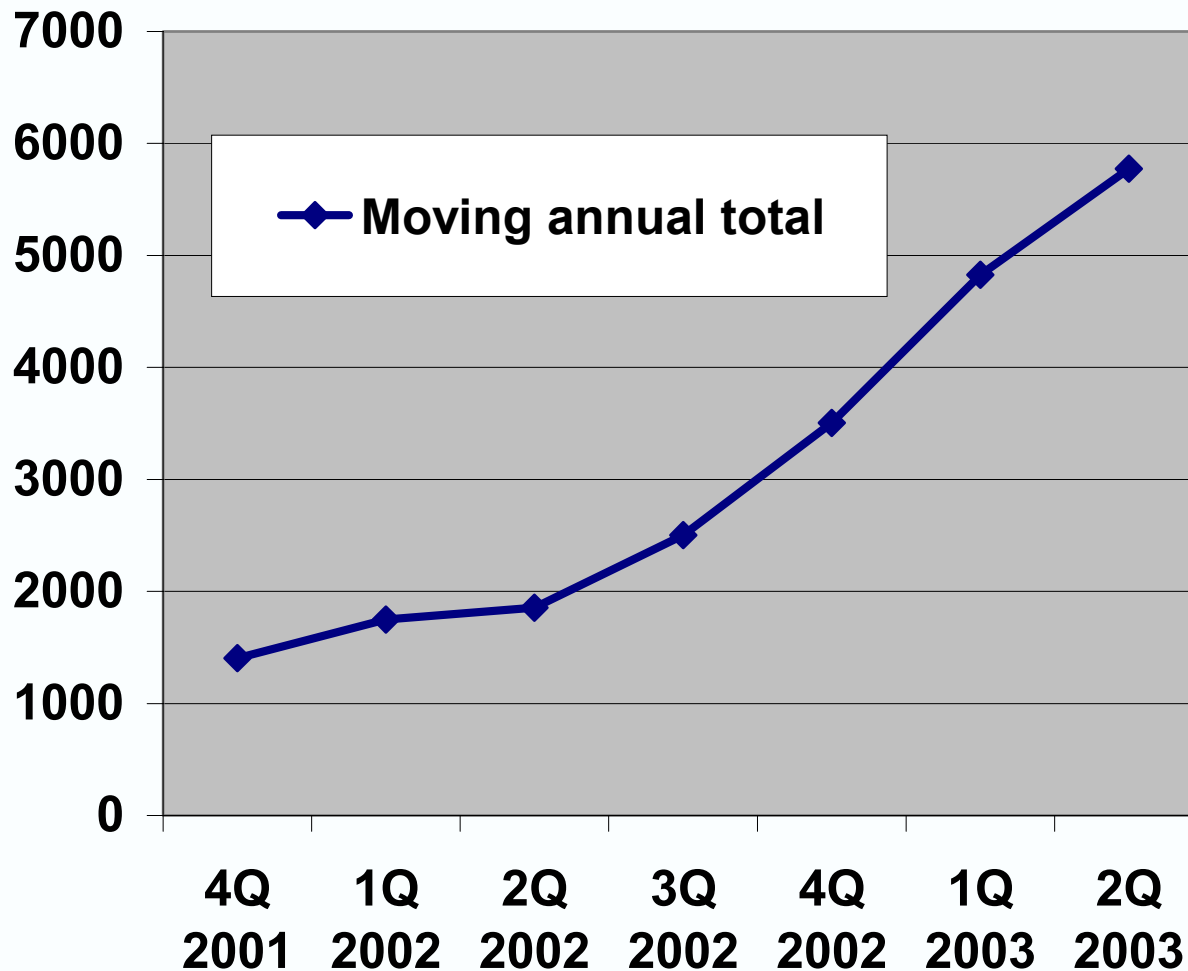
- Drug reimbursement obtained at standard rate of 50% of sales price – April 2003



# Metvix®

– increasing sales in the Nordic area

## Number of tubes sold to pharmacies



# Metvix®

## – targeting increased sales in the Nordic area

- Increase usage at established clinics
  - Train additional doctors and nurses
  - Expand usage to additional lesions and patients
  - Improve patient and illumination logistics
- Establish new centers
- Establish drug reimbursement and procedure codes
- Increase GP awareness and patient referral to established clinics
- Increase patient awareness and pressure



# Metvix®

## – expanding the commercial potential

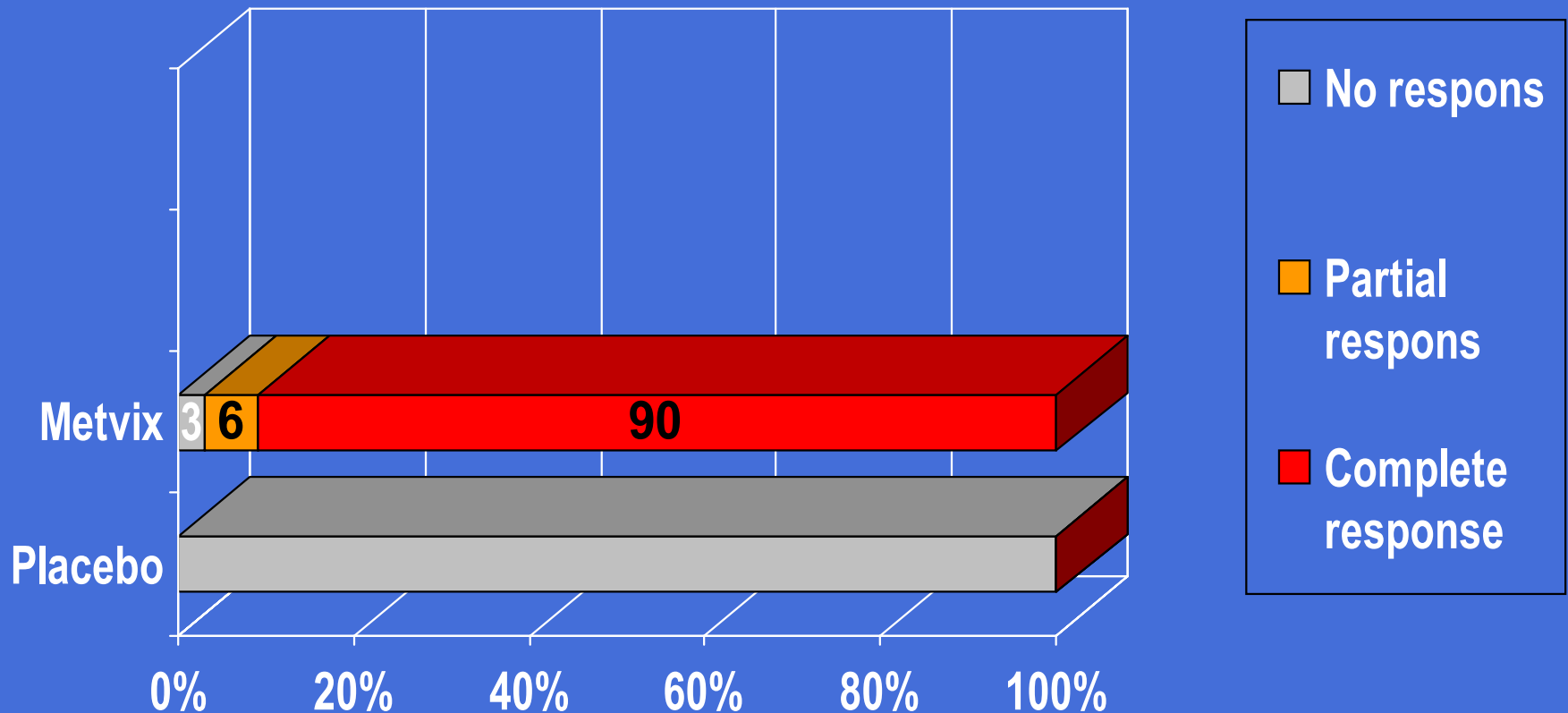
- Approvable letter from US FDA – September 2002
- NDA filed for BCC indication in the US – February 2003
  - Advisory committee meeting – September 2003
- Approval in Australia for AK & BCC– April & July 2003
- Recommended for approval in Switzerland for AK & BCC – July 2003
- Positive clinical results in squamos cell carcinoma – April 2003
- Positive clinical results in immuno suppressed organ transplant patients – May 2003



# Metvix<sup>®</sup>

– positive results in organ transplant patients

## Actinic keratosis - lesion response



# Metvix<sup>®</sup>

– positive results in organ transplant patients

## Conclusion

- Effective and safe treatment for Actinic Keratosis (AK) in organ transplant patients
- Metvix<sup>®</sup> may prevent progression of AK to other cancers
- Possibility for repeated treatments of large lesional areas



# 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**

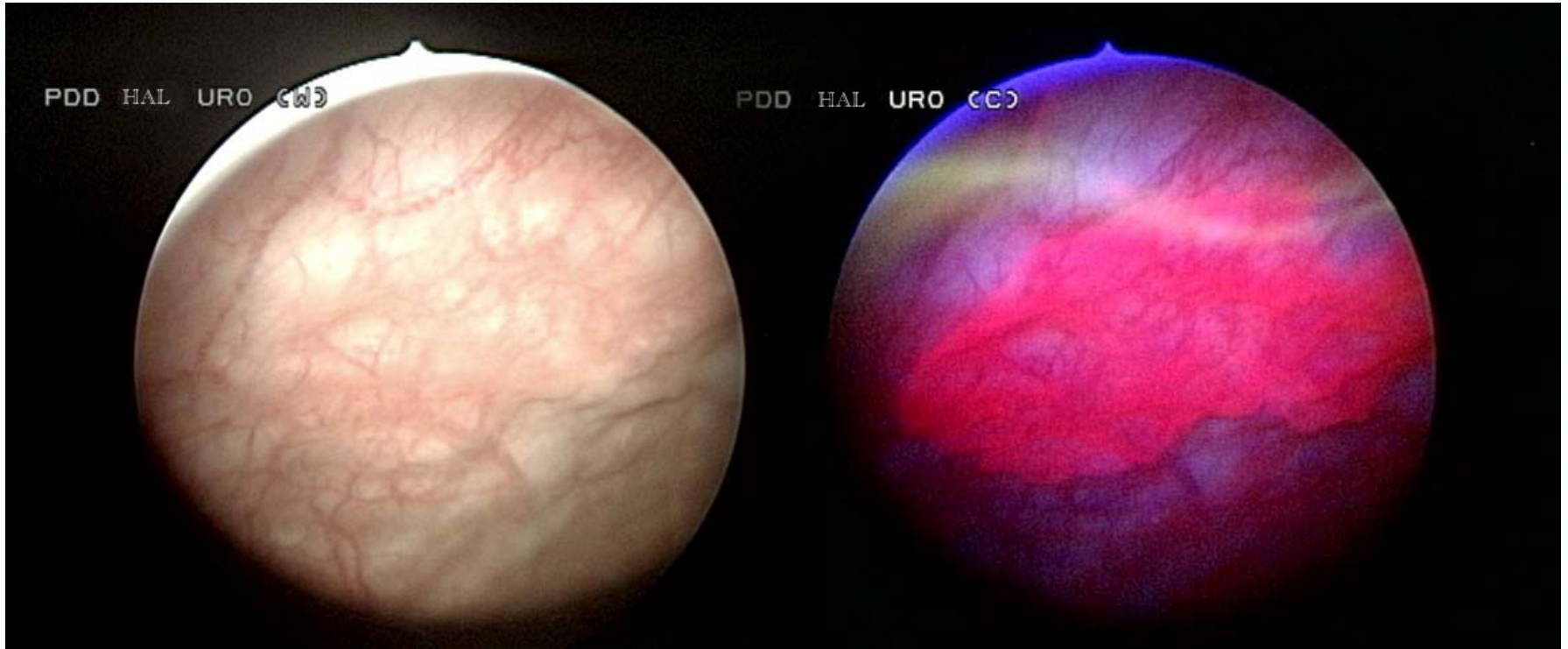
Hexvix® solution

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



# Hexvix®

– CIS detected with Hexvix® only



# Hexvix®

## – Collaboration with Karl Storz

- Karl Storz is a leading manufacturer of cystoscopes for urologists as well as for other types of advanced endoscopes
- Karl Storz has a world wide presence in marketing and sales
- Its D-Light (blue light) system is used in all clinical trials with Hexvix® conducted by PhotoCure
- The D-Light system is already approved in Europe
- The US authorities (FDA) requires a combined application for approval of the D-light system and Hexvix®
- Karl Storz and PhotoCure have agreed to co-operate on filing for approval in the US



# Hexvix®

– excellent results in two phase III studies

**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>

**Improved bladder cancer detection changed patient management in 20 to 30% of bladder cancer patients**



# Hexvix®

## – 1<sup>st</sup> MAA already filed

### ■ Europe

- Clinical phase III studies completed with positive results
- Marketing application for EU filed Dec. 2003 in Sweden

### ■ USA

- Investigational New Drug status obtained
- Phase III studies on-going
- Marketing application to be filed next year



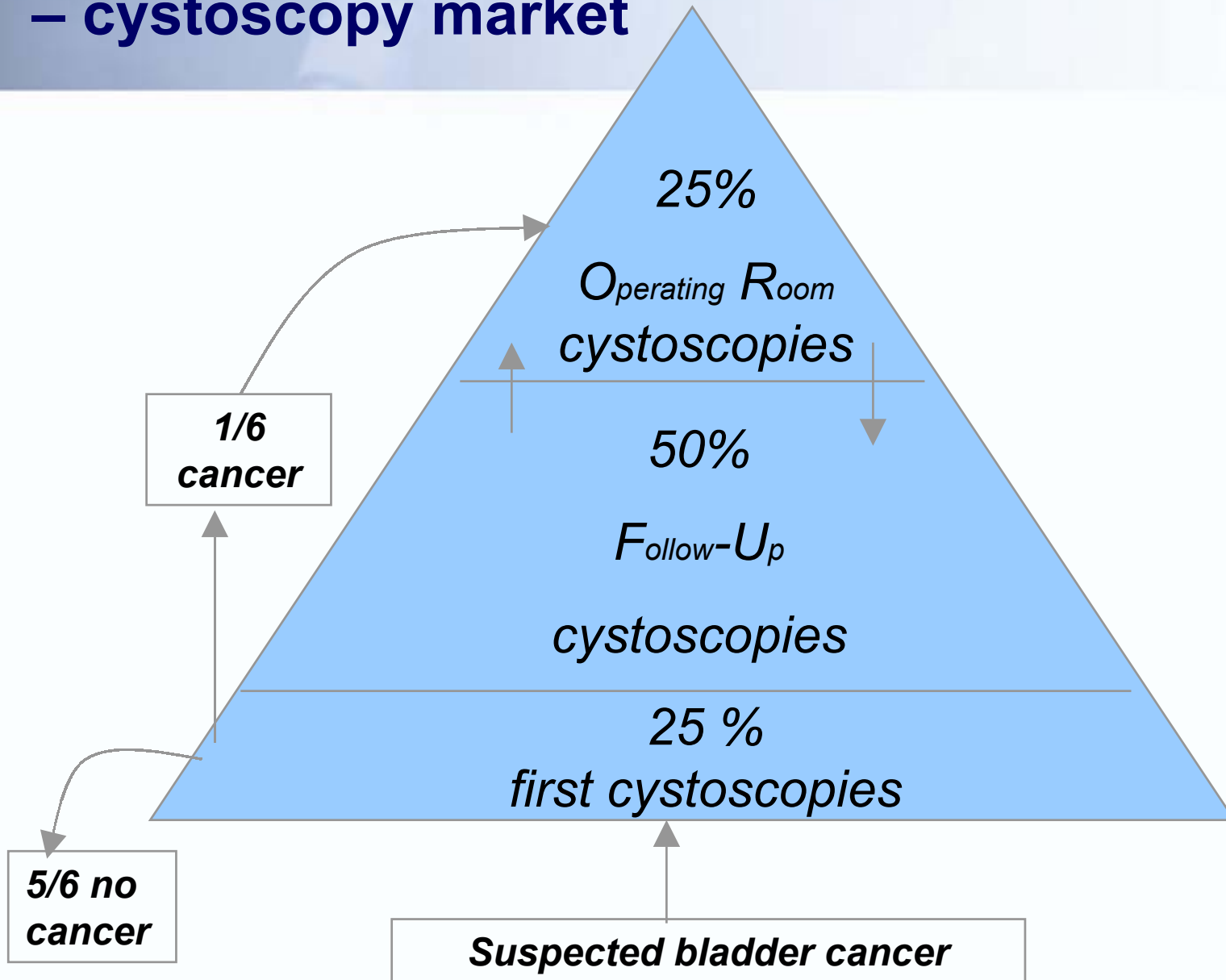
# Hexvix®

## – the cystoscopy market explained

- 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®

## – pre-Launch activities underway

- Contract manufacturer selected
- Agreement signed with Karl Storz
- Market research study completed
- Price and reimbursement preparations ongoing
- Clinical data presented at American Urology Association's annual congress as well as to Scandinavian Urologists
- Out-licensing activities initiated
  - PhotoCure will retain the Nordic area as with Metvix®



# Explorative projects – Strong pipeline

Encouraging clinical pilot data generated



# Explorative projects

## – strong pipeline

### R&D opportunities outside of dermatology and urology

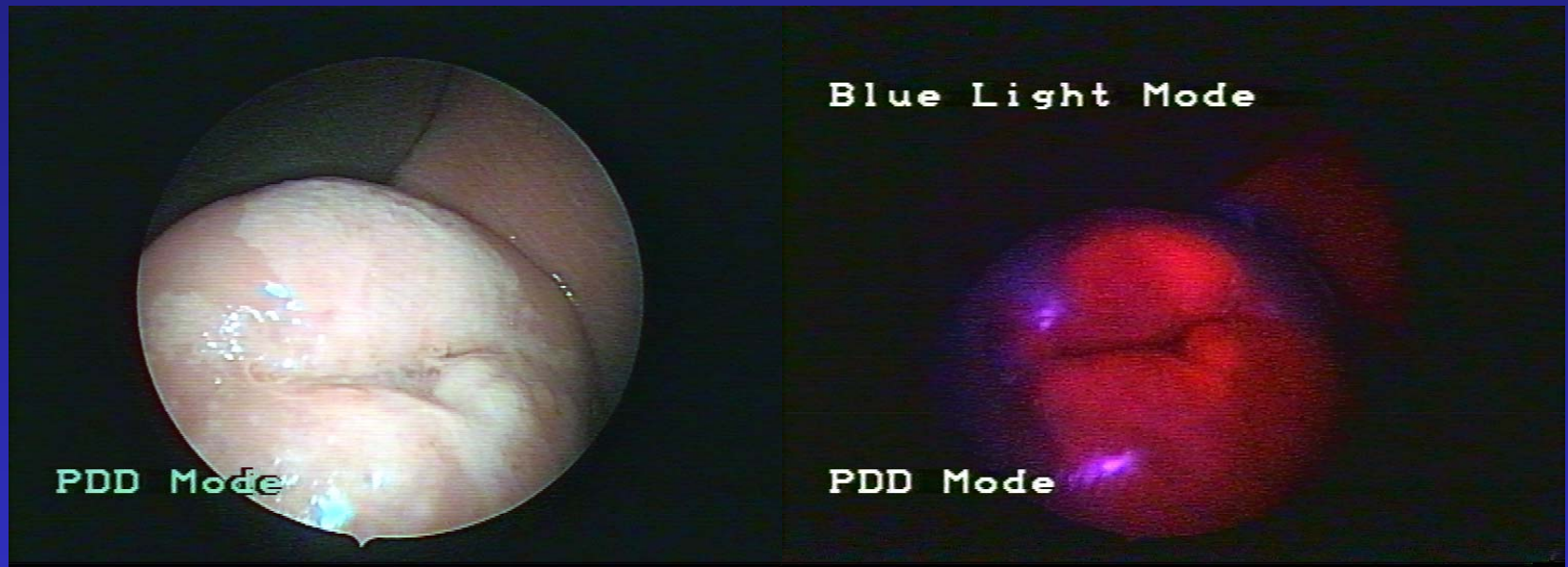
- Gastroenterology
  - Colo-rectal cancer - Clinical pilot study ongoing
  - Barrets oesophagus - Clinical pilot study initiated
- Gynaecology (vulva, cervix, ovarian)
  - Cervix cancer - Clinical pilot study ongoing
- Other areas
  - Bronchial cancers
  - Lesions in mouth, pharynx and larynx
  - Brain tumours
  - Mammary tumours (breast conserving surgery)



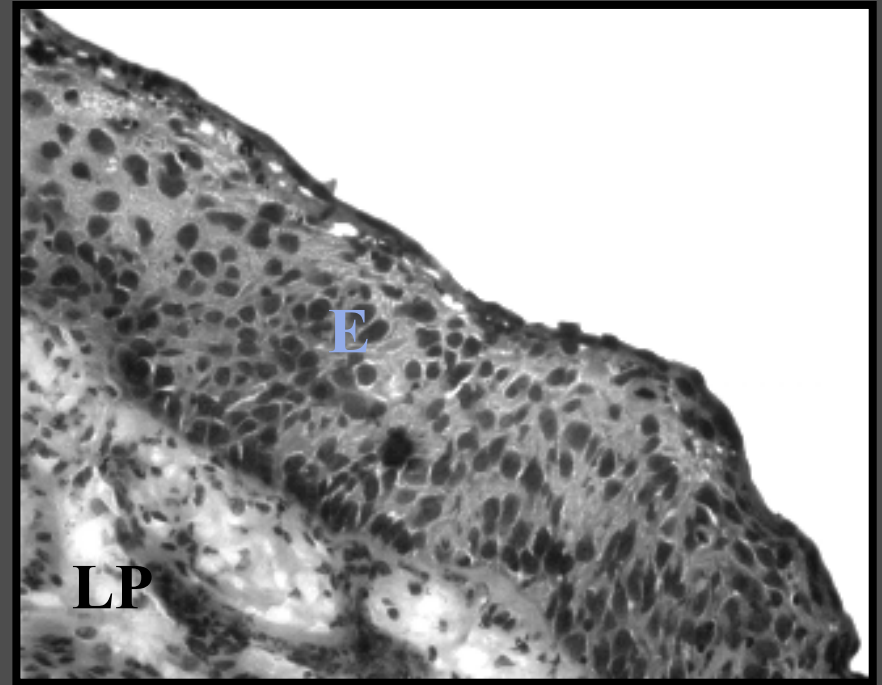
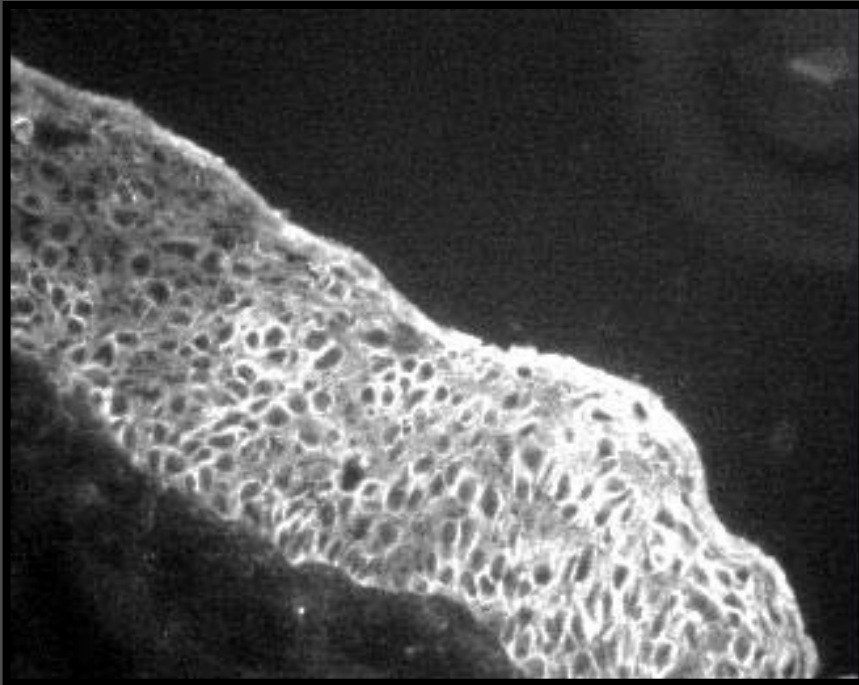
# Fluorescence and standard image of cervical intraepithelial neoplasia

White light

Fluorescence

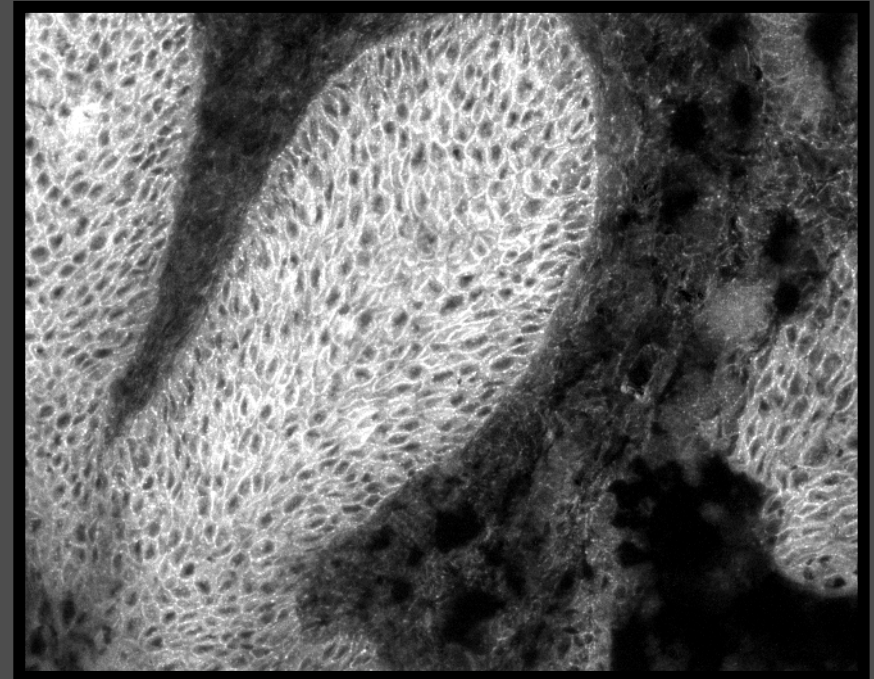
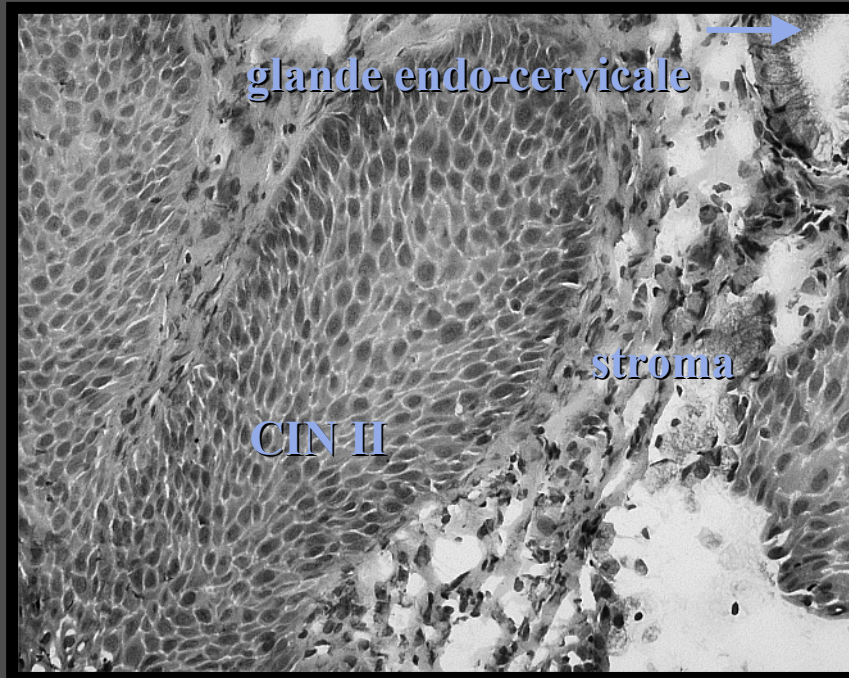


*CIN III x20 (exocol), HAL 0,5%, 75 min  
application*



**E- epithelium, LP-lamina propria**

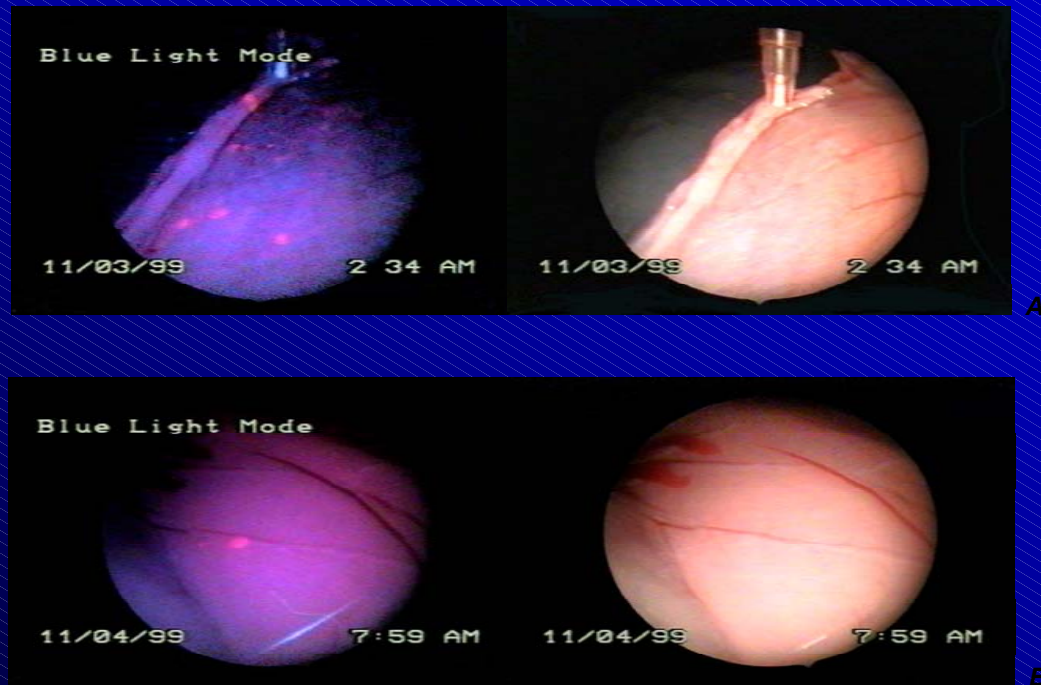
*CIN II x 20 (exocol), HAL 0,5%, 180 min  
application*



# Explorative projects

- ovarian cancer

## Epithelial ovarian cancer PDD in NuTu-19 rat model



8mM h-ALA IP prior to photodetection 2 hours later

# Explorative projects

## – colon cancer

- Second leading cause of cancer death
- 270.000 new patients (1990/94) EU+US
- 140.000 deaths
- Screening recommended age 40-50
- High risk patients (ulcerous colitis, family)



# We will continue to deliver

## – milestones for the next twelve months

### ■ Metvix®

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

### ■ Hexvix®

- Swedish marketing approval
- File marketing application (Mutual Recognition Procedure) in the EU
- Start clinical studies for treatment of bladder cancer

### ■ Benzvix®

- Complete ongoing clinical studies – initiate new studies

### ■ PCI Biotech AS

- First product on the research market



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# Financial Statements



# Financial Statements

## – Profit & Loss (group)

Three months ended		All figures in NOK 1,000	Six months ended		2002
30/06/2003	30/06/2002		30/06/2003	30/06/2002	01.01-31.12
24,285	4,594	Sales revenues	34,710	8,291	25,222
1,045	6	Other operating revenues	2,090	130	3,486
<b>25,330</b>	<b>4,601</b>	<b>Total operating revenues</b>	<b>36,800</b>	<b>8,422</b>	<b>28,708</b>
1,634	536	Cost of products sold	5,464	606	5,832
5,383	1,028	Payroll expenses	12,725	4,874	18,796
4,299	21,821	External R&D costs	18,518	45,356	77,300
423	312	Ordinary depreciation	860	545	1,269
9,739	10,348	Other operating expenses	18,229	19,249	35,039
<b>21,478</b>	<b>34,045</b>	<b>Total operating expenses</b>	<b>55,796</b>	<b>70,630</b>	<b>138,235</b>
<b>3,852</b>	<b>-29,444</b>	<b>Operating income/-loss</b>	<b>-18,996</b>	<b>-62,208</b>	<b>-109,527</b>
<b>3,710</b>	<b>2,275</b>	<b>Net financial income</b>	<b>8,080</b>	<b>5,529</b>	<b>13,521</b>
7,561	-27,169	Income/-loss before tax	-10,917	-56,678	-96,006
-	-	Tax expenses	-	-	-
<b>7,561</b>	<b>-27,169</b>	<b>Net income/-loss for the period</b>	<b>-10,917</b>	<b>-56,678</b>	<b>-96,006</b>
-157	-235	Of this minority interests	-230	-548	-906
0.43	-1.56	Earnings/-loss per share (NOK)	-0.63	-3.26	-5.51



# Financial Statements

## - Balance Sheet (group)

Figures in NOK 1,000	30.06.03	30.06.02	31.12.02
Fixed assets	11,815	11,413	12,421
Inventory	26,147	19,400	26,132
Receivables	16,734	4,781	10,950
Securities	181,949	221,229	215,414
Cash and bank deposits	31,278	83,930	34,089
<b>Total assets</b>	<b>267,924</b>	<b>340,752</b>	<b>299,006</b>
Shareholders' equity	161,651	206,212	166,999
Long term liabilities	17,661	17,524	17,879
Current liabilities	88,612	117,016	114,127
<b>Total shareholders' capital &amp; liabilities</b>	<b>267,924</b>	<b>340,752</b>	<b>299,006</b>



# Financial Statements

## - Cash Flow Statement (group)

	Six months ended		2002
	30.06.03	30.06.02	01.01-31.12
Loss before taxes	-10,917	-56,678	-96,006
Other operational items	-30,425	61,330	45,100
<b>Net Cash Flow from Operations</b>	<b>-41,341</b>	<b>4,652</b>	<b>-50,906</b>
Cash Flow from Investing	-101	-8,022	-8,906
Cash Flow from Financing	5,167	3,350	4,137
<b>Net Change in Cash &amp; cash equivalents</b>	<b>-36,276</b>	<b>-20</b>	<b>-55,675</b>
Cash & cash equivalents at beginning of period	249,503	305,178	305,178
<b>Cash &amp; cash equivalents at end of period</b>	<b>213,227</b>	<b>305,158</b>	<b>249,503</b>

