

# **PhotoCure ASA**

## **Presentation**

### **Results 1 Quarter 2004**

**7<sup>th</sup> of May 2004**



# Progress towards sustained profitability

## Continued product roll out

### ■ Metvix<sup>®</sup>

- European sales continue to grow
- Final US approval for Actinic Keratosis expected during 2Q 2004
- Patient enrollment in Tx study completed

### ■ Hexvix<sup>®</sup>

- Approval expected during 2004
  - Pharmacokinetic study initiated – to be completed next month
- Pre-launch activities ongoing
  - Exhibited at Annual Urology Congress in Vienna
  - First phase III study published in Journal of Urology



# Metvix<sup>®</sup> roll out continues



# Metvix<sup>®</sup>

– quick and easy treatment

*Lesion preparation*



*Metvix<sup>®</sup> application*



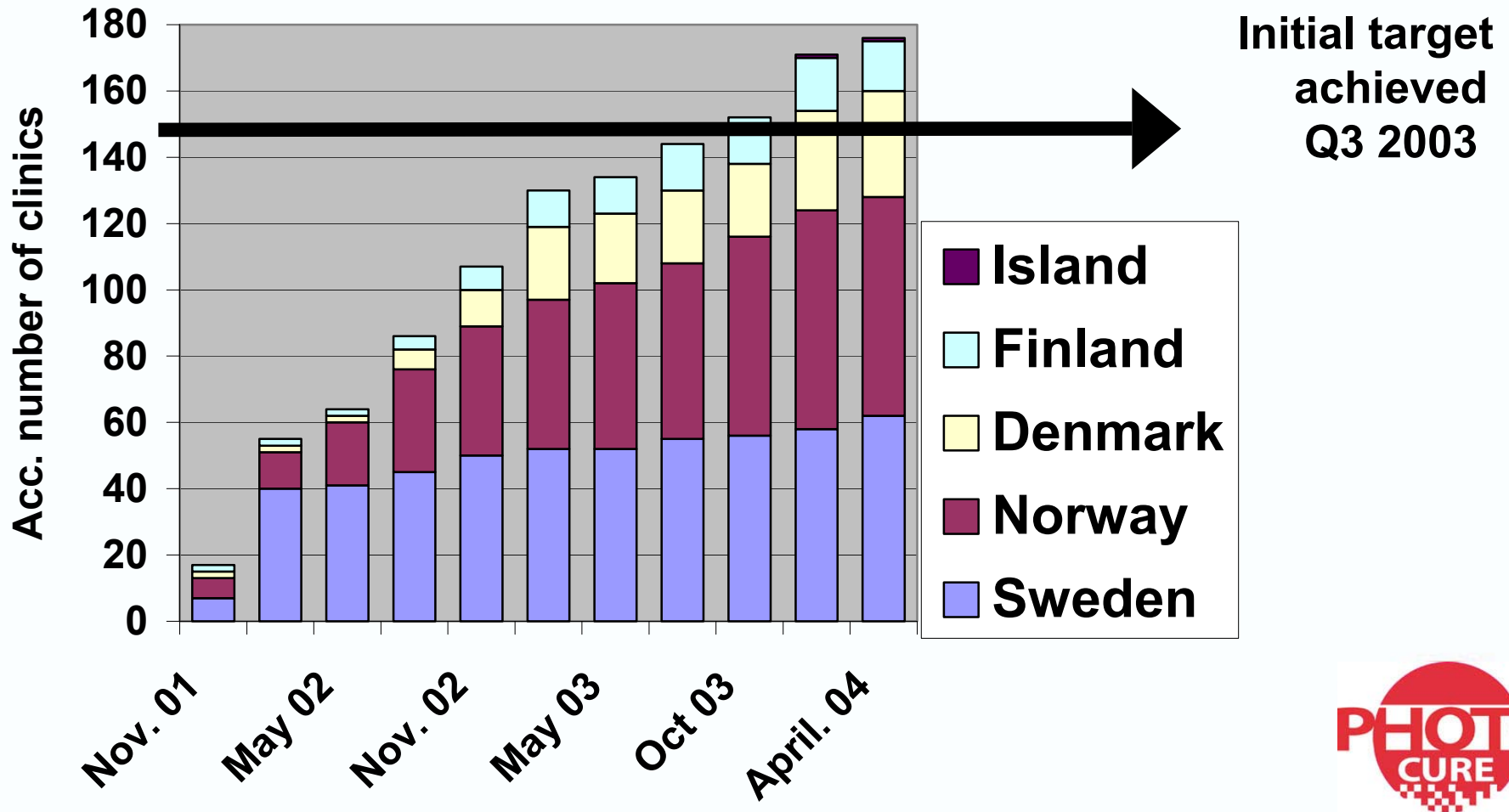
*Red light illumination*



# Metvix<sup>®</sup>

– continued increase in clinics providing Metvix

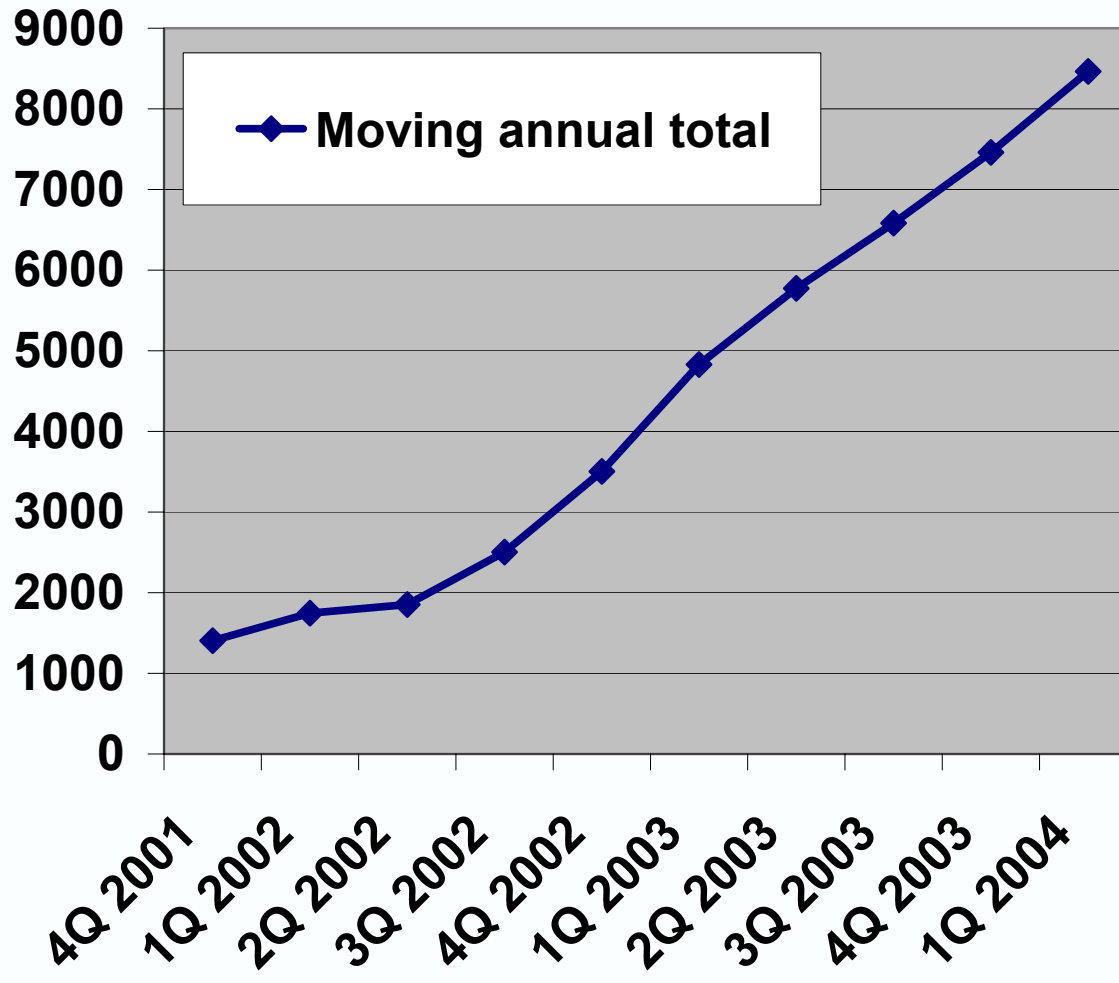
## Clinics with PhotoCure lamps



**Metvix®**

– continued increase in sales in the Nordic area

## Number of tubes sold to pharmacies



# Metvix®

## – expanding the commercial potential

- Approved in 19 countries - Hungary latest approval
- Pending applications in 6 countries
- Approvable letter for AK from US FDA
  - Final approval expected during second quarter
- NDA filed for BCC indication in the US – February 2003
  - Non approval from the FDA – December 2003
  - Communications with FDA regarding approvability ongoing
  - Amendment in the process of being filed
- Skin cancer and AK in immune suppressed organ transplant patients
  - Galderma and PhotoCure are jointly performing new trial – patient enrollment completed



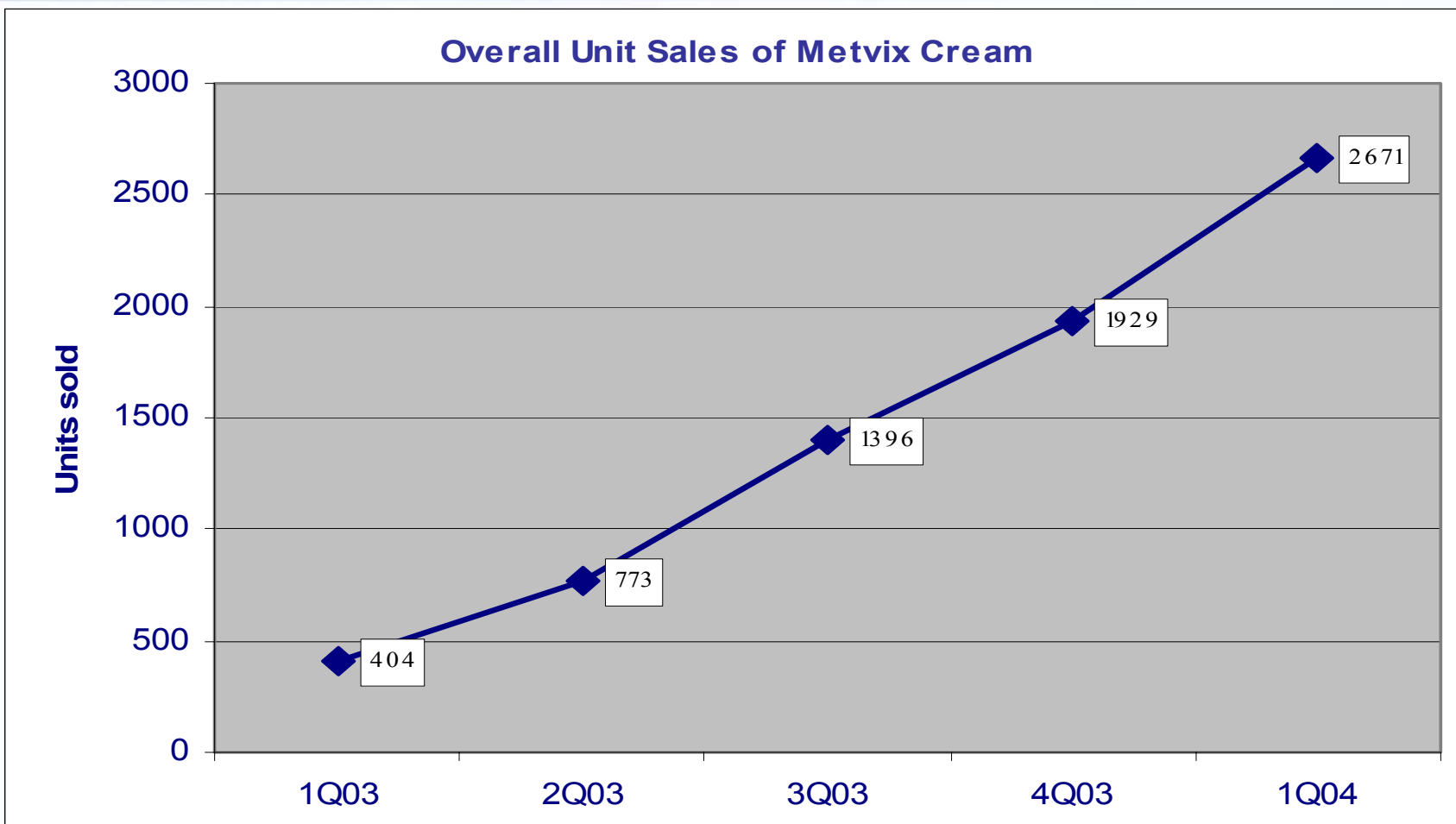
## – international roll out by Galderma



- Launch initiated in Germany, UK and New Zealand in 2003
  - Initial sales ongoing in Switzerland
  
- Launch preparations ongoing
  - Launch in Italy, Spain, Belgium, Australia and Switzerland during 2004
  
- Continue to file new marketing authorisation applications
  - Filed in South Africa, Czech Republic, Slovenia, Brazil and Mexico
  - Galderma plans to file in other countries that recently joined EU as well as in Argentina during 2004
  - PhotoCure will file in Netherlands and Portugal during 2004



– continued increase in sales in Galderma's area



# 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**

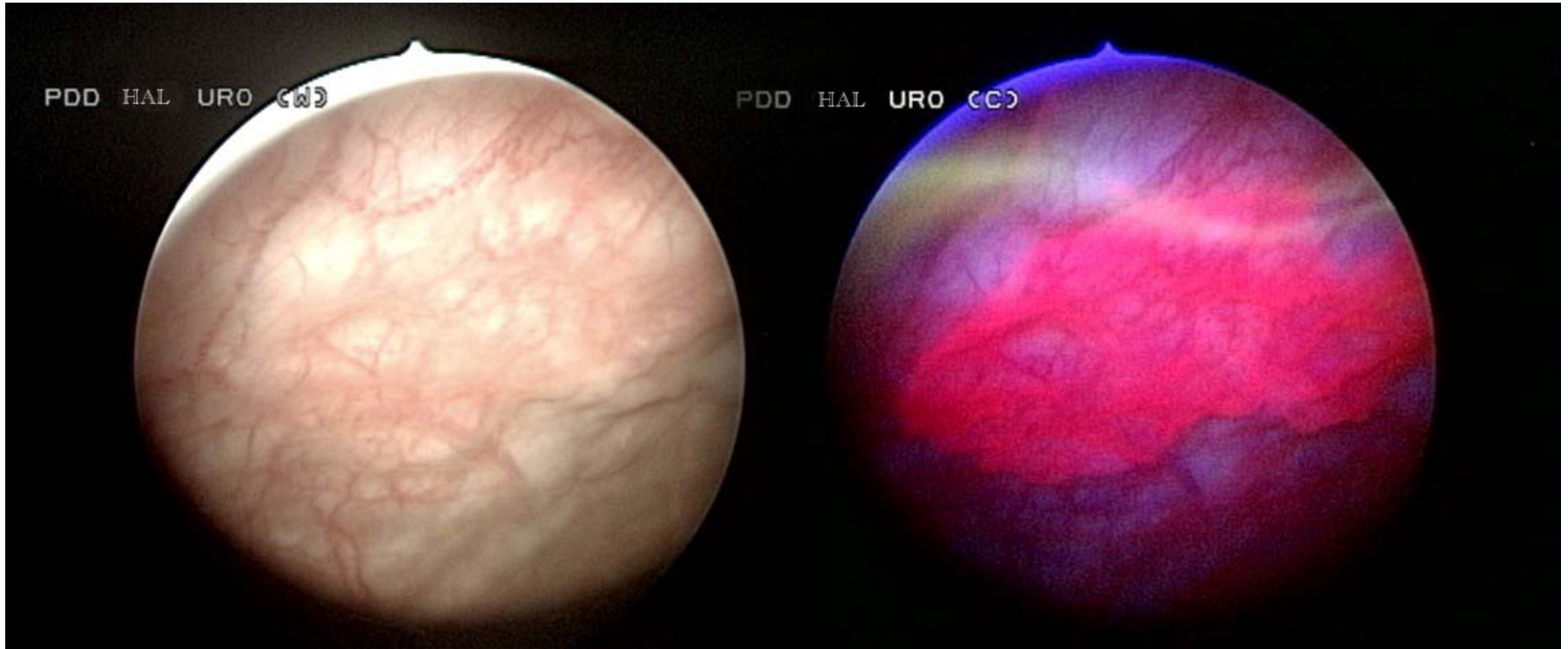
Hexvix® solution

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



# Hexvix®

– CIS detected with Hexvix® only



**Hexvix<sup>®</sup>**

**– excellent results in phase III studies on CIS**

Study	No. pts. included	No. (%) Pts with CIS	Hexvix increment (%)
301	211	79 (37%)	27%
302	196	53 (27%)	20%
303	146	29 (20%)	16%
<b>TOTAL</b>	<b>553</b>	<b>161 (29%)</b>	<b>23%</b>



# Hexvix®

– excellent results in phase III studies on papillary tumors

Study	No. pts. included	No. (%) pts with Ta/T1	Pts. (%) with more Ta/T1
301	211	155 (73%)	38 (25%)
302	196	116 (59%)	34 (29%)
303	146	74 (51%)	15 (20%)
TOTAL	553	345 (62%)	87 (25%)

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



# Hexvix®

## – closer to approval

### ■ Europe

- Clinical phase III studies completed with positive results
- Marketing application for EU filed Dec. 2002 in Sweden
  - Clinical efficacy demonstrated
  - Pharmacokinetic study initiated
  - Approval expected 2004

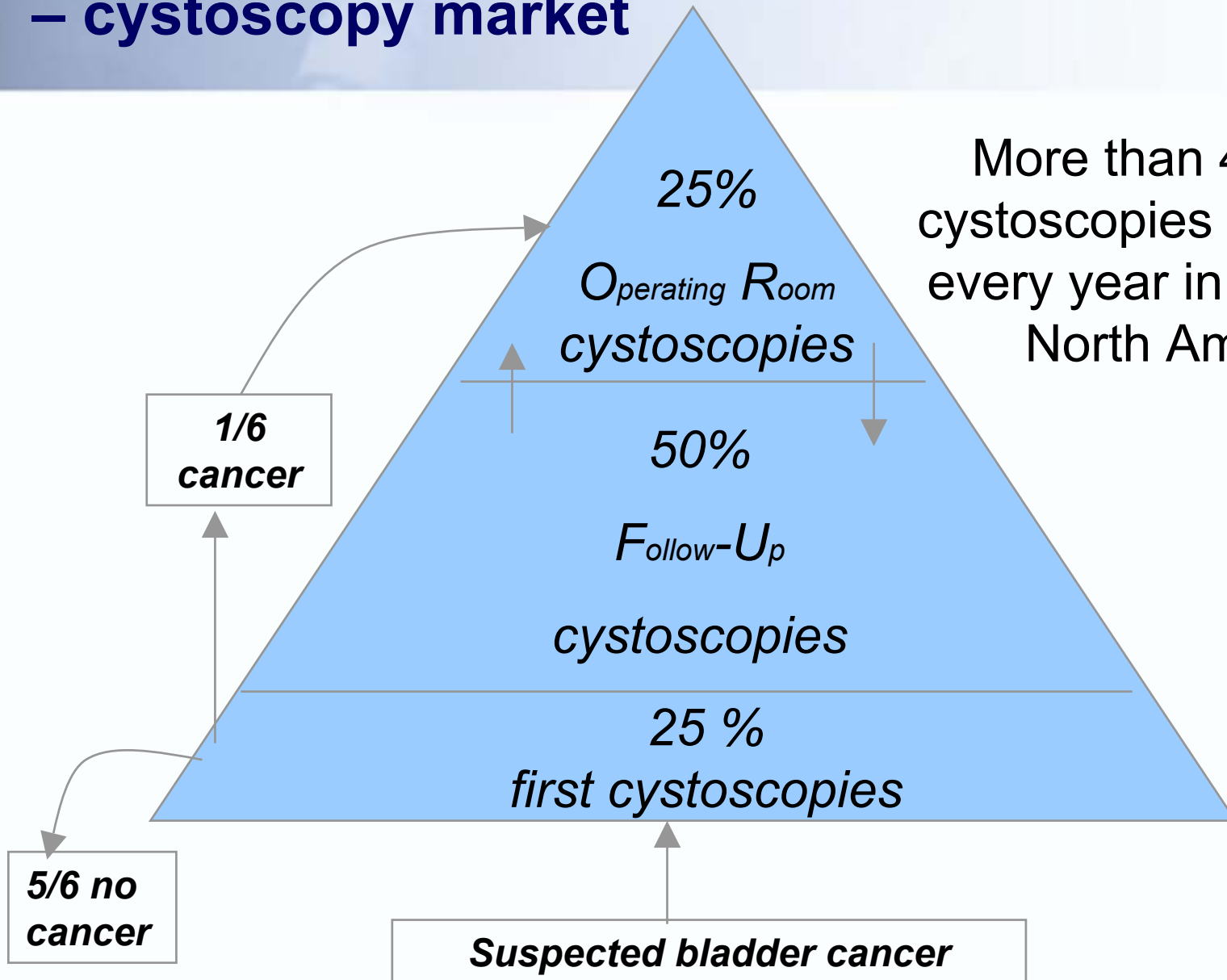
### ■ USA

- Investigational New Drug status obtained
- Agreed final clinical development plan with FDA
- Phase III studies on-going



# Hexvix® – cystoscopy market

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





# Hexvix®

## – pre-Launch activities underway

- Marketing collaboration with Karl Storz and other device manufactures
- Market research study completed
- Price and reimbursement preparations ongoing
- Clinical data accepted for publications in major urology journals and continued presentations at major scientific meetings
- Established off-license use at several key clinics in Europe
- Out-licensing activities in progress
  - PhotoCure will retain the Nordic area as with Metvix®



# Financial Statements (Group)



# Profit & Loss

Three months ended			2003	2002
31.03.04	31.03.03	All figures in NOK 1,000	01.01-31.12	01.01-31.12
14 087	10 425	Sales and milestone revenues	55 154	25 222
1 263	1 045	Other operating revenues	5 150	3 486
<b>15 350</b>	<b>11 470</b>	<b>Total operating revenues</b>	<b>60 304</b>	<b>28 709</b>
3 999	3 830	Cost of products sold	9 514	5 832
8 077	7 343	Payroll expenses	27 757	18 796
6 478	14 219	External R&D	38 377	77 300
389	437	Ordinary depreciation	1 677	1 269
13 160	8 490	Other operating expenses	36 635	35 039
<b>32 102</b>	<b>34 318</b>	<b>Total operating expenses</b>	<b>113 959</b>	<b>138 235</b>
<b>-16 752</b>	<b>-22 848</b>	<b>Operating loss</b>	<b>-53 655</b>	<b>-109 526</b>
<b>538</b>	<b>4 370</b>	<b>Net financial income</b>	<b>10 888</b>	<b>13 521</b>
-16 214	-18 478	Income/-loss before tax	-42 767	-96 005
-	-	Tax expenses	-	-
<b>-16 214</b>	<b>-18 478</b>	<b>Net income/-loss for the period</b>	<b>-42 767</b>	<b>-96 005</b>
-112	-72	Of this minority interests	-441	-906
-0.92	-1.06	Net income/-loss per share (NOK)	-2.44	-5.51



# Balance Sheet

<b>Figures in NOK 1,000</b>	<b>31.03.04</b>	<b>31.03.03</b>	<b>31.12.03</b>
Machinery & equipment	2,850	4,315	3,222
Financial fixed assets	8,013	7,850	7,832
Inventory	22,309	26,431	23,167
Receivables	16,337	17,208	13,335
Securities	147,336	197,687	170,309
Cash & cash equivalents	16,201	17,870	15,536
<b>Total assets</b>	<b>213,046</b>	<b>271,361</b>	<b>233,402</b>
Shareholders' equity	115,922	148,722	131,897
Long term liabilities	13,519	17,941	13,519
Current liabilities	83,606	104,698	87,985
<b>Total shareholders' capital &amp; liabilities</b>	<b>213,046</b>	<b>271,361</b>	<b>233,402</b>



# Cash Flow Statement

All amounts in NOK 1000

	Three months ended		2003
	31.03.04	31.03.03	01.01 - 31.12.
Loss before taxes	-16,214	-18,478	-42,767
Other operational items	-6,274	-15,458	-27,740
<b>Net cash flow from operations</b>	<b>-22,487</b>	<b>-33,936</b>	<b>-70,507</b>
Cash flow from investments	-17	-10	-1,426
Cash flow from capital transactions	197	0	8,275
<b>Net change in cash during the period</b>	<b>-22,308</b>	<b>-33,946</b>	<b>-63,658</b>
Cash & cash equivalents at beginning of period	185,845	249,503	249,503
<b>Cash &amp; cash equivalents at end of period</b>	<b>163,537</b>	<b>215,557</b>	<b>185,845</b>



# Future prospects

## ■ Metvix<sup>®</sup>

- Sales growth in existing markets
- New launches
- New approvals - Final US approval for Actinic Keratosis expected during 2Q 2004

## ■ Hexvix<sup>®</sup>

- First marketing approval in Sweden during 2004
- Marketing authorisation applications in Europe and US
- Product launches

## ■ Research and development

- Metvix proved in other dermatology indications
- Develop new products in oncology

