Brilliance in photodynamic technology ™

# Photocure ASA

## First quarter 2009

April 29th, 2009

Kjetil Hestdal, President & CEO and Christian Fekete, CFO

# Highlights first quarter 2009

**Sales revenue increased by 36 % to NOK 29.1 million (21.4)**

**Operating profit of NOK -5.7 million (-22.5), an improvement of NOK 16.7 million**

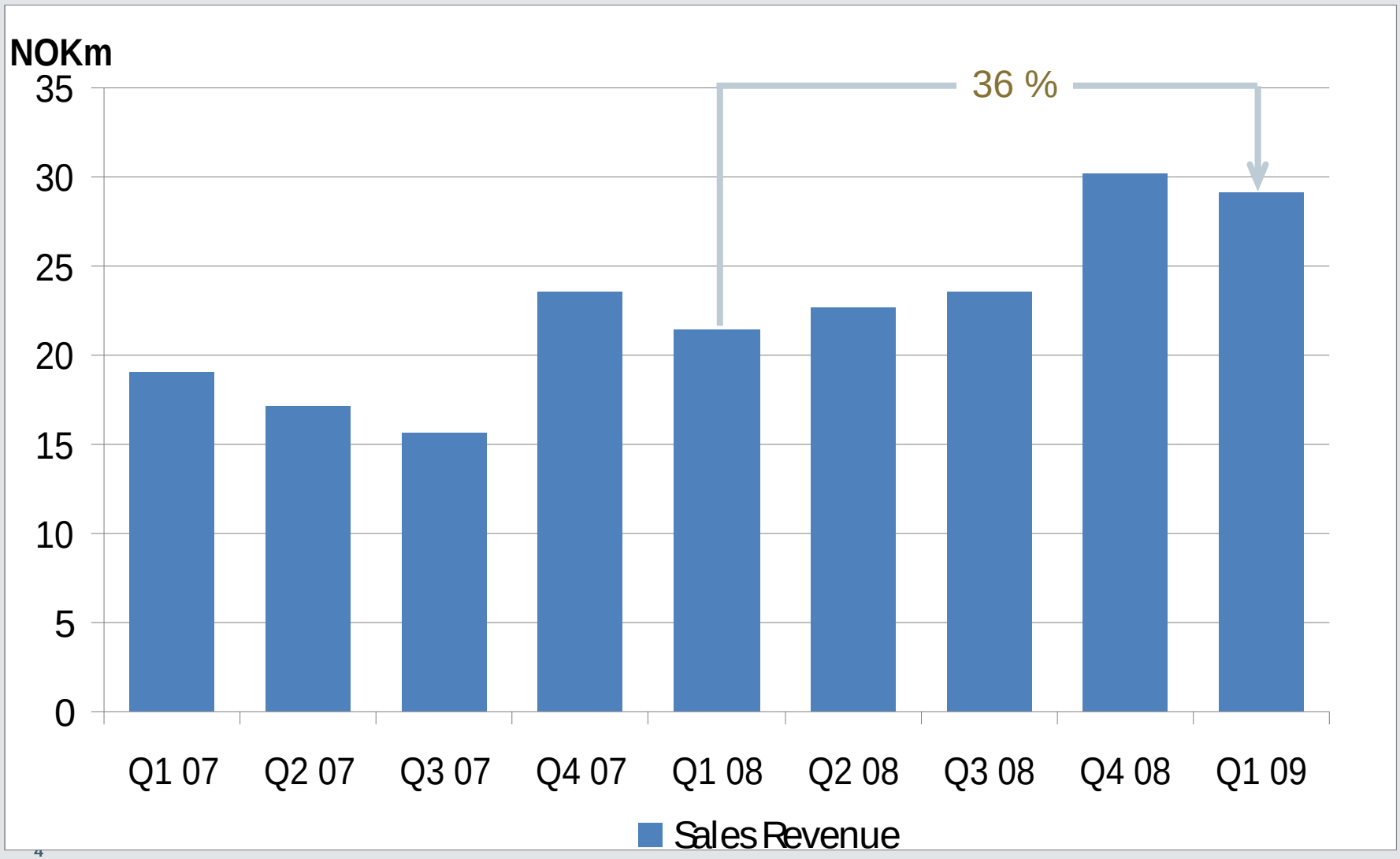
**Progress in R&D**

- Visonac™ - Completed meetings with FDA and EU regulatory agencies
- Cevira™ - Started phase I/II proof-of-concept study in CIN I patients
- Lumacan™ - Started phase I/II proof-of-concept study with oral formulation for detection of colon cancer

**Strengthened the patent protection for Metvixia™ in the USA**

# Financial statements

# 36 % increase in sales revenue



# Profit & Loss

- Sales revenue growing 36%
- Increased margin to 84%
- Reduced losses
  - Lower R&D expenses due to few ongoing clinical trials
  - Marketing & Sales expenses at 2008 level
- Write-down of NOK 4.2 million related to the shares in PCI Biotech Holding ASA

| *Numbers in NOK thousand (unaudited)* | Q1 09 | Q1 08 | FY 2008 | FY 2007 |
|---|---|---|---|---|
| Sales revenue | 29 073 | 21 411 | 100 917 | 75 252 |
| Signing fee & milestone revenues | 0 | 1 303 | 1 303 | 23 754 |
| **Total revenues** | **29 073** | **22 713** | **102 220** | **99 006** |
| Cost of products sold | -4 529 | -4 501 | -19 074 | -17 326 |
| **Gross profit** | **24 545** | **18 212** | **83 147** | **81 679** |
| Other income | 562 | 1 954 | 6 257 | 7 625 |
| Indirect manufacturing expenses | -2 688 | -2 510 | -8 607 | -8 512 |
| R&D expenses | -11 688 | -20 979 | -84 303 | -112 098 |
| Marketing & sales expenses | -12 612 | -12 009 | -45 916 | -39 766 |
| G&A expenses | -3 874 | -7 140 | -17 951 | -16 378 |
| **Operating profit/ loss (EBIT)** | **-5 734** | **-22 473** | **-67 374** | **-87 450** |
| Net financial items | -2 877 | 2 449 | 2 991 | 12 480 |
| **Profit/ loss before tax (EBT)** | **-8 611** | **-20 024** | **-64 382** | **-74 970** |
| Tax expenses | 0 | 0 | 0 | 0 |
| **Net profit/ loss** | **-8 611** | **-20 024** | **-64 328** | **-74 970** |

# Segment information – Q1 2009

| *(unaudited)* | Q1 2009 | | | | | Q1 2008 | | | |
|---|---|---|---|---|---|---|---|---|---|
| *Numbers in NOK thousand* | **Own** | **Partner** | **R&D*** | **Total** | ***% vs. 08*** | **Own** | **Partner** | **R&D*** | **Total** |
| Sales revenue Metvix/ Aktilite | 8 081 | 11 323 | | 19 404 | *38 %* | 5 640 | 8 450 | | 14 090 |
| Sales revenue Hexvix | 3 818 | 5 851 | | 9 669 | *32 %* | 2 233 | 5 088 | | 7 321 |
| **Total sales revenues** | **11 899** | **17 174** | | **29 073** | ***36 %*** | **7 872** | **13 538** | | **21 411** |
| Milestone revenue | 0 | 0 | | 0 | | 0 | 1 303 | | 1 303 |
| **Total revenues** | **11 899** | **17 174** | | **29 073** | ***28 %*** | **7 872** | **14 841** | | **22 713** |
| Cost of goods sold | -571 | -3 957 | | -4 529 | *1 %* | -581 | -3 920 | | -4 501 |
| **Gross profit** | **11 328** | **13 217** | | **24 545** | ***35 %*** | **7 292** | **10 921** | | **18 212** |
| Gross profit (ex milestones) | 95% | 77% | | 84% | | 93% | 74% | | 80% |
| Operating expenses | -10 740 | -4 560 | -14 979 | -30 279 | *-26 %* | -10 620 | -6 107 | -23 958 | -40 685 |
| **Operating profit** | **587** | **8 657** | **-14 979** | **-5 734** | ***-74 %*** | **-3 328** | **4 814** | **-23 958** | **-22 473** |
| Net finance | 0 | 0 | 0 | -2 877 | *NA* | 0 | 0 | 0 | 2 449 |
| **Profit before tax** | **587** | **8 657** | **-14 979** | **-8 611** | ***-57 %*** | **-3 328** | **4 818** | **-23 958** | **-20 024** |
| ** Including share of general & administrative expenses* | | | | | | | | | |

# Balance sheet - assets

- Shares in PCI Biotech Holding ASA written down by NOK 4.2 million in Q1 to NOK 7.3 million
- Cash and cash equivalents of NOK 161.9 million

| *Numbers in NOK thousand (unaudited)* | 31.3.2009 | 31.12. 2008 |
|---|---|---|
| **Non-current assets** | | |
| Intangible assets, software | 511 | 534 |
| Machinery & Equipment | 3 721 | 3 939 |
| Other investments | 7 336 | 11 528 |
| **Total non-current assets** | **11 568** | **16 001** |
| | | |
| **Current assets** | | |
| Inventory | 18 621 | 12 792 |
| Receivables | 29 924 | 29 158 |
| Cash & cash equivalents | 161 872 | 179 897 |
| **Total current assets** | **210 418** | **221 846** |
| | | |
| **Total assets** | **221 986** | **237 847** |

# Balance sheet - equity & liabilities

- NOK 192.0 million in shareholder's equity
- No interest bearing debt

| *Numbers in NOK thousand (unaudited)* | 31.3.2009 | 31.12.2008 |
|---|---|---|
| Paid-in capital | 11 047 | 11 047 |
| Other paid-in capital | 189 562 | 15 467 |
| Retained earnings | -8 611 | 173 181 |
| **Shareholders' equity** | **191 997** | **199 694** |
| | | |
| | | |
| **Total equity** | **191 997** | **199 694** |
| | | |
| Current liabilities | 29 989 | 38 153 |
| **Total liabilities** | **29 989** | **38 153** |
| | | |
| **Total equity and liabilities** | **221 986** | **237 847** |

# Cash Flow

- NOK –18.0 million in Net change in cash during Q1.
- Other operational items include:
  - Inventory incr. MNOK -5.8
  - Reduced ST debt MNOK -8.6
  - PCI write-down MNOK 4.2

| *Numbers in NOK thousand (unaudited)* | Q1 2009 | FY 2008 |
|---|---|---|
| Income/ loss before tax | -8 611 | -64 382 |
| Other operational items | -11 766 | 4 704 |
| **Net cash flow from operations** | **-20 378** | **-59 677** |
| | | |
| **Cash flow from investments** | **2 353** | **-12 865** |
| | | |
| **Cash flow from capital transactions** | **0** | **-13** |
| | | |
| **Net change in cash during the period** | **-18 025** | **-72 555** |
| | | |
| Cash & cash equivalents beginning of period | 179 897 | 252 452 |
| | | |
| **Cash & cash equivalents beginning end period** | **161 872** | **179 897** |

# Financial Summary – Q1 2009

- Sales revenues growing 36 % to NOK 29.1 million
- Margin improved to 84%
- Lower R&D expenses due to few ongoing clinical trials
- Marketing & Sales expenses at 2008 level
- Operating income improved by NOK 16.7 million
- Nordic operating profit of NOK 0.6 million
- NOK 161.9 million in cash

Brilliance in photodynamic technology ™

# Hexvix®
## - a breakthrough in bladder cancer diagnostics

# Hexvix® value proposition
## - the only licensed product of its type

- Enables doctors to carry out a more effective tumour removal
- Strong improvement compared to standard diagnostic procedures

| | Hexvix results |
|---|---|
| Detection of patients w/ bladder cancer | 30% more[1.] |
| Detection of patients w/ CIS lesions | 28% more[2.] |
| Detection of CIS lesions | 67% more |
| Recurrence - relative reduction | 22% [5.] |
| Patient management improvement | 1 in 5[3.] |
| Cost effective | Yes[4.] |

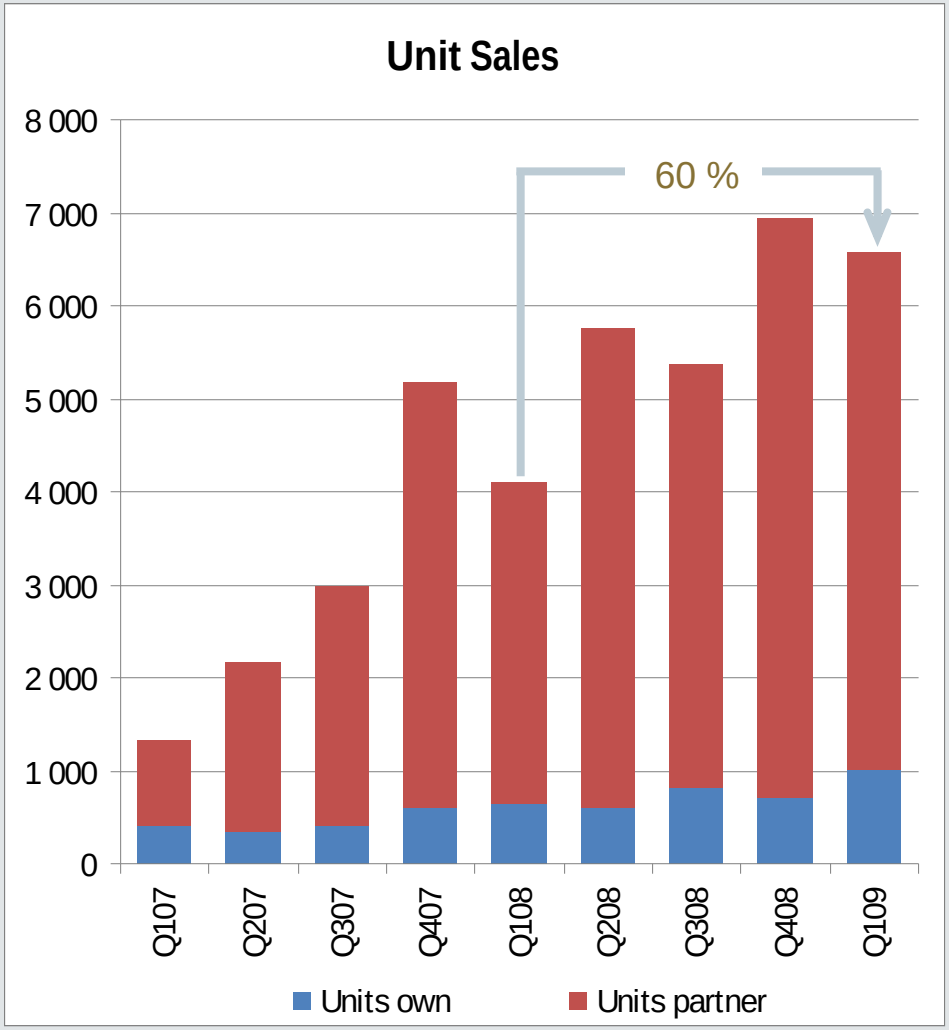
1. Jichlinski P et. al. J Urol, 2003;170:226-229
2. Scmidbauer J et. al. J Urol, 2004;171:135-138
3. Jocham D et. al. J Urol, 2005;174:862-866
4. Burger et. al. Eur J Urol, 2007;52:142-147
5. Publication in progress

# Hexvix
# - status first quarter 2009

- Excellent feedback from urologists at EAU, Stockholm
- Presented phase III clinical study in 766 patients with non-muscle invasive papillary tumors (Ta/T1)
  - Relative reduction in recurrence rate of 22 % (P=0.029)
  - More lesions detected in 17 % of patients (P=0.0005)

Representatives from GE Healthcare and Photocure receiving the award for best exhibition at EAU from Prof. Per-Anders Abrahamsson, President of EAU (right)

# Hexvix® key sales drivers




Key sales drivers:

- Urologists acceptance
- Equipment base
- Use at established centres
- Inflow of new centres
- Reimbursement
- Therapeutic area
- Geographical expansion

# Hexvix – roadmap

HEXVIX®
HEXAMINOLEVULINATE

- Increase public awareness
- Improve reimbursement procedures
- Perform clinical studies to increase therapeutic indication and scope, and to develop new treatment options for follow up-patients
- Secure US approval
    - Submission of NDA in Q3 2009

PHOTOCURE®

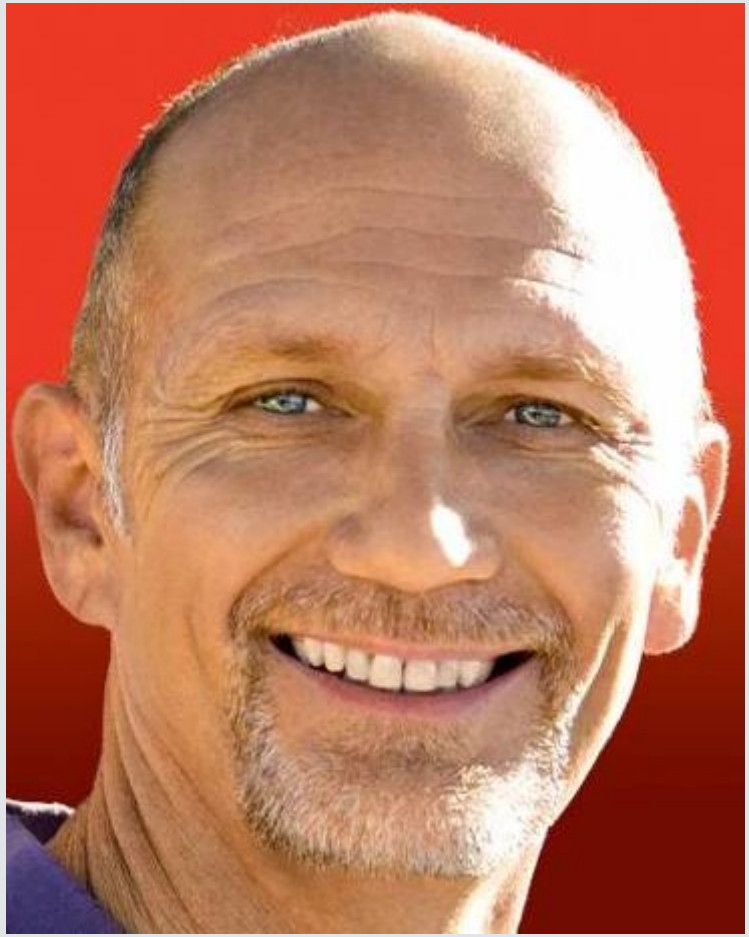
Brilliance in photodynamic technology ™

# Metvix® and Aktilite®

## - treatment of skin cancer without scarring

# Actinic keratosis and NMSC

- Actinic Keratosis (AK):
  - Overall prevalence 11-25%
  - 15 million diagnosed in EU/ US per year
- NMSC (Non Melanoma Skin Cancer):
  - Most common malignancies in the Caucasian population
  - > 1/3 of all adult cancers in the US
  - Incidence increased 3-8% per year worldwide since 1964



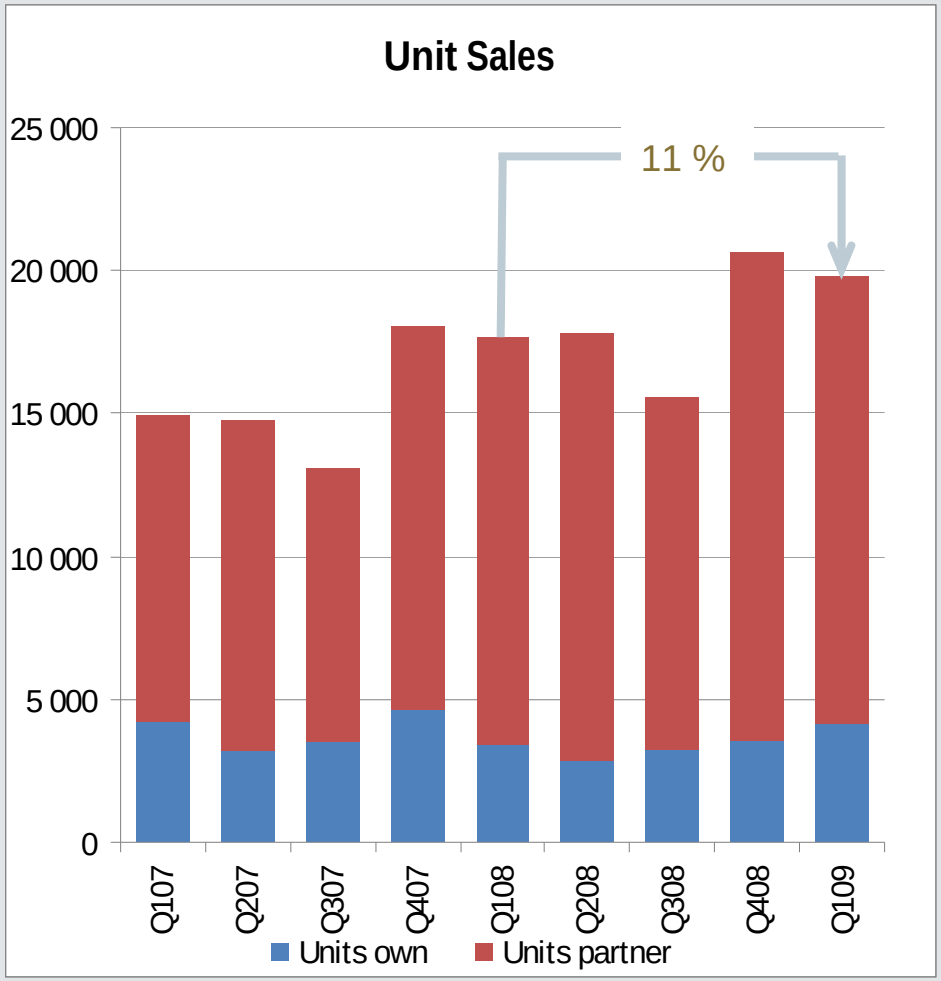
# Metvix® value proposition

## Precisely directed treatment without scarring

metvix
methyl aminolevulinate

- Approved for AK, BCC and Bowen's (BD)
- PDT recommended as first-line treatment for AK/BCC/BD in international guidelines
- Physician-controlled - 100% compliance
- Clinically effective
  - Limited & predictable side-effect profile
- Superior cosmetic outcome
  - Non-invasive - no scarring
  - Targeted and selective - reduced recovery
  - Can safely be repeated

# Metvix® key sales drivers

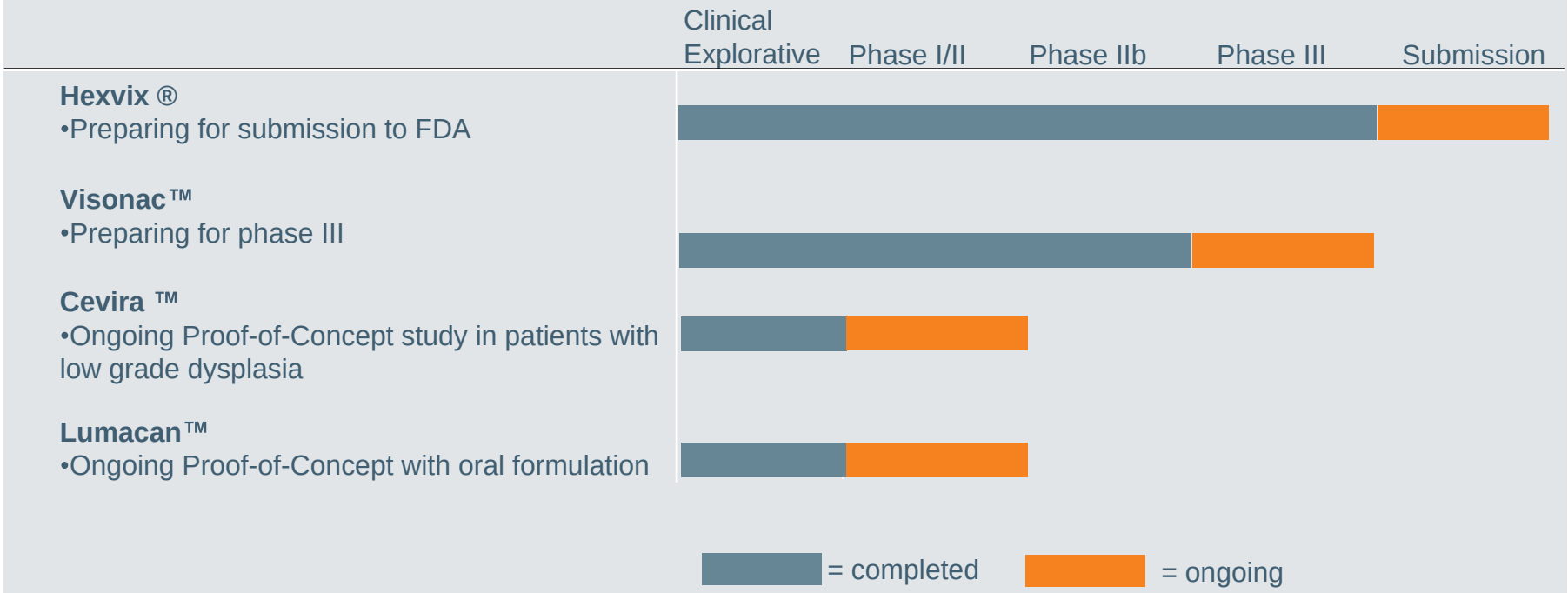



Key sales drivers:

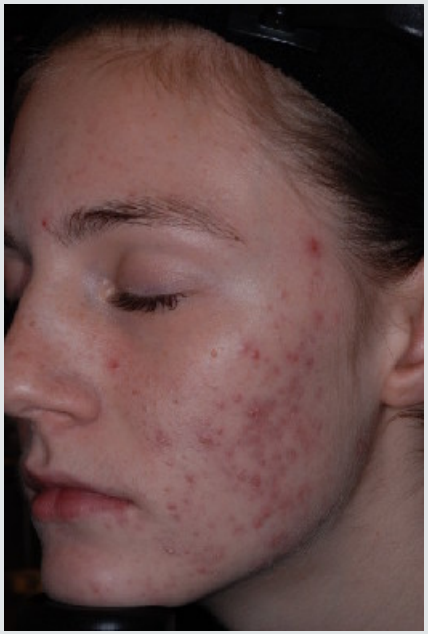
- Placement/ sale of Aktilite lamps
- Train doctors and nurses
- Use at established centres
- Dedicated sales force
- Reimbursement
- Therapeutic area
- Geographical expansion

# Research & Development

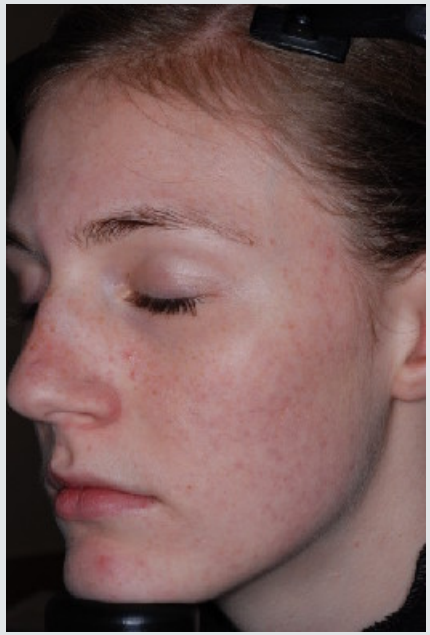
# Progress in the R&D programs



# Acne
## - need for new treatments



Acne patient before treatment



Acne patient after treatment

- US doctors annually register ~ 3 million visits concerning acne
- ~70% of these have moderate to severe acne
- Market for topical treatment of moderate to severe acne USD 1.3 billion per year
- Existing treatments have significant side effects
- Photocure has a patented technology in acne until 2018+, with new patents filed
- Visonac meets patient need for an effective treatment with limited side effects

# Visonac™ roadmap

## USA

Guidance meeting held with FDA in January 2009

- Positive feedback on Visonac™ documentation
- Discussions on the clinical development program
- Recommended that Photocure get additional clinical data on a patient population down to 9-12 years in combination with the acne lamp

## EUROPE

Guidance meeting held with EMEA in March 2009

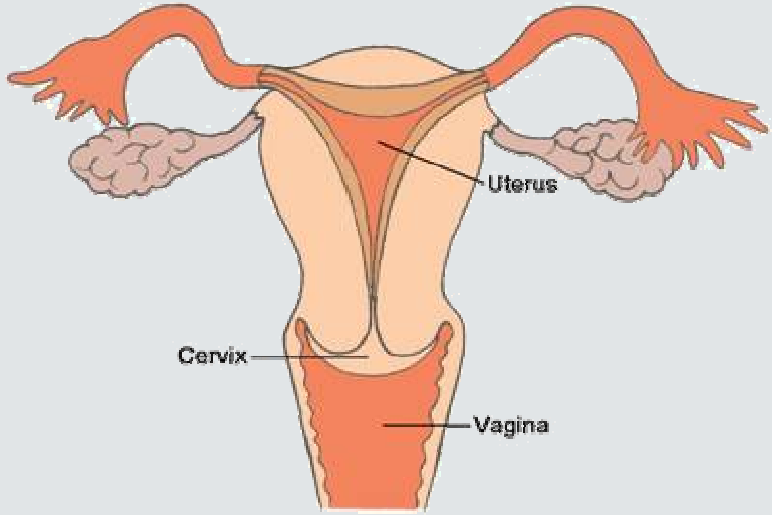
- Supported start of phase III based on existing data

- *Plan to seek additional scientific and regulatory advice in the EU*
- *Plan to start enrollment in phase II in the US in Q3 2009*
- *Plan to start phase III in EU/US in 2010*

# Cervix
## - clinical challenges

### Patients with mild lesions (CIN1)

- Poor diagnostic sensitivity (20-30% CIN2+)
- Positive HPV testing
- No standard therapy
- Patient anxiety
- Time-consuming and costly follow-ups
- Patients lost to follow up




### Patients with severe lesions (CIN2/3)

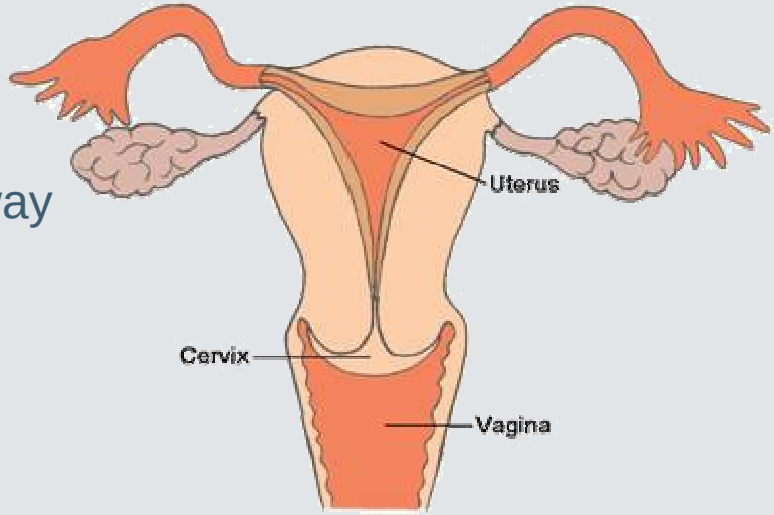
- Invasive surgery
- Requires local or general anaesthesia
- Risk of undesirable side effects (bleeding, stenosis, infection, preterm labour)

# Cevira™ roadmap

IND opened in 2008 in the US

Phase I/II study started in Q1 2009

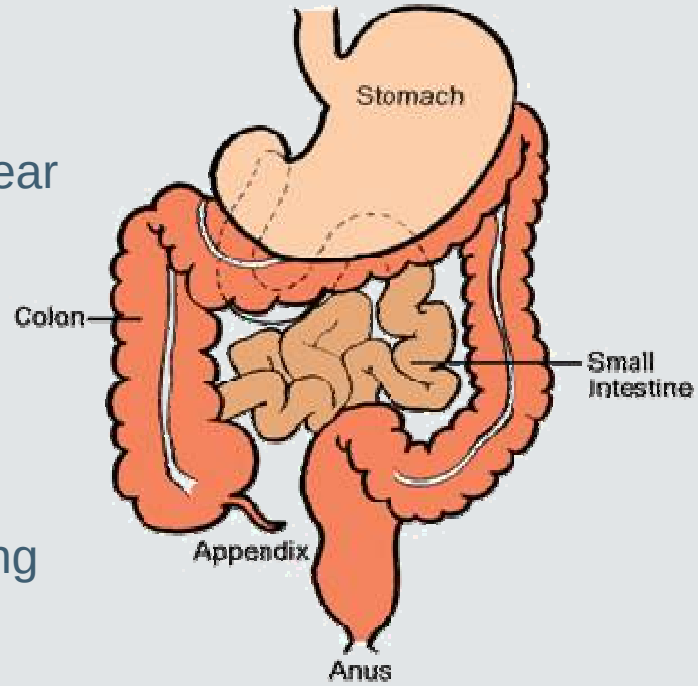
- Focus on CIN1
- 5 centres in France, Germany and Norway
- 6 months follow-up
- Primary endpoint: 6 months response
- 13 of 70 patients included per April 22nd
- Initial results in Q1 2010



# Colorectal cancer

## - growing health problem, among most lethal cancers

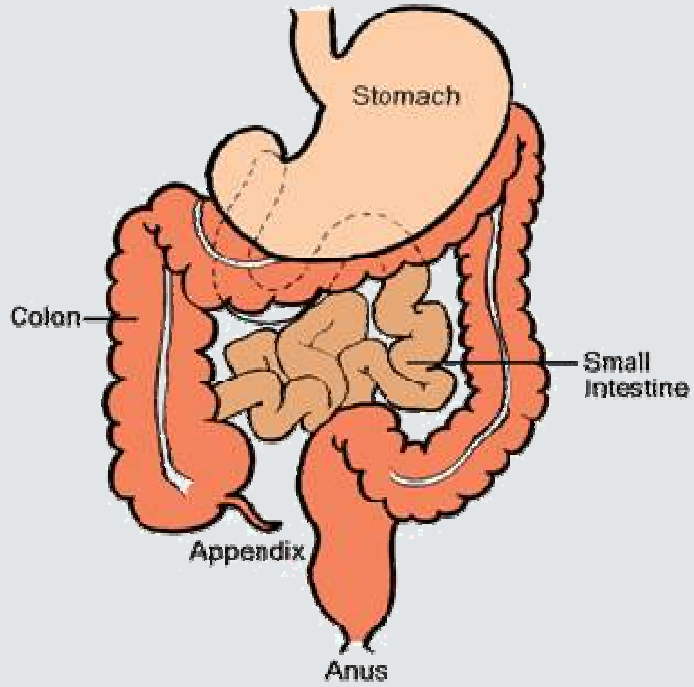
- Colorectal cancer - large and growing area
- Among the most lethal cancers
- > 500,000 cases diagnosed in US & EU per year
- Five years survival rate is 50 – 60%
- Colonoscopy screening may prevent up to 80% of deaths from Colorectal Cancer
- Use of colonoscopy is growing rapidly, and colorectal cancer screening programs are being rolled-out in many countries



# Lumacan™ value proposition

## Diagnosis of colorectal cancer

- Significant improvement of colorectal cancer diagnosis, based on established technology
- Strong intellectual property

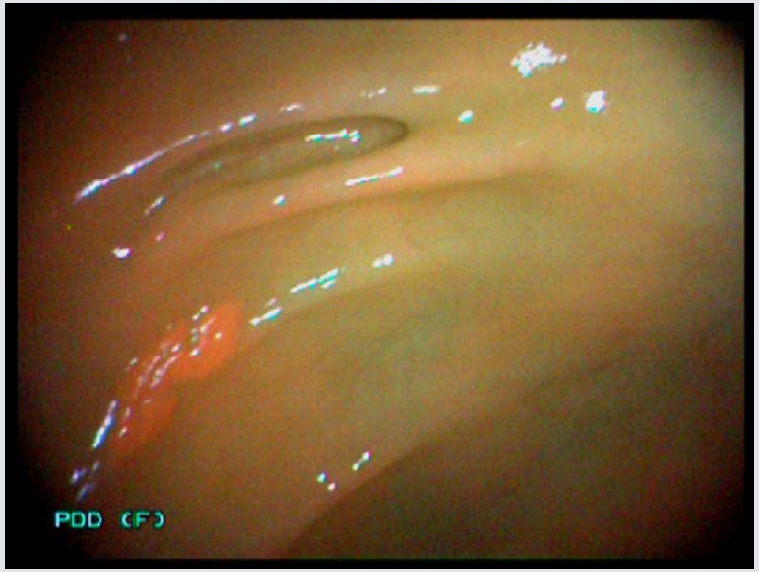


# Lumacan ™ roadmap

Started Phase I/II study in 2009

Proof-of-Concept with oral formulation:

- Open, dose-finding
- 4 centres in Germany and 50-70 patients
- Sponsored by Norwegian Research Council
- 6 of up to 70 patient included by April 22
- Planned completion in 2009
- The results will be available in Q1 2010




First PoC-study in Munich, Germany.
One flat lesion showing fluorescence in colon.
Courtesy: Prof. Dr. B. Mayinger

# Strategic goals

**Continue to grow Metvix/Aktilite**

- Support Galderma in strengthening Metvix/Aktilite in dermatology

**Continue to grow Hexvix**

- Support GE Healthcare in introducing Hexvix in EU
- Secure Hexvix approval in the US

**Capture value through licensing deals for Visonac™, Cevira™ and Lumacan™**