# PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

## RESULTS OF FIRST QUARTER 2015

6 MAY 2015

Kjetil Hestdal, MD, President & CEO
Erik Dahl, CFO

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# PROGRESS ON KEY OBJECTIVES

| KEY OBJECTIVES | 1Q2015 KEY ACHIEVEMENTS |
|---|---|
| • Hexvix/Cysview global in-market unit sales growth of ≥10% | • 10% growth in-market value to 51 MNOK<br>• 61% in-market unit growth in US<br>• Commercial franchise profitability of 4.2 MNOK |
| • Submit Special Protocol Assessment Request (SPAR) by mid-2015 | • Submitted in 1Q2015 |
| • Initiate Phase 3 clinical trial to expand the use of Hexvix/Cysview into the surveillance market and fulfill the US post marketing commitments in 2015 | • Progressed according to plan to start patient enrollment by end of 2015 |
| • Secure partnership for further development and commercialization of Visonac and Cevira reflecting the product potential | • Discussions continued with potential partners |

Improved financial performance (EBIT) with 6.5 million NOK



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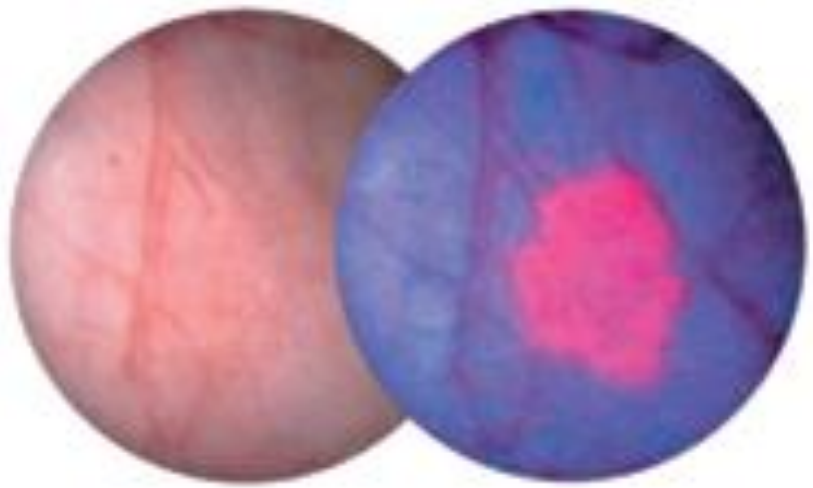
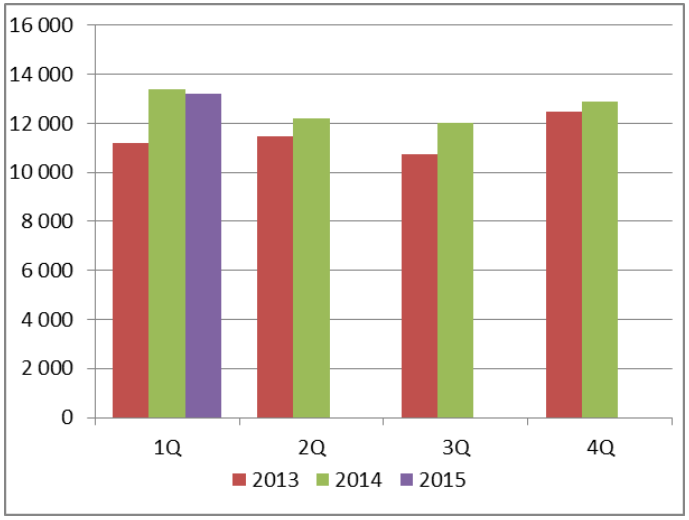
# *Commercial Update*

# HEXVIX/CYSVIEW
# A SIGNIFICANT GLOBAL SPECIALTY BRAND

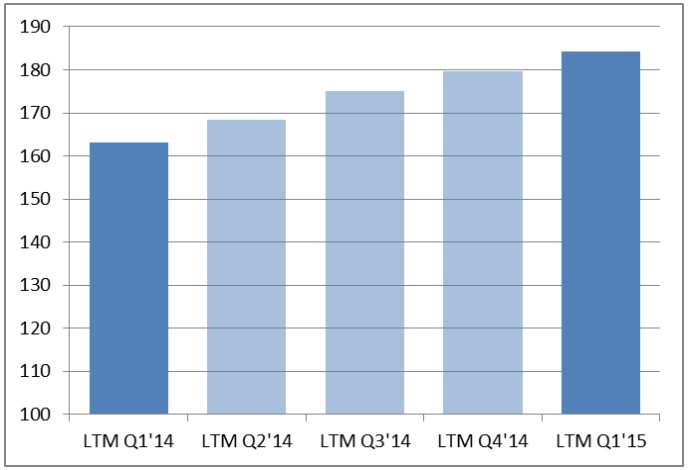
- Value of in-market sales of Hexvix/Cysview increased YoY 10% in the quarter to NOK 184 million LTM
- Hexvix/Cysview global in-market volume declined YoY 1% in the quarter, partly driven by purchases in advance of an April 2014 price increase in Germany
- Overall franchise operating profit in the quarter at NOK 4.2 million



**Global in-market unit sales (by Q)**



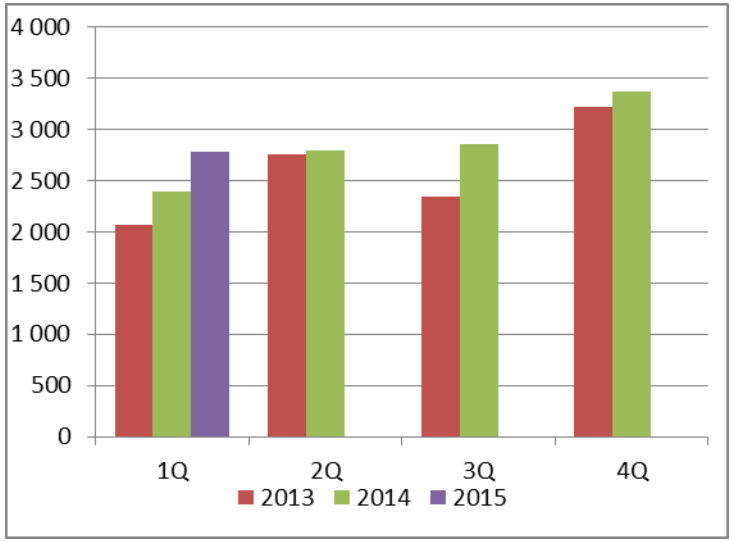

**Global in-market value NOK mill (LTM)**



# HEXVIX/CYSVIEW
# SOLID PERFORMANCE IN NORDICS AND USA

- Photocure own sales revenue in the US and Nordics increased 44% YoY in 1Q to NOK 12.8 million
- US revenue increased 116% YOY
  - Driven by in-market volume growth of 61%, price increases and Fx
  - Permanent Blue Light Cystoscope placements of 52 at the end of 1Q
  - Actively pursuing passage of bill to provide separate payment to hospitals for Cysview
- Nordic revenue in 1Q increased 22% YoY
  - In-market volume growth of 6%
  - Continued double digit in-market volume growth in Sweden

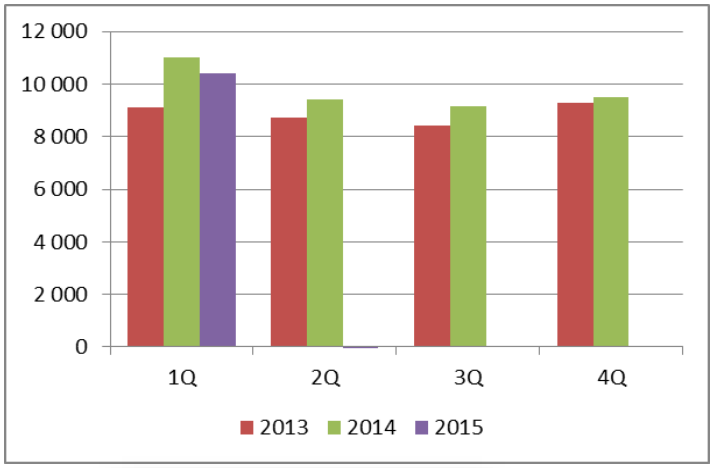
**Own Hexvix/Cysview in-market unit sales Nordic and US**

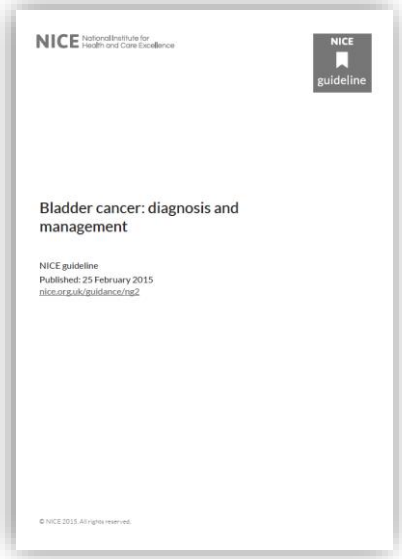


# HEXVIX/CYSVIEW PROGRESS IN EUROPE

- Partner revenue increased 33% in 1Q
  - Driven by timing of inventory replenishments in the 1Q 2014
- 1Q end user volume reduction YoY of 5%
  - Decline driven by high sales during first quarter 2014 in advance of price increase in Germany in April 2014
- Double digit growth in France and UK
- NICE in UK recommends PDD in first guideline on bladder cancer

**Hexvix Partner Unit Sales Per Quarter**



# *Pipeline Update*

# CREATING VALUE
# CLINICAL DEVELOPMENT PROGRAMS

| | Technology | Indication | Phase 1 | Phase 2 | Phase 3 | Status |
|---|---|---|---|---|---|---|
| Cevira® | PDT | Treatment of precursors of cervical cancer |  | | | Positive Phase 2b results<br>Submitted SPAR request in 1Q<br>Exploring partnerships |
| Visonac® | PDT | Treatment of moderate to severe acne |  | | | Positive Phase 2b results<br>SPA and PIP approved<br>Exploring partnerships |
| Hexvix®<br>Cysview® | PDD | Detection of bladder cancer, surveillance segment |  | | | Phase 3 clinical study initiated.<br>Patient recruitment is planned to start 3Q 2015 |



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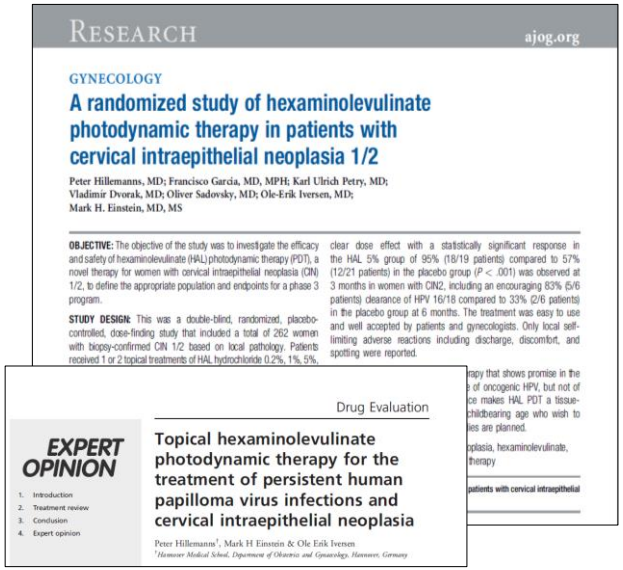
# CEVIRA
# A MAJOR OPPORTUNITY

- Breakthrough single use and fully integrated drug-device technology to satisfy high need for novel therapies to treat global epidemic of HPV/CIN populations
  - A well tolerated non-systemic treatment option for patients which preserves fertility and avoids the morbidities of invasive surgery
- Results of the Phase 2b trial are significant
  - Statistically significant HSIL (CIN2,3) regression in the FDA agreed phase 3 patient population (p=0.004)
  - Statistically significant virologic clearance of oncogenic HPV at 9 months after first treatment (p=0.045)
  - Excellent tolerability and high physician & patient acceptance
- Continuing progress in determining next steps in development
  - Submitted Special Protocol Assessment Review (SPAR)
  - Confirmed readiness for Phase 3 with major EU regulators

Cevira®



RESEARCH ajog.org

GYNECOLOGY

**A randomized study of hexaminolevulinate photodynamic therapy in patients with cervical intraepithelial neoplasia 1/2**

Peter Hillemanns, MD; Francisco Garcia, MD, MPH; Karl Ulrich Petry, MD; Vladimir Dvorak, MD; Oliver Sadovsky, MD; Ole-Erik Iversen, MD; Mark H. Einstein, MD, MS

**OBJECTIVE:** The objective of the study was to investigate the efficacy and safety of hexaminolevulinate (HAL) photodynamic therapy (PDT), a novel therapy for women with cervical intraepithelial neoplasia (CIN) 1/2, to define the appropriate population and endpoints for a phase 3 program.

**STUDY DESIGN:** This was a double-blind, randomized, placebo-controlled, dose-finding study that included a total of 262 women with biopsy-confirmed CIN 1/2 based on local pathology. Patients received 1 or 2 topical treatments of HAL hydrochloride 0.2%, 1%, 5%,

clear dose effect with a statistically significant response in the HAL 5% group of 95% (18/19 patients) compared to 57% (12/21 patients) in the placebo group ($P < .001$) was observed at 3 months in women with CIN2, including an encouraging 83% (5/6 patients) clearance of HPV 16/18 compared to 33% (2/6 patients) in the placebo group at 6 months. The treatment was easy to use and well accepted by patients and gynecologists. Only local self-limiting adverse reactions including discharge, discomfort, and spotting were reported.



EXPERT OPINION

1. Introduction
2. Treatment review
3. Conclusion
4. Expert opinion

Drug Evaluation

**Topical hexaminolevulinate photodynamic therapy for the treatment of persistent human papilloma virus infections and cervical intraepithelial neoplasia**

Peter Hillemanns[1], Mark H Einstein & Ole Erik Iversen

[1]Hannover Medical School, Department of Obstetrics and Gynaecology, Hannover, Germany

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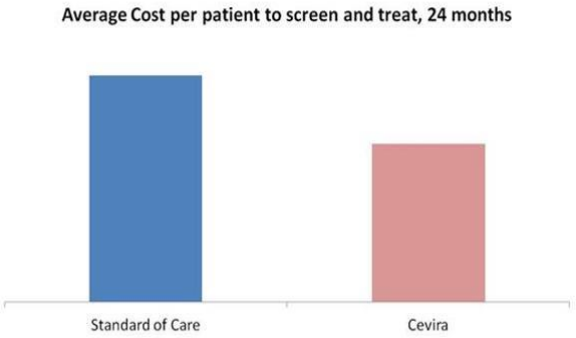
# CEVIRA
# SIGNIFICANT SALES POTENTIAL

- Large patient population based on biopsy confirmed histology of HSIL
  - ~1M cases HSIL annually in US & West EU[1,2] detected through routine cervical screening programs; 50% of these are caused by HPV strain 16 or 18[3]
  - ~30% risk of progress to cervical cancer[4]
  - Upside exists in Latin America, Asia and East EU, where burden of HPV is higher
- LCM Opportunity for clearance of oncogenic HPV in patients with normal cytology/LSIL
  - It is estimated that ~35M are HPV infected in US & EU, with a prevalence of HPV strains 16 or 18 of 32% (~11M)
  - 10-15M cases oncogenic HPV annually in US & West EU[6] detected through routine cervical screening programs
  - Persistent infection occurs in 10-20% of the cases[7]
- Blockbuster sales potential based on premium pricing opportunity
  - At premium price levels, cost impact model demonstrates cost savings / benefit to the US health care system as compared to current treatment practice[5]
  - Additional significant savings when avoidance of costs associated with preterm births factored in[5]
- Continued discussions with potential partners for development and commercialization



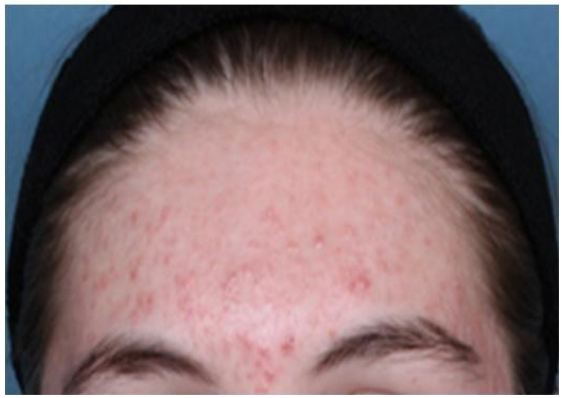



1.Solomon 2007, Antilla 2009 2. Stoler 2011, Wright 2012 3. Smith 2007 4. Stanley 2010 5. Internal assessment perfomed by Bridgehead 6. Wright 2012, Dunne 2007 7. Moscicki 1998

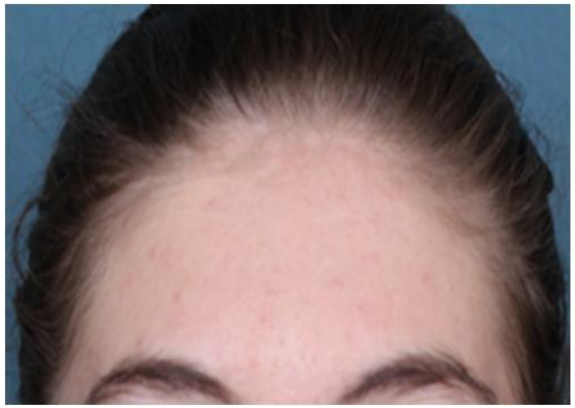
# VISONAC
# PHASE 3 READY ASSET

- High unmet need for novel treatments for moderate/ severe acne
  - 1st Photodynamic treatment for inflammatory acne
  - Broad geographic fit
- Positive Phase 2b results
  - Significant reduction in inflammatory lesions
  - Overall improvement in acne severity
  - Well tolerated regimen
- Phase 3 Ready
  - SPA (US) and PIP (EU) agreed for global registration program
  - Development and regulatory risks significantly reduced

Baseline

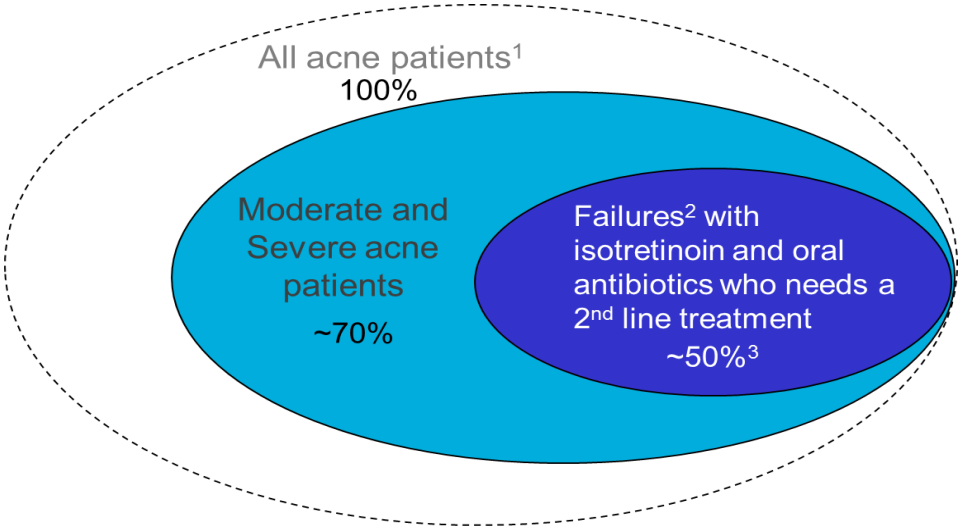


Week 12
6 weeks after last treatment



# VISONAC
# CONSIDERABLE SALES POTENTIAL

- Value of moderate to severe acne pharma market segment estimated at ~$900 MUSD globally
  - Dermatologist main prescriber of oral antibiotics and retinoids
- Visonac positioned as second line alternative
  - In US and EU, >2M patients in need of second line treatment options
  - Favorable benefit/risk profile compared to existing treatment options and sustained efficacy allows for premium price
- Continued interest from potential partners for development and commercialization




[1]Patients who require some form of prescription medicine treatment

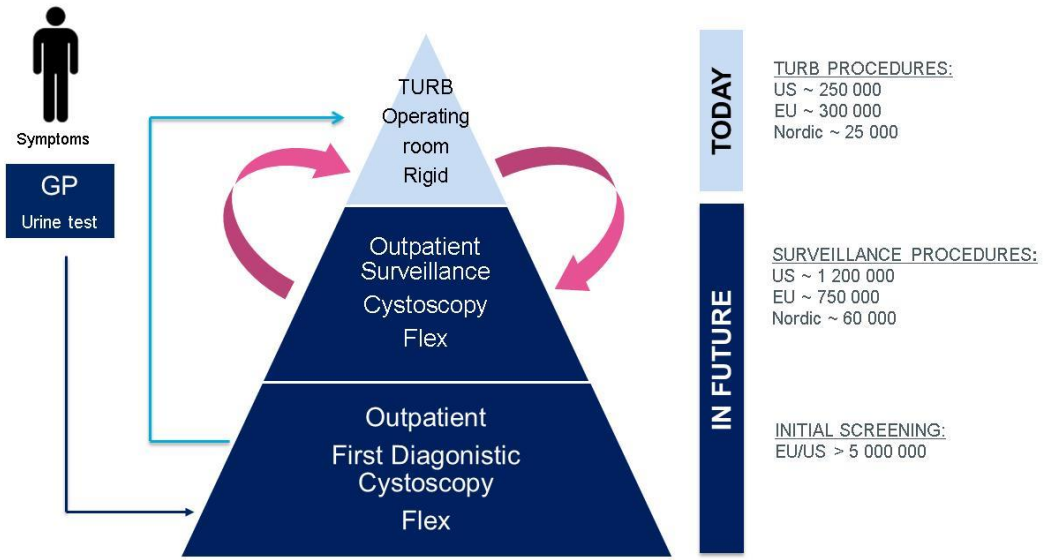
[2]Patients who are unsuitable for, or recalcitrant to, oral antibiotics and/or isotretinoin

[3]Estimate based on market research among dermatologists

# HEXVIX/CYSVIEW
# EXPANDING INTO THE SURVEILLANCE SEGMENT

- Surveillance following initial diagnosis represents a significant growth opportunity of 2-3 times current TURB segment
- Initiation of Phase 3 study with 360 patients for examining improved detection rate of Cysview blue light cystoscopy vs white light cystoscopy
  - Secured alignment with FDA on study design necessary to obtain label extension

Global Cystoscopy Market Consists of Three Distinct Market Segments



# *Financials*

# HEXVIX/CYSVIEW CONTINUED GROWTH FIRST QUARTER 2015

- Revenue from own sales of Hexvix/ Cysview increased 44% in 1Q YoY
  - Nordic 1Q revenue growth of 22%
  - US revenue increased 116% in 1Q
- Partner 1Q revenue increased 33% YoY
  - Changed timing of supply to partner compared to the same period in 2014
- Total in market sales value increased 10% in 1Q YoY
  - LTM value NOK 184 million

| *SALES - MNOK* | Q1 '15 |
|---|---|
| **Hexvix own sales** | **12,8** |
| *YoY growth* | *44 %* |
| **Hexvix partner sales** | **13,9** |
| *YoY growth* | *33 %* |
| **Total Photocure** | **26,7** |
| *YoY growth* | *38 %* |
| **Revenue in-market (*)** | **50,6** |
| *YoY growth* | *10 %* |
| **Units in-market (*)** | **13 214** |
| *YoY growth* | *-1 %* |

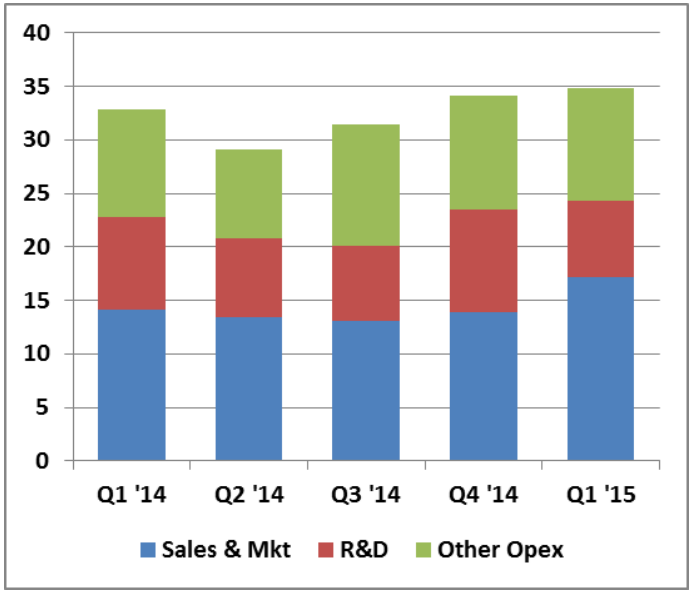
**(*) Calculated in-market sales**

# PROFIT & LOSS
# FIRST QUARTER 2015

- Revenue increase of 43% YoY
  - Other sales revenue is sales of active ingredients.
- Operating expenses increase 6% YoY
  - R&D expenses at NOK 7.1 million in 1Q, down 19% from last year.
  - 1Q S&M expenses at NOK 17.2 million, YoY increase of 22%, significantly impacted by FX.
- 1Q operating loss (EBIT) at NOK 7.2 million
  - Improvement of NOK 6.5 million from last year

| *MNOK* | Q1 '15 | Q1 '14 | Change |
|---|---|---|---|
| Hexvix / Cysview revenues | 26,7 | 19,3 | 38 % |
| Other sales revenues | 1,7 | 0,2 | |
| Signing fee and milestones | 1,2 | 1,2 | 5 % |
| **Total revenues** | **29,6** | **20,7** | **43 %** |
| **Gross profit** | **27,6** | **19,1** | **44 %** |
| Operating expenses | -34,8 | -32,9 | 6 % |
| **Operating profit/loss(-)** | **-7,2** | **-13,7** | |
| **Profit/loss(-) before tax** | **-7,0** | **-13,0** | |

**Operating expenses NOK mill**



# SEGMENTS
# FIRST QUARTER 2015

- Segment reporting changed from 2015:
- Commercial franchise:
  - Hexvix /Cysview by sales channel, own sales and partner sales
  - Other sales, currently including sale of active ingredients.
- Development portfolio:
  - Split by development of commercial products and pipeline products

| *MNOK* | Q1 '15 | Q1 '14 | Change | LTM | FY '14 |
|---|---|---|---|---|---|
| **Commercial Franchise** | | | | | |
| Total revenues | 29,6 | 20,7 | 43 % | 107,1 | 98,2 |
| Gross profit | 27,6 | 19,1 | 44 % | 99,7 | 91,2 |
| Operating expenses | -23,4 | -19,1 | 23 % | -79,6 | -75,3 |
| **EBIT** | **4,2** | **0,0** | | **20,1** | **15,9** |
| **Development Portfolio** | | | | | |
| Total revenues | 0,0 | 0,0 | | 0,0 | 0,0 |
| Gross profit | 0,0 | 0,0 | | 0,0 | 0,0 |
| Operating expenses | -11,4 | -13,8 | -17 % | -49,9 | -52,3 |
| **EBIT** | **-11,4** | **-13,8** | **-17 %** | **-49,9** | **-52,3** |
| **Total** | | | | | |
| **EBIT** | **-7,2** | **-13,7** | **-48 %** | **-29,8** | **-36,4** |
| **(*) One-Off's excluded** | | | | | |
| Salix termination fee | | | | 30,8 | 30,8 |

# CASH FLOW
# FIRST QUARTER 2015

- 1Q cash flow from operations NOK -11.9 million.
  - Improvement of NOK 6.8 million from last year.
  - Working capital net outflow of NOK 4.8 million.
- 1Q cash flow from investments NOK -3.6 million.
  - Includes investments of NOK 5.3 million in the initiation of a phase 3 post-marketing commitment trial.
- Quarter end cash balance at NOK 150 million.

| *MNOK* | Q1 '15 | Q1 '14 | Change |
|---|---|---|---|
| **Cash flow from:** | | | |
| - Operations | -11,9 | -18,7 | -36 % |
| - Investments | -3,6 | 1,1 | |
| - Financing | 0,0 | 0,0 | |
| **Net change in cash** | **-15,5** | **-17,5** | **-12 %** |
| **Ending cash balance** | **149,7** | **149,7** | **0 %** |

# BALANCE SHEET PER 31 MARCH 2015

- Non current assets includes NOK 19 million in shares in PCI Biotech and deferred tax asset of NOK 27 million
- No interest bearing debt at quarter end
- Shareholder's equity of NOK 233 million
- Equity ratio of 90%
- Photocure held 35,476 own shares at end of quarter

| ***MNOK*** | **31.03 2015** | **31.12 2014** |
|---|---|---|
| Non-current assets | 80,4 | 76,5 |
| Inventory & receivables | 30,0 | 28,8 |
| Cash & equivalents | 149,7 | 165,2 |
| **Total assets** | **260,1** | **270,6** |
| | | |
| Shareholders equity | 233,0 | 240,1 |
| Long term liabilities | 3,3 | 3,1 |
| Current liabilities | 23,9 | 27,5 |
| **Total equity & liabilities** | **260,1** | **270,6** |
| | | |
| Equity ratio | 90 % | 89 % |

# *Outlook*

# OUTLOOK

**FINANCIAL**

- Hexvix/Cysview global in-market unit sales growth of ≥10% in 2015

**CLINICAL**

- Submit Special Protocol Assessment Request (SPAR) by mid-2015
- Initiate Phase 3 clinical trial to expand the use of Hexvix/Cysview into the surveillance market and fulfill the US post marketing commitments in 2015

**PARTNERSHIP**

- Secure partnership for further development and commercialization of Visonac and Cevira reflecting the product potential



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