

# PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

RESULTS FOR SECOND QUARTER  
AND FIRST HALF YEAR 2016

23 AUGUST 2016

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# DELIVERING ON KEY OBJECTIVES

## KEY OBJECTIVES

- Increase Hexvix/Cysview global in-market unit sales growth rate
- Finalize recruitment and reporting of clinical results of Hexvix/Cysview phase 3 market expansion study in 2017
- Secure Partnership for further development and commercialization of Visonac and Cevira reflecting the product potential

## 2Q/1H2016 KEY ACHIEVEMENTS

- Hexvix/Cysview global in-market volume increased YoY 6%
- Hexvix/Cysview in-market value increased YoY 19% to NOK 124 million
- BLC with Cysview recommended in new American Urology Association bladder cancer guidelines
- Two new independent publications on the long term benefits of BLC with Hexvix/Cysview
- >50% of target patient numbers enrolled
- Discussions ongoing with potential partners

*Commercial Update*

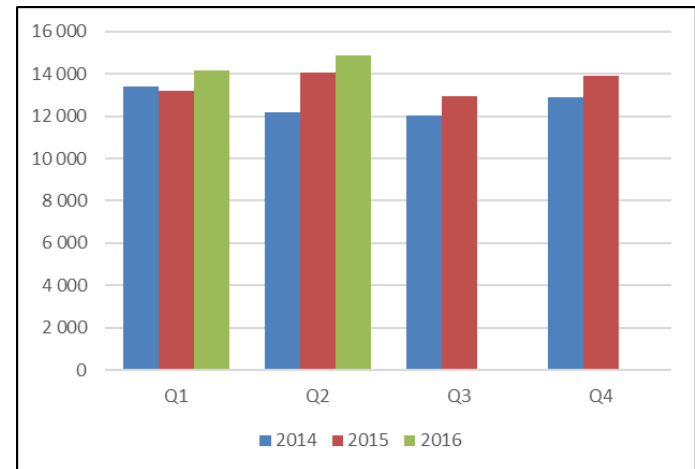


# HEXVIX/CYSVIEW

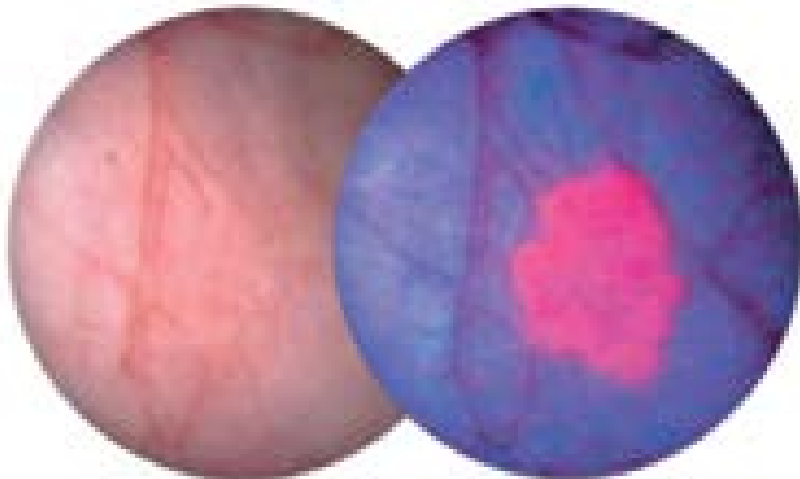
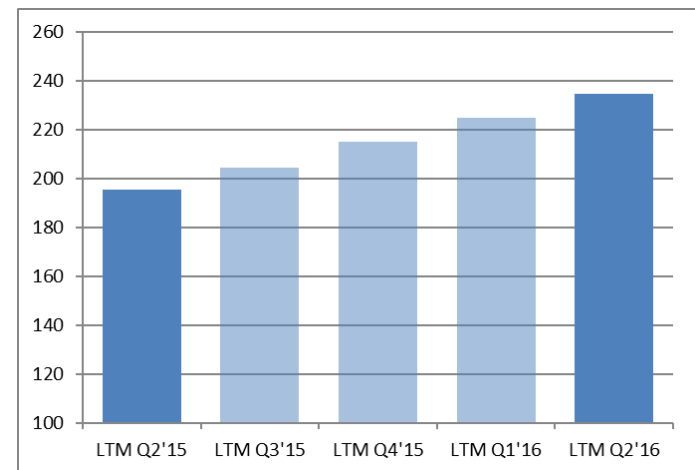
## A SIGNIFICANT GLOBAL SPECIALTY BRAND

- Value of in-market sales of Hexvix/Cysview in the quarter increased YoY 18% to NOK 63 million. Year to date at NOK 124 million (+19%)
- Hexvix/Cysview global in-market volume increased YoY 6% in the quarter and 6% year to date
- Overall franchise EBITDA year to date at NOK 11.3 million, EBITDA margin of 16%

Global in-market unit sales (by Q)



Global in-market value NOK mill (LTM)



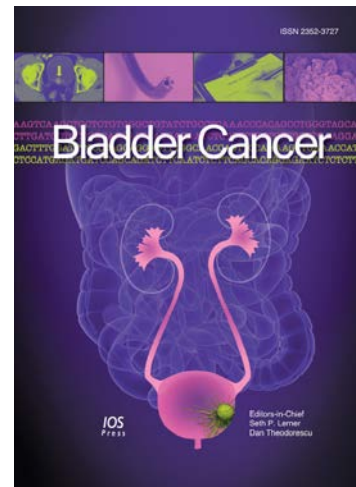
# HEXVIX/CYSVIEW PROVIDES CLINICAL BENEFITS

- Use of Blue Light Cystoscopy with Cysview/Hexvix recommended in the new AUA/SUO bladder cancer guideline
  - Recommended based on the large body of evidence supporting both increased detection and reduced recurrence of non-muscle invasive bladder cancer
- New publications in *Bladder Cancer* shows Blue light Cystoscopy with Cysview/Hexvix significantly improves long time outcomes
  - Significantly prolongs time to progressions of bladder cancer (*Kamat et al, April*)
  - Significantly reduces progression of bladder cancer (*Gakis et al, August*)
- Approval of new Hexvix/Cysview drug packaging in EU and the US

## Research Report

### Systematic Review and Meta-Analysis on the Impact of Hexaminolevulinate- Versus White-Light Guided Transurethral Bladder Tumor Resection on Progression in Non-Muscle Invasive Bladder Cancer

Georgios Gakis\* and Omar Fahmy<sup>§</sup>  
 \*Department of Urology, University Hospital Tübingen, Tübingen, Germany  
 §Department of Urology, University Putra Malaysia (UPM), Selangor, Malaysia



**Abstract:**  
**Introduction:** Although there is evidence that hexaminolevulinate (HAL)-based transurethral bladder tumor resection (TURBT) improves the detection of T<sub>1</sub>T<sub>1</sub> non-muscle-invasive bladder cancer (NMIBC) as well as carcinoma *in situ* there is uncertainty about its beneficial effects on progression.  
**Material and Methods:** A systematic literature search was conducted according to the PRISMA statement to identify studies reporting on HAL- vs. white-light (WL)-based TURBT in non-muscle invasive bladder cancer between 2000 and 2016. A 10-stage selection process was utilized to determine eligible studies. Of a total of 294 studies, 5 (4 randomized and one prospective) were considered for final analysis. The primary objective was the rate of progression.  
**Results:** The median follow-up for patients treated with HAL- and WL-TURBT was 27.6 (1–25.1) and 28.9 (1–53) months, respectively. Of a total of 1301 patients, 644 underwent HAL- and 657 WL-based TURBT. Progression was reported in 44 (6.44 patients (6.8%) with HAL- and 70 (10.7%) with WL-TURBT, respectively (median odds ratio: 1.64, [1.0, 2.45 for HAL vs. WL], p=0.01). Data on progression-free survival was reported in a single study with a trend towards improved survival for patients treated with HAL-TURBT (p=0.05).  
**Conclusion:** In this meta-analysis the rate of progression was significantly lower in patients treated with HAL- vs. WL-based TURBT. These results support the initiation of randomized trials on HAL with progression as primary endpoint.

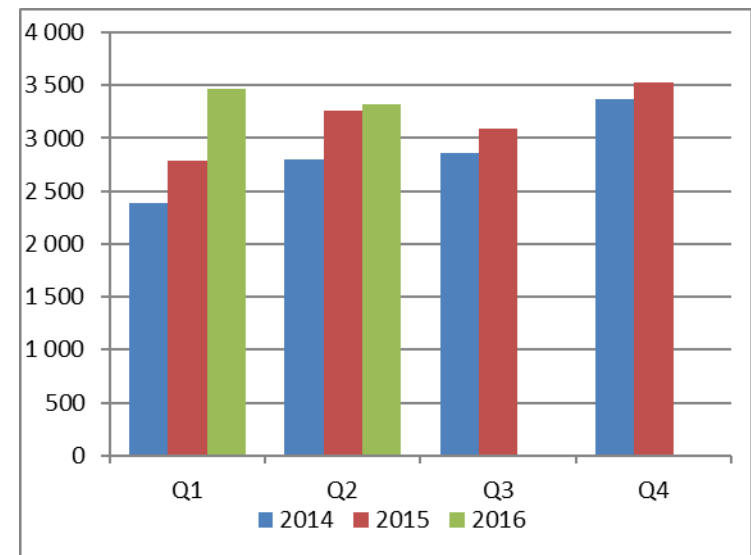


# HEXVIX/CYSVIEW

## SOLID PERFORMANCE IN NORDICS AND USA

- Photocure own sales revenue in the US and Nordics increased YoY 12% in the quarter and 24% year to date to NOK 35.4 million
- US revenue increased year to date YoY 42%
  - Driven by YoY in-market volume growth of 22%, price increases and FX
  - Permanent Blue Light Cystoscope placements of 79 at the end of Q2 (2015 year end 65)
  - The bill to provide separate and additional payments to hospitals was announced and recorded in Committee hearing in House of Representatives in June
- Nordic revenue increased year to date YoY 14%
  - In-market volume growth of 9%, partly due to changed seasonality pattern
  - Continued double digit in-market volume growth in Sweden, year to date 22% growth

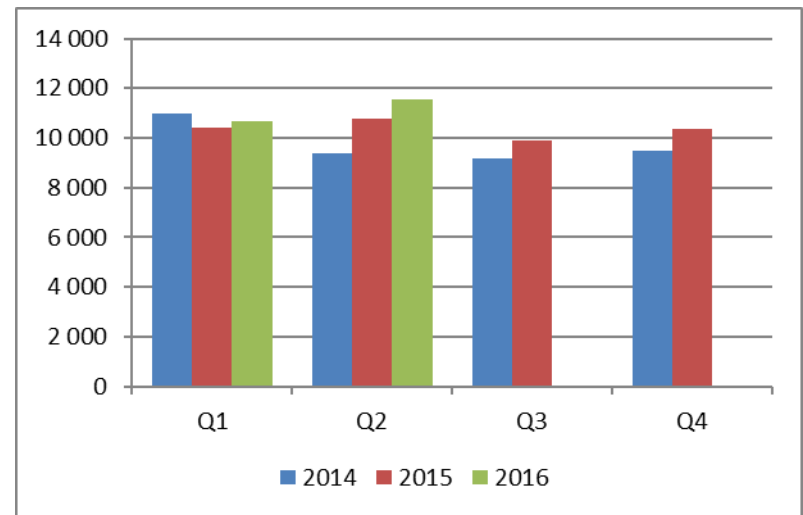
Own Hexvix/Cysview in-market unit sales Nordic and US



# HEXVIX/CYSVIEW PARTNER PROGRESS

- Partner revenue increased YoY 26% in the quarter and 20% year to date to NOK 32.3 million
- End user YoY volume growth 7% in the quarter and 5% year to date
- New territories & partners
  - BioSyent Pharma in Canada
    - Expect commercial sales Q3 2016
  - Juno Pharmaceuticals in Australia and New Zealand
    - Expect MAA approval in Australia 2H 2016
- Russia: Marketing approval received
  - Partner search ongoing

Hexvix Partner Unit Sales Per Quarter





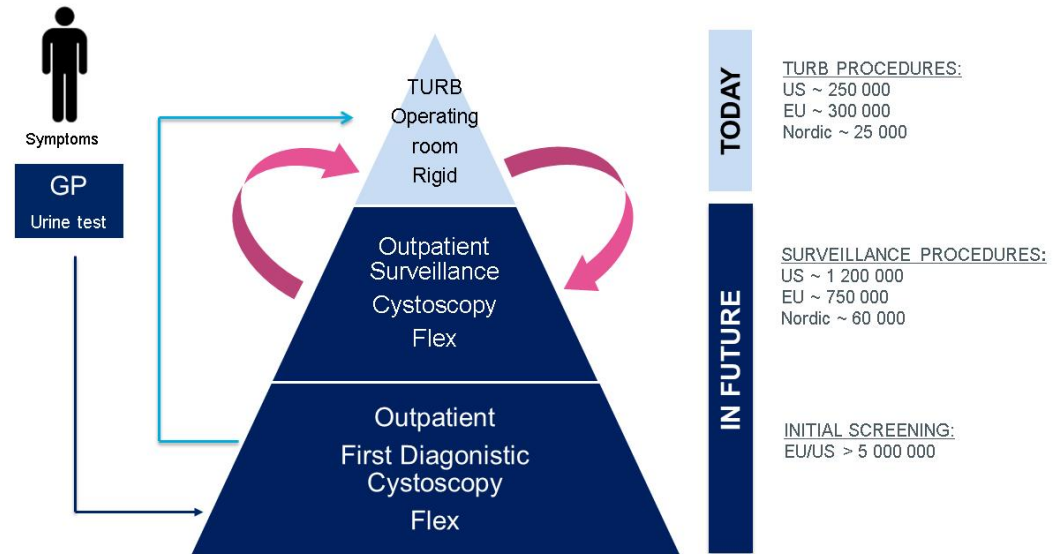
# *Pipeline Update*



# HEXVIX/CYSVIEW EXPANDING INTO THE SURVEILLANCE SEGMENT

- Surveillance following initial diagnosis represents a significant growth opportunity of 2-3 times current TURB segment
- Patient enrollment in Hexvix/Cysview Phase 3 market expansion progressing according to plan
  - >50% of required patients enrolled
  - Study results expected in 2017
  - Secured alignment with FDA on study design necessary to obtain label extension

Global Cystoscopy Market Consists of Three Distinct Market Segments



# CEVIRA & VISONAC PHASE 3 READY PRODUCTS WITH SIGNIFICANT SALES POTENTIAL

- Cevira - Breakthrough single use and fully integrated drug-device technology to satisfy high need for novel non-surgical therapies to treat global epidemic of HPV/HSIL populations
- Visonac – Novel topical non-antibiotic/non-isotretinoin treatment to satisfy high unmet medical need among patients with inflammatory, severe acne (IGA 4)
- Cevira and Visonac both phase 3 ready with Special Protocol Agreement on phase 3 program with FDA
- Cevira and Visonac both addressing large patient populations with significant unmet medical needs
  - Cevira with blockbuster sales potential based on premium pricing opportunity in large patients populations
- Cevira and Visonac have granted patents with extensive patent life and additional patent applications can provide additional extension
- Continued interest from potential partners for development and commercialization

RESEARCH ajog.org

**GYNECOLOGY**

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

Peer Hillmann, MD; Francisco Garcia, MD, MPH; Karl Ulrich Petry, MD; Vladimir Dvorak, MD; Oliver Sudowj, 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, non-randomized study that included a total of 200 women.

clear case effect with a statistically significant response in the HAL 5% group of 85% (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 85% CIN2 patients clearance of HPV 16/18 compared to 20% (2/10 patients) in the placebo group at 9 months. The treatment was easy to use and well accepted by patients and gynecologists. Only local self-

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colitis.

intraepithelial

Drug Evaluation

**EXPERT OPINION**

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

Peer Hillmann\*, Mark H. Einstein & Ole Erik Iversen  
\*Hannover Medical School, Department of Obstetrics and Gynecology, Hannover, Germany

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



# *Financials*



# SEGMENTS

## SECOND QUARTER 2016

### Commercial franchise:

- Continued revenue growth for Hexvix/Cysview, YoY quarter growth 18%, year to date 22% (in constant FX: 12%)
- Total revenues negatively impacted by API revenues and milestone revenues
- Increased operating expenses, sales & marketing in US and trials to support surveillance-market, spending related to partner activities
- EBITDA margin at 16% year to date

### Development portfolio:

- Activities related to regulatory work and intellectual property. Cysview post marketing commitment phase 3 capitalized

<i>MNOK</i>	<u>Q2 '16</u>	<u>YTD '16</u>	<u>YTD '15</u>
<b><u>Commercial Franchise</u></b>			
Nordic revenues	10,6	20,7	18,2
US revenues	7,1	14,7	10,3
Partner revenues	16,5	32,3	27,0
<b>Hexvix / Cysview</b>	<b>34,2</b>	<b>67,7</b>	<b>55,6</b>
API revenues	0,0	0,0	4,3
Signing fee & milestones	1,3	2,6	4,5
<b>Total revenues</b>	<b>35,5</b>	<b>70,3</b>	<b>64,4</b>
Cost of goods sold	-2,1	-4,5	-4,2
<b>Gross profit</b>	<b>33,4</b>	<b>65,9</b>	<b>60,2</b>
Operating expenses	-27,4	-54,6	-45,4
<b>EBITDA</b>	<b>5,9</b>	<b>11,3</b>	<b>14,8</b>
<b><u>Development Portfolio</u></b>			
Operating expenses	-8,3	-17,3	-22,5
<b>EBITDA</b>	<b>-8,3</b>	<b>-17,3</b>	<b>-22,5</b>
<b><u>Total</u></b>			
<b>EBITDA</b>	<b>-2,3</b>	<b>-6,1</b>	<b>-7,7</b>

# PROFIT & LOSS

## SECOND QUARTER 2016

- Total revenue increase YoY 9% year to date
  - Negatively impacted by sales of API and reduced milestone revenues
- Operating expenses increase YoY 6% year to date
  - R&D reduction 43%
  - Sales & marketing increase 17%
  - Other Opex increase 22%
- EBITDA at NOK -2.3 million for the quarter, NOK -6,1 million year to date
- EBIT impacted by amortization of phase 3 Cysview
- Tax net income (non-cash) driven by change in transfer pricing method

<i>MNOK</i>	<b>Q2 '16</b>	<b>YTD '16</b>	<b>YTD '15</b>
Hexvix / Cysview revenues	34,2	67,7	55,6
Other sales revenues (API)	0,0	0,0	4,3
Signing fees and milestones	1,3	2,6	4,5
<b>Total revenues</b>	<b>35,5</b>	<b>70,3</b>	<b>64,4</b>
Cost of goods sold	-2,1	-4,5	-4,2
<b>Gross profit</b>	<b>33,4</b>	<b>65,9</b>	<b>60,2</b>
Operating expenses	-35,7	-71,9	-67,9
<b>EBITDA</b>	<b>-2,3</b>	<b>-6,1</b>	<b>-7,7</b>
Depreciation & Amortization	-2,0	-3,2	-1,3
<b>EBIT</b>	<b>-4,4</b>	<b>-9,2</b>	<b>-9,1</b>
Net financial items excl PCI	0,7	1,2	1,7
<b>Profit/loss(-) before PCI &amp; Tax</b>	<b>-3,6</b>	<b>-8,0</b>	<b>-7,4</b>
Impairment loss shares PCI	-	-	-7,7
Tax expenses	21,8	25,4	-6,7
<b>Net profit/loss(-)</b>	<b>18,1</b>	<b>17,4</b>	<b>-21,8</b>
Other comprehensive income	-0,9	1,4	0,1
<b>Total comprehensive income</b>	<b>17,2</b>	<b>18,8</b>	<b>-21,6</b>

# CASH FLOW

## SECOND QUARTER 2016

<i>MNOK</i>	<u>Q2 '16</u>	<u>YTD '16</u>	<u>YTD '15</u>
<b>Cash flow from:</b>			
- Operations	-12,8	-22,1	-14,4
- Investments	-3,1	-8,3	-5,1
- Financing	-0,2	0,7	0,9
<b>Net change in cash</b>	<b>-16,2</b>	<b>-29,6</b>	<b>-18,6</b>
<b>Ending cash balance</b>	<b>104,4</b>	<b>104,4</b>	<b>146,7</b>

- Year to date cash flow from operations at NOK -22.1 million (prior year NOK 14.4 million)
  - Change in working capital NOK -15.7 million (prior year NOK -6,4 million) year to date. Increased outflow driven by inventory & receivables (revenue driven) and movements for accounts payables
- Year to date cash flow from investments NOK -8.3 million, includes investments of NOK 7.8 million in intangible assets mainly related to the initiation of the phase 3 post-marketing commitment trial for Cysview
- Quarter end cash balance at NOK 104.4 million
  - Payment from Galderma 2016.12.31 of EUR 4.0 million

# BALANCE SHEET PER 30 JUNE 2016

- Non current assets include NOK 20.7 million in investments in tangible and intangible assets, NOK 7.9 million in shares in PCI Biotech and deferred tax asset of NOK 48.9 million
- Current assets include NOK 35.0 million in remaining settlement sale of Metvix, due 31.12.2016
- No interest bearing debt
- Shareholder's equity of NOK 232.9 million. Equity ratio of 89%
- Photocure held 809 own shares at end of Q2

<i>MNOK</i>	<b>30.06 2016</b>	<b>31.12 2015</b>
Non-current assets	77,4	43,6
Inventory & receivables	80,1	70,4
Cash & equivalents	104,4	134,0
<b>Total assets</b>	<b>262,0</b>	<b>248,1</b>
Shareholders equity	232,9	210,1
Long term liabilities	3,2	4,0
Current liabilities	25,9	34,0
<b>Total equity &amp; liabilities</b>	<b>262,0</b>	<b>248,1</b>
Equity ratio	89 %	85 %



# *Outlook*



# DELIVERING ON KEY OBJECTIVES

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