

PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

RESULTS FOR FIRST QUARTER
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

1Q2016 KEY ACHIEVEMENTS

- Hexvix/Cysview global in-market volume increased YoY 7%, with 25% volume growth in own markets
- Hexvix/Cysview in-market value increased YoY 19%
- BLC with Cysview recommended in new American Urology Association bladder cancer guidelines
- Patient enrollment according to plan
- Discussions ongoing with potential partners



Commercial Update

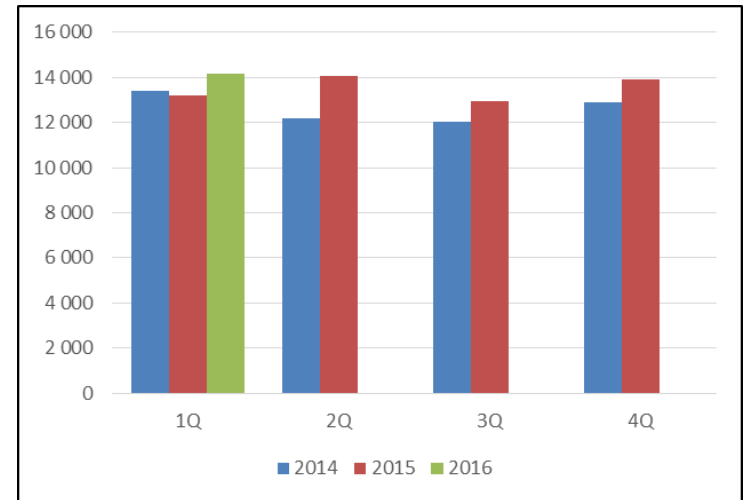


HEXVIX/CYSVIEW

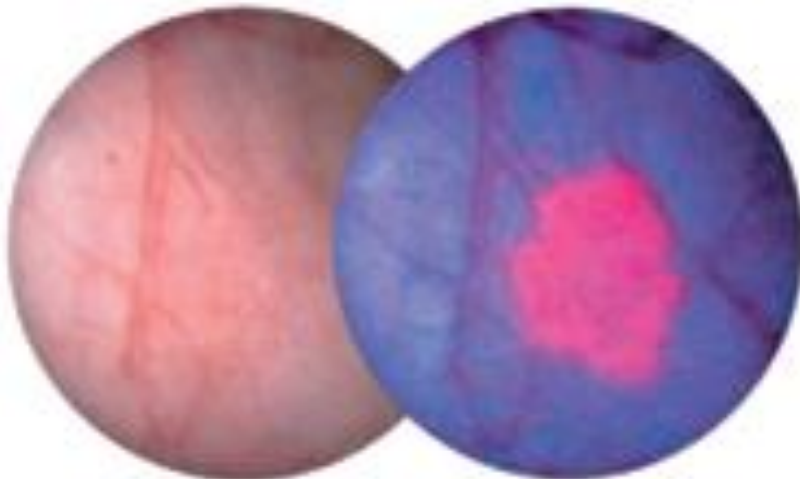
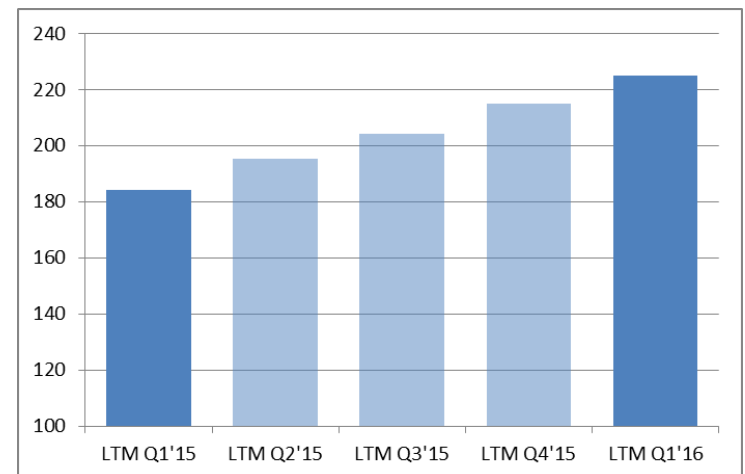
A SIGNIFICANT GLOBAL SPECIALTY BRAND

- Value of in-market sales of Hexvix/Cysview in the first quarter increased YoY 19% to NOK 60 million
- Hexvix/Cysview global in-market volume increased YoY 7% in the first quarter
- Overall franchise EBITDA for the first quarter at NOK 5.3 million, improvement of 19% from first quarter prior year

Global in-market unit sales (by Q)



Global in-market value NOK mill (LTM)



HEXVIX/CYSVIEW CONTINUED VALIDATION OF 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 publication in *Bladder Cancer* shows Cysview/Hexvix significantly prolongs time to progression of bladder cancer
- Publication at European Association of Urology on “real life experience” with Hexvix/Cysview confirms the clinical benefits in routine clinical practice

American Urological Association
Advancing Urology™

ABOUT US EDUCATION RESEARCH ADVOCACY INTERNATIONAL PRACTICE RESOURCES

EDUCATION > Guidelines & Policies > Guidelines > Non-Muscle Invasive Bladder Cancer

Guidelines

AUA University
All your educational needs, all in one place!
Now, enhanced access and resources just for AUA members. [Learn More](#)

NON-MUSCLE INVASIVE BLADDER CANCER

[Download the unabridged version of this guideline \[pdf\]](#)
[Download Non-Muscle Invasive Bladder Cancer Treatment Algorithm \[pdf\]](#)

DIAGNOSIS AND TREATMENT OF NON-MUSCLE INVASIVE BLADDER CANCER: AUA/SUO GUIDELINE

Sam S. Chang, MD, MBA; Stephen A. Boorjian, MD; Roger Chou, MD; Peter E. Clark, MD; Siamak Daneshmand, MD; James J. Lee, MD; Chad R. Ritchie, MD; James M. McKiernan, MD

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Purpose
The survival rate is favorable; however, non-muscle invasive bladder cancer (NMIBC) are important

Bladder Cancer

ISSN 2352-3727

Editor-in-Chief
P. Lerner
Theodoros

PRESS RELEASE

Blue-light-guided bladder resection with Hexvix® improves detection of lesions and reduces the risk of recurrence

Photodynamic diagnosis with hexaminolevulinate (HAL) in real-life experience

Munich/Germany, 12 March 2016 – Ipsen (Euronext: IPN ; ADR: IPSEY) informed that photodynamic diagnosis (PDD)-assisted cystoscopy using Hexvix®, hexaminolevulinate (HAL), significantly improves the detection of non-muscle-invasive bladder cancer (NMIBC) and lowers the risk of recurrence.^{1,4} The advantages of the HAL-guided blue-light cystoscopy compared to the standard white-light (WL) procedure alone were evidenced in several randomised, controlled clinical trials and confirmed in real-life settings. Even three years after an initial transurethral resection of bladder tumor (TURB), HAL-guided TURB showed significant improvement in recurrence-free survival, compared with good-quality (GO)-WL-TURB.⁵

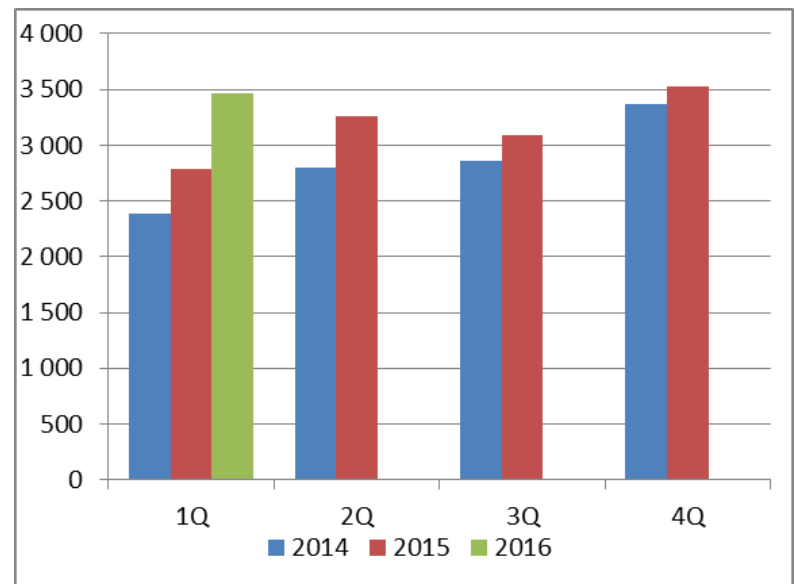


HEXVIX/CYSVIEW

SOLID PERFORMANCE IN NORDICS AND USA

- Photocure own sales revenue in the US and Nordics increased YoY 38% in 1Q to NOK 17.7 million
- US revenue increased YoY 66% in the quarter
 - Driven by YoY in-market volume growth of 37%, price increases and FX
 - Permanent Blue Light Cystoscope placements of 73 at the end of 1Q (2015 year end 65)
 - Continued progress on passage of bill to provide separate payment to hospitals
- Nordic revenue increased YoY 23% in the quarter
 - In-market volume growth of 20%, partly due to changed seasonality pattern
 - Continued double digit in-market volume growth in Sweden, first quarter 32% growth

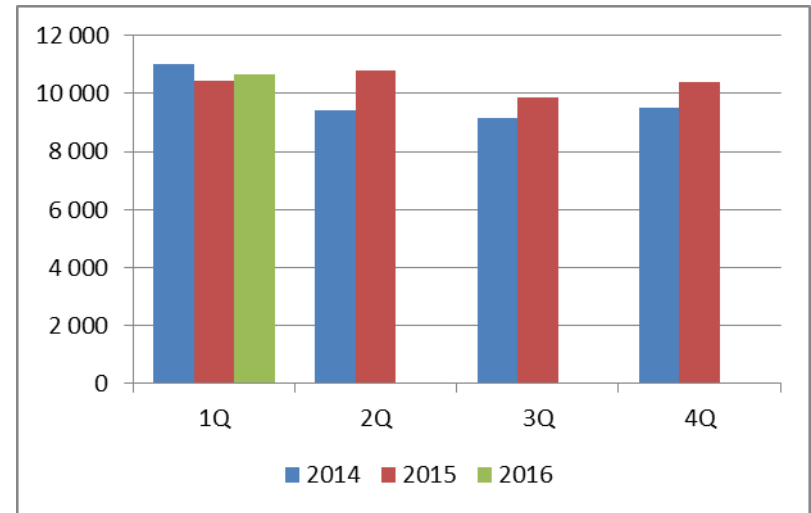
Own Hexvix/Cysview in-market unit sales
Nordic and US



HEXVIX/CYSVIEW PARTNER PROGRESS

- Partner revenue increased 14% in 1Q to NOK 15.8 million
 - First quarter sales included the first shipment to BioSyent Pharma in Canada
- End user YoY volume growth 2% in 1Q
- Strong visibility for Hexvix at European Association of Urology congress
- New territories & partners
 - BioSyent Pharma in Canada
 - Expect commercial sales 2Q/3Q 2016
 - Juno Pharmaceuticals in Australia and New Zealand
 - Expect MAA approval in Australia 2H 2016
- Russia: Marketing approval received

Hexvix Partner Unit Sales Per Quarter



EAU16 | MUNICH
 11-15 March 2016
 Sharing knowledge - Raising the level of urological care

ADVERTORIAL

The economic impact of bladder cancer
 Improved techniques for initial detection may decrease the economic burden

Abstract
 Bladder cancer is the most common urological malignancy and the second most common cause of cancer-related death in men. The economic burden of bladder cancer is substantial, with direct and indirect costs estimated at \$1.5 billion in the United States in 2010. The economic burden of bladder cancer is expected to increase significantly in the coming years due to the aging population and the increasing incidence of the disease. This review discusses the economic impact of bladder cancer and the potential for improved techniques for initial detection to decrease the economic burden.

Introduction
 Bladder cancer is the most common urological malignancy and the second most common cause of cancer-related death in men. The economic burden of bladder cancer is substantial, with direct and indirect costs estimated at \$1.5 billion in the United States in 2010. The economic burden of bladder cancer is expected to increase significantly in the coming years due to the aging population and the increasing incidence of the disease. This review discusses the economic impact of bladder cancer and the potential for improved techniques for initial detection to decrease the economic burden.

Conclusion
 The economic burden of bladder cancer is substantial, and improved techniques for initial detection may decrease the economic burden. Further research is needed to evaluate the effectiveness of these techniques and to determine the optimal approach for initial detection of bladder cancer.



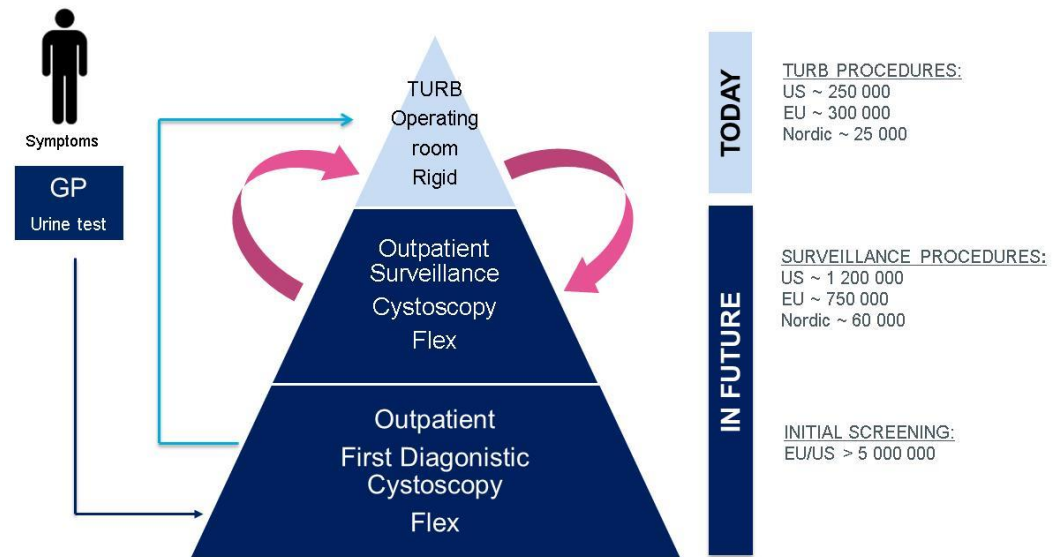
Pipeline Update



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
 - Study including 360 patients examining improved detection rate of Hexvix/Cysview blue light cystoscopy vs white light cystoscopy
 - 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

Peter Hillermann, 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-toxicity study that included a total of 200 women.

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 63% (6/9 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-

Drug Evaluation

EXPERT OPINION

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

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

Peter Hillermann*, Mark H Einstein & Ole Erik Iversen
*Hannover Medical School, Department of Obstetrics and Gynecology, Hannover, Germany



Financials



SEGMENTS

FIRST QUARTER 2016

- Commercial franchise:
 - Continued revenue growth for Hexvix/Cysview, First quarter growth 26% YoY (in constant currencies: 15%)
 - Main growth drivers own sales in US (+66%) and Nordic (+23%)
 - Increased operating expenses driven by sales & marketing in US and trials to support surveillance-market
 - EBITDA increased 19%, margin at 15%
- Development portfolio:
 - Activities related to regulatory work and intellectual property
 - Cysview post marketing commitment phase 3 capitalized

<i>MNOK</i>	<u>Q1 '16</u>	<u>Q1 '15</u>	<u>Change</u>
<u>Commercial Franchise</u>			
Nordic revenues	10,1	8,3	23 %
US revenues	7,6	4,6	66 %
Partner revenues	15,8	13,9	14 %
Hexvix / Cysview	33,5	26,7	26 %
API revenues	0,0	1,7	-100 %
Signing fee & milestones	1,3	1,2	10 %
Total revenues	34,9	29,6	18 %
Gross profit	32,5	27,6	18 %
Operating expenses	-27,2	-23,1	18 %
EBITDA	5,3	4,5	19 %
<u>Development Portfolio</u>			
Operating expenses	-9,1	-11,1	-18 %
EBITDA	-9,1	-11,1	-18 %
<u>Total</u>			
EBITDA	-3,7	-6,6	-44 %



PROFIT & LOSS

FIRST QUARTER 2016

- Total revenue increase YoY 18% in first quarter
 - Sales revenue negatively impacted by reduced sales of API
- Operating expenses increase YoY 6% in first quarter
 - Sales & marketing increased 17%
 - R&D reduced 28%
- EBITDA at NOK -3,7 million for first quarter
 - EBITDA improvement from 2015 of 44%
- EBIT impacted by amortization of phase 3 Cysview
- Tax expenses are non cash, tax asset

<i>MNOK</i>	Q1 '16	Q1 '15	Change
Total sales revenues	33,5	28,4	18 %
Signing fee and milestones	1,3	1,2	10 %
Total revenues	34,9	29,6	18 %
Gross profit	32,5	27,6	18 %
Operating expenses	-36,2	-34,2	6 %
EBITDA	-3,7	-6,6	
Depreciation & Amortization	-1,1	-0,6	
EBIT	-4,9	-7,2	
Net financial items excl PCI	0,5	0,3	
Profit/loss(-) before tax	-4,4	-7,0	
Tax expenses	3,6	-4,0	
Net profit/loss(-)	-0,7	-11,0	
Other comprehensive income	2,4	2,9	
Total comprehensive income	1,7	-8,1	
Net result per share, diluted	-0,03	-0,51	

CASH FLOW

FIRST QUARTER 2016

<i>MNOK</i>	<u>Q1 '16</u>	<u>Q1 '15</u>	<u>Change</u>
Cash flow from:			
- Operations	-9,3	-11,9	-22 %
- Investments	-5,1	-3,6	42 %
- Financing	1,0	0,0	
Net change in cash	-13,4	-15,5	-14 %
Ending cash balance	120,6	149,7	

- First quarter cash flow from operations NOK -9.3 million, reduction of 22% from 2015
 - Change in working capital NOK -5.2 million, last year NOK -4,8 million
- First quarter cash flow from investments NOK -5.1 million.
 - Includes investments of NOK 4.1 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 120.6 million

BALANCE SHEET PER 31 MARCH 2016

- Non current assets include investments in tangible and intangible assets, NOK 8.6 million in shares in PCI Biotech and deferred tax asset of NOK 27.1 million
- Current assets include NOK 33.8 million in remaining settlement sale of Metvix, due 31.12.2016
- No interest bearing debt
- Shareholder's equity of NOK 213.5 million. Equity ratio of 86%
- Photocure held 809 own shares at end of 1Q

<i>MNOK</i>	31.03 2016	31.12 2015
Non-current assets	54,6	43,6
Inventory & receivables	74,2	70,4
Cash & equivalents	120,6	134,0
Total assets	249,5	248,1
Shareholders equity	213,5	210,1
Long term liabilities	4,2	4,0
Current liabilities	31,8	34,0
Total equity & liabilities	249,5	248,1
Equity ratio	86 %	85 %

Outlook



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