

PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

RESULTS FOR FOURTH QUARTER
AND FULL YEAR 2015

11 FEBRUARY 2016

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DELIVERING ON KEY OBJECTIVES

KEY OBJECTIVES

- Hexvix/Cysview global in-market unit sales growth of 10%
- Submit Special Protocol Assessment Request (SPAR) for Cevira 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
- Secure partnership for further development and commercialization of Visonac and Cevira reflecting the product potential

2015 KEY ACHIEVEMENTS

- Hexvix/Cysview global in-market volume increased YoY 7% full year, with 11% volume growth in own markets
- Hexvix/Cysview in-market value increased YoY 20% full year
- Achieved Special Protocol Agreement for Cevira with FDA
- Patient enrollment initiated October 1
- Discussions ongoing with potential partners



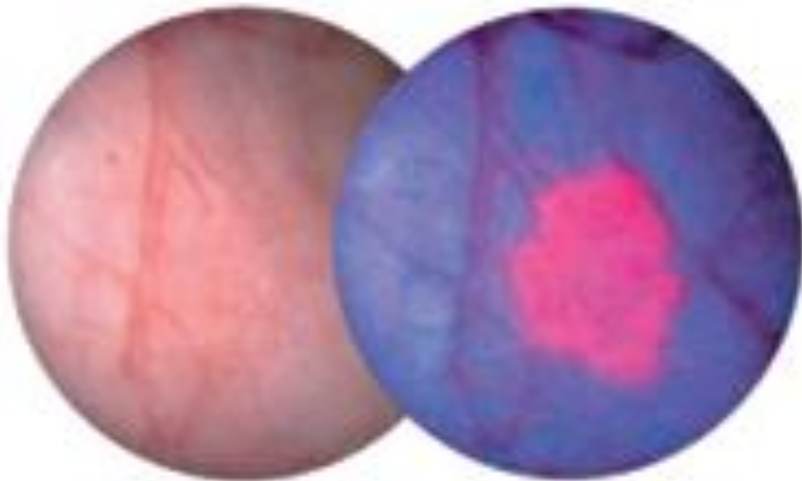
Commercial Update



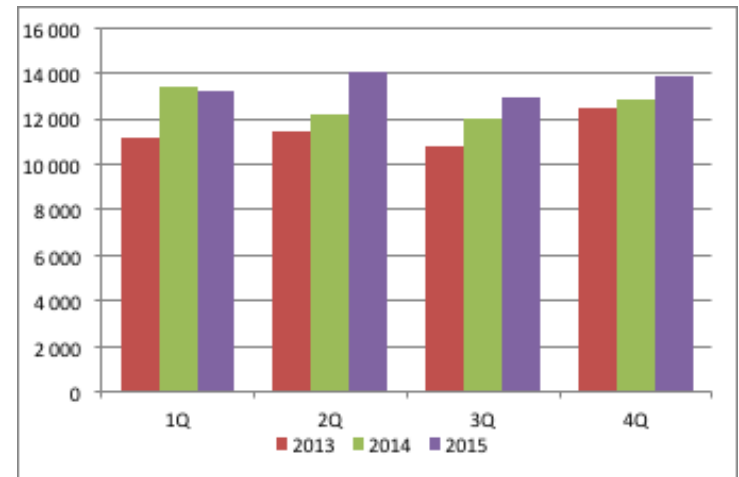
HEXVIX/CYSVIEW

A SIGNIFICANT GLOBAL SPECIALTY BRAND

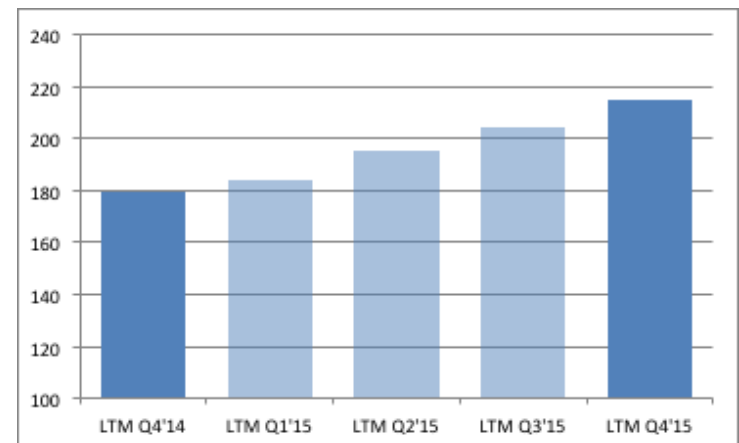
- Value of in-market sales of Hexvix/Cysview increased YoY 20% full year to NOK 215 million
- Hexvix/Cysview global in-market volume increased YoY 8% in the quarter, and 7% full year
- Overall franchise EBITDA for the year at NOK 28.7 million, improvement of 70% from prior year



Global in-market unit sales (by Q)



Global in-market value NOK mill (LTM)

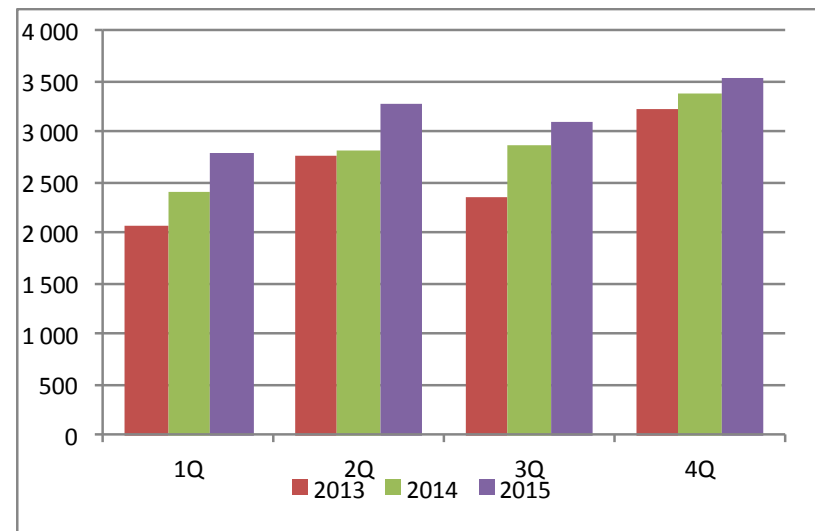


HEXVIX/CYSVIEW

SOLID PERFORMANCE IN NORDICS AND USA

- Photocure own sales revenue in the US and Nordics increased YoY 34% in 4Q and 35% full year to NOK 61.7 million
- US revenue increased full year 87%
 - Driven by in-market volume growth of 33%, price increases and FX
 - Permanent Blue Light Cystoscope placements of 65 at the end of 4Q
 - Continued progress on passage of bill to provide separate payment to hospitals for Cysview
- Nordic revenue increased full year 16%
 - In-market volume growth of 5%, market share increased to 40%
 - Continued double digit in-market volume growth in Sweden, full year 17% growth

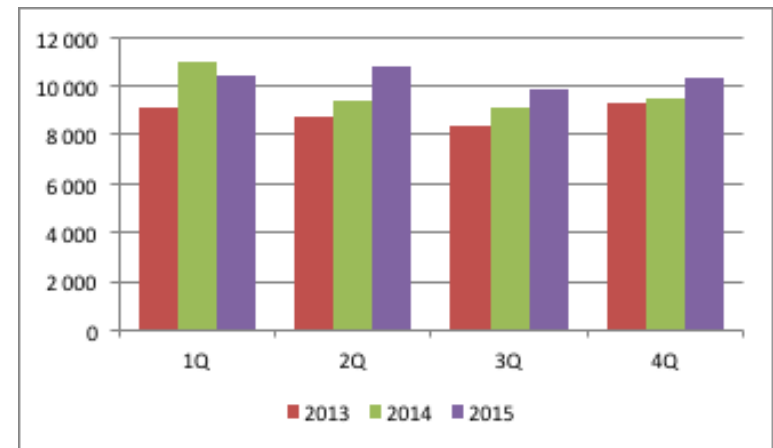
Own Hexvix/Cysview in-market unit sales
Nordic and US



HEXVIX/CYSVIEW PARTNER PROGRESS

- Partner revenue increased 34% in 4Q and 17% full year to NOK 54.1 million
 - 4Q revenue driven by timing of inventory replenishments in 2014
- End user volume growth 9% in 4Q and 6% full year
- Double digit unit growth full year in Germany and France
- New territories & partners in 2015
 - BioSyent Pharma in Canada
 - Expect commercial sales 1H 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



Pipeline Update



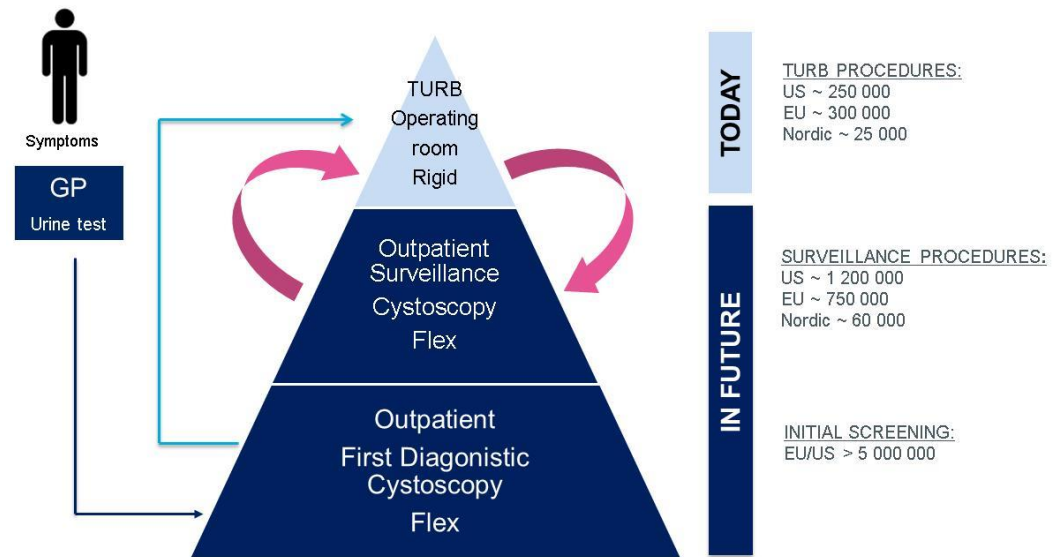
CREATING VALUE CLINICAL DEVELOPMENT PROGRAMS

	Technology	Indication	Phase 1	Phase 2	Phase 3	Status
Cevira®	PDT	Treatment of precursors of cervical cancer				Positive Phase 2b results published in British Journal of Dermatology SPA approved Exploring partnerships
Visonac®	PDT	Treatment of moderate to severe acne				Positive Phase 2b results SPA and PIP approved Exploring partnerships
Hexvix® Cysview®	PDD	Detection of bladder cancer, surveillance segment				First Patient, First Visit in October

HEXVIX/CYSVIEW EXPANDING INTO THE SURVEILLANCE SEGMENT

- Surveillance following initial diagnosis represents a significant growth opportunity of 2-3 times current TURB segment
- First Patient, First Visit in Hexvix/Cysview Phase 3 market expansion study in October
 - Study including 360 patients to 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

A MAJOR OPPORTUNITY

- Breakthrough single use and fully integrated drug-device technology to satisfy high need for novel non-surgical therapies to treat global epidemic of HPV/CIN populations
- Results of the Phase 2b trial are significant in HSIL patients
 - Statistically significant ($p=0.004$) HSIL (CIN2,3) regression
 - Statistically significant ($p=0.045$) virologic clearance of oncogenic HPV
 - Excellent tolerability and high physician & patient acceptance
- Achieved Special Protocol Agreement on phase 3 program with FDA for patients with HSIL
- Blockbuster sales potential based on premium pricing opportunity in large patients populations
 - ~1M cases HSIL annually in US & West EU with additionally 10-15M cases oncogenic HPV annually in US & West EU detected through routine cervical screening programs
 - HSIL and LSIL in need for new treatment options
 - At premium price levels, cost impact model demonstrates cost savings / benefit to the US health care system as compared to current treatment practice
- Further strengthened patent portfolio with issuance on new patents
- Continued interest from potential partners for development and commercialization

Cevira®



ajog.org

RESEARCH

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 Sadowky, 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 1/2, to define the appropriate population and endpoints for a phase 3 program.

3 months in women with CIN2, including an encouraging 83% (6/6 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.

hat shows promise in the oncogenic HPV, but not of other HAL PDT a tissue-bearing age who wish to be planned.

a, hexaminolevulinate, by

s with cervical intraepithelial

Drug Evaluation

EXPERT OPINION

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

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



VISONAC

PHASE 3 READY ASSET WITH CONSIDERABLE SALES POTENTIAL

- As documented in scientific literature and dermatology guidelines high unmet medical need for non-antibiotic, non-retinoid treatments in severe acne segment
 - Mono therapy with oral antibiotics (tetracyclines) effectiveness not well documented
 - Combinations of oral antibiotics plus topical agents or systemic retinoids only currently available effective treatment options
 - Toxicities of available agents/combination of agents make them unsuitable for long term use
- Positive Phase 2b results published in *British Journal of Dermatology*
 - Significant reduction in inflammatory lesions and improvement of overall acne severity as a topical monotherapy
 - Well tolerated regimen
- Phase 3 Ready with significantly reduced regulatory risk
 - SPA (US) and PIP (EU) agreed for global registration program
- Further strengthened patent portfolio with issuance of new patents
- Continued interest from potential partners for development and commercialization



Financials



HEXVIX/CYSVIEW CONTINUED GROWTH FOURTH QUARTER 2015

- Revenue from own sales of Hexvix/
Cysview increased YoY 34% in 4Q and
35% full year
 - Nordic 4Q revenue growth of 13%
 - US 4Q revenue growth of 95%
- Partner 4Q revenue increased YoY
34% and full year 17%
 - Changed timing of supply to partner compared
to last year
- Total in market sales value increased
YoY 22% in 4Q and 20% year to date
 - Full year value NOK 215 million

SALES - MNOK	Q4 '15	FY '15
Hexvix - Nordic	12,3	38,7
<i>YoY growth</i>	13 %	16 %
Cysview - US	7,3	23,0
<i>YoY growth</i>	95 %	87 %
Hexvix own sales	19,6	61,7
<i>YoY growth</i>	34 %	35 %
Hexvix partner sales	13,6	54,1
<i>YoY growth</i>	34 %	17 %
Total Photocure	33,2	115,8
<i>YoY growth</i>	34 %	26 %
Revenue in-market (*)	59,5	215,0
<i>YoY growth</i>	22 %	20 %
Units in-market (*)	13 907	54 129
<i>YoY growth</i>	8 %	7 %

(*) Calculated in-market sales

PROFIT & LOSS

FOURTH QUARTER 2015

<i>MNOK</i>	Q4 '15	Q4 '14	Change	FY '15	FY '14	Change
Hexvix / Cysview revenues	33,2	24,8	34 %	115,8	92,0	26 %
Other sales revenues	0,0	0,0		6,5	1,6	
Signing fee and milestones	1,3	1,2	9 %	12,4	35,4	-65 %
Total revenues	34,5	26,0	33 %	134,7	129,0	4 %
Gross profit	32,5	24,1	34 %	126,5	122,0	4 %
Operating expenses	-41,2	-33,8	22 %	-144,6	-126,1	15 %
EBITDA	-8,7	-9,7		-18,1	-4,2	
EBIT	-10,2	-10,0		-22,0	-5,6	
Net financial items excl PCI	0,1	4,6		4,5	7,2	
Impairment loss shares PCI	-3,0	-8,2		-10,6	-8,2	
Profit/loss(-) before tax	-13,1	-13,6		-28,1	-6,7	
Tax expenses	3,7	-18,0		-8,1	-18,0	
Net profit/loss(-)	-9,4	-31,6		-36,2	-24,7	

- Total revenue increase YoY 33% in 4Q and 4% full year
 - Revenue increase excluding signing fees & milestones at 34% in 4Q and full year 31%
 - Operating expenses increase YoY 22% in 4Q and 15% full year
 - Mainly driven by FX, year to date approx. 4% increase in constant currencies
 - EBITDA at NOK -18,1 million full year
- 15 – EBITDA improvement excluding signing fees and milestones of NOK 9.0 million



SEGMENTS

FOURTH QUARTER 2015

- Commercial franchise:
 - Improvement in revenues and EBITDA
 - EBITDA margin full year at 21%

<i>MNOK</i>	<u>Q4 '15</u>	<u>Q4 '14</u>	<u>FY '15</u>	<u>FY '14</u>	<u>Change</u>
<u>Commercial Franchise</u>					
Total revenues	34,5	26,0	134,7	98,2	37 %
Gross profit	32,5	24,1	126,5	91,2	39 %
Operating expenses	-27,9	-19,1	-97,8	-74,4	32 %
EBITDA	4,5	5,1	28,7	16,8	70 %

- Development portfolio:
 - Activities related to Cevira SPAR
 - Cysview post marketing commitment phase 3 capitalized

<u>Development Portfolio</u>					
Total revenues	0,0	0,0	0,0	0,0	
Gross profit	0,0	0,0	0,0	0,0	
Operating expenses	-13,2	-14,7	-46,8	-51,8	-10 %
EBITDA	-13,2	-14,7	-46,8	-51,8	-10 %
<u>Total</u>					
EBITDA	-8,7	-9,7	-18,1	-34,9	-48 %

(*) One-Off's excluded

Salix termination fee

30,8

CASH FLOW

FOURTH QUARTER 2015

<i>MNOK</i>	Q4 '15	Q4 '14	FY '15	FY '14
Cash flow from:				
- Operations	-1,8	-2,9	-21,0	-6,1
- Investments	-3,6	0,6	-12,6	3,4
- Financing	0,0	0,7	2,4	0,7
Net change in cash	-5,4	-1,6	-31,2	-2,0
Ending cash balance	134,0	165,2	134,0	165,2

- 4Q cash flow from operations NOK -1.8 million, full year NOK -21.0
 - Full year improvement of NOK 15.9 million from last year, excluding impact of Salix NOK 30.8 million
- Full year cash flow from investments NOK -12.6 million.
 - Includes investments of NOK 14.4 million in intangible assets mainly related to the initiation of the phase 3 post-marketing commitment trial for Cysview
- Year end cash balance at NOK 134.0 million

BALANCE SHEET

PER 31 DECEMBER 2015

- Non current assets includes NOK 5.9 million in shares in PCI Biotech and deferred tax asset of NOK 23.5 million
- No interest bearing debt at year end
- Shareholder's equity of NOK 210.1 million
- Equity ratio of 85%
- Photocure held 35,476 own shares at end of year

<i>MNOK</i>	31.12 2015	31.12 2014
Non-current assets	76,4	76,5
Inventory & receivables	37,6	28,8
Cash & equivalents	134,0	165,2
Total assets	248,1	270,6
Shareholders equity	210,1	240,1
Long term liabilities	4,0	3,1
Current liabilities	34,0	27,5
Total equity & liabilities	248,1	270,6
Equity ratio	85 %	89 %

Outlook



OUTLOOK

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FINANCIAL

- Increased Hexvix/Cysview unit sales growth rates in 2016

CLINICAL

- Finalize recruitment and reporting of clinical results of Hexvix/Cysview phase 3 market expansion study in 2017

PARTNERSHIP

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