

PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

RESULTS OF THE FOURTH QUARTER AND
FULL YEAR 2013

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



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HIGHLIGHTS FOURTH QUARTER AND FULL YEAR 2013

- Hexvix/Cysview sales revenues increased 28% in 4Q 2013, 16% for FY 2013, driven by strong customer demand across major markets
 - Photocure's own sales revenues in US and Nordics increased 34% in 4Q 2013, 29% for FY 2013
 - Partner sales revenues increased 23% in 4Q 2013, 5% for FY 2013
 - Value of global in-market sales reach NOK 150 million for FY 2013
- Agreement with Galderma (Nestle Skin Care) triggers exploration of potential development and commercialization partners for Visonac
- CMS packaged payment policy including Cysview announced in 4Q 2013, effective 01 Jan 2014
- Discussions with the US FDA on appropriate Cevira Phase 3 population initiated post response to Fast Track Application
- Operating loss (excl. restructuring and one offs) of NOK 10.5 million 4Q 2013, NOK 63.0 million FY 2013
- Cash and cash equivalents of NOK 167 million

Commercial Update

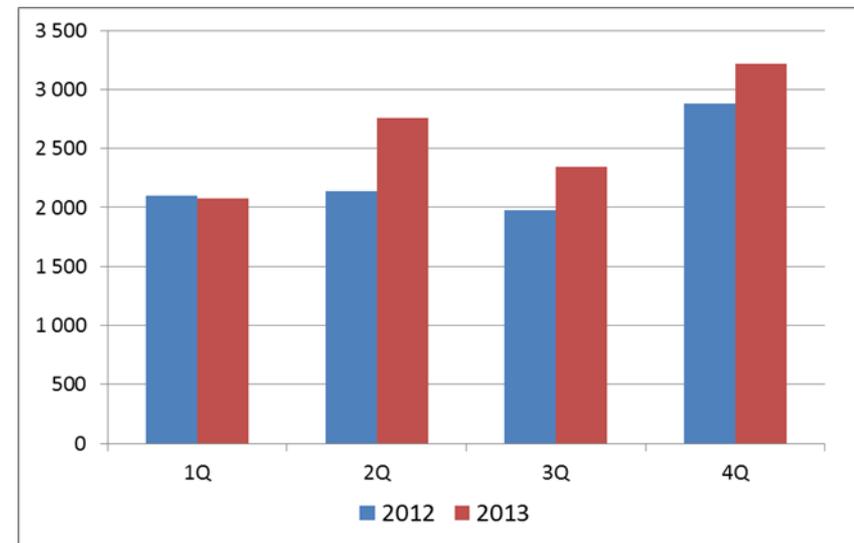


HEXVIX/CYSVIEW

SOLID PERFORMANCE IN NORDICS

- Photocure own sales revenues in the US and Nordics increased 34% in 4Q 2013 and 29% for FY 2013
- Key drivers include strong customer demand and price increases in Nordics
- Nordic revenue growth of 33% in 4Q 2013 and 21% for FY 2013
 - Volume growth of 10% in 4Q 2013 and 8% for FY 2013
 - Volume growth in Sweden was 47% in 4Q, and 38% for FY 2013
 - Regional market share increased to 38% of TURBs
 - Increasing both number and productivity of blue light cystoscopies

Own Hexvix/Cysview in-market unit sales



HEXVIX/CYSVIEW CMS RULING HINDERS US GROWTH

- US 4Q 2013 revenue growth of 37% and 68% for FY 2013
 - Volume growth of 19% in 4Q 2013 and 51% for FY 2013
- CMS packaged payment policy released in 4Q 2013 and includes Cysview into overall procedure payment without increasing payment for cost of drug
 - Impacts growth of BLCs, exit year at 36 permanent installations, 3 under evaluation and 10 awaiting capital approval
- Photocure working with all key stakeholders to secure sustainable reimbursement
 - Urologists, KOLs, AUA, ACS, Patients, BCAN, interested members of US Congress



Bladder Cancer Advocacy Network
BCAN
Leading the way to answers and a cure

FIND ANSWERS **ADVANCE RESEARCH** **GET INVOLVED**

Home > Blog > Access to Blue Light Cystoscopy

CATEGORIES

Blog

ARCHIVES

February 2014 (1)
January 2014 (4)
December 2013 (6)

Access to Blue Light Cystoscopy

December 5, 2013
by Monica Smith

Over the past few days, you may have heard about the issue regarding reimbursement of blue light cystoscopy. As all of you know, there are very few treatments and innovations for bladder cancer. It to BCAN's position that everyone should have equal access to all treatments, tests and innovations that have been approved by the FDA.

When reimbursement is restricted, it limits access for patients to care that may improve their quality of life. As a patient



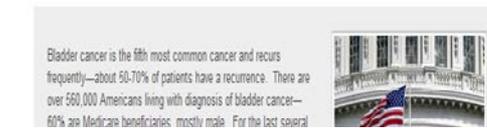
Action Home Congressional Directory Issues

Action Home / Save Patient Access to Bladder Cancer Diagnosis and Treatment

Recommend Shares 184 8-1 3 Tweet 10 Email

Save Patient Access to Bladder Cancer Diagnosis and
Treatment

Send Letters to Congress : 1,646 Letters Sent So Far



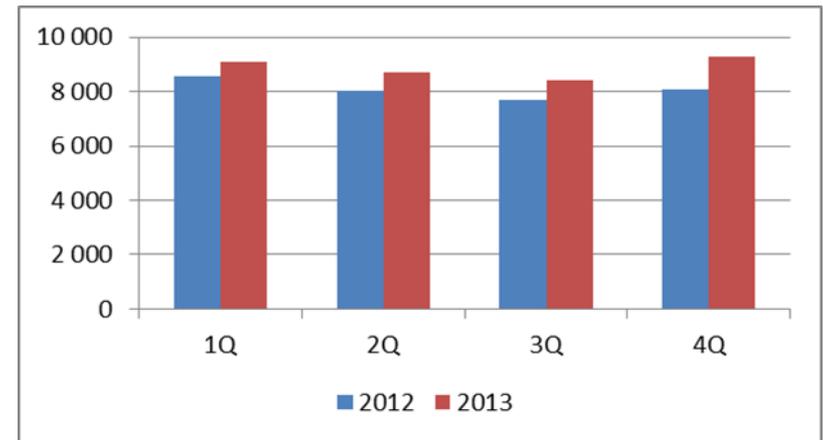
Bladder cancer is the fifth most common cancer and recurs frequently—about 50-70% of patients have a recurrence. There are over 500,000 Americans living with diagnosis of bladder cancer—60% are Medicare beneficiaries, mostly male. For the last several

HEXVIX

IPSEN STRONG PARTNER IN EUROPE

- Partner revenue increased 23% in 4Q 2013 and 5% for FY 2013
 - Volume growth of 15% in 4Q 2013, and 10% for FY 2013
 - Double digit growth in key markets
 - Strong customer demand
 - Germany represents 68% of total revenue
- Positive momentum leading into 2014 with 4Q 2013 reimbursement gains in Italy and France

Hexvix Partner Unit Sales Per Quarter



Pipeline Update



CREATING VALUE

DIVERSE PRODUCT PORTFOLIO

	Technology	Indication	Phase 1	Phase 2	Phase 3	Status
Lumacan®	PDD	Detection of colorectal cancer				Worldwide license with Salix Phase 1 / 2 Clinical trial underway
Visonac®	PDT	Treatment of moderate to severe acne				Positive Phase 2b results SPA approved Exploring partnerships
Cevira®	PDT	Treatment of precursors of cervical cancer				Positive Phase 2b results In discussion with FDA on Phase 3 patient population Exploring partnerships

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 agreed in 2Q 2013
 - Development and regulatory risks significantly reduced
- Agreement with Galderma (Nestlé Skin Care) in 4Q 2013 allows Photocure freedom to explore early partnerships
 - Outreach to potential partners for development and commercialization initiated in 4Q 2013

Baseline

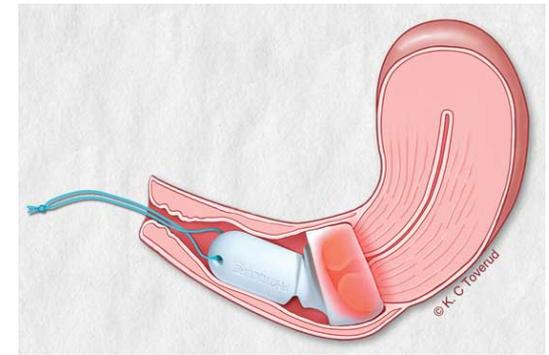


Week 12
6 weeks after last treatment

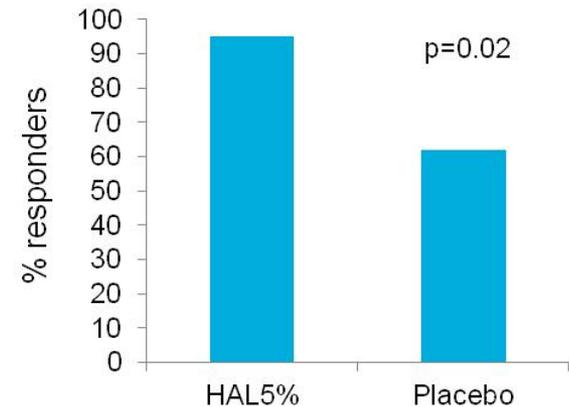


CEVIRA A MAJOR OPPORTUNITY

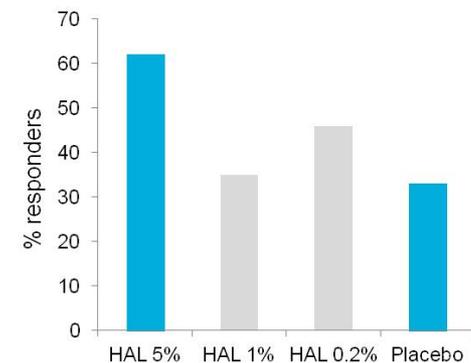
- High unmet medical need for novel therapies to treat global epidemic of HPV/CIN populations
- Single use and integrated drug-device
 - Breakthrough technology allows for convenience and simplicity which can be integrated in even under-developed healthcare systems
- Results of the Phase 2b trial are significant
 - Significant overall response in CIN 2
 - High clearance of HPV, including highly oncogenic HPV 16/18
 - Excellent tolerability and high physician & patient acceptance



CIN2 patient response 6 months after last treatment (n=40)



HPV 16/18 clearance in CIN 1/2 patients 6 months after last treatment (n=50)



CEVIRA STATUS OF REGULATORY INTERACTIONS

- In 4Q 2013 FDA transferred review responsibility to Division of Bone, Reproductive and Urologic Products (DBRUP) from Oncology Division
- Photocure initiated discussion with DBRUP, focused on recently published diagnostic and clinical management guidelines
 - The recently published diagnostic guidelines classify cervical lesions in a two tiered system rather than the previous three tiers
 - Low-grade Squamous Intraepithelial Lesions (LSIL), previously classified as CIN1
 - High-grade Squamous Intraepithelial Lesions (HSIL), previously classified as CIN2 and CIN3
 - The recently published management guidelines include the updated diagnostic guidelines, while recognizing the need to manage women of child bearing potential with CIN2 differently, due to the serious morbidities associated with surgery
- Photocure will re-evaluate the Phase 2b clinical data in accordance with recently published diagnostic guidelines and continue discussions with the FDA to align on the Phase 3 patient population
- Fast Track application not approved at this time
- Potential partner discussions continue concurrently

Financials



STRONG VOLUME GROWTH

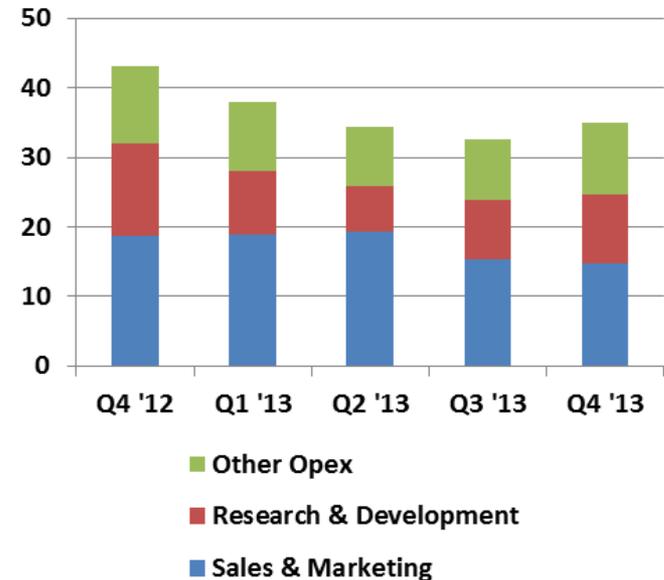
- Revenue from own sales of Hexvix/ Cysview increased 34% in 4Q 2013
 - Nordic revenue increased 33%. In-market unit sales to pharmacies increased 10%
 - US revenue increased 37% driven by end user volume growth of 19%, price increase of 10% and FX impact
- Partner 4Q 2013 revenue increased 23%
 - In-market volume growth of 15%
 - Supply to partner compared to deliveries in 2012 and FX impact
- Total in market sales increased 28% in 4Q 2013 and 18% for FY 2013 to NOK 150 million

SALES - MNOK	Q4 '13	FY '13
Hexvix own sales	13,0	38,1
<i>YoY growth</i>	34 %	29 %
Hexvix partner sales	11,5	39,8
<i>YoY growth</i>	23 %	5 %
Total Photocure	24,5	77,9
<i>YoY growth</i>	28 %	16 %
Revenue in-market (*)	44,0	150,9
<i>YoY growth</i>	28 %	18 %
Units in-market (*)	12 496	45 916
<i>YoY growth</i>	14 %	11 %

(*) Calculated in-market sales to hospitals/pharmacies

TIGHT FISCAL MANAGEMENT

- R&D expenses at NOK 9.8 million in 4Q 2013
 - Main activity related to development of Cevira and Visonac as well as ongoing regulatory work for Hexvix/Cysview
- 4Q 2013 S&M expenses at NOK 14.8 million
 - In line with 3Q 2013
 - A decline from 1H 2013 level due to cessation of marketing support program with partner
 - FY 2013 reduction of 3% compared to FY 2012
- Other OPEX down FY 14% excluding one offs
 - Restructuring finalized
 - One-off related to payment to Galderma of USD 1.5 million



<i>MNOK</i>	Q4 '13	FY '13	Change
Research & Development	9,8	34,0	-32 %
Sales & Marketing	14,8	68,4	-3 %
Other Opex	10,3	37,4	-14 %
Operating expenses	34,9	139,8	-15 %
Restructuring	-0,3	3,7	
One-Off items	8,9	8,9	
Total	43,5	152,3	-7 %

PROFIT & LOSS

FOURTH QUARTER 2013

<i>MNOK</i>	Q4 '13	Q4 '12	Change	FY '13	FY '12	Change
Hexvix / Cysview revenues	24,5	19,1	28 %	77,9	67,8	15 %
Other sales revenues	0,7	0,6	9 %	1,4	7,3	-81 %
Signing fee and milestones	1,1	27,6	-96 %	4,3	58,7	-93 %
Total revenues	26,3	47,3	-44 %	83,6	133,8	-38 %
Gross profit	24,4	45,6	-46 %	76,8	124,4	-38 %
Operating expenses	-34,9	-43,1	-19 %	-139,8	-163,7	-15 %
Operating profit/loss(-) recurring	-10,5	2,5		-63,0	-39,2	
Restructuring expenses	0,3	-		-3,7	-	
One-Off items	-8,9	-		-8,9	-	
Net profit/loss(-)	-9,2	3,3		-59,0	-47,9	

- Total revenues for 4Q 2013 NOK 26.3 million, decreased 44% from prior year driven by lower milestone revenues and sales of API
- FY 2013 recurring operating loss excluding milestones at NOK 67.3 million compared to last year NOK 97.9 million

CASH FLOW

FOURTH QUARTER 2013

<i>MNOK</i>	Q4 '13	Q4 '12	FY '13	FY '12
Cash flow from:				
- Operations	-17,8	27,5	-99,7	-54,9
- Investments	0,9	1,7	4,5	9,1
- Financing activities	1,9	-0,2	-40,4	-6,5
Net change in cash	-15,0	29,0	-135,6	-52,4
Ending cash balance	167,3	302,8	167,3	302,8

- 4Q 2013 cash flow from operations NOK -17.8 million, including payment to Galderma of NOK 8.9 million
- FY 2013 operational cash flow negatively impacted by significant non-recurring working capital changes
- Dividend payment of NOK 42.4 million in 2Q 2013
- Year end cash balance at NOK 167.3 million

BALANCE SHEET

PER 31 DECEMBER 2013

- Non current assets includes NOK 32.6 million in shares in PCI Biotech and deferred tax asset of NOK 49.1 million
- No interest bearing debt
- Shareholder's equity of NOK 269.1 million
- Equity ratio of 89%
- Photocure held 72,976 own shares at year end

<i>MNOK</i>	31.12	31.12
	2013	2012
Non-current assets	104,8	104,9
Inventory & receivables	29,7	25,3
Cash & equivalents	167,3	302,8
Total assets	301,7	433,0
Shareholders equity	269,1	380,3
Long term liabilities	2,3	1,6
Current liabilities	30,3	51,1
Total equity & liabilities	301,7	433,0
Equity ratio	89 %	88 %

Summary and Outlook



EXECUTING OUR STRATEGY

- Build a speciality pharma company, focused on cancer and dermatology
- Maximize the potential of the company's Photodynamic Technology Platform – Photocure Technology™
- Leverage our experience to develop, register and commercialize new products based on Photocure Technology™
- Build a strong commercial platform in select territories

Key Achievements FY 2013:

- ✓ Strong Nordic and Partner sales of Hexvix
- ✓ Built momentum in own sales of Cysview
- ✓ SPA approved and EU Scientific Advice aligned for Visonac Phase 3 program
- ✓ Galderma agreement reached allowing for early exploration of partnerships for Visonac
- ✓ Successful completion of Phase 2b trial of Cevira
- ✓ Tight fiscal management

OUTLOOK & TARGETS 2014

- Hexvix/Cysview global in-market unit sales growth of $\geq 10\%$
- Obtain sustainable reimbursement solution in US
- Secure partnership for development and commercialization of Visonac
- Secure regulatory alignment on Cevira clinical development to progress partner discussions
- End of year cash reserve \geq NOK 105 million, excluding milestone payments