

PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

RESULTS OF FOURTH QUARTER
AND FULL YEAR 2014

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DELIVERING ON KEY OBJECTIVES

KEY 2014 OBJECTIVES

2014 ACHIEVEMENTS

- | | |
|---|--|
| • Hexvix/Cysview global in-market unit sales growth of $\geq 10\%$ | 10% Growth |
| • Obtain sustainable reimbursement solution in US | Bill with strong bipartisan support introduced to US Congress |
| • Secure partnership for development and commercialization of Visonac | Established interest with key dermatology players; discussions to continue in 2015 |
| • Secure regulatory alignment on Cevira clinical development to progress partner discussions | Successful end of phase 2 meeting with FDA, and Positive Scientific Advice meetings with key EU regulators on Cevira phase 3 program |
| • End of year cash reserve of NOK 145-155 million incl. termination payment, excl. milestone payments | Cash of NOK 165 million at year end |

KEY HIGHLIGHTS FOR Q4 2014 AND FY 2014

- Hexvix/Cysview franchise reached profitability in 2014
 - Seven consecutive quarters of improved results
 - Global in-market sales growth of 11% in 4Q to NOK 49 million and 19% for the full year to NOK 180 million. Full year unit growth at 10%, in line with guidance
 - *World Journal of Urology* publication January 2015 showed that Hexvix fluorescence-guided bladder resection significantly improved overall survival and recurrence free survival compared to resection performed with standard white light
- Significant improvement in financial performance
 - Full year net result before tax at break even (NOK 1.5 million) versus a loss of NOK 66.9 million in 2013

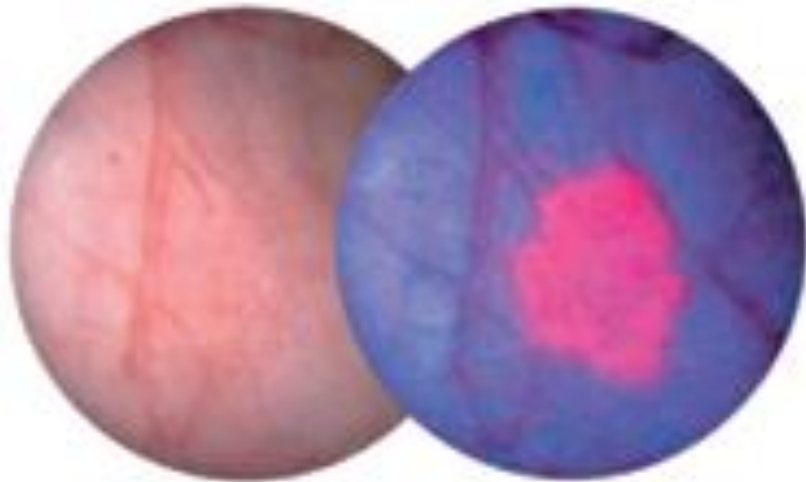
Commercial Update



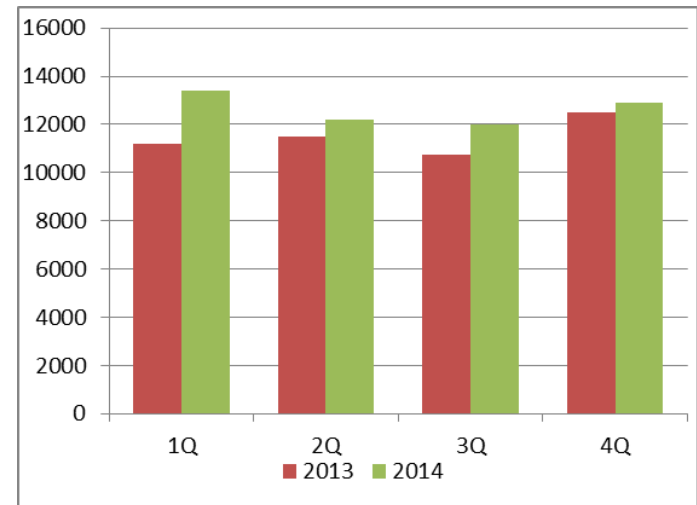
HEXVIX/CYSVIEW

A SIGNIFICANT GLOBAL SPECIALTY BRAND

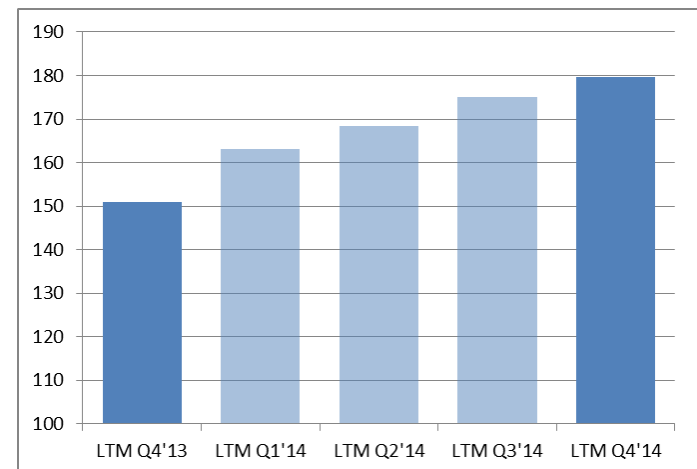
- Value of in-market sales of Hexvix/Cysview increased YOY 11% in the quarter and 19% FY 2014 to NOK 180 million
- Hexvix/Cysview global in-market volume growth YOY 3% in the quarter and 10% FY 2014
- Overall franchise operating profit FY 2014 at NOK 10.4 million



Global in-market unit sales (by Q)



Global in-market value NOK mill (LTM)

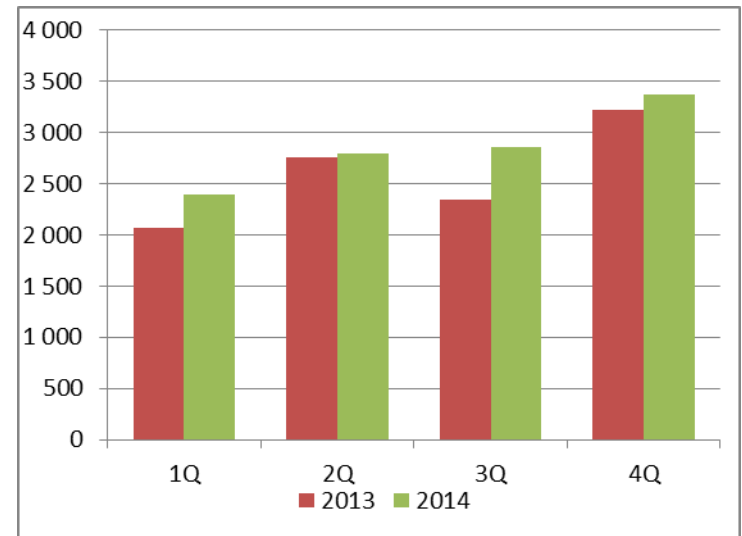


HEXVIX/CYSVIEW

SOLID PERFORMANCE IN NORDICS

- Photocure own sales revenue in the US and Nordics increased 13% in 4Q to NOK 14.6 million and 20% FY 2014 to NOK 45.7 million
- Key drivers include strong customer demand and price increases
- Nordic revenue in 4Q increased 2%, FY 2014 12%
 - In-market unit growth of 5% FY 2014
 - Double digit in-market volume growth in Sweden
 - Increasing both number and productivity of blue light cystoscopes
- Price increase in Denmark effective in December

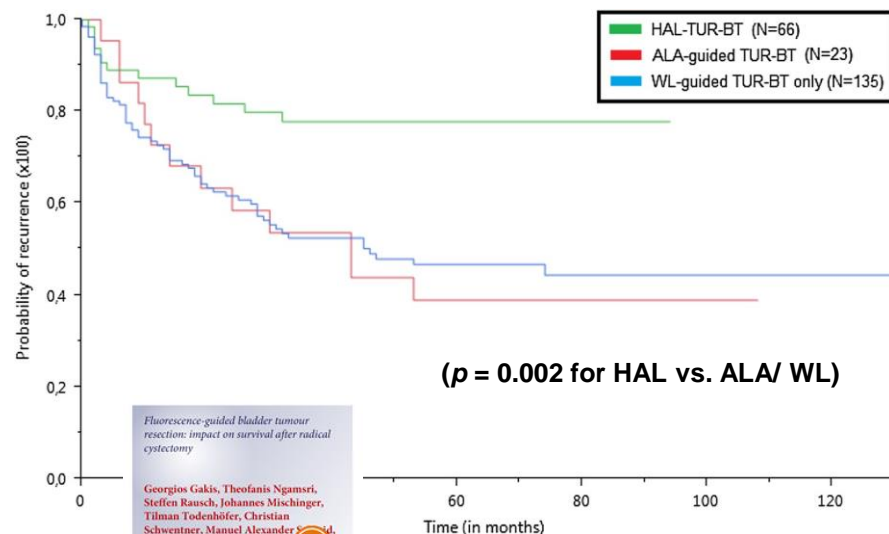
Own Hexvix/Cysview in-market unit sales
Nordic and US



HEXVIX/CYSVIEW INCREASED MOMENTUM IN US

- US 4Q revenue growth of 60% and FY 2014 of 49%
- Key drivers include 33% volume growth, price increases and FX
- Despite limited 2014 CMS reimbursement, permanent Blue Light Cystoscope placements increased to 51 in 4Q, compared to 36 at YE 2013
- Continued progress towards securing sustainable reimbursement
 - Broad bi-partisan support for legislation introduced to US Congress in June to provide separate payment to hospitals for Cysview
 - Bill not acted upon in 2014, expect passage in 2015

- Continued positive data flow fuels forward momentum
 - *World Journal of Urology* publication validating positive impact on overall and progression free survival



*Recurrence-free survival

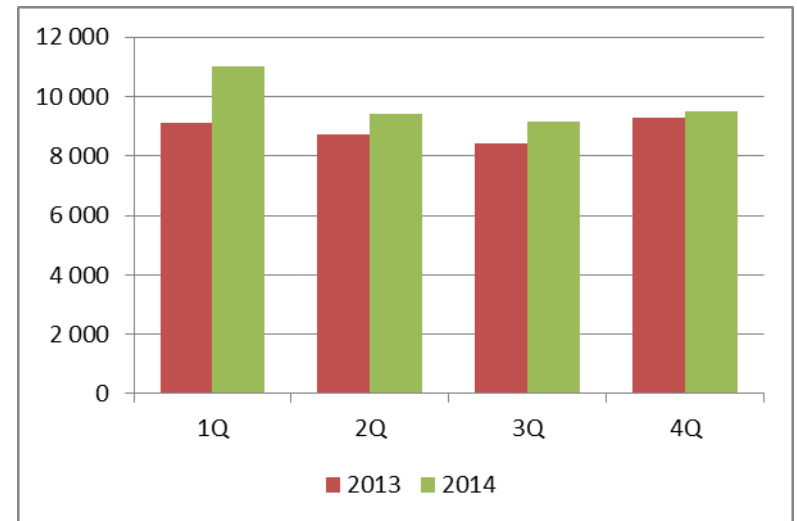


HEXVIX/CYSVIEW

STRONG PERFORMANCE IN EUROPE

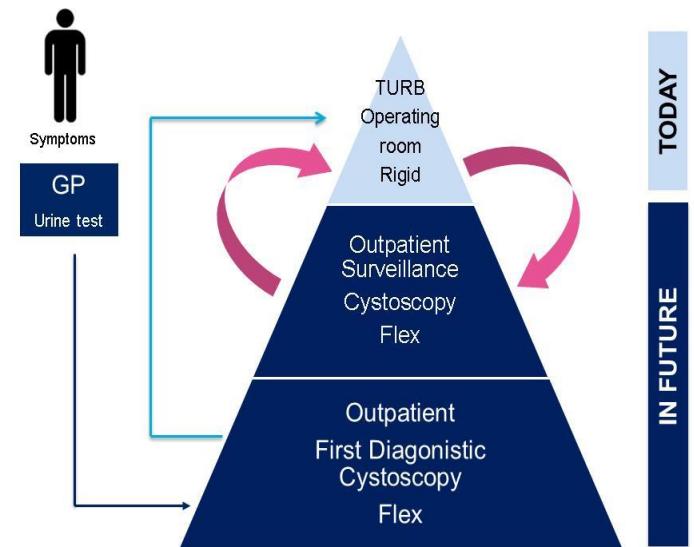
- Strong customer demand with end user volume growth 3% 4Q, 10% FY 2014
- Partner revenue decreased 12% in 4Q
 - Timing of inventory replenishments in the 4Q 2013
- FY 2014 partner revenue increased 16% to NOK 46.3 million
- FY 2014 growth driven mainly by sales in Germany, France and Austria

Hexvix Partner Unit Sales Per Quarter



HEXVIX/CYSVIEW NEAR AND MID-TERM GROWTH DRIVERS

- Volume growth in existing markets
 - Increased penetration in the US
 - Incorporation in national guidelines (EU & US); publication of expert opinions
- Improve profitability of Hexvix/Cysview franchise
- Expand into new markets and territories
 - Surveillance following initial diagnosis represents significant opportunities
 - Positive early clinical experience with flexible cystoscope
 - Initiation of Phase 3 study with 360 patients for examining improved detection rate of Cysview blue light cystoscopy vs white light cystoscopy
 - Alignment with FDA on study design necessary to obtain label extension
 - Cysview approved by Health Canada and evaluation of commercial options ongoing






Pipeline Update



CREATING VALUE

DIVERSE PRODUCT PORTFOLIO

	Technology	Indication	Phase 1	Phase 2	Phase 3	Status
Cevira®	PDT	Treatment of precursors of cervical cancer				Positive Phase 2b results Submit US SPA request by mid 2015 Exploring partnerships
Visonac®	PDT	Treatment of moderate to severe acne				Positive Phase 2b results SPA and PIP approved Exploring partnerships
Lumacan®	PDD	Detection of colorectal cancer				License agreement with Salix terminated Development on hold

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
- Results of the Phase 2b trial are significant
 - Significant overall response in patients with CIN 2
 - High clearance of highly oncogenic HPV
 - Excellent tolerability and high physician & patient acceptance
- Continuing progress in determining next steps in development
 - Confirmed readiness for Phase 3 with major EU regulators in CIN 2 patient population
 - Successful end of Phase 2 meeting with FDA
 - Plan to submit Special Protocol Assessment Request (SPAR) by mid-2015
- Continued discussions with 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 Hillemanns, MD; Francisco García, 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%, and placebo ointment and were evaluated for response after 3-6 months based on biopsy, Papanicolaou test, and oncogenic human papillomavirus (HPV) test. All efficacy analyses were performed on blinded central histology review to avoid interreader variability. Adverse events, blood biochemistry, and vital signs were assessed after 3 months.

RESULTS: There were no statistically significant differences between placebo and either the CIN 1 or combined CIN 1/2 populations. A 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% (5/8 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.

CONCLUSION: HAL PDT is a novel therapy that shows promise in the treatment of CIN2 including clearance of oncogenic HPV, but not of CIN1. The positive risk/benefit balance makes HAL PDT a tissue-preserving alternative in women of childbearing age who wish to preserve the cervix. Confirmatory studies are planned.

Key words: cervical intraepithelial neoplasia, hexaminolevulinate, human papillomavirus, photodynamic therapy.

Cite this article as: Hillemanns P, García F, Petry KU, et al. A randomized study of hexaminolevulinate photodynamic therapy in patients with cervical intraepithelial neoplasia 1/2. Am J Obstet Gynecol 2014;212:e8-x.e8.

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

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



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
- High level of interest from potential partners for development and commercialization

Baseline



Week 12
6 weeks after last treatment



LUMACAN STRATEGY

- Global development and commercialization rights licensed to Salix in October 2010
 - Received upfront and development payments of \$8.5M
- Following the proposed merger agreement between Salix and Cosmo Pharmaceuticals SpA Photocure and Salix agreed to terminate the license
 - Salix paid PHO \$5M, all rights and IP revert to PHO
- Comprehensive evaluation performed of clinical data, competitive landscape, pricing and reimbursement scenarios
- Additional clinical trials will not be initiated at this time



Financials



HEXVIX/CYSVIEW CONTINUED GROWTH FOURTH QUARTER 2014

- Revenue from own sales of Hexvix/
Cysview increased 13% in 4Q and 20% FY
 - Nordic 4Q revenue growth of 2%, FY growth of 12%
 - US revenue increased 60% in 4Q and 49% FY
- Partner 4Q revenue decreased 12% in 4Q, FY increase of 16%
 - Changed timing of supply to partner compared to the same period in 2013
- Total in market sales value increased 11% in 4Q and 19% FY
 - FY value NOK 180 million compared to NOK 151 million in 2013

SALES - MNOK

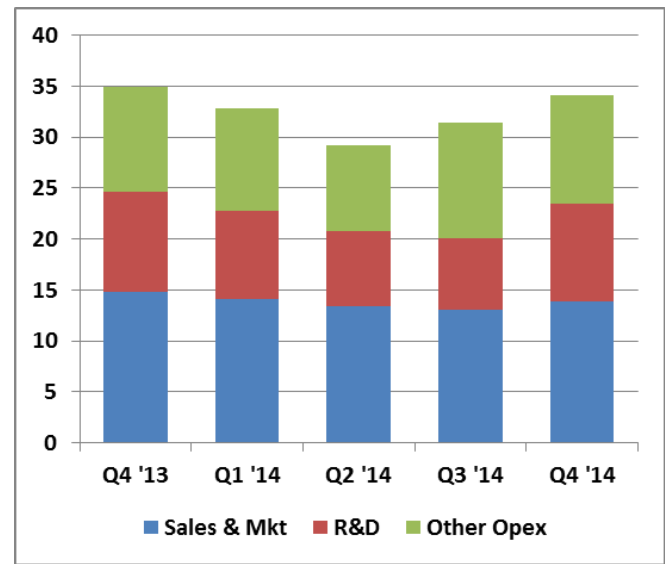
	Q4 '14	FY '14
Hexvix own sales	14,6	45,7
<i>YoY growth</i>	13 %	20 %
Hexvix partner sales	10,1	46,3
<i>YoY growth</i>	-12 %	16 %
Total Photocure	24,8	92,0
<i>YoY growth</i>	1 %	18 %
Revenue in-market (*)	48,7	179,7
<i>YoY growth</i>	11 %	19 %
Units in-market (*)	12 878	50 489
<i>YoY growth</i>	3 %	10 %

(*) Calculated in-market sales

OPERATING EXPENSES FOURTH QUARTER 2014

- Total Opex at NOK 34.1 million in 4Q. FY at NOK 127.6 million, a reduction of 9%.
 - FY reduction including one-off expenses 16%
- R&D expenses at NOK 9.6 million in 4Q
 - FY main activity re-analysis of the Phase 2b Cevira data
- 4Q S&M expenses at NOK 13.9 million, reduction of 6%
 - Reduced spending related to commercial activities in the US awaiting outcome on reimbursement
- 4Q Other Opex at NOK 10.7 million, reduction of 4%

MNOK	Q4 '14	FY '14
Research & Development	9,6	32,6
<i>YoY growth</i>	6 %	1 %
Sales & Marketing	13,9	54,5
<i>YoY growth</i>	-6 %	-20 %
Other Opex	10,7	40,5
<i>YoY growth</i>	-4 %	4 %
Operating expenses	34,1	127,6
<i>YoY growth</i>	-2 %	-9 %



Comparison excludes one-off spending in 2013 of NOK 8.9 million

PROFIT & LOSS

FOURTH QUARTER 2014

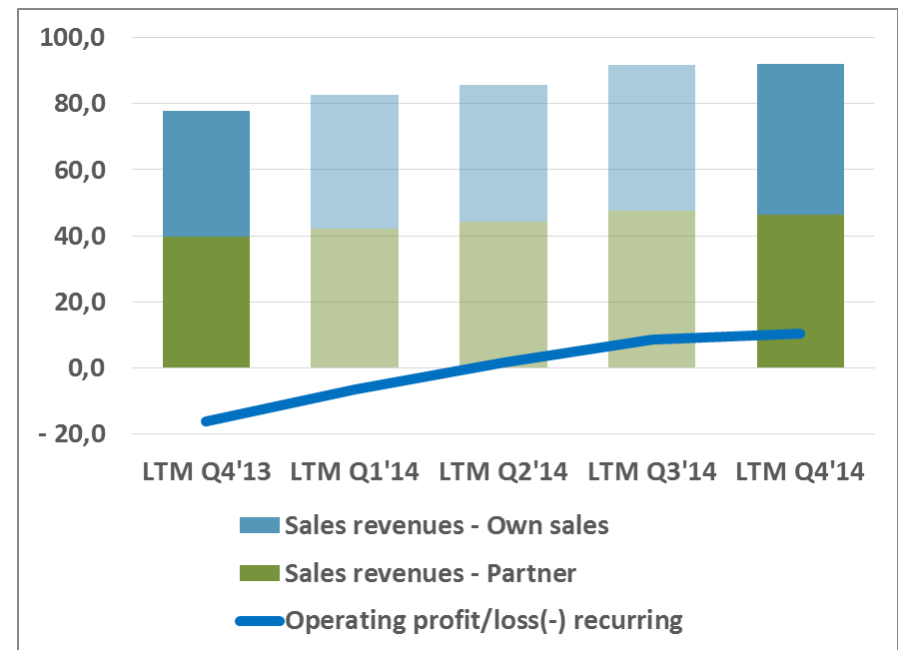
<i>MNOK</i>	Q4 '14	Q4 '13	FY '14	FY '13
Hexvix / Cysview revenues	24,8	24,5	92,0	77,9
Other sales revenues	-	0,7	1,6	1,4
Signing fee and milestones	1,2	1,1	35,4	4,3
Total revenues	26,0	26,3	129,0	83,6
Gross profit	24,1	24,4	122,0	76,8
Operating expenses	-34,1	-34,9	-127,6	-139,8
Operating profit/loss(-) recurring	-10,0	-10,5	-5,6	-63,0
- Excluding Salix termination fee	-10,0	-10,5	-36,4	-63,0
Net financial profit/loss(-)	4,6	1,8	7,2	8,7
Profit/loss(-) before tax	-5,4	-17,3	1,5	-66,9

- 4Q operating loss at NOK 10.0 million, FY at NOK 5.6 million
 - FY improvement excl. Salix payment of NOK 26.6 million
- Full year net result before tax at break even (NOK 1.5 million) versus a loss of NOK 66.9 million in 2013.

HEXVIX/CYSVIEW FRANCHISE FOURTH QUARTER 2014

- FY 2014 operating result for commercial activities at NOK 10.4 million compared to NOK 8.7 million LTM 3Q 2014
 - FY 2014 improvements of NOK 26 million compared to FY 2013
- Seven consecutive quarters with result improvements, driven by both revenue increases as well as cost reductions

Hexvix Sales & Opr Result LTM (NOK mill)



All numbers as per quarterly segment report
 Includes all commercial activities, excluding milestone revenue
 Costs excludes all R&D
 Costs includes allocation of G&A

CASH FLOW

FOURTH QUARTER 2014

<i>MNOK</i>	Q4 '14	Q4 '13	FY '14	FY '13
Cash flow from:				
- Operations	-2,9	-17,8	-6,1	-99,7
- Investments	0,6	0,9	3,4	4,5
- Financing activities	0,7	1,9	0,7	-40,4
Net change in cash	-1,6	-15,0	-2,0	-135,6
Ending cash balance	165,2	167,3	165,2	167,3

- 4Q cash flow from operations NOK -2.9 million, FY NOK -6.1 million; improvement of NOK 93.6 million from 2013
- Year end cash balance at NOK 165 million, above guidance

BALANCE SHEET

PER 31 DECEMBER 2014

- Non current assets includes NOK 16.6 million in shares in PCI Biotech and deferred tax asset of NOK 31.1 million
 - Photocure not participating in PCI share issue in 2015
- No interest bearing debt
- Shareholder's equity of NOK 240.1 million
- Equity ratio of 89%
- Photocure held 35,476 own shares at year end

<i>MNOK</i>	31.12 2014	31.12 2013
Non-current assets	76,5	104,8
Inventory & receivables	28,8	29,7
Cash & equivalents	165,2	167,3
Total assets	270,6	301,7
Shareholders equity	240,1	269,1
Long term liabilities	3,1	2,3
Current liabilities	27,5	30,3
Total equity & liabilities	270,6	301,7
Equity ratio	89 %	89 %

Outlook



OUTLOOK

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FINANCIAL

- Hexvix/Cysview global in-market unit sales growth of $\geq 10\%$ 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