

PHOTOCURE ASA  
BUILDING A  
SPECIALTY PHARMA  
COMPANY

RESULTS OF THE THIRD QUARTER 2013

23 October 2013

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# DISCLAIMER

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# HIGHLIGHTS THIRD QUARTER 2013

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- Hexvix/Cysview volume increased 11% in 3Q 2013 driven by strong customer demand across major markets
  - Own Hexvix/Cysview sales revenues in 3Q increased 29% compared to prior year
  - Partner sales revenues in 3Q decreased 14% compared to prior year impacted by inventory replenishment following transfer of production to Patheon in 3Q 2012, underlying customer demand strong
  - Total Hexvix/Cysview sales revenues Year-To-Date increased 10% compared to prior year
- Early clinical experience of Hexvix in surveillance of bladder cancer segment encouraging
- Total revenues of NOK 19.2 million impacted by lower API sales and milestone revenues
- Improved operating loss of NOK 14.9 million (22.3 million) driven by lower operating expenses
- Cash and cash equivalents of NOK 182 million

*Commercial Update*

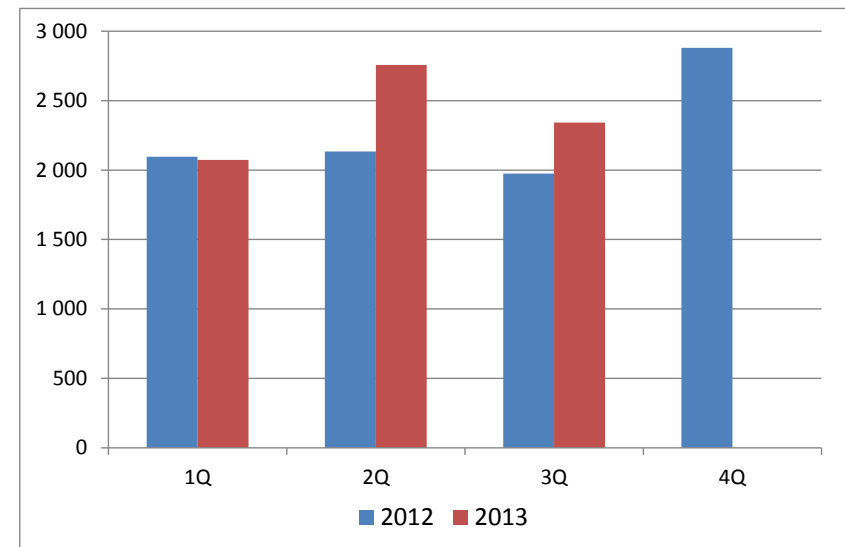


# HEXVIX/CYSVIEW

## SOLID PERFORMANCE IN OWN SALES GEOGRAPHIES

- PHO 3Q own sales revenues in the US and Nordics +29% v PY
- Key drivers include strong customer demand, increased BLC placements and price increases
  - Additional price increase planned in three Nordic countries this quarter
- Nordic 3Q volume growth +9%, revenue growth +15% v PY
  - Sweden 46% v PY
- US 3Q volume growth +69%, revenue growth +85% v PY
  - Installed base increased to 49 BLCs, remain on target to reach 55-60 BLCs by YE
  - Actively working to insure equitable reimbursement to hospitals by CMS in 2014

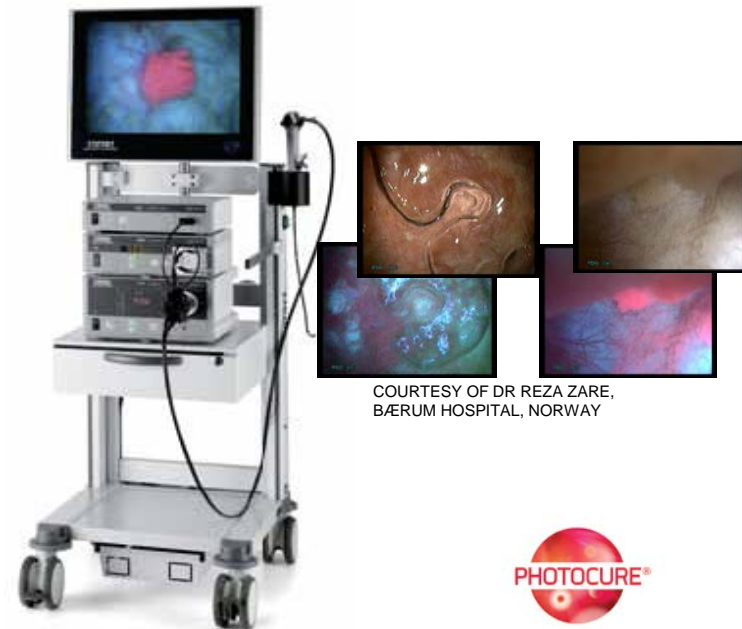
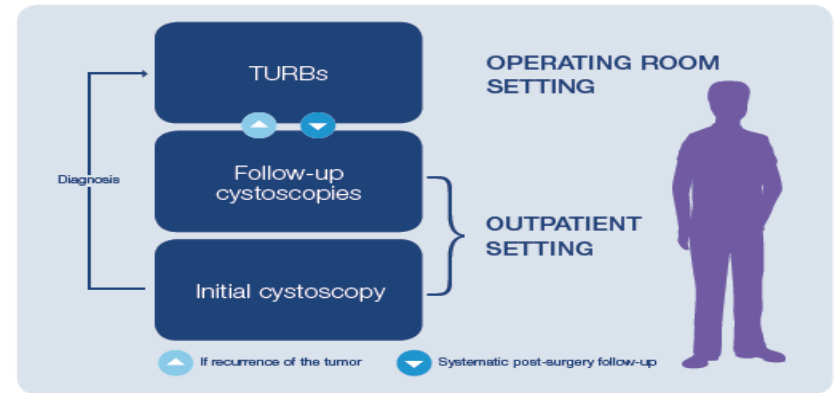
Own Hexvix/Cysview in-market unit sales



# HEXVIX/CYSVIEW

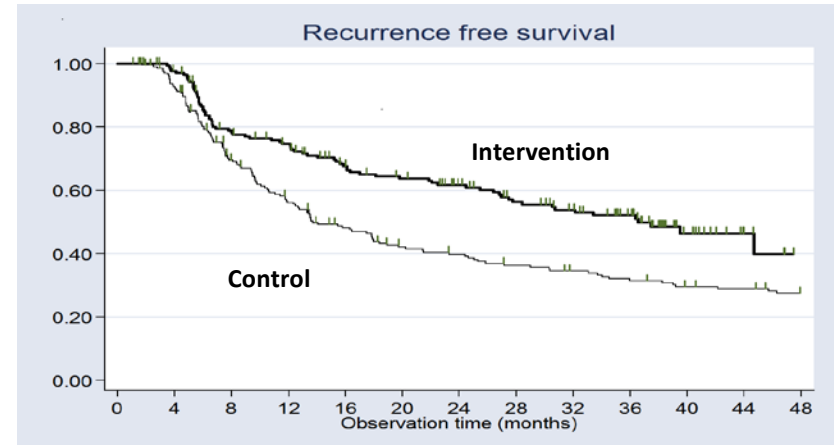
## ENCOURAGING EARLY RESULTS IN NEW MARKET SEGMENT

- Following the initial diagnosis of bladder cancer, all patients are required to have frequent surveillance cystoscopic exams to monitor for recurrence and/or progression of disease
  - These exams are frequently performed in the outpatient setting with a flexible, more patient tolerable cystoscope
- This represents a large, untapped potential as Hexvix/Cysview is currently used predominantly in the OR for TURB procedures
- Early clinical experience utilizing Hexvix/Cysview with flexible cystoscope technology in the outpatient setting very positive
- Additional clinical trials and additional market research underway to further evaluate utility in the important new segment



# HEXVIX/CYSVIEW NEW TRIAL RESULTS SHOW IMPROVED LONG TERM CLINICAL BENEFIT

- Long term bladder cancer recurrence data from Randers Hospital in Denmark
  - Retrospective data collected in >400 bladder cancer patients
    - The patients were either in an intervention group or historical control
    - Intervention group initially treated with TURB with Hexvix followed by single instillation of Mitomycin C
    - Control group treated with TURB without Hexvix or Mitomycin C
- The study showed significant reduction in risk of recurrence ( $p= 0.0002$ ) with improved recurrence free survival at 2 years (61% vs 39%) in patients receiving TURB with Hexvix followed by single instillation of Mitomycin C
- The study also showed that reduced risk in recurrence reduced the cost to the health care system as patients in the intervention group had a 27% reduction in repeated TURBs



HR 0.59, 95%CI 0.45-0.78,  $p=0.0002$

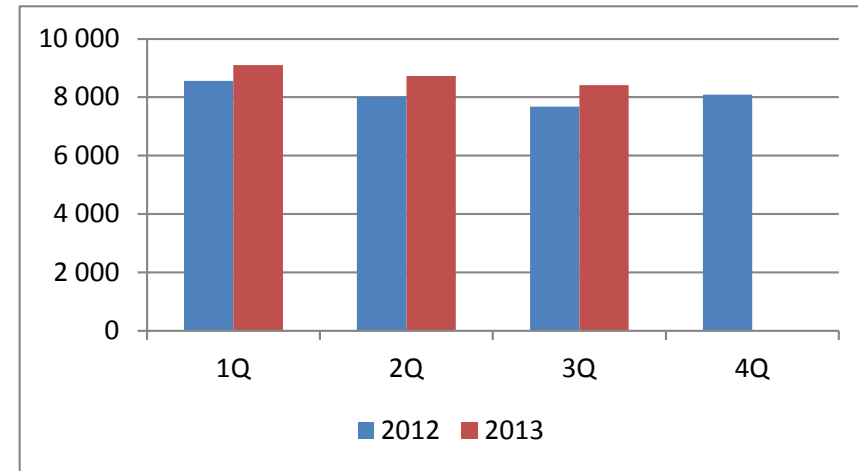
Risager MB et al.: NUF 2013, poster #75 (session 5B)



# IPSEN STRONG PARTNER IN EUROPE

- Partners driving robust customer demand in 3Q
  - Volume +10% v PY
  - Double digit growth in Germany, Italy, other major markets
- PHO revenues from Partner -14% v PY
  - Following transfer of production to Patheon, first replenishment stocks shipped 3Q 2012, making YOY comparisons difficult
- Ipsen reports on 30 October

Hexvix Partner Unit Sales Per Quarter








# *Pipeline Update*



# CREATING VALUE DIVERSE PRODUCT PORTFOLIO

	Technology	Indication	Phase 1	Phase 2	Phase 3	Status
<b>Lumacan®</b>	<b>PDD</b>	Detection of colorectal cancer				<ul style="list-style-type: none"> <li>Worldwide license with Salix</li> <li>Clinical trial with various formulations underway</li> </ul>
<b>Visonac®</b>	<b>PDT</b>	Treatment of moderate to severe acne				<ul style="list-style-type: none"> <li>Positive Phase 2b results</li> <li>SPA approved</li> <li>Exploring partnerships</li> </ul>
<b>Cevira®</b>	<b>PDT</b>	Treatment of precursors of cervical cancer				<ul style="list-style-type: none"> <li>Positive final Phase 2b results</li> <li>Significant interest from potential partners</li> <li>Fast Track application filed</li> </ul>

# VISONAC PHASE 3 READY ASSET

- High unmet need for novel treatments for moderate – severe acne
  - Significant reduction in inflammatory lesions
  - Overall improvement in acne severity
  - Well tolerated regimen
- Positive Phase 2b results
  - Significant reduction in inflammatory lesions
  - Overall improvement in acne severity
  - Well tolerated regimen
- Preparing for Phase 3 registration trials
  - SPA agreed in 2Q
  - Reduces risk of Phase 3 registration program
- Patent family for use in acne expanded to include the US
  - Coverage through 2025

Baseline



Week 12  
6 weeks after last treatment



# BREAKTHROUGH PLATFORM TECHNOLOGY DESIGNED FOR EASE OF USE

- First fully integrated drug-delivery device in photodynamic technology
- Novel single use, disposable intra-vaginal device developed for ease of use
  - Obviates clinical and commercial barriers
- Simple application in office setting
  - Does not require additional equipment
  - Auto-activation
  - Patient free to resume normal daily activities
- Designed to treat the entire epithelial sheet
- Outstanding Physician and Patient Acceptance



# CEVIRA A MAJOR OPPORTUNITY

- High unmet medical need for novel therapies to treat epidemic proportions of HPV/CIN populations
  - Fast track application for CIN 2 population submitted to FDA
- 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 and lay the foundation for the Phase 3 registration program
  - Significant overall response in CIN 2
  - High clearance of HPV, including highly oncogenic HPV 16/18
  - Excellent tolerability and high physician & patient acceptance
- Health economic models demonstrate significant cost savings to health care systems at premium pricing
- Discussions underway to secure ideal development and commercialization partner

# *Financials*



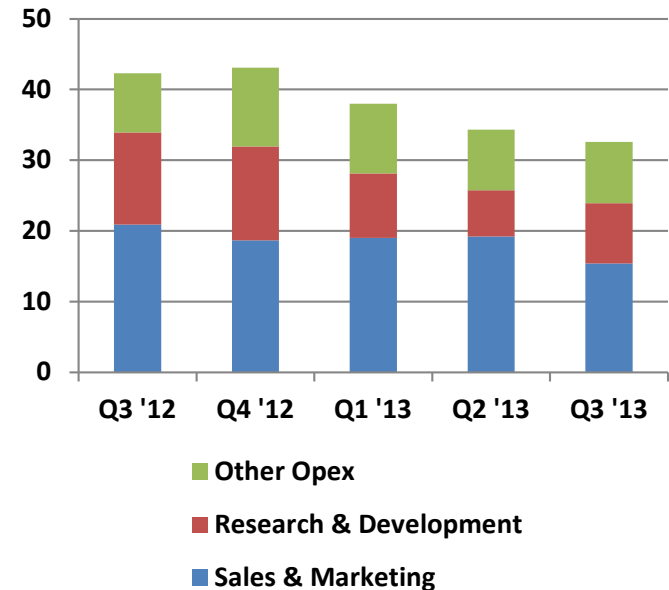
# STRONG VOLUME GROWTH

- Revenue from own sales of Hexvix/  
Cysview up 29% in the quarter
  - Nordic revenue increased 15%. In-market unit sales to pharmacies up 9%
  - US revenue increased 85% driven by end user volume growth of 69%, price increase of 10% and FX impact
- Partner 3Q revenue decline of 14%
  - In-market volume growth of 10%
  - Inventory adjustments and timing of deliveries in 2012
- Milestone revenues and API revenues lower driving total revenue down 17% in 3Q

<i>MNOK</i>	<b>Q3 '13</b>	<b>YTD '13</b>
<b>Hexvix own sales</b>	<b>8,3</b>	<b>25,2</b>
<i>YoY growth</i>	28,6 %	27,0 %
<b>Hexvix partner sales</b>	<b>9,7</b>	<b>28,3</b>
<i>YoY growth</i>	-14,2 %	-1,0 %
<b>Total Hexvix sales</b>	<b>18,0</b>	<b>53,4</b>
<i>YoY growth</i>	1,5 %	10,5 %
<b>Other sales</b>	<b>0,1</b>	<b>0,7</b>
<b>Total sales revenue</b>	<b>18,1</b>	<b>54,1</b>
<i>YoY growth</i>	-10,2 %	-2,2 %
<b>Milestones</b>	<b>1,1</b>	<b>3,2</b>
<b>Total revenue</b>	<b>19,2</b>	<b>57,3</b>
<i>YoY growth</i>	-16,6 %	-33,8 %

# EXPENSE REDUCTIONS AND ORGANIZATIONAL STREAMLINING

- R&D expenses at NOK 8.5 million in 3Q
  - Main R&D activity Cevira and Visonac drug/device manufacturing readiness for Phase 3
- Quarter S&M expenses at NOK 15.4 million
  - Decline from previous quarters due to cessation of marketing support program with partner
  - Increased commercial activities in the US drives a YTD increase of 4%
- Other OPEX down YTD 16%
  - Restructuring finalized



<i>MNOK</i>	Q3 '13	YTD '13	Change
Research & Development	8,5	24,2	-34 %
Sales & Marketing	15,4	53,6	4 %
Other Opex	8,7	27,1	-16 %
<b>Operating expenses</b>	<b>32,6</b>	<b>104,9</b>	<b>-13 %</b>
Restructuring	-0,1	4,0	
<b>Total</b>	<b>32,5</b>	<b>108,9</b>	<b>-10 %</b>



# PROFIT & LOSS

## THIRD QUARTER 2013

<i>MNOK</i>	Q3 '13	Q3 '12	Change	YTD '13	YTD '12	Change
Sales revenues	18,1	20,1	-10 %	54,1	55,4	-2 %
Signing fee and milestones	1,1	2,9	-62 %	3,2	31,1	-90 %
<b>Total revenues</b>	<b>19,2</b>	<b>23,0</b>	<b>-17 %</b>	<b>57,3</b>	<b>86,5</b>	<b>-34 %</b>
<b>Gross profit</b>	<b>17,7</b>	<b>20,0</b>	<b>-11 %</b>	<b>52,4</b>	<b>78,8</b>	<b>-34 %</b>
Operating expenses	-32,6	-42,3	-23 %	-104,9	-120,6	-13 %
<b>Operating profit/loss(-) recurring</b>	<b>-14,9</b>	<b>-22,3</b>	<b>-33 %</b>	<b>-52,5</b>	<b>-41,7</b>	<b>26 %</b>
Restructuring expenses	0,1	-		-4,0	-	
<b>Operating profit/loss(-)</b>	<b>-14,8</b>	<b>-22,3</b>		<b>-56,5</b>	<b>-41,7</b>	
<b>Profit/loss(-) before tax</b>	<b>-13,0</b>	<b>-20,7</b>		<b>-49,5</b>	<b>-35,8</b>	
<b>Total comprehensive income</b>	<b>-16,1</b>	<b>-26,1</b>		<b>-67,7</b>	<b>-57,6</b>	

- Total revenues for 3Q NOK 19.2 million, down 17% from prior year driven by both milestone revenues and sales of API
- Improved operating loss before restructuring in the quarter NOK 14.9 million

# CASH FLOW

## THIRD QUARTER 2013

<i>MNOK</i>	<b>Q3 '13</b>	<b>Q3 '12</b>	<b>YTD '13</b>	<b>YTD '12</b>
<b>Cash flow from:</b>				
- Operations	-17,7	-24,9	-82,0	-82,4
- Investments	1,0	2,9	3,6	7,4
- Financing activities	0,5	-1,7	-42,3	-6,3
<b>Net change in cash</b>	<b>-16,3</b>	<b>-23,7</b>	<b>-120,6</b>	<b>-81,3</b>
<b>Ending cash balance</b>	<b>182,2</b>	<b>273,9</b>	<b>182,2</b>	<b>273,9</b>

- Quarter cash flow from operations NOK -17.7 million
- Dividend payment of NOK 42.4 million in the second quarter
- Cash and cash equivalents on 30 September 2013 of NOK 182.2 million, compared to 31 December 2012 at NOK 302.8 million

# BALANCE SHEET

## PER 30 SEPTEMBER 2013

- Non current assets includes NOK 28.9 million in shares in PCI Biotech
- Deferred tax asset of NOK 40.8 million
- No interest bearing debt
- Shareholder's equity of NOK 271.8 million
- Equity ratio of 91%
- Photocure held 136,546 own shares at end of 3Q

<i><b>MNOK</b></i>	<b>30.09</b>	<b>31.12</b>
	<b>2013</b>	<b>2012</b>
Non-current assets	91,5	104,9
Inventory & receivables	25,8	25,3
Cash & equivalents	182,2	302,8
<b>Total assets</b>	<b>299,5</b>	<b>433,0</b>
Shareholders equity	271,8	380,3
Long term liabilities	2,2	1,6
Current liabilities	25,5	51,1
<b>Total equity &amp; liabilities</b>	<b>299,5</b>	<b>433,0</b>
Equity ratio	91 %	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 3Q 2013:**

- ✓ Strong partner sales of Hexvix
- ✓ Continue to build momentum in own sales of Hexvix/Cysview
- ✓ Fast Track designation for Cevira submitted
- ✓ Finalizing strategy for Visonac

# KEY MILESTONES

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Q4 2013 – 1H 2014

## Focus

- Drive growth of Cysview in the US
- Work closely in partnership with Ipsen to increase sales of Hexvix in Europe
- Progress partner discussions for Cevira
- Lumacan oral prototypes enter clinical development
- Progress partner discussions for Visonac