## PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

RESULTS OF SECOND QUARTER AND FIRST HALF YEAR 2014

26 AUGUST 2014

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#### HIGHLIGHTS SECOND QUARTER 2014

- Hexvix/Cysview sales revenues increased 14% to NOK 23.8 million in 2Q 2014, driven by strong customer demand across major markets
  - Hexvix/Cysview global in-market sales value increased 14% to NOK 43 million
  - Partner sales revenues increased 22% to NOK 12.8 million
- Legislation to secure reimbursement for Cysview introduced to the US Congress
- Re-analysis of Cevira phase 2b data per updated pathology guidelines supports further FDA discussions
- Operating loss of NOK 5.7 million, improvement of 59% over prior year, driven by revenue increase and tight cost control
- Cash and cash equivalents of NOK 141 million
- In August, partnership on Lumacan terminated with USD 5 million in termination payment and all technology know-how and IP returned to PHO

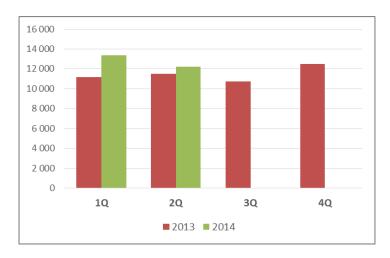


## HEXVIX/CYSVIEW STRONG GROWTH IN ALL MARKETS

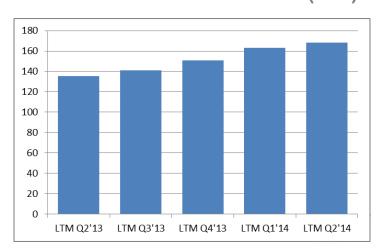
- Hexvix/Cysview global in-market volume growth 13% YTD
- Value of in-market sales of Hexvix/Cysview increased YOY 14% in 2Q and 24% YTD

# 5

#### Global in-market unit sales (by Q)



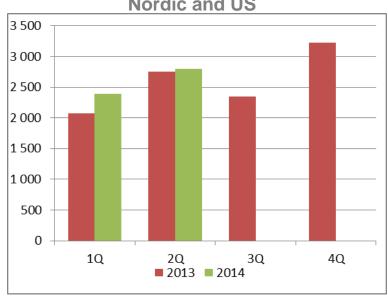
#### Global in-market value NOK mill (LTM)



## HEXVIX/CYSVIEW SOLID PERFORMANCE IN NORDICS

- Photocure own sales revenues in the US and Nordics increased 6% in 2Q 2014 to NOK 11.1 million and 19% YTD to NOK 20.0 million
- Key drivers include strong customer demand and price increases
- Nordic revenue in Q2 2014 at level with last year. YTD revenue growth of 15%
  - In-market volume growth YTD of 6%
  - Double digit in-market volume growth in Sweden
  - Increasing both number and productivity of blue light cystoscopies
- Price increase in Norway effective in May







## HEXVIX/CYSVIEW INCREASED MOMEMTUM IN US

- US 2Q 2014 revenue growth of 30%. YTD revenue growth of 33%
- Key drivers include volume growth of 17% in 2Q and 15% YTD, price increases and FX
- Despite limited 2014 CMS reimbursement policy, Blue Light Cystoscope placements increased to 47 in 2Q 2014, compared to 36 at YE 2013 and 43 in 1Q 2014.
- Continued progress towards securing sustainable reimbursement
  - Legislation introduced to US Congress to provide separate payment to hospitals for Cysview



Press Release Congressman Tom Reed

#### REED INTRODUCES BILL TO GIVE PATIENTS ACCESS TO BREAKTHROUGH TREATMENTS

Bill makes most up-to-date treatments available to patients; requires fair payment policy for hospitals

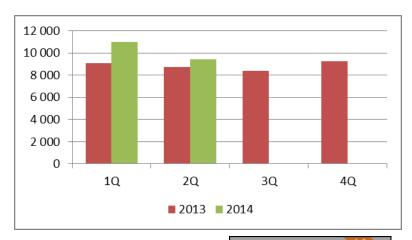
Jun 24, 2014 Issues: Health

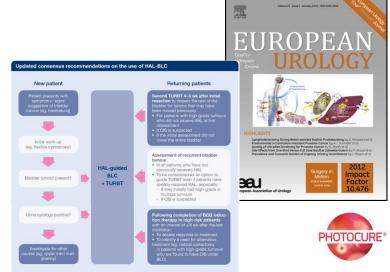
A bill authored by Tom Reed would ensure seniors suffering from cancer, heart disease and other illnesses have access to the most up-to-date, state-of-the-art treatments.....

## HEXVIX IPSEN STRONG PERFORMANCE IN EUROPE

- Partner revenue increased 22% in 2Q 2014 to NOK 12.8 million. YTD growth of 25% to NOK 23.2 million
- Strong customer demand with end user volume growth of 14% YTD
- YTD double digit volume growth in France, Germany and Austria
- Price increase in Germany effective in April
- Expert Recommendations on the Clinical and Cost Effectiveness of Hexvix® blue-light cystoscopy published in European Urology
  - Reduces costs and Improves Quality Adjusted Life Years

#### **Hexvix Partner Unit Sales Per Quarter**







## CREATING VALUE DIVERSE PRODUCT PORTFOLIO

|                     | Technology | Indication                                 | Phase 1 | Phase 2 | Phase 3 | Status  |
|---------------------|------------|--|---------|---------|---------|---|
| Lumacan®            | PDD        | Detection of<br>colorectal<br>cancer       |         |         |         | License agreement with Salix<br>terminated  |
| Visonac®            | PDT        | Treatment of moderate to severe acne       |         |         |         | Positive Phase 2b results<br>SPA and PIP approved<br>Exploring partnerships                               |
| Cevira <sup>®</sup> | PDT        | Treatment of precursors of cervical cancer |         |         |         | Positive Phase 2b results In discussion with Health Authorities on phase 3 program Exploring partnerships |



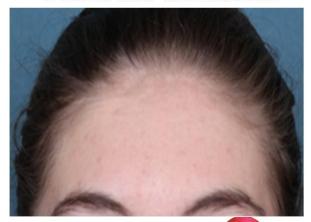
#### VISONAC PHASE 3 READY ASSET

- 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 (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

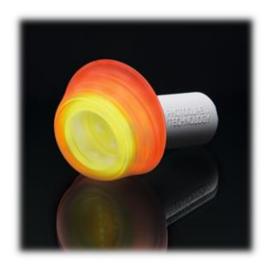




#### CEVIRA A MAJOR OPPORTUNITY

- High unmet medical need for novel therapies to treat global epidemic of HPV/CIN populations
- Breakthrough single use and fully integrated drug-device technology
- 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
- Securing agreement with Regulators on phase 3 design and target patient population
  - Supportive Scientific Advice meetings completed with major European regulators
  - Completed re-analysis of the Phase 2b clinical data with similar efficacy improvements as in previous data set allows for continued discussions with FDA







#### POSITIVE SCIENTIFIC ADVICE EUROPE

- Scientific Advice Meetings held with three Health Authorities during
   2Q
  - All leading agencies in review of other HPV technologies
- Advice was positive and consistent across the three
  - Cevira phase 2b results and proposed phase 3 plan discussed
  - Alignment that CIN 2 as target indication is clinically relevant and acceptable for phase 3
  - Central pathology read at diagnosis and follow up is acceptable
  - Design and statistical analysis of proposed phase 3 discussed



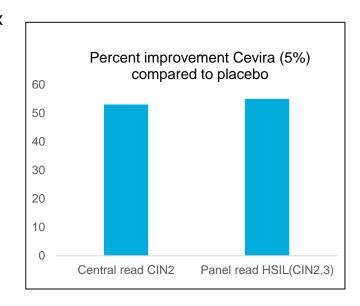
### RE-ANALYSIS CONFIRMS CLINICAL BENEFIT OF CEVIRA

#### FDA requested re-analysis of the pathology data to include:

- Blinded panel of three pathologists required to provide initial diagnosis and post treatment evaluation
- Diagnosis of the patients with cervical intraepithelial lesions of cervix should be defined as HSIL (CIN2,3) and LSIL (CIN1), per updated LAST classification system
- Histology together with HPV analysis (oncogenic subtypes pooled)
   was-used as primary efficacy outcome

#### Results of re-analysis

- Panel read completed according to LAST classification system on 99% study subjects
- 50% of subjects (131/261) initially diagnosed as HSIL by panel
- As per endpoints acceptable to FDA, Cevira 5% provided clinically significant efficacy vs placebo, 59% vs 38%, p>0.05
- The results reach statistical significance when corrected for uneven distribution of lesion size, Cevira 67% vs placebo 22%, p= 0.01





#### LUMACAN PARTNERSHIP TERMINATED



- Global development and commercialization rights licensed to Salix in October 2010
  - Received upfront and development payments of \$8.5M to date
- Following the proposed merger agreement between Salix and Cosmo Pharmaceuticals SpA
  - Agreed to terminate Salix license
  - Salix paid PHO \$5M
  - All rights and IP revert to PHO
- Evaluation of options to secure further development and optimal value ongoing





## HEXVIX/CYSVIEW - CONTINUED GROWTH SECOND QUARTER 2014

- Revenue from own sales of Hexvix/
   Cysview increased 6% in 2Q 2014 and 19%
   YTD
  - Nordic 2Q revenue at level with last year,
     YTD growth of 15%.
    - Volume growth, price increases and FX
  - US revenue increased 30% in 2Q and 33% YTD
    - Volume growth, price increase and FX
- Partner 2Q 2014 revenue increased 22% in 2Q and 25% YTD
  - In-market volume growth of 14% YTD
- Total in market sales value increased 14% in 2Q and 24% YTD
  - LTM value NOK 168 million compared to NOK 151 million at year end

| SALES - MNOK                      | Q2 '14            | YTD '14             |
|-----------------------------------|-------------------|---------------------|
| Hexvix own sales  YoY growth      | <b>11,1</b> 6 %   | <b>20,0</b><br>19 % |
| Hexvix partner sales  YoY growth  | <b>12,8</b> 22 %  | <b>23,2</b> 25 %    |
| Total Photocure  YoY growth       | <b>23,8</b> 14 %  | <b>43,2</b> 22 %    |
| Revenue in-market (*)  YoY growth | <b>42,9</b> 14 %  | <b>88,9</b> 24 %    |
| Units in-market (*)  YoY growth   | <b>12 207</b> 6 % | <b>25 595</b>       |

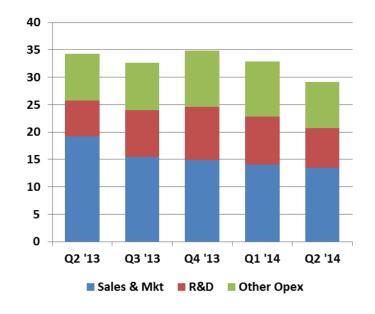
(\*) Calculated in-market sales



## OPERATING EXPENSES SECOND QUARTER 2014

- Total OPEX at NOK 29.2 million in 2Q. YTD at NOK 62.0 million, a reduction of 14%
- R&D expenses at NOK 7.3 million in 2Q
  - Main R&D activity related to reanalysis of the phase 2b Cevira data
- Quarter S&M expenses at NOK 13.5 million
  - Decline from previous quarters due to completion of the contractual cofunding arrangement of the marketing activities with partner
  - Reduced spending related to commercial activities in the US awaiting outcome on reimbursement

| MNOK                              | Q2 '14            | YTD '14           |
|-----------------------------------|-------------------|-------------------|
| Research & Development YoY growth | <b>7,3</b>        | 16,0<br>2 %       |
| Sales & Marketing YoY growth      | <b>13,5</b> -30 % | <b>27,6</b> -28 % |
| Other Opex YoY growth             | <b>8,4</b> -2 %   | 18,5<br>0 %       |
| Operating expenses YoY growth     | <b>29,2</b> -15 % | <b>62,0</b> -14 % |



#### PROFIT & LOSS SECOND QUARTER 2014

| MNOK                               | Q2 '14 | Q2 '13 | Change | YTD '14 | YTD '13 | Change |
|------------------------------------|--------|--------|--------|---------|---------|--------|
| Hexvix / Cysview revenues          | 23,8   | 20,9   | 14 %   | 43,2    | 35,4    | 22 %   |
| Other sales revenues               | 0,5    | 0,5    | 9 %    | 0,7     | 0,7     | 11 %   |
| Signing fee and milestones         | 1,1    | 1,1    | 8 %    | 2,3     | 2,1     | 10 %   |
| Total revenues                     | 25,5   | 22,5   | 14 %   | 46,2    | 38,1    | 21 %   |
| Gross profit                       | 23,5   | 20,4   | 15 %   | 42,6    | 34,7    | 23 %   |
| Operating expenses                 | -29,2  | -34,3  | -15 %  | -62,0   | -72,3   | -14 %  |
| Operating profit/loss(-) recurring | -5,7   | -13,9  | -59 %  | -19,4   | -37,6   | -48 %  |
| Operating profit/loss(-)           | -5,7   | -18,0  |        | -19,4   | -41,7   |        |
| Net profit/loss(-)                 | -4,2   | -15,2  |        | -17,2   | -36,6   |        |

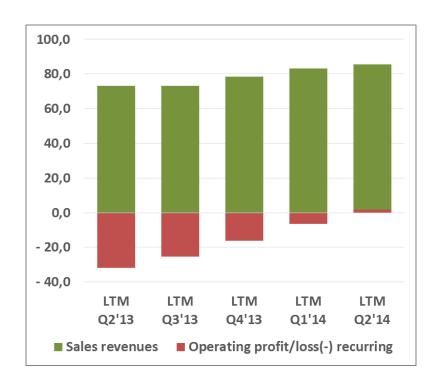
- Operating loss reduced 59% in the quarter and 48% YTD:
  - Increased revenue of Hexvix/Cysview in all markets, 14% in 2Q and 22% YTD
  - Cost reductions of 15% in 2Q and 14% YTD
- Hexvix/Cysview commercial activities profitable in 2Q and YTD 2014



## HEXVIX/CYSVIEW FRANCHISE SECOND QUARTER 2014

- LTM (last twelve months) 2Q 2014 operating result for commercial activities at NOK +1.7 million compared to NOK -31.8 million LTM 2Q 2013
- Consistent quarterly 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 SECOND QUARTER 2014

| MNOK                                     | Q2 '14 | Q2 '13 | YTD '14 YTD '13 |        |
|--|--------|--------|-----------------|--------|
| Cash flow from:                          |        |        |                 |        |
| - Operations                             | -9,8   | -37,5  | -28,5           | -64,2  |
| - Investments                            | 0,8    | 0,9    | 1,9             | 2,7    |
| <ul> <li>Financing activities</li> </ul> | 0,0    | -42,2  | 0,0             | -42,8  |
| Net change in cash                       | -9,0   | -78,8  | -26,5           | -104,3 |
| Ending cash balance                      | 140,7  | 198,5  | 140,7           | 198,5  |

- 2Q 2014 cash flow from operations NOK -9.8 million
- Quarter working capital and provision changes negative NOK 4.8 million, compared to last year negative NOK 20.7 million
- Quarter end cash balance at NOK 140.7 million



#### BALANCE SHEET PER 30 JUNE 2014

- Non current assets includes NOK 41.5 million in shares in PCI Biotech and deferred tax asset of NOK 49.1 million
- No interest bearing debt
- Shareholder's equity of NOK 262.0 million
- Equity ratio of 92%
- Photocure held 72,976 own shares at quarter end

| MNOK                                       | 30.06<br>2014 | 31.12<br>2013 |
|--|---------------|---------------|
| Non-current assets Inventory & receivables | 115,5<br>27,8 | 104,8<br>29,7 |
| Cash & equivalents                         | 140,7         | 167,3         |
| Total assets                               | 284,0         | 301,7         |
| Shareholders equity                        | 262,0         | 269,1         |
| Long term liabilities                      | 2,7           | 2,3           |
| Current liabilities                        | 19,4          | 30,3          |
| Total equity & liabilities                 | 284,0         | 301,7         |
| Equity ratio                               | 92 %          | 89 %          |





#### GOOD PROGRESS MADE TOWARDS 2014 GOALS

| KEY 2014 OBJECTIVES   | 1H ACHIEVEMENTS   |
|---|---|
| Hexvix/Cysview global in-market unit sales growth of ≥10%   | YTD growth 13%  |
| Obtain sustainable reimbursement solution in US   | Bill introduced to US Congress  |
| Secure partnership for development and commercialization of Visonac   | Established high interest with key dermatology players  |
| Secure regulatory alignment on Cevira clinical development to progress partner discussions                  | Positive Scientific Advice<br>meetings with key EU regulators<br>on Cevira phase 3 program<br>Re-analysis of Cevira data<br>completed |
| End of year cash reserve of NOK 140-150 million including termination payment, excluding milestone payments | Cash of NOK 141 million at end of 2Q  |

