

PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

RESULTS OF SECOND QUARTER
AND FIRST HALF YEAR 2015

13 AUGUST 2015

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



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PROGRESS ON KEY OBJECTIVES

KEY OBJECTIVES

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

2Q2015 KEY ACHIEVEMENTS

- 15% growth in-market unit sales
- 55% in-market unit growth in US
- Commercial franchise profitability 9.9 MNOK
- In August, achieved Special Protocol Agreement for Cevira with FDA
- On track to start patient enrollment by end of 2015
- Discussions continued with potential partners

Significant improvement of Commercial Franchise financial performance (EBIT) with 8.7 MNOK YTD



Commercial Update

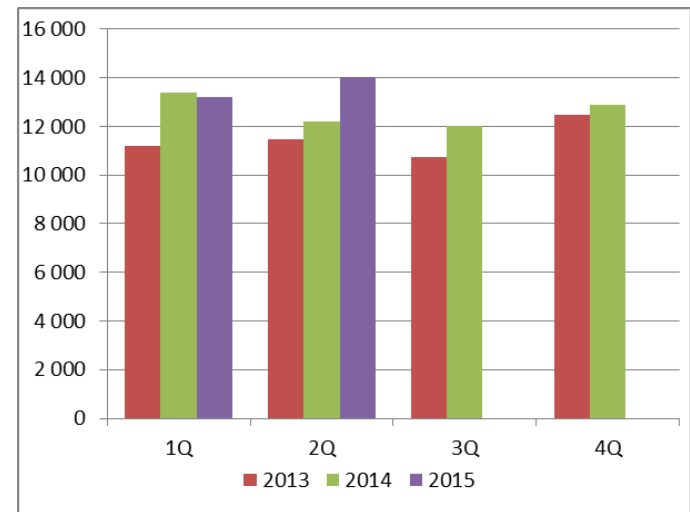


HEXVIX/CYSVIEW

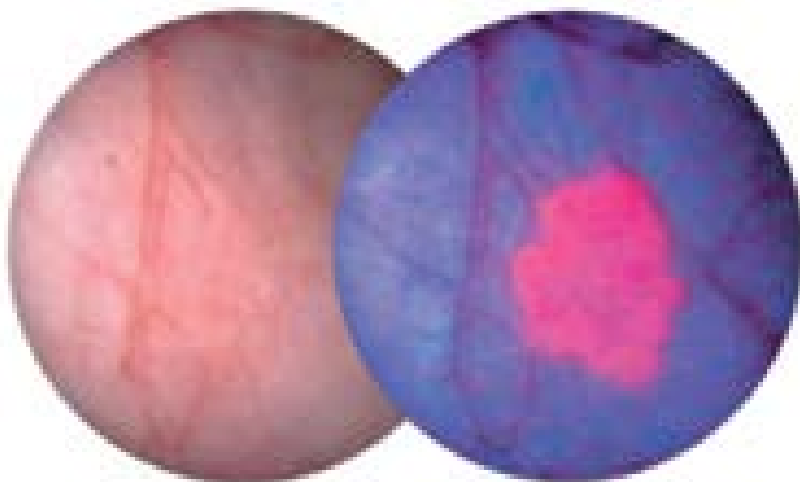
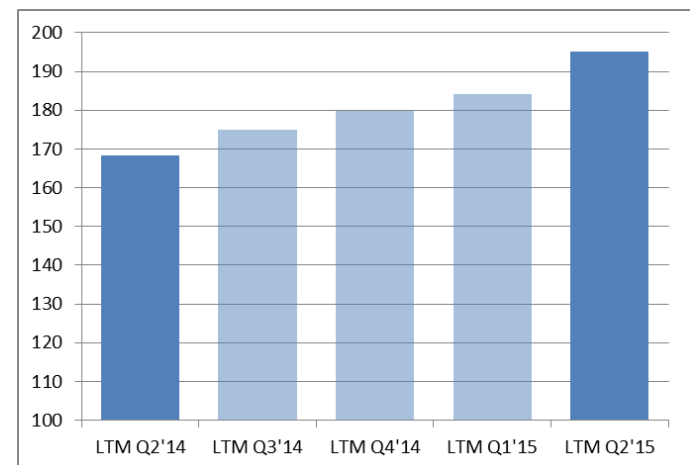
A SIGNIFICANT GLOBAL SPECIALTY BRAND

- Value of in-market sales of Hexvix/Cysview increased YoY 17% year to date to NOK 195 million LTM
- Hexvix/Cysview global in-market volume increased YoY 15% in the quarter, and 6% year to date
- Overall franchise operating profit year to date at NOK 14.1 million, improvement of NOK 8.7 million from prior year

Global in-market unit sales (by Q)



Global in-market value NOK mill (LTM)

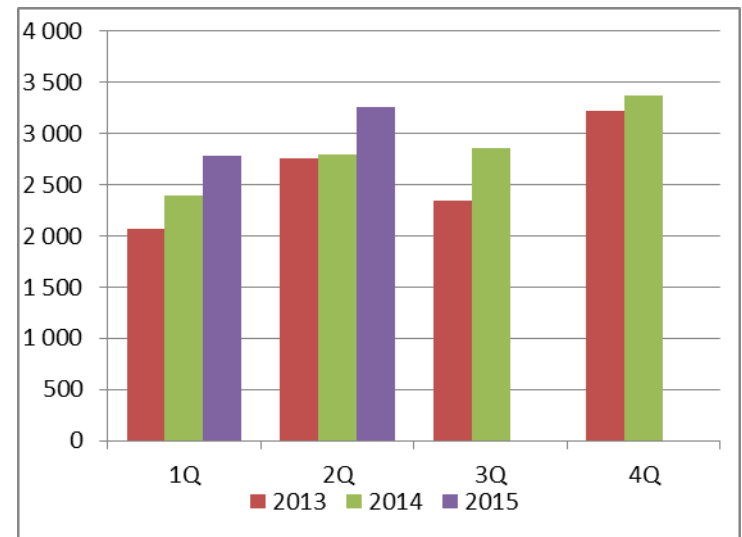


HEXVIX/CYSVIEW

SOLID PERFORMANCE IN NORDICS AND USA

- Photocure own sales revenue in the US and Nordics increased YoY 42% in 2Q and 43% year to date to NOK 28.6 million
- US revenue increased year to date 117% YoY
 - Driven by in-market volume growth of 57%, price increases and FX
 - Permanent Blue Light Cystoscope placements of 58 at the end of 2Q
 - Continued progress on passage of bill to provide separate payment to hospitals for Cysview
- Nordic revenue increased year to date 20% YoY
 - In-market volume growth of 6%
 - Continued double digit in-market volume growth in Sweden

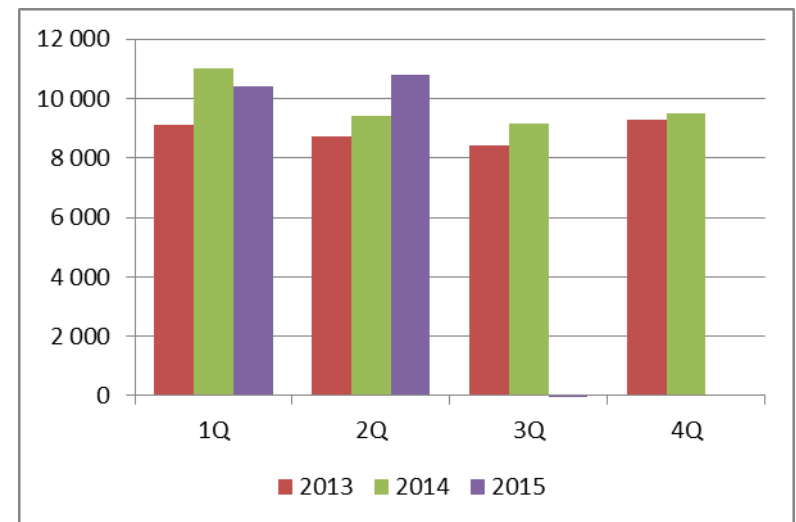
Own Hexvix/Cysview in-market unit sales
Nordic and US



HEXVIX/CYSVIEW PARTNER PROGRESS

- Partner revenue increased YoY 3% in 2Q and 16% year to date to NOK 27.0 million
 - 2Q revenue driven by timing of inventory replenishments in 2014
- End user volume growth 15% in 2Q and 4% year to date
- Double digit unit growth in 2Q in Germany, France and Italy
- Executed distribution agreement with Juno Pharmaceuticals for Hexvix in Australia and New Zealand.
 - €250 000 received at signing, an additional € 250 000 upon approval
 - Juno is responsible for the regulatory filings, which are progressing according to plan
- Hexvix approved in Russia




Hexvix Partner Unit Sales Per Quarter



Pipeline Update



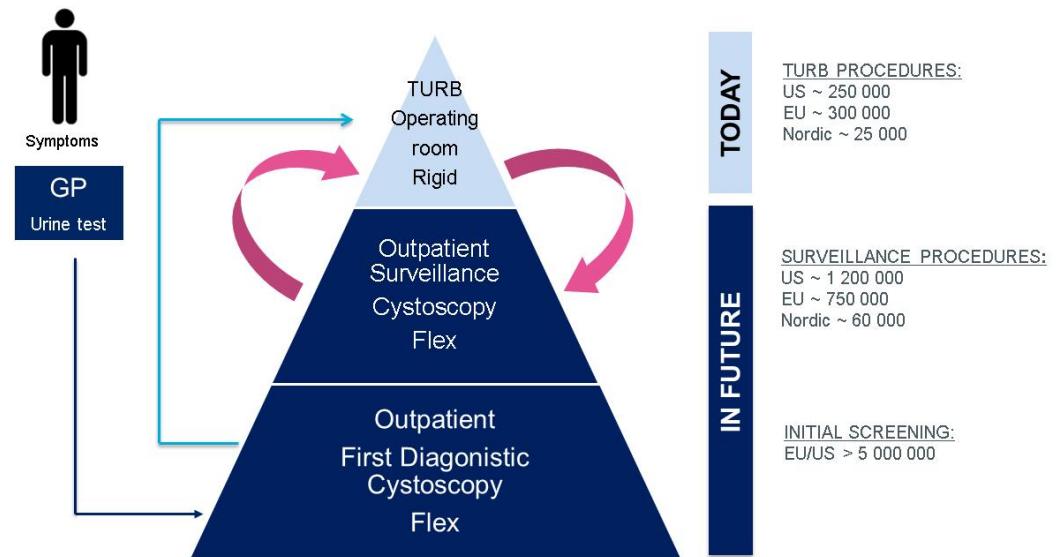
CREATING VALUE CLINICAL DEVELOPMENT PROGRAMS

	Technology	Indication	Phase 1	Phase 2	Phase 3	Status
Cevira®	PDT	Treatment of precursors of cervical cancer				Positive Phase 2b results 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				Phase 3 clinical study initiated. Patient recruitment is planned to start by end of 2015

HEXVIX/CYSVIEW EXPANDING INTO THE SURVEILLANCE SEGMENT

- Surveillance following initial diagnosis represents a significant growth opportunity of 2-3 times current TURB segment
- Initiation of Phase 3 study with 360 patients for examining improved detection rate of Cysview blue light cystoscopy vs white light cystoscopy
- 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 therapies to treat global epidemic of HPV/CIN populations
 - A well tolerated non-systemic treatment option for patients which preserves fertility and avoids the morbidities of invasive surgery
- Results of the Phase 2b trial are significant
 - Statistically significant HSIL (CIN2,3) regression in the FDA agreed phase 3 patient population ($p=0.004$)
 - Statistically significant virologic clearance of oncogenic HPV at 9 months after first treatment ($p=0.045$)
 - Excellent tolerability and high physician & patient acceptance
- Achieved Special Protocol Agreement with FDA in August for patients with HSIL
 - Alignment on clinical phase 3 program of two similar double blind, placebo controlled studies with 200 patients in each study with primary efficacy end point 6 months after treatment

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 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, hydroxychloroquine (0.2%, 1%, 5%, clear dose effect with a statistically significant response in the HAL 5% group: of 95% (16/19 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.

ergy that shows promise in the s of oncogenic HPV, but not of ce makes HAL PDT a tissue- childbearing age who wish to ces are planned.

ptosis, hexaminolevulinate, therapy

patients 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

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

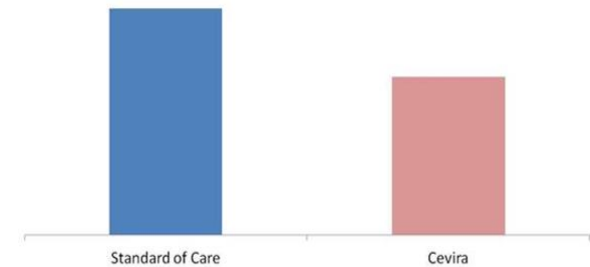


CEVIRA

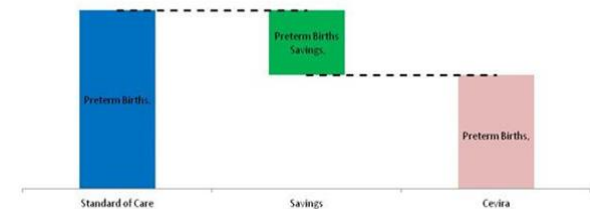
SIGNIFICANT SALES POTENTIAL

- Large patient population based on biopsy confirmed histology of HSIL
 - ~1M cases HSIL annually in US & West EU^{1,2} detected through routine cervical screening programs; 50% of these are caused by HPV strain 16 or 18³
 - ~30% risk of progress to cervical cancer⁴
 - Upside exists in Latin America, Asia and East EU, where burden of HPV is higher
- LCM Opportunity for clearance of oncogenic HPV in patients with normal cytology/LSIL
 - It is estimated that ~35M are HPV infected in US & EU, with a prevalence of HPV strains 16 or 18 of 32% (~11M)
 - 10-15M cases oncogenic HPV annually in US & West EU⁶ detected through routine cervical screening programs
 - Persistent infection occurs in 10-20% of the cases⁷
- Blockbuster sales potential based on premium pricing opportunity
 - At premium price levels, cost impact model demonstrates cost savings / benefit to the US health care system as compared to current treatment practice⁵
 - Additional significant savings when avoidance of costs associated with preterm births factored in⁵
- Continued discussions with potential partners for development and commercialization

Average Cost per patient to screen and treat, 24 months



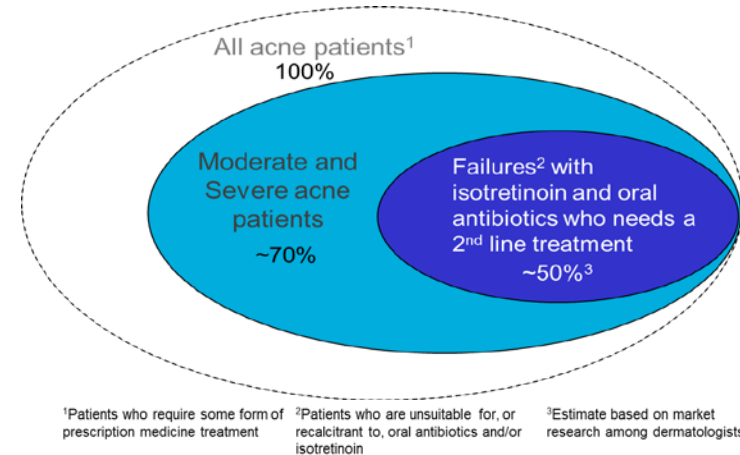
Birth Year Medical Costs, With and Without Cevira



VISONAC

PHASE 3 READY ASSET WITH CONSIDERABLE SALES POTENTIAL

- High unmet need for novel treatments for moderate/ severe acne
- Positive Phase 2b results
 - Significant reduction in inflammatory lesions and improvement of overall acne severity
 - Well tolerated regimen
- Phase 3 Ready with significant reduced regulatory risk
 - SPA (US) and PIP (EU) agreed for global registration program
- Value of moderate to severe acne pharma market segment estimated at ~\$900 MUSD globally
 - Dermatologist main prescriber of oral antibiotics and retinoids
- Visonac positioned as second line alternative
 - In US and EU, >2M patients in need of second line treatment options
 - Favorable benefit/risk profile compared to existing treatment options and sustained efficacy allows for premium price
- Continued interest from potential partners for development and commercialization



Financials



HEXVIX/CYSVIEW CONTINUED GROWTH SECOND QUARTER 2015

- Revenue from own sales of Hexvix/
Cysview increased YoY 42% in 2Q and
43% year to date
 - Nordic 2Q revenue growth of 19%
 - US 2Q revenue growth of 118%
- Partner 2Q revenue increased YoY 3%
and year to date with 16%
 - Changed timing of supply to partner
compared to the same period in 2014
- Total in market sales value increased
YoY 26% in 2Q and 17% year to date
 - LTM value NOK 195 million

<i>SALES - MNOK</i>	Q2 '15	YTD '15
Hexvix - Nordic	10,0	18,2
<i>YoY growth</i>	<i>19 %</i>	<i>20 %</i>
Cysview - US	5,8	10,3
<i>YoY growth</i>	<i>118 %</i>	<i>117 %</i>
Hexvix own sales	15,7	28,6
<i>YoY growth</i>	<i>42 %</i>	<i>43 %</i>
Hexvix partner sales	13,2	27,0
<i>YoY growth</i>	<i>3 %</i>	<i>16 %</i>
Total Photocure	28,9	55,6
<i>YoY growth</i>	<i>21 %</i>	<i>29 %</i>
Revenue in-market (*)	53,8	104,4
<i>YoY growth</i>	<i>26 %</i>	<i>17 %</i>
Units in-market (*)	14 043	27 257
<i>YoY growth</i>	<i>15 %</i>	<i>6 %</i>

(*) Calculated in-market sales

PROFIT & LOSS

SECOND QUARTER 2015

<i>MNOK</i>	Q2 '15	Q2 '14	Change	YTD '15	YTD '14	Change
Hexvix / Cysview revenues	28,9	23,8	21 %	55,6	43,2	29 %
Other sales revenues	2,6	0,5		4,3	0,7	>100%
Signing fee and milestones	3,3	1,1		4,5	2,3	96 %
Total revenues	34,8	25,5	36 %	64,4	46,2	39 %
Gross profit	32,6	23,5	39 %	60,2	42,6	41 %
Operating expenses	-34,5	-29,2	18 %	-69,2	-62,0	12 %
EBIT / Operating profit/loss(-)	-1,9	-5,7	-67 %	-9,1	-19,4	-53 %
Profit/loss(-) before PCIB and tax	-0,4	-4,2		-7,4	-17,2	

- Total revenue increase YoY 36% in 2Q and 39% year to date
- Operating expenses increase YoY 18% in 2Q and 12% year to date
 - Mainly driven by planned activities in sales and marketing, as well as FX impact
- Operating loss (EBIT) at NOK 1.9 million in 2Q and NOK 9.1 million year to date
 - Significant improvements from last year

SEGMENTS

SECOND QUARTER 2015

- Commercial franchise:
 - Continued improvement in revenues and EBIT
 - EBIT margin year to date at 22%

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

<i>MNOK</i>	<u>Q2 '15</u>	<u>Q2 '14</u>	<u>YTD '15</u>	<u>YTD '14</u>	<u>LTM</u>
<u>Commercial Franchise</u>					
Total revenues	34,8	25,5	64,4	46,2	116,4
Gross profit	32,6	23,5	60,2	42,6	108,8
Operating expenses	-22,7	-18,1	-46,1	-37,2	-84,1
EBIT	9,9	5,4	14,1	5,4	24,6
<u>Development Portfolio</u>					
Total revenues	0,0	0,0	0,0	0,0	0,0
Gross profit	0,0	0,0	0,0	0,0	0,0
Operating expenses	-11,8	-11,0	-23,2	-24,8	-50,7
EBIT	-11,8	-11,0	-23,2	-24,8	-50,7
<u>Total</u>					
EBIT	-1,9	-5,7	-9,1	-19,4	-26,0
(*) One-Off's excluded					
Salix termination fee					30,8

CASH FLOW

SECOND QUARTER 2015

<i>MNOK</i>	<u>Q2 '15</u>	<u>Q2 '14</u>	<u>YTD '15</u>	<u>YTD '14</u>
Cash flow from:				
- Operations	-2,5	-9,8	-14,4	-28,5
- Investments	-1,5	0,8	-5,1	1,9
- Financing	0,9	0,0	0,9	0,0
Net change in cash	-3,1	-9,0	-18,6	-26,5
Ending cash balance	146,7	140,7	146,7	140,7

- 2Q cash flow from operations NOK -2.5 million, year to date NOK -14.4
 - Year to date improvement of NOK 14.1 million from last year.
- Year to date cash flow from investments NOK -5.1 million.
 - Includes investments of NOK 7.0 million in intangible assets mainly related to the initiation of the phase 3 post-marketing commitment trial for Cysview
- Quarter end cash balance at NOK 147 million

BALANCE SHEET PER 30 JUNE 2015

- Non current assets includes NOK 8.9 million in shares in PCI Biotech and deferred tax asset of NOK 24.3 million
- No interest bearing debt at quarter end
- Shareholder's equity of NOK 220.9 million
- Equity ratio of 89%
- Photocure held 35,476 own shares at end of quarter

<i>MNOK</i>	30.06 2015	31.12 2014
Non-current assets	70,0	76,5
Inventory & receivables	32,8	28,8
Cash & equivalents	146,7	165,2
Total assets	249,5	270,6
Shareholders equity	220,9	240,1
Long term liabilities	3,5	3,1
Current liabilities	25,1	27,5
Total equity & liabilities	249,5	270,6
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

- Initiate necessary documentation for the Cevira device to ensure readiness for the Phase 3 trial following the SPA approval
- 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