

Photocure ASA

JANUARY 2017



Disclaimer

.....

The information included in this Presentation contains certain forward-looking statements that address activities, events or developments that Photocure ASA (“the Company”) expects, projects, believes or anticipates will or may occur in the future. These statements are based on various assumptions made by the Company, which are beyond its control and are subject to certain additional risks and uncertainties. The Company is subject to a large number of risk factors including but not limited to economic and market conditions in the geographic areas and markets where Photocure is or will be operating, IP risks, clinical development risks, regulatory risks, fluctuations in currency exchange rates, and changes in governmental regulations. For a further description of other relevant risk factors we refer to Photocure’s Annual Report for 2015. As a result of these and other risk factors, actual events and our actual results may differ materially from those indicated in or implied by such forward-looking statements. The reservation is also made that inaccuracies or mistakes may occur in this information given above about current status of the Company or its business. Any reliance on the information above is at the risk of the reader, and Photocure disclaims any and all liability in this respect.

Photocure – Investment Highlights

.....

Commercial-stage company focused on Urology

- Hexvix®/Cysview® for improved detection and management of bladder cancer
 - Improved detection, reduced disease recurrence and progression rates with cost benefits
 - ~USD 30M global in market sales (LTM); EBITDA USD 2.8 million (LTM)
- Specialist salesforce established in US and Nordic region and additional emerging operations in other high value territories through partners
 - Ipsen (EU), Juno Pharmaceuticals (Australia/New Zealand), BioSyent Pharma (Canada)

Value building opportunities anticipated in next 12 – 24 months

- Large untapped potential for Hexvix/Cysview in existing and new market segments/territories
 - New clinical data in Flex scope/surveillance use with potential label extension in the US; clarity on reimbursement in US
- Partnering opportunities for non-urology assets
 - Cevira® (cervical disease) and Visonac® (Acne)
- Exploring expansion of urology portfolio to leverage commercial infrastructure

Hexvix/Cysview



The Current State of Bladder Cancer

Bladder Cancer is 5th most common cancer type

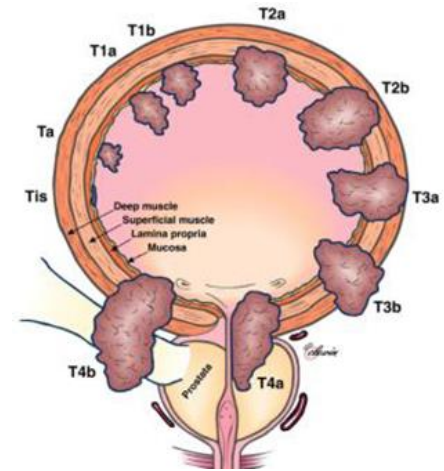
- Most expensive cancer: \$96-187K/patient¹
- > 200,000 new patients annually
- 75% of patients diagnosed with NMIBC²
- > 16,000 will die from bladder cancer in US in 2016

Key therapeutic aim is to avoid progression from NMIBC to muscle invasive disease

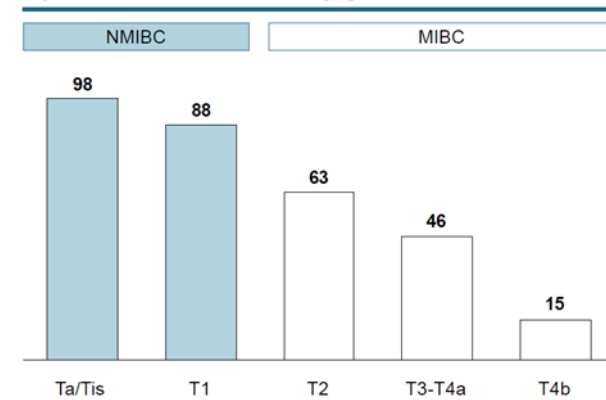
- ~ 6 million cystoscopies for initial screening annually worldwide
- ~ 600,000 surgical procedures (TURBs³) annually worldwide
- 10% – 30% progression rate

Regular ongoing surveillance required

- Recommend follow up cystoscopies every 3-9 months
- >2M follow up surveillance cystoscopies annually worldwide



5-year relative survival rate¹⁾ [%]



Unmet Medical Needs

Bladder cancer is associated with a high risk of

- Recurrence:¹
 - Up to 61% at 1 year
 - Up to 78% at 5 years for NMIBC
- Progression to muscle-invasive disease:¹
 - Up to 17% at 1 year
 - Up to 45% at 5 years
 - Common in patients with CIS, which are often difficult to detect²

High rate of residual tumor after TURBT:

- 34–76% of patients have evidence of tumor on repeat TURBT at 2–6 weeks³⁻⁵

Patients with incomplete initial resection are at high risk of recurrence⁴

- Continued growth of microscopic lesions which were not observed at initial TURBT⁶
- New growth of small residual traces of tumor, often at surgical margins⁷

Improving Bladder Cancer Management

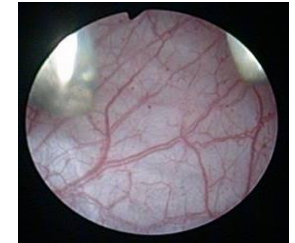
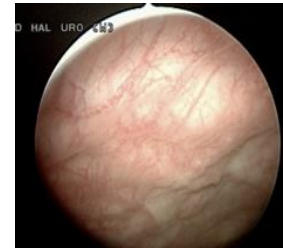
Blue Light Cystoscopy (BLC) with Hexvix® (EU) / Cysview® (US) for improved detection and management of bladder cancer

- Hexvix/Cysview is a colorless contrast solution that is used with a blue-light cystoscope
- First approved drug-device procedure; launched in US in 2012
- Recommended use in 50-70% of TURB's (bladder cancer resection procedures); included in AUA guidelines

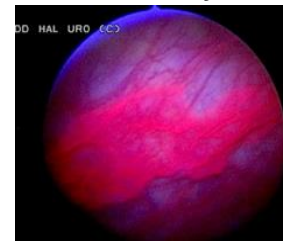
Utilizes the body's own biology to detect malignant cells

- Hexvix/Cysview contains precursors which are converted inside the cell to form an endogenous photoactive entity (PpIX)
- The solution is administered into the bladder directly and accumulates in cancerous cells, which then fluoresce red when blue-light is shone upon them

View of Bladder with use of WLC



Same view using Blue Light Cystoscopy with Hexvix/Cysview



A Significant Global Specialty Brand

Value of in-market sales of Hexvix/Cysview in the quarter increased YoY 11% to USD 7 million

- YTD in-market sales at USD 22 million (+10%)
- Hexvix/Cysview global in-market volume increased YoY 3% in the quarter and 5% year to date

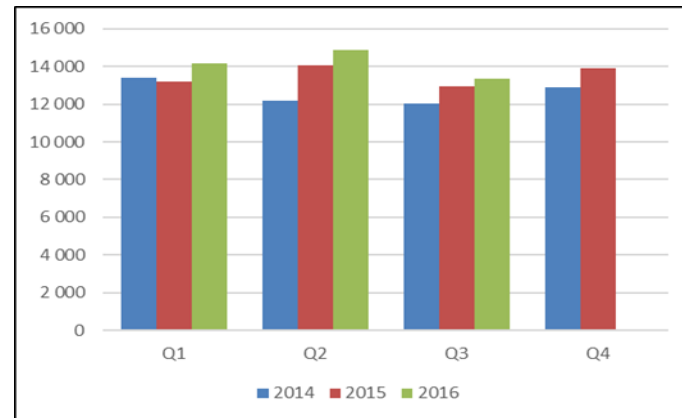
US revenue increased year to date YoY 35%

- YoY in-market volume growth of 27%
- Services 81 hospitals and urology centers at the end of Q3 (2015 year end 65)
- We are working on a Congressional bill to give additional separate reimbursement for Medicare patients.

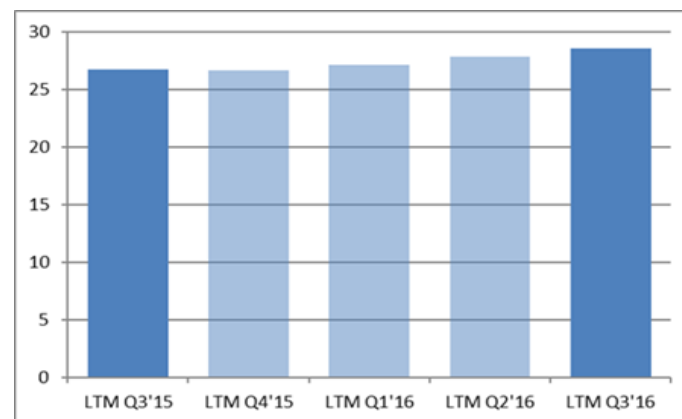
Partner revenue increased 10% year to date YoY to USD 5.6 million

- End user YoY volume growth 5% year to date
- BioSyent Pharma: Preparing launch
- Juno Pharmaceuticals: MAA approval in Australia received

Global in-market unit sales (by Q)



Global in-market value USD mill (LTM)



Increasing Exposure in Medical Community

Continued positive data flow fuels forward momentum

- New publications in *Bladder Cancer* show Blue Light Cystoscopy (BLC) with Hexvix/Cysview significantly improves long time outcomes
 - Significantly prolongs time to progression of bladder cancer (*Kamat et al, April*)
 - Significantly reduces progression of bladder cancer (*Gakis et al, August*)
- Publication in *The Journal of Urology* shows BLC with Hexvix/Cysview has no increase in adverse events when a one-off procedure to compared to repeats ¹
- New study in *World Journal of Urology* shows that BLC with Hexvix/Cysview significantly improves detection of NMIBC ²



Inclusion in National Guidelines

Transforming clinical practice

- US Guidelines: Use of Blue Light Cystoscopy with Hexvix/Cysview receives highest level of recommendation in the new AUA/SUO bladder cancer guideline
 - Recommended based on the large body of evidence supporting both increased detection and reduced recurrence of non-muscle invasive bladder cancer
- Included in European and National Guidelines in several EU countries
 - Strong recommendation recently received within French National Guidelines for Blue Light Cystoscopy with Hexvix
 - EAU altered guidelines to include the use of Hexvix as a preferential diagnosis procedure
 - NICE recommended the use of cystoscopies and that photodynamic diagnosis should be offered to patients
- Recommended use in 50-70% of TURB procedures ¹

American Urological Association
Advancing Urology™

ABOUT US EDUCATION RESEARCH ADVOCACY INTERNATIONAL PRACTICE RESOURCES

Guidelines

EDUCATION > Guidelines & Policies > Guidelines > Non-Muscle Invasive Bladder Cancer

AUA University
All your educational needs, all in one place!
Now, enhanced access and resources just for AUA members. [Learn More](#)

NON-MUSCLE INVASIVE BLADDER CANCER

[Download the unabridged version of this guideline \[pdf\]](#)

[Download Non-Muscle Invasive Bladder Cancer Treatment Algorithm \[pdf\]](#)

DIAGNOSIS AND TREATMENT OF NON-MUSCLE INVASIVE BLADDER CANCER: AUA/SUO GUIDELINE

Sam S. Chang, MD, MBA; Stephen A. Boorjian, MD; Roger Chou, MD; Peter E. Clark, MD; Siamak Daneshmand, MD; Badrinath R. Konety, MD, FACS, MBA; Raj Pruthi, MD, FACS; Diane Z. Quale; Chad R. Ritch, MD, MBA; John D. Seigne, MD; Ella Curlee Skinner, MD; Norm D. Smith, MD; James M. McKiernan, MD

Purpose
The survival rate for the majority of patients with non-muscle invasive bladder cancer (NMIBC) is favorable; however, the rates of recurrence and progression to muscle-invasive bladder cancer (MIBC) are important surrogate endpoints for overall prognosis, as these are major determinants

EAU GUIDELINES ON NON-MUSCLE INVASIVE (Ta, T1, CIS) BLADDER CANCER

(Limited text update March 2016)

M. Babjuk (Chair), A. Böhle, M. Burger, E. Compérat, E. Kaasinen, J. Palou, B.W.G. van Rhijn, M. Rouprêt, S. Shariat, R. Sylvester, R. Zigeuner
Guidelines Associates: O. Capoun, D. Cohen, V. Hernández, V. Soukup

Eur Urol 2011 Apr;59(4):584-94
Eur Urol 2013 Oct;64(4):639-53

Introduction

The EAU Working Group has published guidelines on Non-muscle-invasive bladder cancer (NMIBC). It comprises Ta and T1 tumours as well as carcinoma in situ (CIS).

Staging and classification systems

The TNM Classification of Malignant Tumours, 7th Edn., 2009 will apply (Table 1).

Table 1: TNM Classification 2009

T - Primary tumour	
TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour



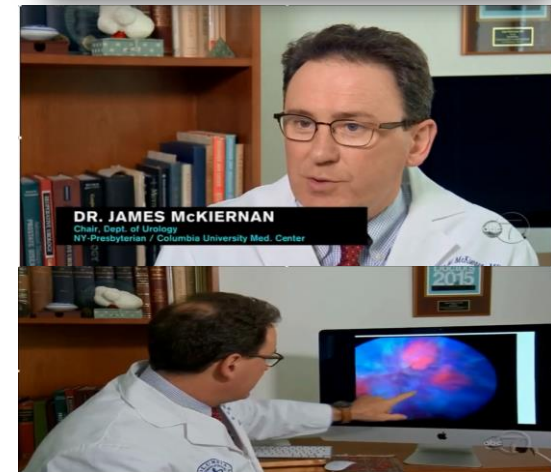
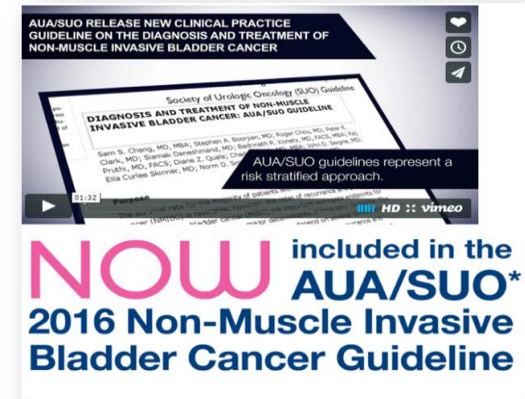
Cysview US - Significant Growth Opportunity

Number of bladder cancer resections (TURBs) > 300 000 per year in the US

- Majority of TURBT's done at 400 centers in the US with more than 100 MUSD potential
- BLC with Cysview available at 81 centers up from 65 in 2017 as of Q3 2016
- Obtained market share of over 20% across current accounts

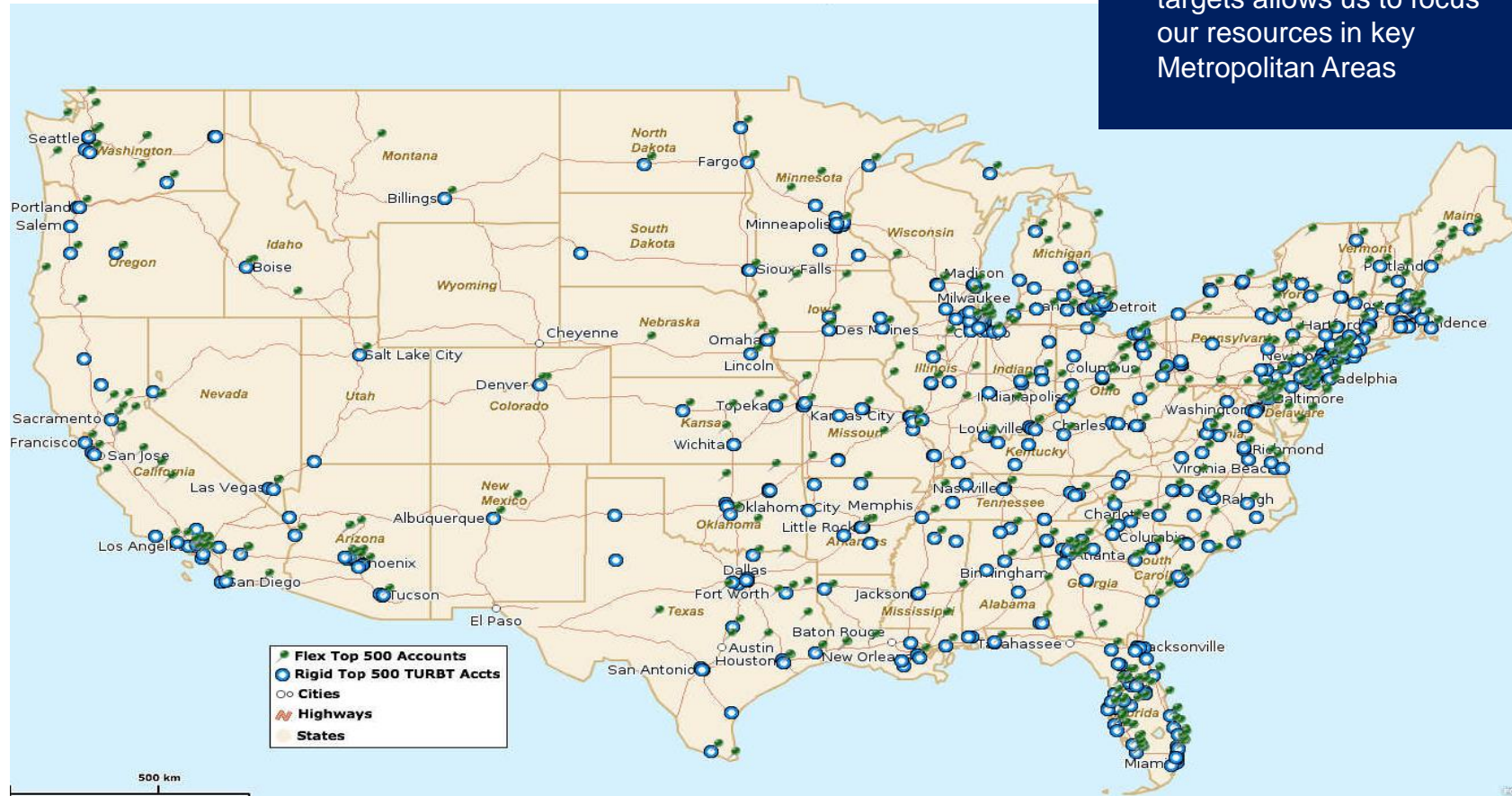
Foundation for continued growth

- Inclusion of BLC with Cysview in the AUA guidelines validated the high unmet medical needs
- Established a major bladder cancer patient registry with over 500 patients providing data on clinical benefits from real world clinical of BLC with Cysview
- Increased awareness with support from leading urologists
- Broaden coverage with increased sales and marketing resources



Concentration of Top - TURBT & Cystoscopy Targets

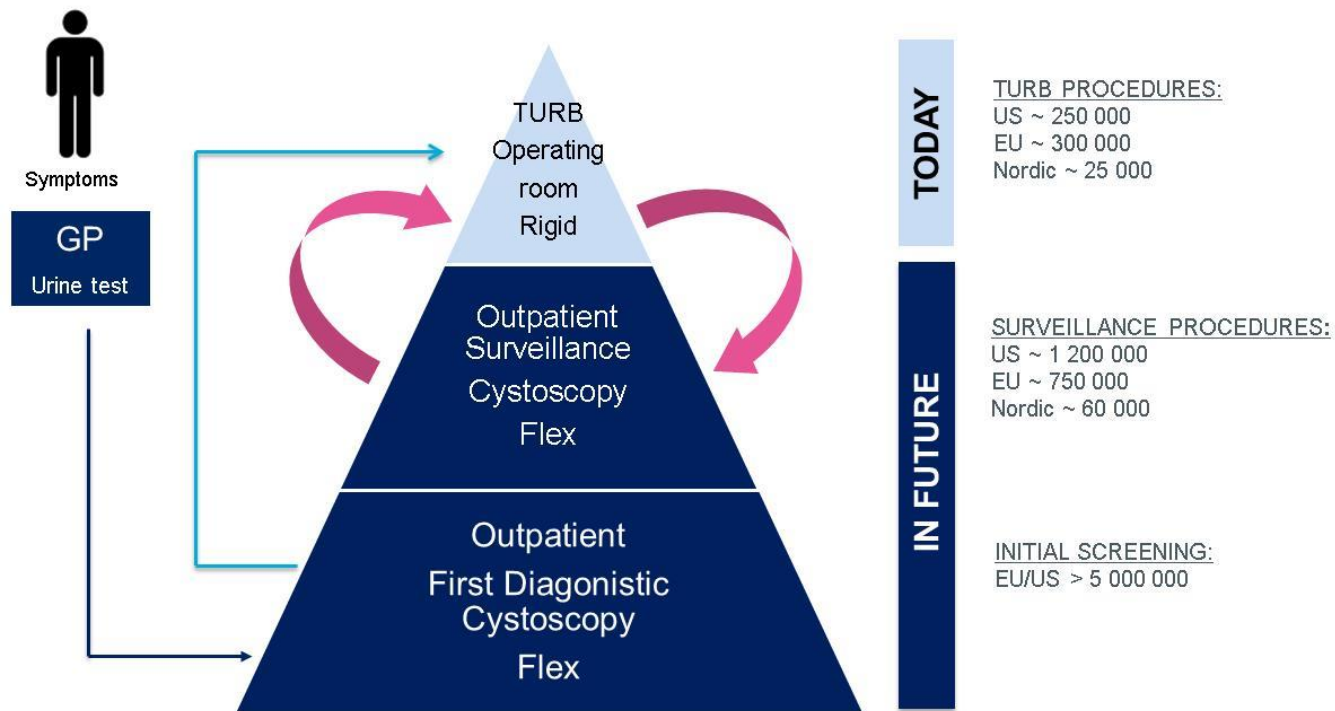
- Hyper concentration of top targets allows us to focus our resources in key Metropolitan Areas



Expanding into the Surveillance Segment

Surveillance following initial diagnosis represents a significant growth opportunity of 2-3 times current TURB segment

Global Cystoscopy Market Consists of Three Distinct Market Segments



US Surveillance Study

Overview

- Compare use of Blue Light Cystoscopy with Cysview and White Light using the blue light enabled Flexible cystoscope device (Karl Storz)
- 100mg of Cysview as intravesical solution will be instilled in the bladder and the patient will wait an hour before the Cystoscopy

Endpoints

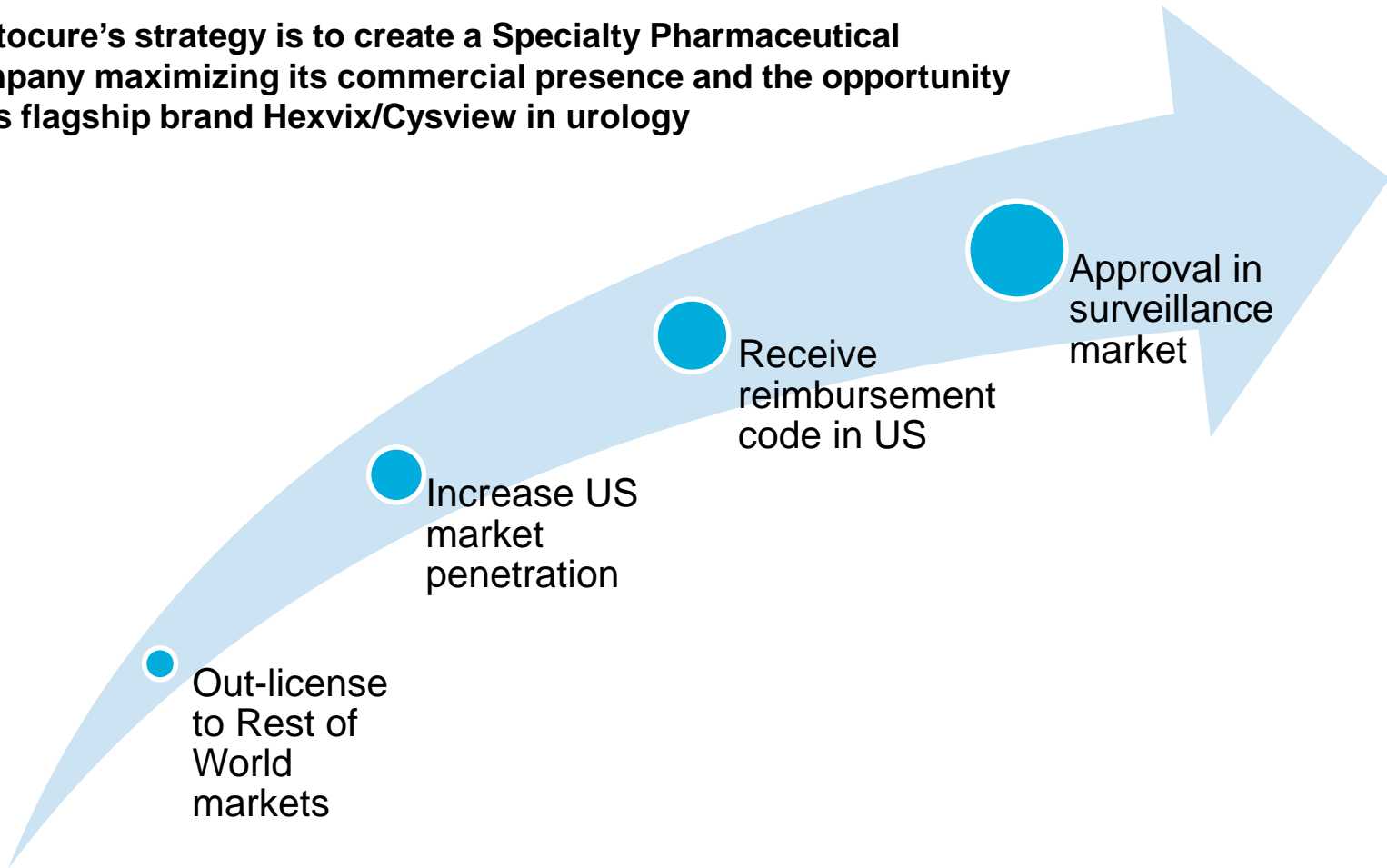
- 1° endpoint is to look at the rate at which malignancy is detected with Cysview compared to white light using flexible scopes
- 2° endpoint (1) is to look at the proportion of patients with adverse events from the procedure after repeated administration
- 2° endpoint (2) is to compare the amount of patients with one or more CIS (Carcinoma in situ; flat, aggressive lesions) lesions that are detected with Cysview when white light detects none

Current Status

- Secured alignment with FDA on study design necessary to obtain label extension on three significant areas (use in combination with flexible scope, repeated use, increased detection of CIS)
- Study results expected in 2017

Longer Term Potential for Urology Franchise

Photocure's strategy is to create a Specialty Pharmaceutical Company maximizing its commercial presence and the opportunity of its flagship brand Hexvix/Cysview in urology



Non-Urology Pipeline



Cevira – A Major Opportunity in Cervical disease

Breakthrough single use and fully integrated drug-device technology to satisfy high need for novel non-surgical therapies to treat global epidemic of HPV/CIN populations

Results of the Phase 2b trial are significant in HSIL patients

- Statistically significant ($p=0.004$) HSIL (CIN2,3) regression
- Statistically significant ($p=0.045$) virologic clearance of oncogenic HPV
- Excellent tolerability and high physician & patient acceptance

Achieved SPA on Phase 3 program with FDA for patients with HSIL

Blockbuster sales potential based on premium pricing opportunity in large patients populations

- ~1M cases HSIL annually in US & West EU with additionally 10-15M cases oncogenic HPV annually in US & West EU detected through routine cervical screening programs
- At premium price levels, cost impact model demonstrates cost savings/benefit to the US health care system

Further strengthened patent portfolio with issuance on new patents

Ongoing discussions and due diligence with potential partners for development and commercialization



Visonac – Addressing a Need for Newer, Safer Acne Therapies

As documented in scientific literature and dermatology guidelines high unmet medical need for non-antibiotic, non-retinoid treatments in severe acne segment

- Mono therapy with oral antibiotics (tetracyclines) effectiveness not well documented
- Combinations of oral antibiotics plus topical agents or systemic retinoids only currently available effective treatment options
- Toxicities of available agents/combination of agents make them unsuitable for long term use

Positive Phase 2b results published in *British Journal of Dermatology*

- Significant reduction in inflammatory lesions and improvement of overall acne severity as a topical monotherapy

Phase 3 Ready with significantly reduced regulatory risk

- SPA (US) and PIP (EU) agreed for global registration program

Further strengthened patent portfolio with issuance of new patents

Ongoing discussions and due diligence with potential partners for development and commercialization

Baseline



Week 12
6 weeks after last treatment



Financials & Outlook



Financial Snapshot (Third Quarter 2016)

.....

Commercial franchise

- Continued revenue growth for Hexvix/Cysview, YoY quarter growth 16%, year to date 13% (in constant FX: 13%)
- EBITDA margin at 18% year to date
 - Increased operating expenses, sales & marketing in US and trials to support surveillance-market

Total

- EBITDA at USD -0.2 million for the quarter, USD -0.9 million year to date

Cash Flow

- Quarter end cash balance at USD 11.7 million
 - Payment from Galderma 2016.12.31 of EUR 4.0 million (USD 4.2 million)
 - Sale of shares in PCI Biotech in December, NOK 32.5 million (USD 3.8 million)

Delivering on Key Objectives

Key Objectives

- Increase Hexvix/Cysview global in-market unit sales growth rate
- Finalize recruitment and reporting of clinical results of Hexvix/Cysview phase 3 market expansion study in 2017
- Secure Partnership for further development and commercialization of Visonac and Cevira reflecting the product potential

9M 2016 Key Achievements

- Hexvix/Cysview global in-market volume increased YoY 5%
- Hexvix/Cysview in-market value increased YoY 10% to USD 22 million
- BLC with Cysview recommended in new American Urology Association bladder cancer guidelines
- Continuous stream of publications on the benefits of BLC with Hexvix/Cysview
- Strong patient enrollment in third quarter
- Lower total project costs than originally planned
- Discussions ongoing with potential partners

Photocure – Investment Highlights

Commercial-stage company focused on Urology

- Hexvix®/Cysview® for improved detection and management of bladder cancer
 - Improved detection, reduced disease recurrence and progression rates with cost benefits
 - ~USD 30M global in market sales (LTM); EBITDA USD 2.8 million (LTM)
- Specialist salesforce established in US and Nordic region and additional emerging operations in other high value territories through partners
 - Ipsen (EU), Juno Pharmaceuticals (Australia/New Zealand), BioSyent Pharma (Canada)

Value building opportunities anticipated in next 12 – 24 months

- Large untapped potential for Hexvix/Cysview in existing and new market segments/territories
 - New clinical data in Flex scope/surveillance use with potential label extension in the US; clarity on reimbursement in US
- Partnering opportunities for non-urology assets
 - Cevira® (cervical disease) and Visonac® (Acne)
- Exploring expansion of urology portfolio to leverage commercial infrastructure

Appendix



Segments - Third Quarter 2016

Commercial franchise

- Hexvix/Cysview total revenue growing YoY 17% in the quarter and year to date 20% (in constant FX: 13%)
- Total revenues negatively impacted by API revenues and milestone revenues
- Increased operating expenses; sales & marketing in US and investigator initiated trials to support surveillance-market in Nordics
- EBITDA margin at 18% year to date

Development portfolio

- Activities related to regulatory work and intellectual property. Cysview post marketing commitment phase 3 capitalized

<i>MNOK</i>	<u>Q3 '16</u>	<u>YTD '16</u>	<u>YTD '15</u>
<u>Commercial Franchise</u>			
Nordic revenues	8.7	29.4	26.4
US revenues	7.8	22.4	15.7
Partner revenues	15.1	47.5	40.5
Hexvix / Cysview	31.6	99.4	82.6
API revenues	0.0	0.0	6.5
Signing fee & milestones	3.6	6.2	11.1
Total revenues	35.2	105.5	100.2
Cost of goods sold	-2.2	-6.6	-6.2
Gross profit	33.1	98.9	94.0
Operating expenses	-25.0	-79.6	-69.8
EBITDA	8.0	19.3	24.2
<u>Development Portfolio</u>			
Operating expenses	-9.7	-27.0	-33.5
EBITDA	-9.7	-27.0	-33.5
<u>Total</u>			
EBITDA	-1.6	-7.7	-9.3

Profit & Loss - Third Quarter 2016

Revenue and Expenses

- Total revenue increase YoY 5% year to date
 - Negatively impacted by sales of API and reduced milestone revenues
- Operating expenses increase YoY 3% year to date
 - R&D reduction 40%
 - Sales & marketing increase 13%
 - Other Opex increase 15%

Earnings

- EBITDA at NOK -1.6 million for the quarter, NOK -7,7 million year to date
- EBIT impacted by amortization of phase 3 Cysview
- Tax net income (non-cash) year to date driven by change in transfer pricing method

MNOK

	Q3 '16	YTD '16	YTD '15
Hexvix / Cysview revenues	31.6	99.4	82.6
Other sales revenues (API)	-0.0	-0.0	6.5
Signing fees and milestones	3.6	6.2	11.1
Total revenues	35.2	105.5	100.2
Cost of goods sold	-2.2	-6.6	-6.2
Gross profit	33.1	98.9	94.0
Research & Development	-3.9	-12.2	-20.5
Sales & Marketing	-19.1	-59.2	-52.4
Other Opex	-11.6	-35.2	-30.5
Operating expenses	-34.7	-106.6	-103.4
EBITDA	-1.6	-7.7	-9.4
Depreciation & Amortization	-1.6	-4.8	-2.4
EBIT	-3.2	-12.5	-11.8
Net financial items excl PCI	-0.0	1.2	4.5
Profit/loss(-) before PCI & Tax	-3.3	-11.3	-7.3
Impairment loss shares PCI	-	-	-7.7
Tax expenses	3.3	28.7	-11.8
Net profit/loss(-)	0.1	17.5	-26.7

Cash Flow - Third Quarter 2016

<i>MNOK</i>	Q3 '16	YTD '16	YTD '15
Cash flow from:			
- Operations	-8.6	-30.7	-19.2
- Investments	-2.9	-11.1	-9.0
- Financing	1.0	1.7	2.4
Net change in cash	-10.5	-40.1	-25.8
Ending cash balance	93.9	93.9	139.5

Comments

- Year to date cash flow from operations at NOK -30.7 million (prior year NOK -19.2 million)
 - Change in working capital NOK -22.9 million (prior year NOK -9,6 million) year to date. Increased outflow driven by reduced payables
- Year to date cash flow from investments NOK -11.1 million, includes investments of NOK 10.8 million in development expenses mainly related to the initiation of the phase 3 post-marketing commitment trial for Cysview
- Quarter end cash balance at NOK 93.9 million
 - Payment from Galderma 2016.12.31 of EUR 4.0 million

Balance Sheet per 30 September 2016

Assets

- Non current assets include NOK 22.5 million in investments in tangible and intangible assets, NOK 7.4 million in shares in PCI Biotech and deferred tax asset of NOK 52.2 million
- Current assets include NOK 35.1 million in remaining settlement for sale of Metvix, due 31.12.2016

Equity and Liabilities

- No interest bearing debt
- Shareholder's equity of NOK 234.1 million. Equity ratio of 91%
- Photocure held 809 own shares at end of the quarter

MNOK

Non-current assets
Inventory & receivables
Cash & equivalents
Total assets

Shareholders equity
Long term liabilities
Current liabilities
Total equity & liabilities

Equity ratio

**30.09
2016**

82.0
81.4
93.9
257.3

234.1
3.4
19.8
257.3

91%

**31.12
2015**

43.6
70.4
134.0
248.1

210.1
4.0
34.0
248.1

85%

Shareholders

Shareholder	Acc type	Citizen	No of shares	%
HIGH SEAS AS		NOR	3,350,000	15.54 %
J.P. MORGAN CHASE BANK	NOM	GBR	3,155,822	14.64 %
KLP AKSJENORGE		NOR	1,218,130	5.65 %
RADIUMHOSPITALET FORSKNINGSSTIFTELSE		NOR	1,112,916	5.16 %
KOMMUNAL LANDSPENSJONSKASSE		NOR	838,272	3.89 %
FONDSFINANS NORGE		NOR	825,000	3.83 %
MP PENSJON PK		NOR	810,000	3.76 %
DANSKE INVEST NORSKE C/O DANSKE CAPITAL		NOR	422,603	1.96 %
SKAGEN VEKST		NOR	399,267	1.85 %
EIKA NORGE		NOR	366,001	1.70 %
VICAMA AS		NOR	329,530	1.53 %
DANSKE INVEST NORSKE		NOR	322,414	1.50 %
FONDSFINANS GLOBAL HELSE		NOR	320,000	1.48 %
POLAR CAPITAL GLOBAL HSBC BANK PLC.		GBR	254,537	1.18 %
RUL AS		NOR	224,451	1.04 %
WLH INVEST AS		NOR	201,537	0.93 %
BERGEN KOMMUNALE PENSJONSKASSE		NOR	200,000	0.93 %
EGELAND HOLDING AS		NOR	195,000	0.90 %
KLP AKSJENORGE INDEKS		NOR	188,492	0.87 %
ARTAL AS		NOR	177,349	0.82 %
Total 20 largest shareholders			14,911,321	69.17 %
Total other shareholders			6,646,589	30.83 %
Total number of shares			21,557,910	100.00 %

Contact Information



Erik Dahl
Chief Financial Officer
Tel: + 47 45055000
Ed@photocure.com

