

PHOTOCURE ASA

RESULTS FOR THIRD QUARTER AND THE FIRST NINE MONTHS 2019

7 November 2019

Daniel Schneider, President and CEO
Erik Dahl, CFO



THE
BLADDER CANCER
COMPANY™

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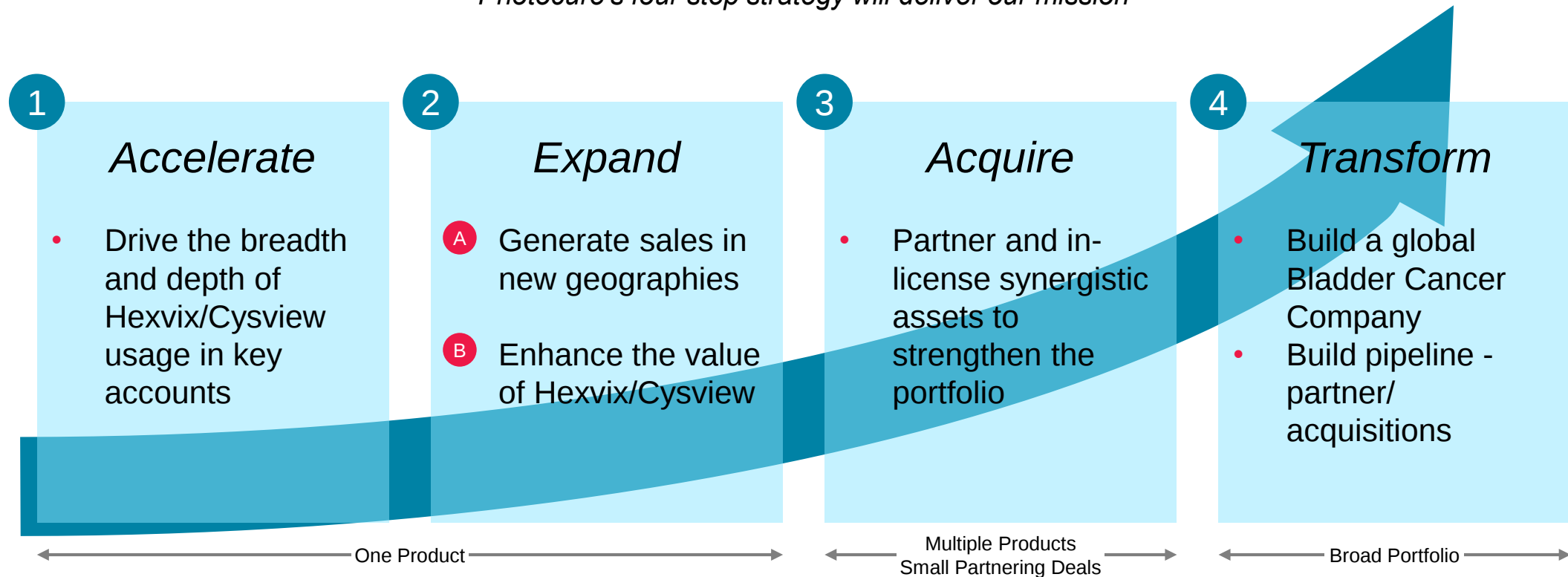
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OUR MISSION IS TO DELIVER TRANSFORMATIVE SOLUTIONS WHICH IMPROVE THE LIVES OF BLADDER CANCER PATIENTS

Photocure's four step strategy will deliver our mission



Photocure's global commercial bladder cancer platform will be the foundation for transformative deals and value growth

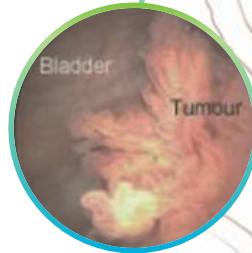
NON-MUSCLE INVASIVE BLADDER CANCER

IS ONE OF THE MOST COMMON CANCERS
WITH SIGNIFICANT RECURRENCE RATE AND HIGH DISEASE BURDEN

~700K

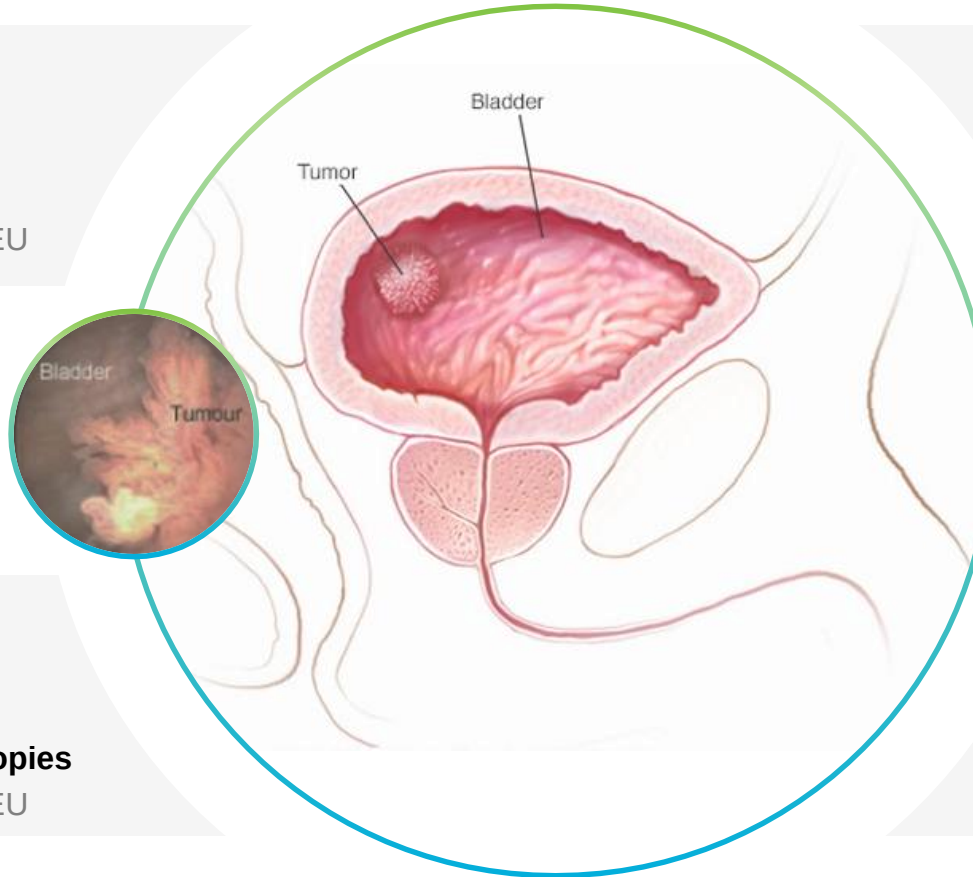
» surgical procedures
annually in USA and EU

Tumor as seen
through a cystoscope



~2.2M

» surveillance cystoscopies
annually in USA and EU



More than 60%

» disease recurrence at 1 year¹

10% – 30%

» disease progression¹

3.7 USD Billion

» in direct medical costs/year²

Picture: Mayo Clinic; Researchgate.net

1. Sylvester RJ et al. Eur Urol 2006; 49: 466-467

2. Direct medical costs in USA in 2001: The health economics of bladder cancer: a comprehensive review of the published literature. Botteman MF et al. Pharmacoeconomics 2003;21 (8), 1315-1330

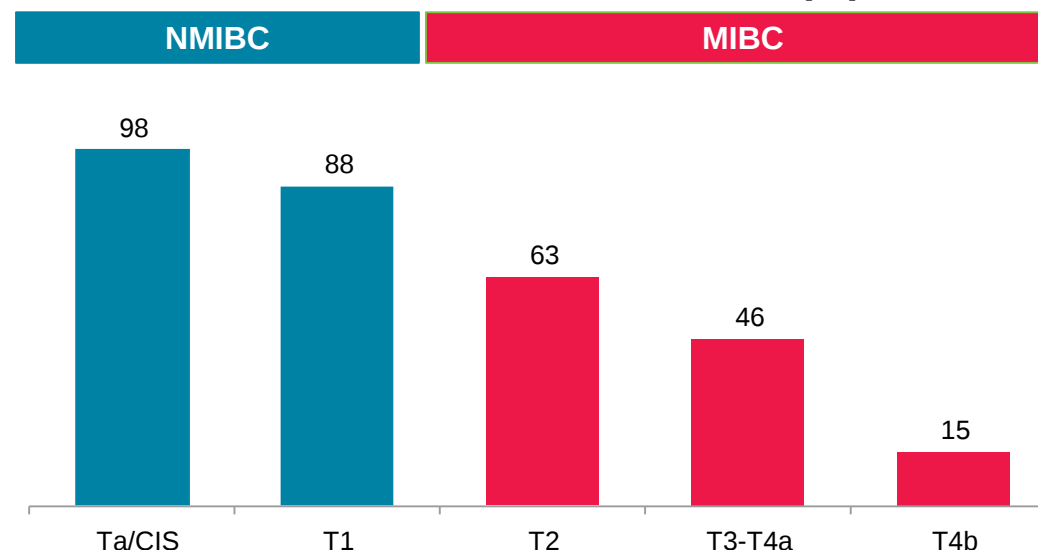
CYSTOSCOPY IS CURRENTLY THE ONLY METHOD FOR MANAGING RECURRING BLADDER CANCER

Bladder Cancer Progression and Recurrence

Key therapeutic aim is to avoid progression from non-muscle invasive bladder cancer (“NMIBC”) to muscle invasive bladder cancer (“MIBC”)

- Among bladder cancer patients, 75% are diagnosed with NMIBC
- Recommend follow-up cystoscopies every three to nine months based on initial TURBT
- Every three months during the first 24 months of diagnosis for high risk patients
- More than 2.2m follow-up surveillance cystoscopies annually of which 1.4m in the US

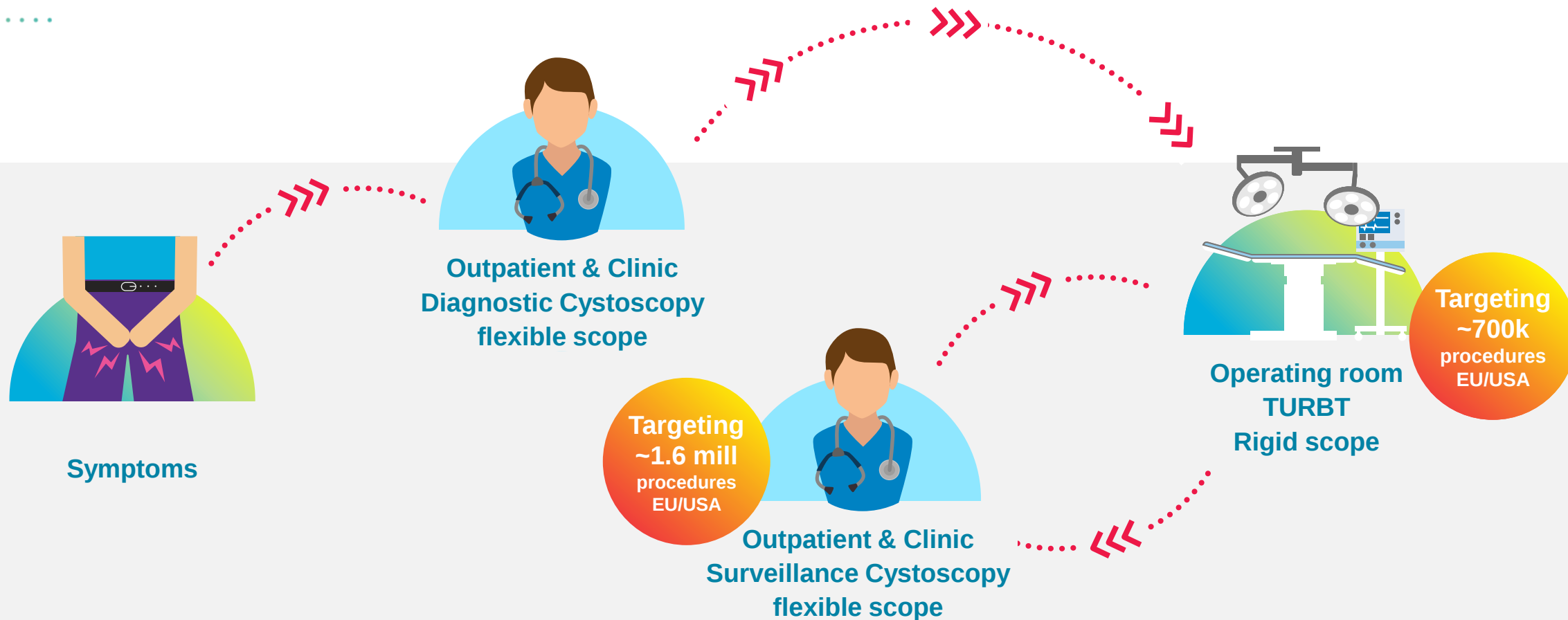
5-Year Relative Survival Rate (%)



Recurrence and progression

Stage	Recurrence rate	Progression to MBIC
Low grade Ta	70%	2%
High-grade Ta	50-80%	14-48%
T1	70%	30-50%
CIS	43-73%	50%

THE PATIENT JOURNEY – CHARACTERIZED BY LONG TERM FOLLOW-UP WITH REPEAT PROCEDURES



HEXVIX®/CYSVIEW® FOR BETTER DETECTION AND MANAGEMENT OF NMIBC

HEXVIX®
Hexaminolevulinate 85mg

CYSVIEW®
Hexaminolevulinate HCl

is taken up selectively
by cancer cells in
the bladder
making **them**
glow bright pink
under blue light

◀◀ A Drug Device combination
for better visual contrast
between benign
and malignant cells ▶▶



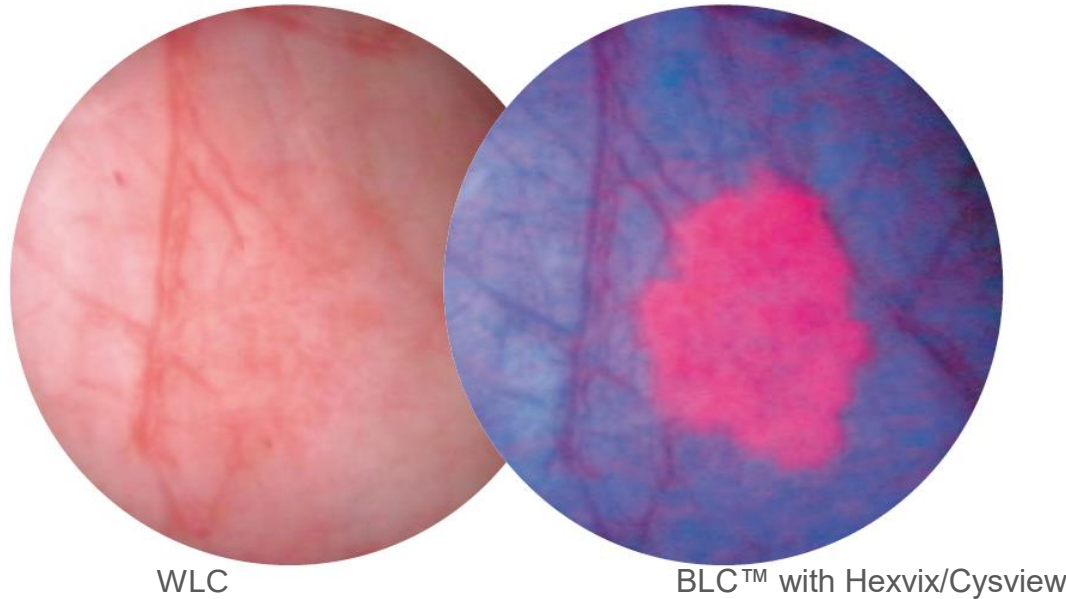
Hexvix / Cysview is used
with a **blue light enabled**
cystoscope, from Karl
Storz, Wolf or Olympus



Use for the 1st TURBT
and for all intermediate and high-risk NMIBC patients
during surgical treatment and surveillance / follow-up.

BLUE LIGHT CYSTOSCOPY WITH HEXVIX®/CYSVIEW®

A TRANSFORMATIVE SOLUTION TO IMPROVE THE LIVES OF PATIENTS WITH BLADDER CANCER



Key benefits

- Improved Patient outcomes (diagnostic accuracy + surgical results)
- Significant reduction of disease recurrence
- Reduction in disease progression
- Improved cost-effective health outcomes

Additional tumors found in **1** out of **4** patients¹

Additional papillary tumors in **25%** of patients¹

35% of patients with CIS were only found with Cysview®²

HEXVIX®/CYSVIEW® OUTLOOK: BEYOND DIAGNOSTICS

- Recent studies – although very early-stage – show a different kind of potential for Hexvix/Cysview
- Photocure has the intention to further investigate Hexvix/Cysview for its therapeutic effect



[< Back to overview](#)

Antitumor effect and induced systemic immune effects of HAL used in PDD doses in an orthotopic model of rat bladder cancer

Myren Kari, Head of Global Medical Affairs and Clinical Development, Photocure ASA, Oslo, Norway

[Show all authors](#)

Abstract



THE
BLADDER CANCER
COMPANY™

Positioned for growth



DELIVERING ON KEY 2019 OBJECTIVES



Significant growth of Cysview® in US TURBT market

- » US Q3 revenue growth in **USD 42%**, in-market volume increase in Q3 of 34%



Accelerate Cysview® in US flexible cystoscopy surveillance market

- » **54% growth YOY** in installed blue light enabled cystoscopes in market
- » Total of **211 cystoscopes** including **22 Flex** cystoscopes



Increase Hexvix® / Cysview® global in-market unit sales

- » **Total Hexvix®/Cysview®** revenue increased 18% YOY to NOK 51.1 MIL

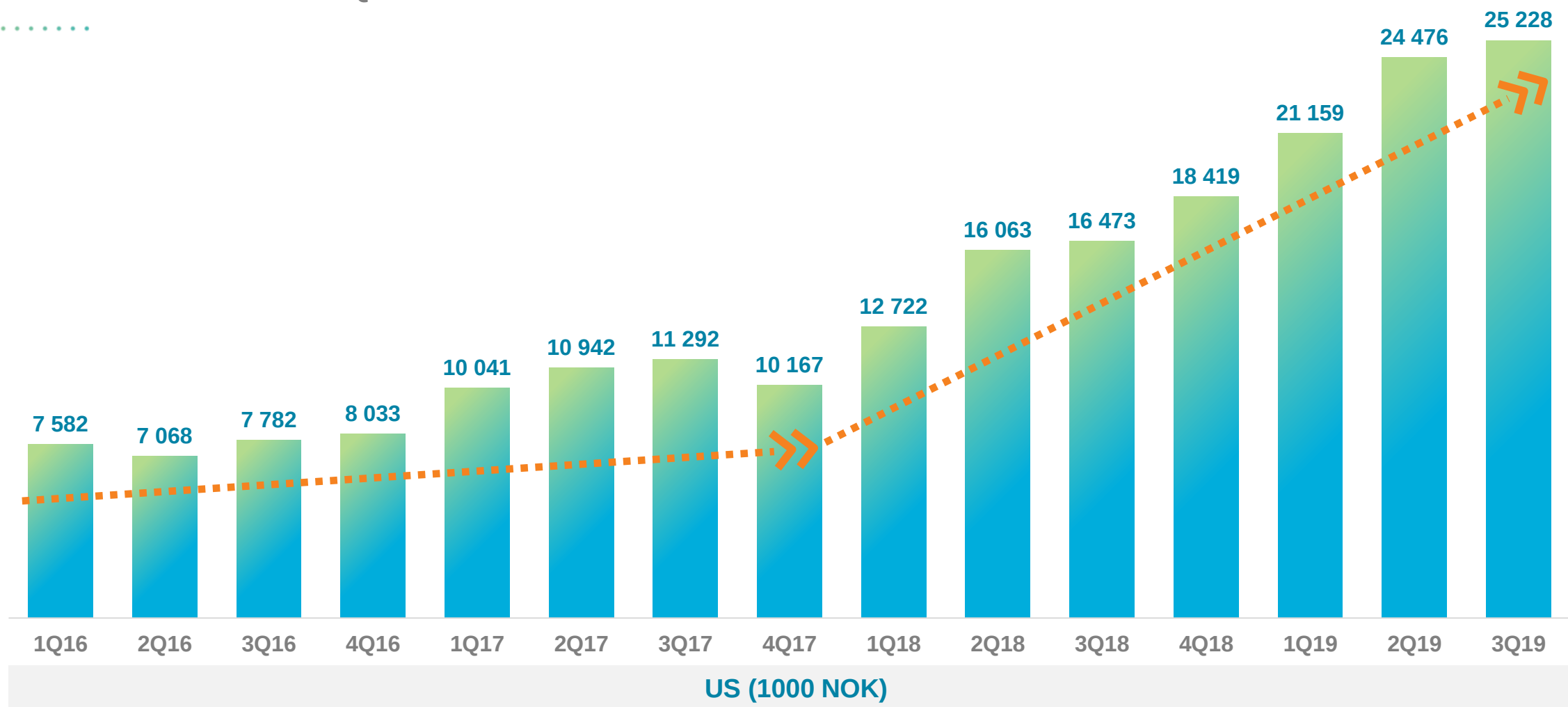


Create opportunities vis-à-vis our strategic partnerships

- » **Total in-market unit** sales increased 6% YOY in Q3

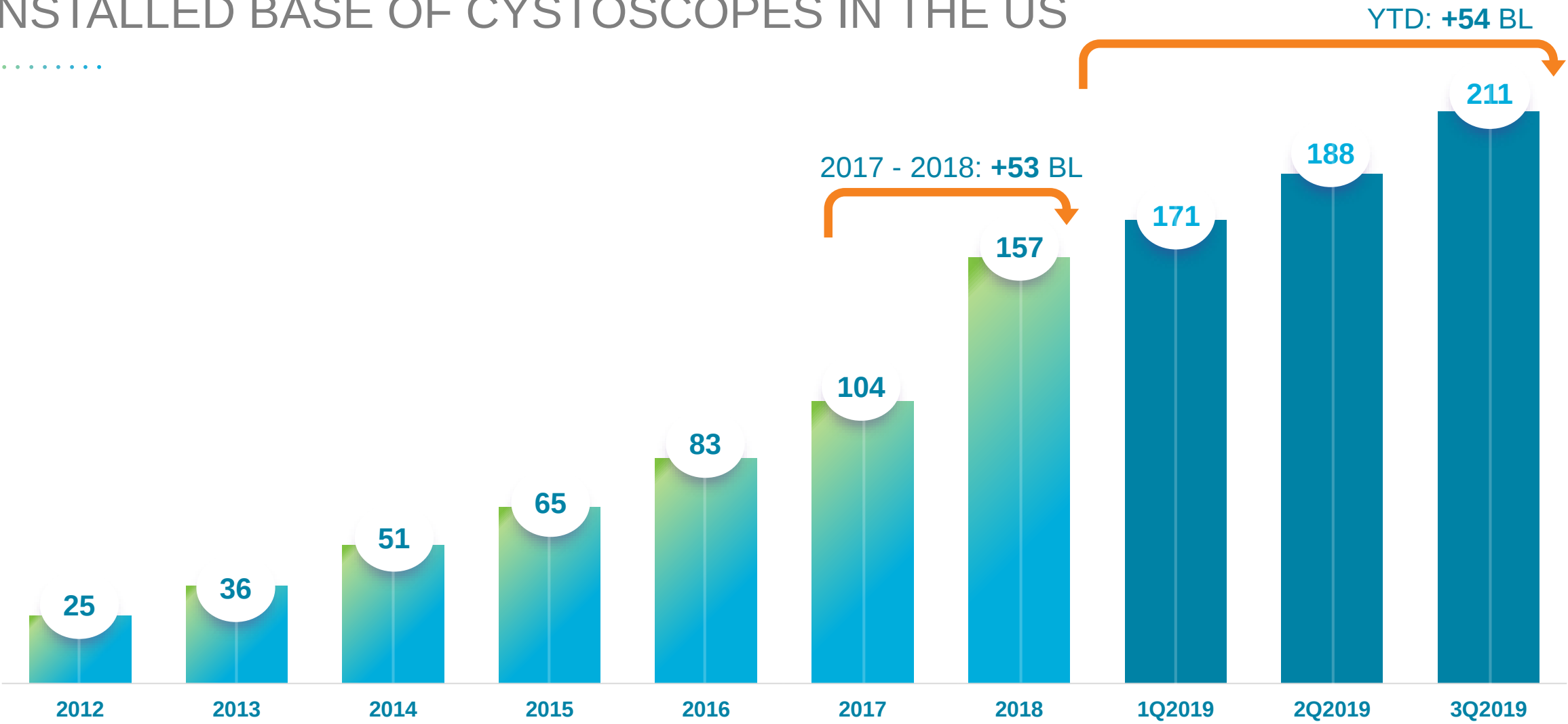
ACCELERATED MOMENTUM

7 CONSECUTIVE QUARTERS OF RECORD REVENUES IN US



ACCELERATED MOMENTUM

INSTALLED BASE OF CYSTOSCOPES IN THE US



THE INVESTMENT MADE WILL DELIVER RETURNS

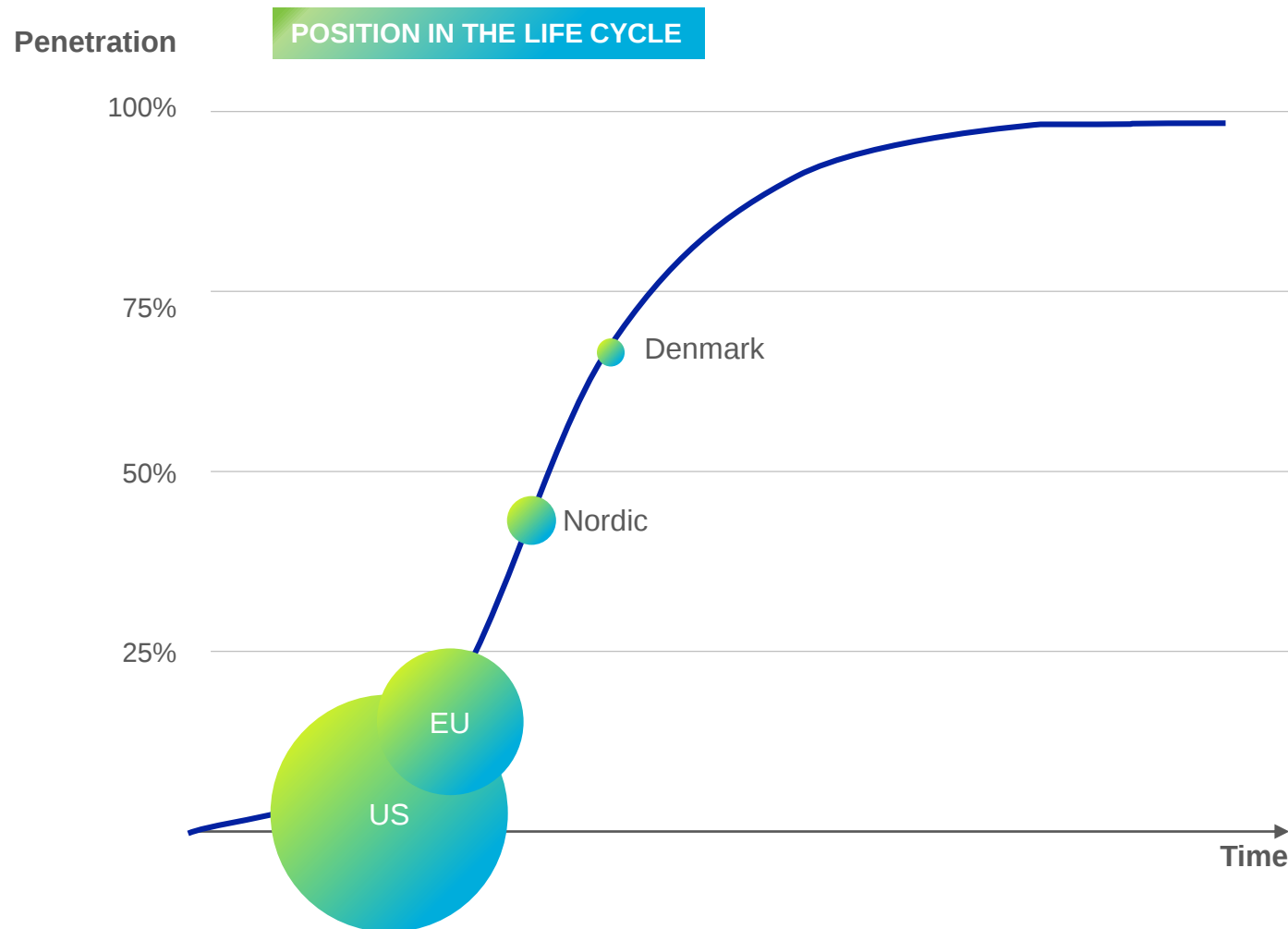


Strategy – Target Key Hospitals in the 30 largest MSAs in the US

2018/19 – We have built the Commercial Foundation

- Sales team focused on top 700+ centers that influence bladder cancer care in their regions
- Team is composed of 27 Surgical Sales Executives (sell to new accounts) and 4 Clinical Support Specialists (increase current account sales) and 2 Corporate Account Managers focused on large health systems
- Average territory for sales rep at peak sales: USD 1.5 - 2 MIL in revenues (20-25 active accounts)
- Future investment would be predicated on gaining optimal account coverage with similar ROI
- Continuous improvement to build a performance driven culture

HEXVIX®/CYSVIEW® – KEY ENABLERS IN PLACE AND READY FOR GROWTH



KEY SUCCESS FACTORS

Approval >>> Surgical & surveillance

Acceptance >>> Major & local guidelines

Access >>> Permanent and favorable reimbursement

“Activated” Awareness >>> Patient demand via advocacy groups and media

Accelerate >>> Commercial investment to optimize the opportunity

SUPPORTIVE ENVIRONMENT & INCREASING AWARENESS

FOR BECOMING THE STANDARD OF CARE FOR THE DETECTION AND MANAGEMENT OF BLADDER CANCER

- **Inclusion in Bladder Cancer treatment guidelines**

BLC™ with Hexvix® /Cysview® is strongly recommended by US, European and national guidelines as well as expert panels.



American
Urological
Association



NICE National Institute for
Health and Care Excellence

- **High adoption rate in top Cancer centers**

Established in >170 key US cancer hospitals and leading institutions.

25% to 70% penetration rate in the Nordics

- **Patient preference**

growing awareness and active preference as shown in recent BCAN survey

- **Favorable and Permanent US Reimbursement 2019**

further improvements to come from January 2020

- **Partnering with prominent Patient Associations**

especially BCAN in the US and the new World Bladder Cancer Patient Coalition



INCREASING AWARENESS THROUGH MARKETING ACTIVITIES, CONGRESS ATTENDANCE, DATA GENERATION & PUBLICATIONS

EMJ

Home > Urology > Implementing Blue Light Flexible Cysto...

IMPLEMENTING BLUE LIGHT FLEXIBLE CYSTOSCOPY IN NON-MUSCLE INVASIVE BLADDER CANCER SURVEILLANCE

05 JULY 2019 | ● UROLOGY

DOWNLOAD AS | PDF



BLUE LIGHT CYSTOSCOPY

BLC is a photodynamic diagnostic technique that involves intravesical instillation of the heme precursor hexaminolevulinate (HAL) (Hexvix®/Cysview®, Photocure ASA, Oslo, Norway) prior to cystoscopy. This results in the preferential accumulation of protoporphyrin IX and other photoactive porphyrins in neoplastic tissue, which fluoresce red when exposed to blue light (Figure 1).¹⁰

White Light Flexible Setting



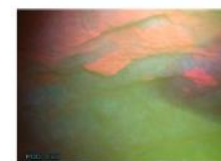
BLC™ with Cysview® for Surveillance



Courtesy of Dr Siamak Daneshmand, Department of Urology, University of Southern California, Los Angeles, California, USA



Courtesy of Dr Siamak Daneshmand, Department of Urology, University of Southern California, Los Angeles, California, USA



Courtesy of Dr Sanjay Patel, Department of Urology, University of Oklahoma, Norman, Oklahoma, USA

Figure 1: Detection of non-muscle invasive bladder cancer with flexible white light and blue light cystoscopy with hexaminolevulinate.

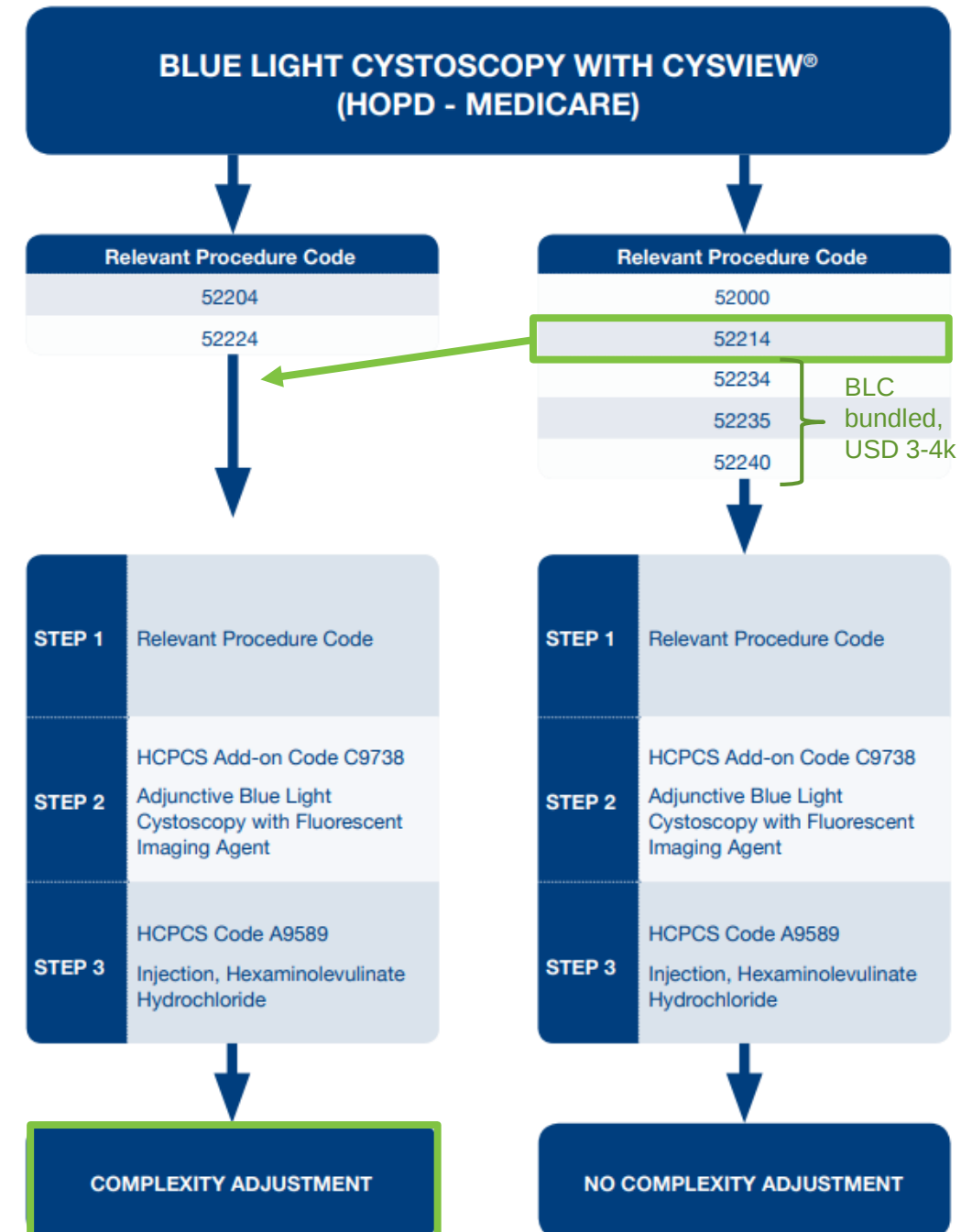
REIMBURSEMENT: CONTINUED IMPROVEMENTS



» CMS just announced **favorable reimbursement evolution for Cysview** in the US, in the Hospital Outpatient setting:

- **Complexity adjustment for one more procedure code (52214)**
- **Additional reimbursement compared to 2019:**
 - **USD 92** increase compared to 2019 for using Blue Light Cystoscopy, effective from January 2020
 - Complexity adjusted rate 2019 – **USD 2,926** 2020 – **USD 3,018**
 - **USD 1,771** for a White Light Cystoscopy vs. **USD 3,018** for a Blue Light Cystoscopy with Cysview (**USD 1,247** complexity adjustment when identified)
- Codes 52234, 52235, 52240: no adjustment needed (acceptable reimbursement)
- Code 52000 is performed in office, not relevant for Hospital Outpatient setting

» Photocure together with several stakeholders in the Urology community will keep up the efforts to further increase patient access to the procedure



Cevira® License Agreement



CEVIRA®: LICENSE AGREEMENT WITH ASIERIS

ASIERIS MEDITECH CO.,
Ltd.



- Asieris is a subsidiary of the China-based Jiangsu Yahong Meditech Co., Ltd., a specialty pharma company fully committed to research, development and commercialization of innovative new medical treatments through their own IP and in-licensing efforts.
- CEO of Asieris: Kevin Pan
- Its leading drug candidate, an oral drug for treating non-muscle invasive bladder cancer, is in a registrational clinical trial in China and Phase Ib trial in the US.
- Asieris has built strong development capabilities in the genitourinary diseases (GU) area in China and is rapidly expanding its global capability.

CEVIRA® – CERVICAL
CANCER



- Potential to fill high unmet need for non-surgical treatment of HPV/CIN populations
- Breakthrough, single use, integrated drug-device technology
- Potential to treat high grade cervical dysplasia independent of HPV genotype
- Easy and convenient for provider and patient

CEVIRA®: TERMS OF LICENSE AGREEMENT WITH ASIERIS

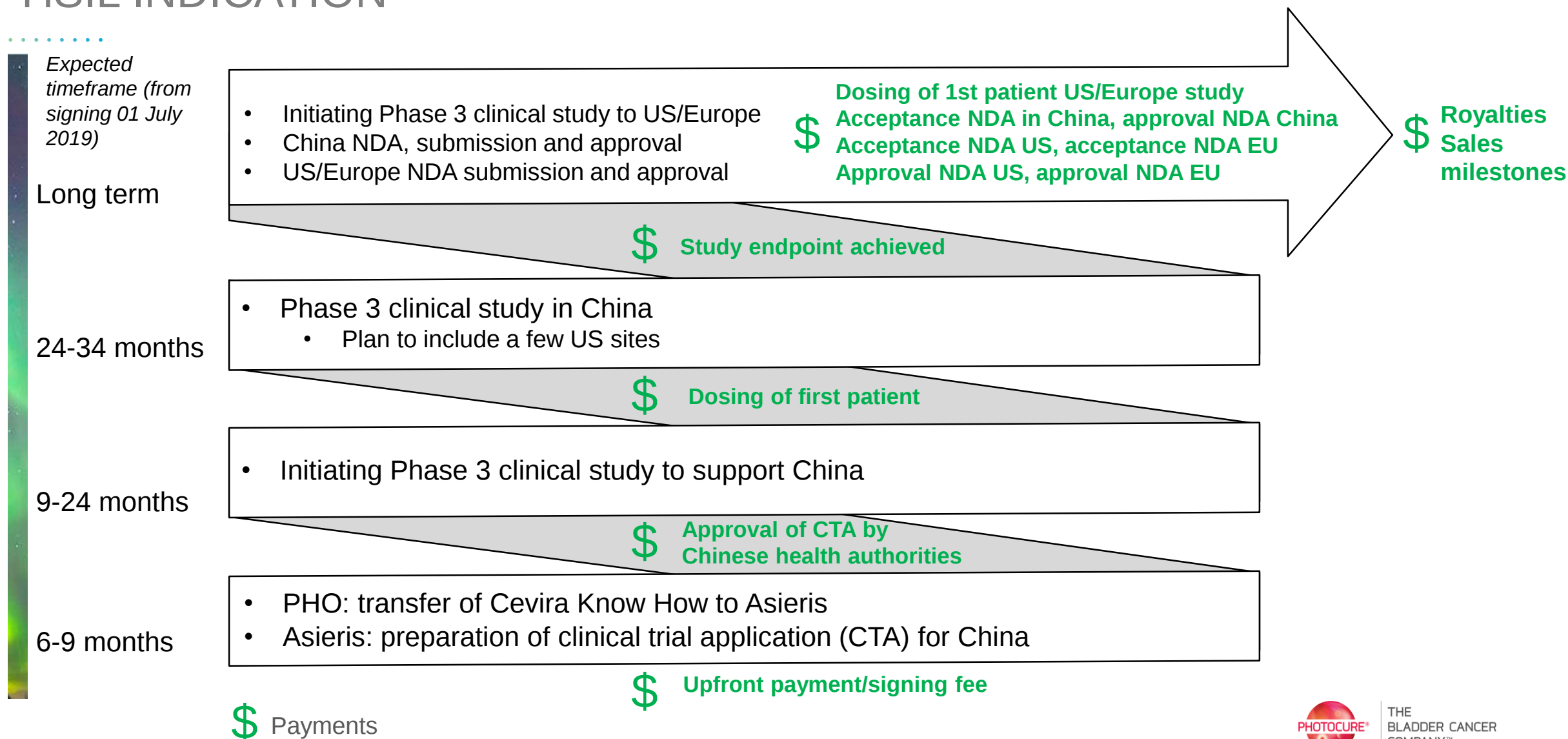
TERMS OF THE LICENSING AGREEMENT*



- Under the License Agreement, Photocure will receive a total signing fee of USD 5 MIL within 6 months after signing.
- Approval of the initial indication will result in USD 18 MIL in China (est 2024) and USD 36 MIL in US/EU (est 2026).
- A second indication in China, the US and the EU would result in payments of up to USD 14 MIL.
- Sales royalties and milestones will apply in all markets.



CEVIRA® – PAYMENTS UNDER THE LICENSE AGREEMENT FOR HSIL INDICATION



THE
BLADDER CANCER
COMPANY™

SEGMENT PERFORMANCE

THIRD QUARTER 2019

<i>Amounts in NOK million</i>	Q3 '19	Q3 '18	Change	YTD '19	YTD '18	Change
Commercial Franchise						
Nordic revenue	9.9	10.6	-7%	33.7	33.5	1%
US revenue	25.2	16.5	53%	70.9	45.3	57%
Partner revenue	16.0	16.4	-2%	49.9	47.8	4%
Total Hexvix/Cysview	51.1	43.5	18%	154.4	126.6	22%
Other revenue	1.0	0.9		2.9	5.1	
Total revenue	52.1	44.4	17%	157.3	131.6	20%
Operating expenses	-44.9	-39.0	15%	-136.9	-112.4	22%
EBITDA ex restruct.	2.6	1.3		5.7	7.1	
Development Portfolio						
Total revenue	8.7	-		8.7	-	
Operating expenses	-2.9	-4.4	-33%	-10.2	-13.5	-24%
EBITDA ex restruct.	5.7	-4.4		-1.6	-13.5	
TOTAL						
EBITDA ex restruct	8.3	-3.1		4.2	-6.4	

Commercial Franchise

- US: Continued strong revenue growth, Q3 42% and YTD 45% in USD
 - Installed base of rigid and flex BLC 211 at quarter end, increased 54% YOY
- Nordic: Q3 revenue decline 7%, YTD at level with last year (+1%)
- Partner: Revenue decline in Q3 2%. YTD growth 4%, driven by Germany, France (Ipsen) and Canada (BioSynt)
- Increased operating expenses, Q3 at 15% YOY, commercial investments in US

Development Portfolio

- Revenue, up-front from Asieris, USD 1.0 MIL
- Operating expenses Q3 and YTD include one-off costs related to agreement with Asieris

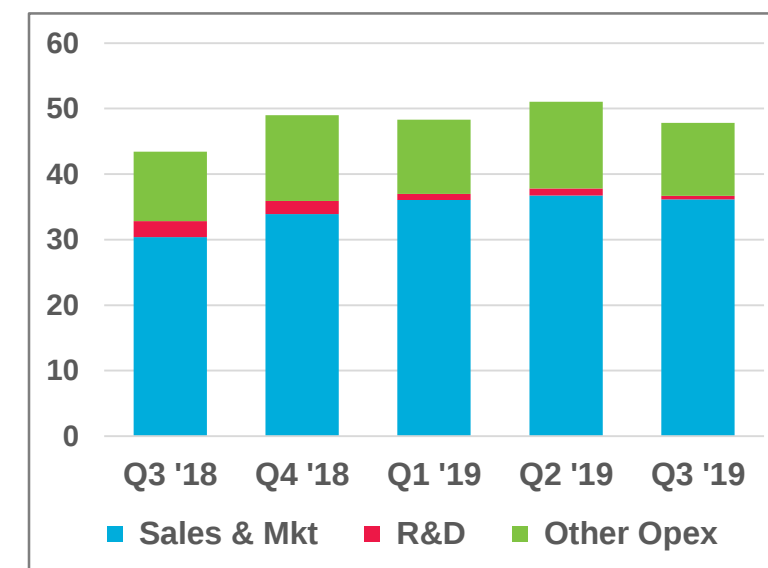
CONSOLIDATED INCOME STATEMENT

THIRD QUARTER 2019

<i>Amounts in NOK million</i>	Q3 '19	Q3 '18	Change	YTD '19	YTD '18	Change
Hexvix/Cysview revenue	51.1	43.5	18%	154.4	126.6	22%
Other revenue	9.7	0.9		11.5	5.1	
Total revenue	60.8	44.4	37%	166.0	131.6	26%
Gross profit	56.1	40.4	39%	151.3	119.5	27%
Operating expenses	-47.8	-43.4	10%	-147.2	-125.9	17%
EBITDA recurring	8.3	-3.1		4.2	-6.4	
Depreciation & Amort.	-4.0	-3.3		-12.4	-9.8	
Restructuring expenses	-	-		-	-13.1	
EBIT	4.3	-6.4		-8.3	-29.3	
Net financial items	1.0	-		0.9	-	
Earnings before tax	5.3	-6.3		-7.4	-29.4	
Tax expenses	-5.9	1.5		-3.3	4.6	
Net earnings	-0.6	-4.8		-10.7	-24.7	

- Operating expenses, increase driven by
 - Planned investments in US commercial operations (sales & marketing)
 - Business development expenses particularly related to Cevira (other operating expenses)
- Operating expenses, significant FX impact
 - Growth in constant currencies YTD approx. 11%

Operating expenses, quarterly



CASH FLOW

THIRD QUARTER 2019

<i>Amounts in NOK million</i>	Q3 '19	Q3 '18	YTD '19	YTD '18
Operations cash flow	9.9	-5.3	-9.8	-35.3
Earnings before tax	5.3	-6.3	-7.4	-29.4
Working capital	1.8	0.5	-10.2	-10.5
Other	2.9	0.5	7.8	4.6
Investments cash flow	-	0.2	0.6	-0.7
Development exp.	-0.1	-	-0.1	-0.6
Other	0.1	0.2	0.7	-0.1
Financing cash flow	-0.7	-	-1.8	-0.6
Share capital	-	-	0.6	-
Other	-0.7	-	-2.4	-0.6
Net change in cash	9.2	-5.1	-10.9	-36.5
Ending cash balance	95.9	92.8	95.9	92.8

- Cash flow from operations Q3 improved MOK 15.2 MIL to NOK 9.9 MIL, driven by payment from Asieris of USD 1.0 MIL and other improvements of NOK 6.5 MIL. YTD improvement of NOK 25.5 MIL to NOK -9.8 MIL
 - 2018 cash flow impacted by restructuring at the end of Q2
- Cash flow from financing includes payment of lease liability totaling NOK 0.7 MIL in Q3 and NOK 2.4 MIL YTD
- Net change in cash improved NOK 14.3 MIL in Q3 and NOK 25.6 MIL YTD compared to last year
- Quarter end cash balance at NOK 95.9 MIL

BALANCE SHEET

30 SEPTEMBER 2019

<i>Amounts in NOK million</i>	30.09 2019	31.12 2018
Non current assets	73.1	77.8
Investments	16.1	24.6
Tax asset	49.1	52.4
Other	8.0	0.7
Inventory & receivables	47.6	46.6
Cash & equivalents	95.9	106.8
Total assets	216.6	231.2
Shareholders equity	166.4	176.3
Long term liabilities	10.8	2.5
Current liabilities	39.5	52.3
Total equity & liabilities	216.6	231.2
<i>Equity ratio</i>	<i>77%</i>	<i>76%</i>

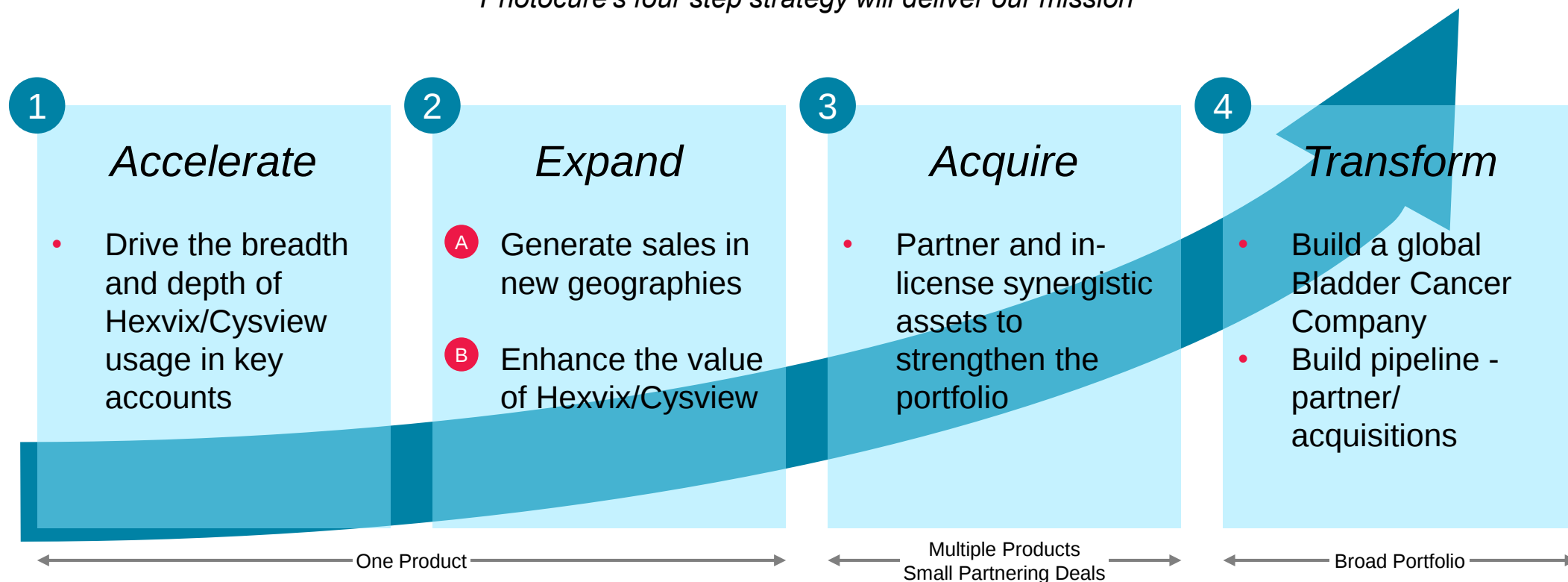
- Non current assets
 - Investments of NOK 16.1 MIL in tangible and intangible assets is driven by investments in Cysview phase 3 project
 - Deferred tax asset of NOK 49.1 MIL
 - Other items includes impact from adoption of IFRS 16 (Leases) from 1 January 2019
- Inventory & receivables driven by revenue increase
- Long term liabilities include impact from adoption of IFRS 16 (Leases) from 1 January 2019
- No interest bearing debt
- Shareholder's equity of NOK 166.4 MIL.
Equity ratio of 77%

Summary and Outlook



OUR MISSION IS TO DELIVER TRANSFORMATIVE SOLUTIONS WHICH IMPROVE THE LIVES OF BLADDER CANCER PATIENTS

Photocure's four step strategy will deliver our mission



Maintain guidance of USD 20-25 MIL in 2020 with significant and sustainable revenue growth in the US market beyond 2020

Back-up slides

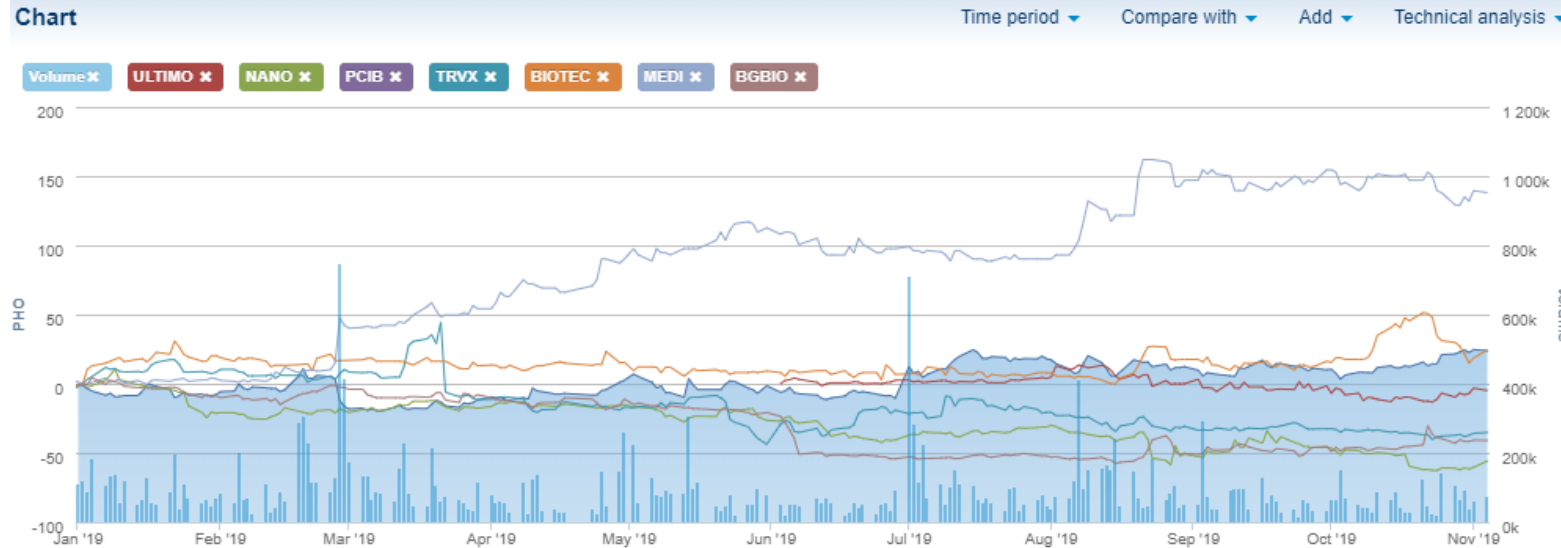


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Stock Exchange

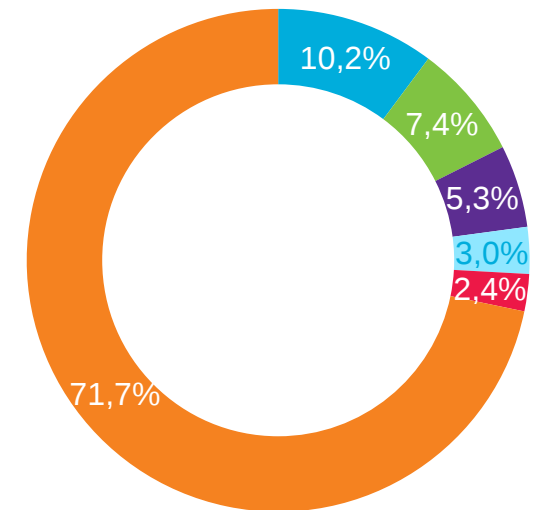
21,796,387
shares issued

>USD 144 MIL
Market cap

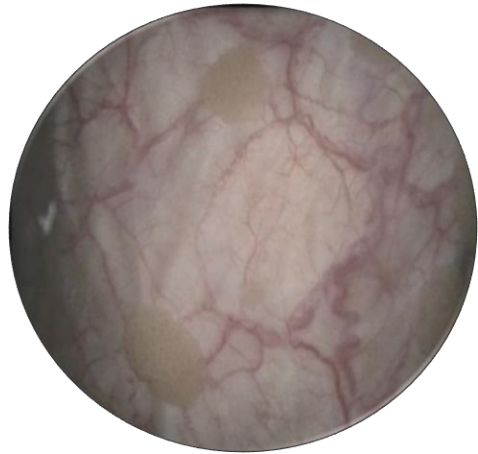


Major shareholders

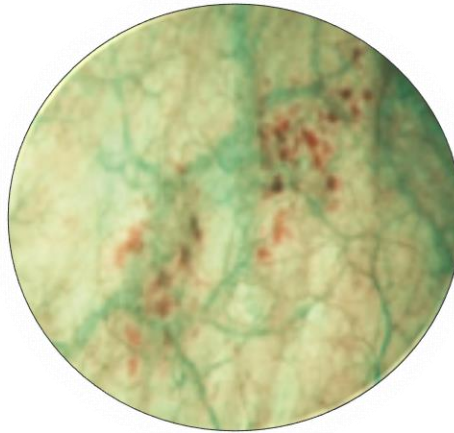
- High Seas AS
- KLP
- Fondsfinans
- Radiumhospitalets Forskningsstiftelse
- Myrlid AS
- Other shareholders (<2.5% stake)



HEXVIX[®]/CYSVIEW[®] VERSUS NBI VERSUS WLC

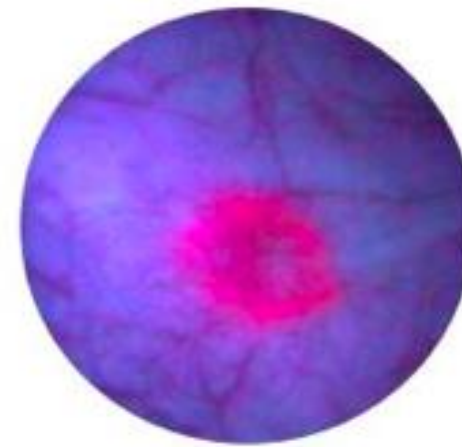


WLC
image with Olympus



NBI
image with Olympus

You see vessels
Narrow Band Imaging
enhances visualization of
blood vessels and surface
structures



BLC[™]
with Hexvix[®] / Cysview[®]

You see the tumors
Cysview[®]/Hexvix[®] is highly selective
and absorbed specifically
by cancerous cells