

# PHOTOCURE ASA

RESULTS FOR FOURTH QUARTER  
AND FULL YEAR 2017

27 FEBRUARY 2018

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# DELIVERING ON KEY 2017 OBJECTIVES

Increase growth of Cysview® in US based on increased investment in US commercial operation

- US sales revenue up 27% YoY in 4Q and 39% FY, driven by in-market volume increase in 4Q of 21% and 31% FY
- New increased CMS reimbursement for Blue Light Cystoscopy (BLC™) with Cysview for use in hospital outpatient departments, starting in from January 2018
- Twenty-five percent growth in blue light enabled cystoscopes in market to over 100 cystoscopes installed by end of LY

Obtain regulatory approval for market expansion of Cysview® into surveillance market

- Clinical results from pivotal phase 3 study announced May 2017 at AUA meeting
- Supplemental NDA filed in August for Blue Light Flexible Cystoscopy (BLFC) with Cysview
- sNDA granted Priority review by US FDA in October
- In February 2018, FDA approved the supplemental NDA

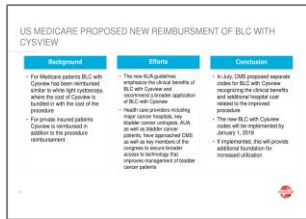
Increase Hexvix® / Cysview® global in-market unit sales

- Total Hexvix/Cysview sales revenue increased 25% to NOK 39.4 million in 4Q
- Hexvix revenue in Nordic in 4Q was record high, 35% growth YoY
- In-market volume in own markets increased YoY 16 % in 4Q and 12% FY
- Total in-market unit sales increased 2% FY, impacted by decline in partner in-market unit sales declined 9% in 4Q and 1% FY

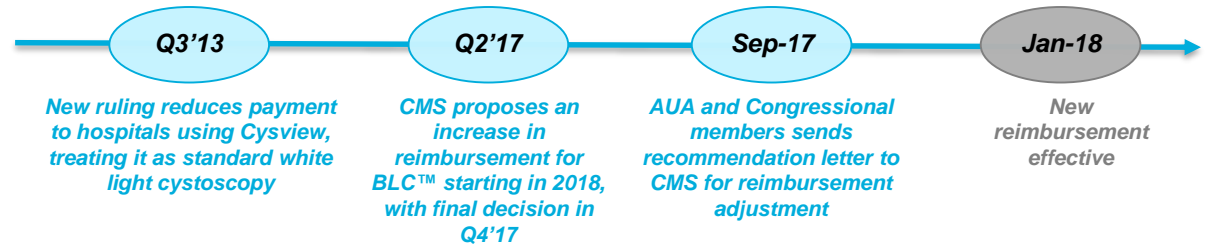
# *Hexvix/Cysview Update*



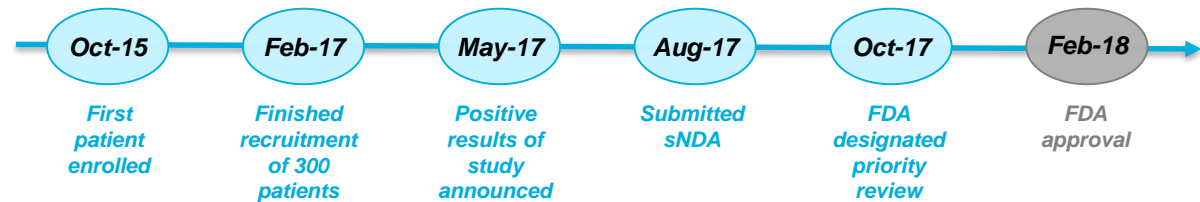
# HEXVIX/CYSVIEW TWO SIGNIFICANT MILESTONES REACHED



**Working closely with CMS<sup>1</sup> to provide appropriate stronger reimbursement opportunity for Cysview – US Medicare Patients**



**Initiate Phase 3 clinical trial to expand the use of Hexvix/Cysview into the surveillance market and fulfil the US post marketing commitments in 2015**



Note: 1) US Center for Medicare & Medicaid Services



# EXPANDED US MARKET OPPORTUNITY THROUGH SUPPLEMENTAL NEW DRUG APPROVAL



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 22555/S-005

Photocure ASA

SUPPLEMENT APPROVAL

- February 2018 obtained US FDA approval of an extension of the Cysview indication
  - Blue Light Cystoscopy (BLC) with Cysview indicated to be used in bladder cancer patients undergoing surveillance cystoscopy for bladder cancer
  - Blue Light Cystoscopy (BLC) with Cysview indicated for use in detection of carcinoma in situ (CIS) in the bladder
  - Blue Light Cystoscopy (BLC) with Cysview allowed to be used repetitively
  - Blue Light Cystoscopy (BLC) with Cysview indicated for use after intravesical immunotherapy (BCG) and chemotherapy

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 15, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cysview (Hexaminolevulinate HCl) for Intravesical Solution, 100mg.

This Prior Approval supplemental new drug application proposes the following changes in labeling and supported by the results of Study PC B308/13:

- expand the indication to include the use of Blue Light Cystoscopy with Cysview as an adjunct to white light cystoscopy in patients undergoing surveillance cystoscopy for bladder cancer;
- expand the indication to include the use of Blue Light Cystoscopy with Cysview as an adjunct to white light cystoscopy for use in detection of CIS of the bladder;
- revise the limitation of use, allowing for repetitive use of Cysview; and
- remove the contraindication to restrict use in patients treated with bacillus Calmette-Guerin immunotherapy or intravesical chemotherapy within the past 90 days.

## APPROVED NEW CYSVIEW INDICATION

Cysview is an optical imaging agent indicated for use in the cystoscopic detection of carcinoma of the bladder, including carcinoma in situ (CIS), among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy, or in patients undergoing surveillance cystoscopy for carcinoma of the bladder. Cysview is used with the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) system to perform Blue Light Cystoscopy (BLC™) as an adjunct to the white light cystoscopy.



# MEDICARE REIMBURSEMENT OF AN ADDITIONAL USD 1,000 PER TURBT FROM 2018\*

	Medicare (~55% of TURBT)	Private payer (~45% of TURBT)
Cystoscopy	<ul style="list-style-type: none"> <li>• Procedure fee for cystoscopy</li> <li>• Cysview paid at ASP** +6%</li> <li>• No change from 2017</li> </ul>	<ul style="list-style-type: none"> <li>• Procedure fee for cystoscopy</li> <li>• Cysview paid at contracted rate (ASP** +6 to 15%)</li> <li>• No change from 2017</li> </ul>
TURBT	<ul style="list-style-type: none"> <li>• <b>Hospital Outpatient Depts. will receive an additional \$1,000 to cover the complexity of using Cysview and Blue Light Cystoscopy procedure for the following codes: 52204, 52214 &amp; 52224</b></li> <li>• Bundled into ambulatory payment classification (APC – varies by TURBT type)<sup>1</sup> for the higher procedure codes of 52234, 52235 and 52240</li> </ul>	<ul style="list-style-type: none"> <li>• Procedure fee for TURBT – varies by type</li> <li>• Cysview paid at (Average Selling Price -ASP +6 to 15%)</li> <li>• No change from 2017</li> </ul>

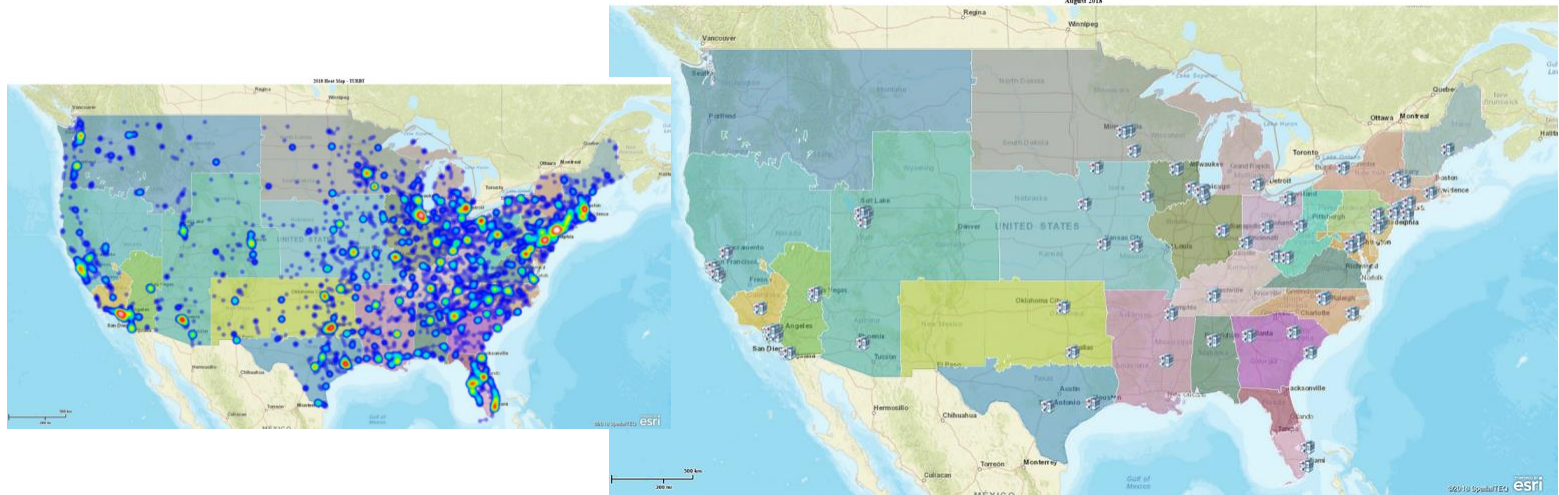
***New Medicare reimbursement accounts for ~50% of TURBT Medicare market***



# MAXIMIZING SALES EFFICIENCY TARGETING TOP 25 US MARKETS – FOCUS ON 400 MAJOR HOSPITALS

- Focus efforts to establish and build Cysview business in top 25 TURBT markets (MSAs)
- 400 major hospitals represents ~40% of total US TURBT market
- Established well known academic hospitals as anchor and referral accounts
- Expand by targeting and establishing new accounts in reachable proximity to the anchor accounts
- Utilize marketing and sales resources in a focused and efficient way
  - Adding sales resources as we expand installed base in target areas; currently 18 sales regions
  - Supported by medical experts and reimbursement/training managers

**TURBT Heat Map and current BLC accounts**



Sales Efficiency Mature Market (Nordic)	Sales Efficiency Immature Market (USA)
6 direct sales employee	18 direct sale employee
~ 1500 Cysview kits per year per employee	~ 400 kits per year per employee





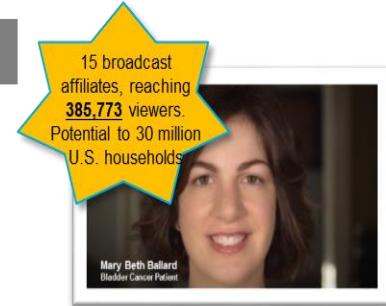
# INCREASING MARKET AWARENESS OF BLC WITH CYSVIEW AMONG BLADDER CANCER PATIENTS

Patient Survey Questions?	January 2018	January 2017
Number of patients participated in the survey*	550	568
Percentage of patients received BLC with Cysview	87%	79%
Percentage of patients where BLC with Cysview helped in managing their cancer	88%	81%
Percentage of patients where BLCC with Cysview improved the confidence in the treatment that they received	89%	37%
Percentage of patients that once diagnosed sought institutions that offered BLCC	87%	74%
Percentage of patients confirmed the importance of having BLCC as part of their disease management	95%	91%

## BLCC Awareness Campaigns

### Market awareness campaign

Focused Blue Light Cystoscopy with Cysview (BLCC) awareness campaign in select high volume markets



### Partnership advocacy

- National sponsor of the Bladder Cancer walk
- Supports Annual Think Tank congress with 300 urologists
- Collaboration with BCAN on patient education



**Increased Marketing budget has allowed for execution of a number of local and national awareness programs that is yielding results with increased interest for BLC with Cysview**



# HEXVIX/CYSVIEW

## SIGNIFICANT GROWTH OPPORTUNITY WITH NEW US LABEL

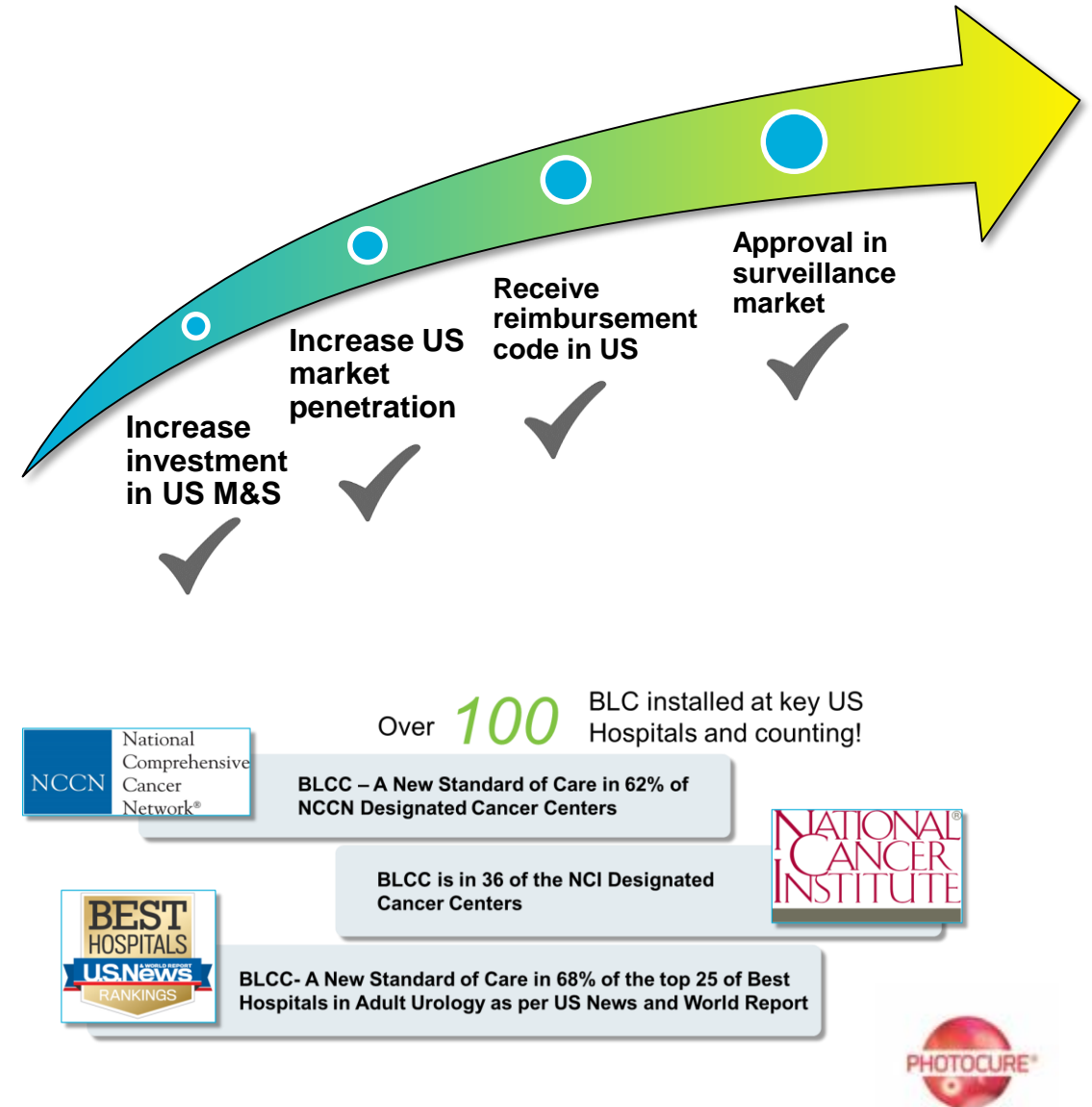
BLC with Cysview Market segment	Total Number of Cystoscopy Procedures	Number of Procedures in top 25 MSA*	Market potential in top 25 MSAs*	Peak sales value with 5% market share in top 25 MSAs*	Peak sales value with 10% market share in top 25 MSAs*	Peak sales value with 20% market share in top 25 MSAs*
TURBT	324,094	130 000	130 MUSD	6.5 MUSD	13 MUSD	26 MUSD
Surveillance Cystoscopy	1.2 - 1.4 million	540 000	540 MUSD	27 MUSD	54 MUSD	108 MUSD

*The new approved label for both TURBT and surveillance flexible cystoscopy constitute a significant new market opportunity in the US*



# HEXVIX/CYSVIEW CONTINUED STRONG MOMENTUM IN US

- Photocure own sales revenue in the US in 2017 increased 39% YoY
  - Driven by YoY in-market volume growth of 31%
- Permanent Blue Light Cystoscope placements of 104 at the end of the year, increase of 21 since end of 2016
  - High penetration in many major and recognized US cancer hospitals
- US strategic investment plan is on track
  - Doubled the sales organization, increased medical headcount and targeted marketing investments to impact the hospital bladder cancer programs



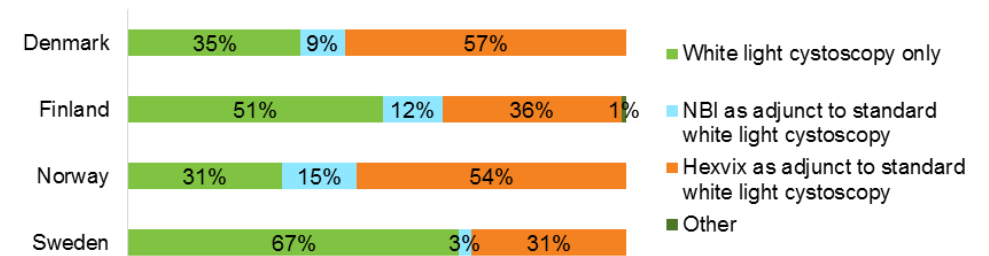
# HEXVIX/CYSVIEW

## RECORD HEXVIX SALES REVENUE IN NORDIC IN 4Q2017

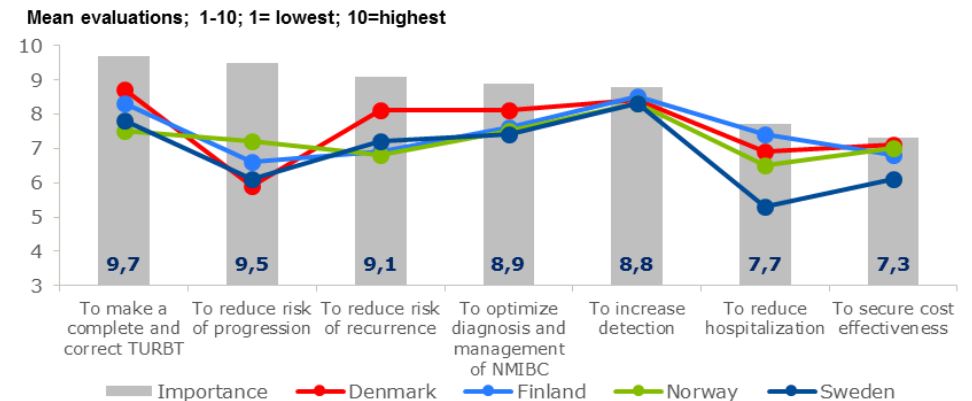
- Photocure own sales revenue in the Nordics increased YoY 35% in fourth quarter to NOK 12.9 MNOK and 11% FY
  - Driven by growth in Norway and Denmark, with Denmark reversed following the decline earlier in 2017
  - In market unit growth of 14% in 4Q
- Survey among 66 urologists at 41 hospitals in Nordic:
  - The survey confirms the high awareness of Hexvix in the Nordic
  - The use of Hexvix is expected to increase in all countries, both in the TURBT and surveillance setting, highest in Sweden

### Treatment distribution – TURBT<sup>1</sup>

Q: Please indicate the option that best describes your experience of the following treatment alternatives in a surgery/ operating room setting



### Scoring of Hexvix Importance<sup>1</sup>

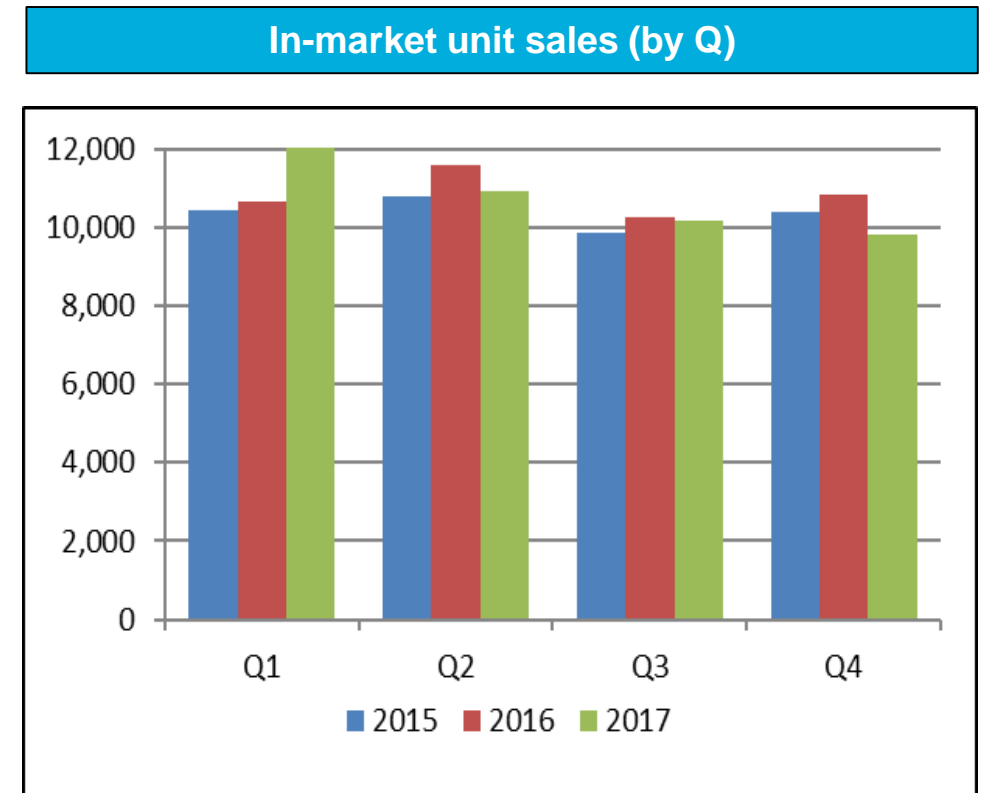


Source: QuintilesMS  
 Note: 1) Respondents DK 17, FI 18, NO 11, SE 20



# HEXVIX/CYSVIEW PARTNER UPDATE

- Partner revenue increased 17% YoY in fourth quarter, driven by inventory build-up
  - In-market unit sales declined 9% partly due to uneven purchase patterns and partly to declined demand. Germany at level with 4Q 2016
- Full year revenue growth of 3% and in-market unit sale decline of 1%





# SEGMENT PERFORMANCE

## FOURTH QUARTER 2017

### Commercial Franchise:

- Hexvix/Cysview total revenue increased YoY 25% in the fourth quarter. Growth in all regions, partly driven by inventory increases at customers and partners
- Fourth quarter own revenues, Nordic and US, increased YoY 31%, while partner revenues increased YoY 17%
- Full year Hexvix/Cysview total revenue increased YoY 14%
- Increased operating expenses in quarter and full year driven by sales & marketing in US

### Development Portfolio:

- Activities related to regulatory work and intellectual property. Cysview post marketing commitment phase 3 capitalized
- One-off items (first quarter): Write down of Nedax lamp inventory and components

<i>MNOK</i>	<u>Q4 '17</u>	<u>Q4 '16</u>	<u>FY '17</u>	<u>FY '16</u>
<b><u>Commercial Franchise</u></b>				
Nordic revenues	12.9	9.6	43.3	39.0
US revenues	10.2	8.0	42.4	30.5
Partner revenues	16.3	14.0	63.3	61.5
<b>Hexvix / Cysview</b>	<b>39.4</b>	<b>31.6</b>	<b>149.0</b>	<b>131.0</b>
Other revenues	0.0	6.5	1.9	12.7
<b>Total revenues</b>	<b>39.4</b>	<b>38.1</b>	<b>150.9</b>	<b>143.6</b>
<b>Gross profit</b>	<b>36.0</b>	<b>35.4</b>	<b>138.9</b>	<b>134.3</b>
Operating expenses	-35.1	-24.6	-128.5	-104.2
<b>EBITDA recurring</b>	<b>0.9</b>	<b>10.7</b>	<b>10.4</b>	<b>30.0</b>
<b><u>Development Portfolio</u></b>				
Operating expenses	-11.8	-11.1	-39.5	-38.1
<b>EBITDA recurring</b>	<b>-11.8</b>	<b>-11.1</b>	<b>-39.5</b>	<b>-38.1</b>
<b><u>Total</u></b>				
<b>EBITDA recurring</b>	<b>-10.8</b>	<b>-0.3</b>	<b>-29.1</b>	<b>-8.0</b>
One-Off items	0.0	0.0	-4.0	0.0
<b>EBITDA</b>	<b>-10.8</b>	<b>-0.3</b>	<b>-33.1</b>	<b>-8.0</b>

# CONSOLIDATED INCOME STATEMENT

## FOURTH QUARTER 2017

- Total revenue increases YoY 3% fourth quarter and 5% full year
  - Strong growth for Hexvix/Cysview partly offset by reduction in milestone revenues and sale of API
- Operating expenses increase YoY 18% full year
  - Significant increase in US sales & marketing expenses, increased 35% in fourth quarter and 29% full year
- Recurring EBITDA at NOK -10.8 million fourth quarter and NOK -29.1 million full year
- Depreciation and amortization driven by amortization of Cysview phase 3 investments

<i>MNOK</i>	<u>Q4 '17</u>	<u>Q4 '16</u>	<u>FY '17</u>	<u>FY '16</u>
Hexvix / Cysview revenues	39.4	31.6	149.0	131.0
Other sales revenues (API)	0.0	5.2	0.2	5.2
Signing fees and milestones	-	1.2	1.7	7.4
<b>Total revenues</b>	<b>39.4</b>	<b>38.1</b>	<b>150.9</b>	<b>143.6</b>
<b>Gross profit</b>	<b>36.0</b>	<b>35.4</b>	<b>138.9</b>	<b>134.3</b>
<b>Operating expenses</b>	<b>-46.8</b>	<b>-35.7</b>	<b>-168.0</b>	<b>-142.3</b>
<b>EBITDA recurring</b>	<b>-10.8</b>	<b>-0.3</b>	<b>-29.1</b>	<b>-8.0</b>
One-Off items	-	-	-4.0	-
Depreciation & Amortization	-3.3	-3.1	-12.1	-7.9
<b>EBIT</b>	<b>-14.1</b>	<b>-3.4</b>	<b>-45.2</b>	<b>-15.9</b>
Net financial items	1.0	27.4	3.6	28.6
<b>Profit/loss(-) before tax</b>	<b>-13.2</b>	<b>24.0</b>	<b>-41.6</b>	<b>12.8</b>
Tax expenses	0.2	-6.2	6.9	22.5
<b>Net profit/loss(-)</b>	<b>-13.0</b>	<b>17.9</b>	<b>-34.7</b>	<b>35.3</b>



# CASH FLOW

## FOURTH QUARTER 2017

- Cash flow from operations fourth quarter NOK 7.5 million, full year NOK -23.6 million
  - Working capital impact full year NOK 6.4 million (FY 2016 NOK -8.8 million)
  - Prior year driven by settlement of deferred revenue Metvix of NOK NOK 37.2 million
- Cash flow from investments fourth quarter NOK -1.2 million, full year NOK -16.3 million (FY 2016 NOK 13.9 million)
  - Includes investments full year of NOK 17.5 million in development expenses
  - Prior year includes sale proceeds shares and subscription rights of NOK 33.2 million
- Year end cash balance at NOK 129.4 million

<i>MNOK</i>	<u>Q4 '17</u>	<u>Q4 '16</u>	<u>FY '17</u>	<u>FY '16</u>
<b>Cash flow from:</b>				
- Operations	7.5	49.9	-23.6	19.2
- Investments	-1.2	25.0	-16.3	13.9
- Financing	0.0	0.4	0.0	2.1
<b>Net change in cash</b>	<b>6.3</b>	<b>75.3</b>	<b>-39.9</b>	<b>35.2</b>
<b>Ending cash balance</b>	<b>129.4</b>	<b>169.2</b>	<b>129.4</b>	<b>169.2</b>

# BALANCE SHEET

## 31 DECEMBER 2017

- Year end working capital at NOK 6.0 million (2016: NOK 12.4 million)
- Non current assets include NOK 34.6 million in investments in tangible and intangible assets and deferred tax asset of NOK 52.9 million
- No interest bearing debt
- Shareholder's equity of NOK 218.1 million. Equity ratio of 83%

<i>MNOK</i>	<b>31.12</b>	<b>31.12</b>
	<b>2017</b>	<b>2016</b>
	<hr/>	<hr/>
Non-current assets	87.5	74.1
Inventory & receivables	46.2	43.0
Cash & equivalents	129.4	169.2
<b>Total assets</b>	<b>263.1</b>	<b>286.3</b>
Shareholders equity	218.1	251.9
Long term liabilities	4.8	3.8
Current liabilities	40.3	30.6
<b>Total equity &amp; liabilities</b>	<b>263.1</b>	<b>286.3</b>
<i>Equity ratio</i>	83 %	88 %

# *Summary and Outlook*



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- Twenty-five percent growth in blue light enabled cystoscopes in market to over 100 cystoscopes installed by end of LY

Obtain regulatory approval for market expansion of Cysview® into surveillance market

- Clinical results from pivotal phase 3 study announced May 2017 at AUA meeting
- Supplemental NDA filed in August for Blue Light Flexible Cystoscopy (BLFC) with Cysview
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- Hexvix revenue in Nordic in 4Q was record high, 35% growth YoY
- In-market volume in own markets increased YoY 16 % in 4Q and 12% FY
- Total in-market unit sales increased 2% FY, impacted by decline in partner in-market unit sales declined 9% in 4Q and 1% FY



# FOCUS & OBJECTIVES 2018

Increase growth of Cysview® in US TURBT market

- Continue investment in the US operations to increase Cysview revenues and achieve 2020 revenue target
- Expand the number of hospitals with blue light enabled scopes
- Continue to increase the awareness of the medical benefits of BLC™ with Cysview among health care providers and patients
- Take full benefit of improved CMS reimbursement for Blue Light Cystoscopy (BLC) with Cysview for use in hospital outpatient departments

Launch Cysview® in US flexible cystoscopy surveillance market

- Following the FDA approval of the label extension, launch BLC™ with Cysview for improved surveillance of bladder cancer patients by mid year 2018

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

- Continue to increase the market share of Hexvix in the Nordic Region
- Focus on development in Europe to stop decline and drive turn-around