

# Photocure ASA

## 4<sup>th</sup> Quarter 2023 Results

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# 4<sup>th</sup> Quarter 2023 Highlights:

*Continued growth and execution on key initiatives despite flexible BLC phase down*

## Product Revenue +20%

Unit sales +4% year-over-year

### Expanding U.S. Saphira™ footprint

- 10 new accounts opened
- 7 upgrades from existing accounts
- 51 Saphira™ towers placed in 2023

### Executing on plan in Europe

- 146 image quality upgrades in 2023
- 23 new accounts opened

### Ongoing challenges:

- Phase down of flex BLC utilization
- Single manufacturer in the U.S.
- Delay of Olympus' upgraded BL equipment launch in Europe

## EBITDA NOK 29.9 million

NOK 29.6M ex-BD expense

### OPEX mostly level excl. FOREX & BD last 8 quarters;

Continued investment behind Hexvix/Cysview

**Biz Dev expense** not material

### Strong Balance Sheet

NOK 260 million in cash and equivalents; no term debt

## Key news and milestone events

### 7 accepted abstracts at major conferences in FY2023. In Q4:

- SUO 2023 Meeting: New RWE shows major decrease in Risk of BCa recurrence with BLC
- Clinical Results for Hexvix Phase III trial in China presented at SIU Congress: 1<sup>st</sup> randomized clin. trial using HD BLC equipment

**Asieris' NDA for Hexvix accepted for regulatory review in China** (Nov 2023)

**Large order of rigid BLC Towers still anticipated;** now expected in Q2 2024

**Citizen's Petition\* to re-classify BLC equipment:** Pacific Edge posts supportive comment on Feb 16, 2024; process ongoing

# Segment Trends

North America and Europe markets



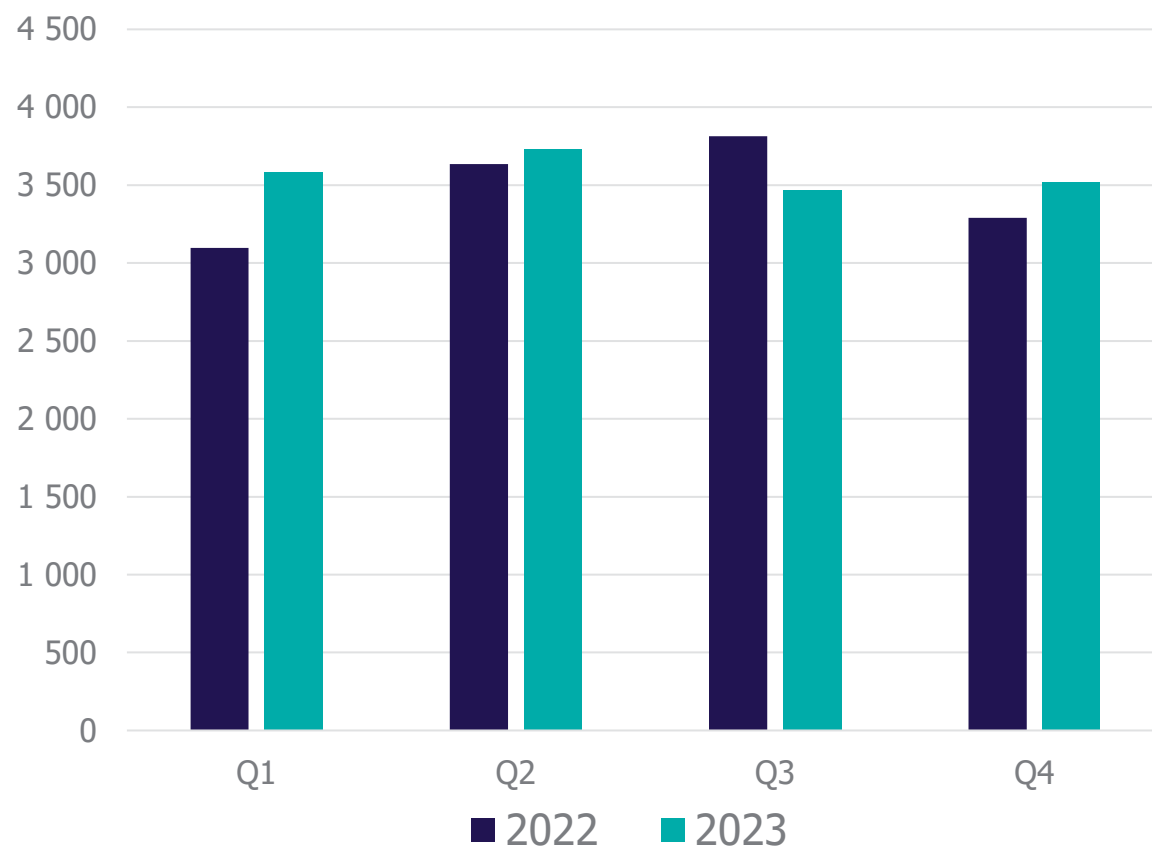
# Hexvix/Cysview Growth In 2023

*Regional In-Market Unit Sales Year-Over-Year by Quarter*

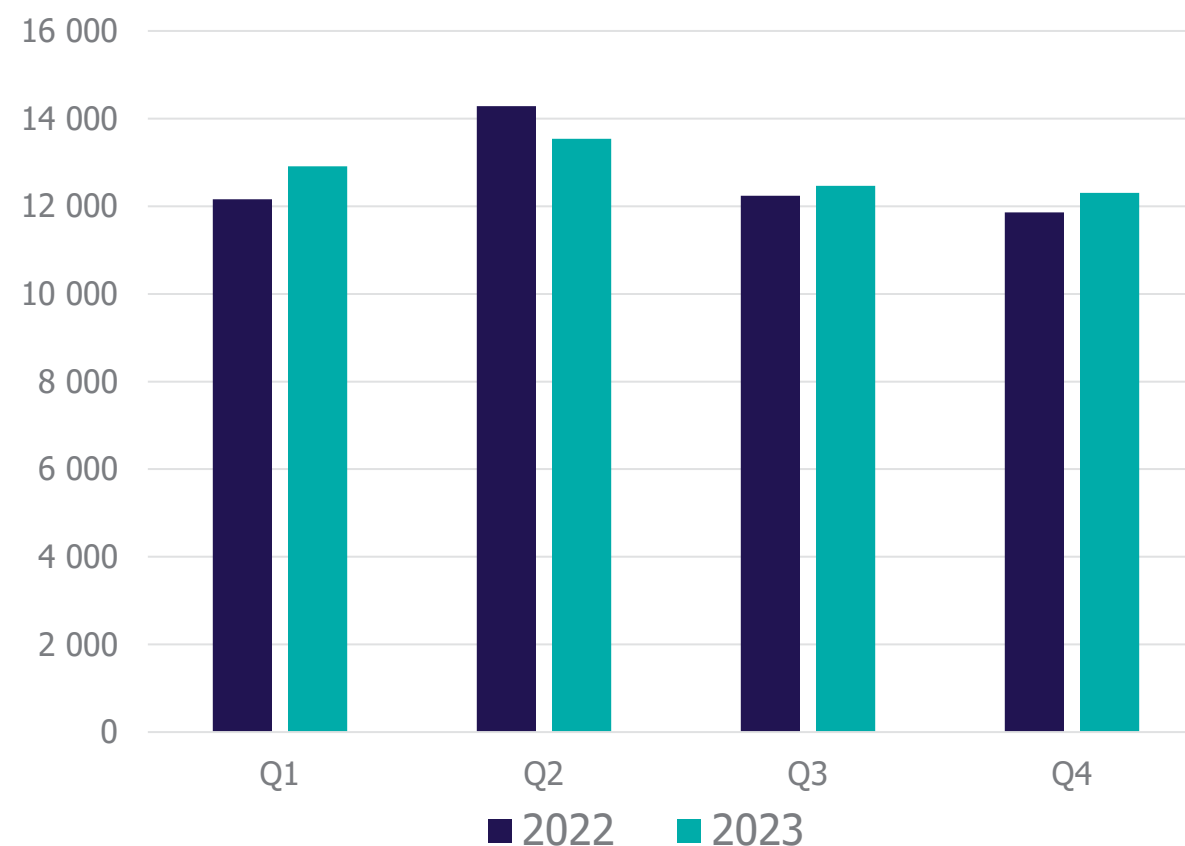


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## North America



## Europe



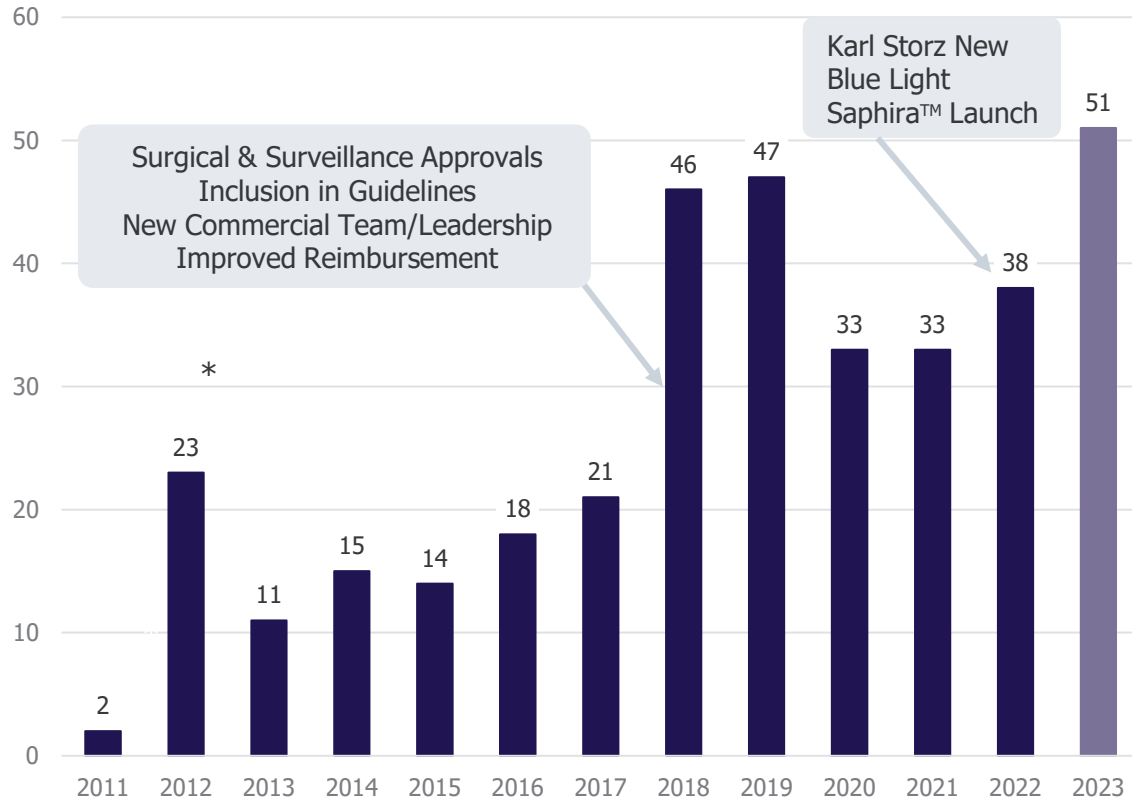
# Saphira™ now 39% of rigid BLC installed base in U.S.



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17 installations in Q4 2023: 10 new account placements & 7 upgrades

## Annual New BLC Tower Installations (Rigid Only)



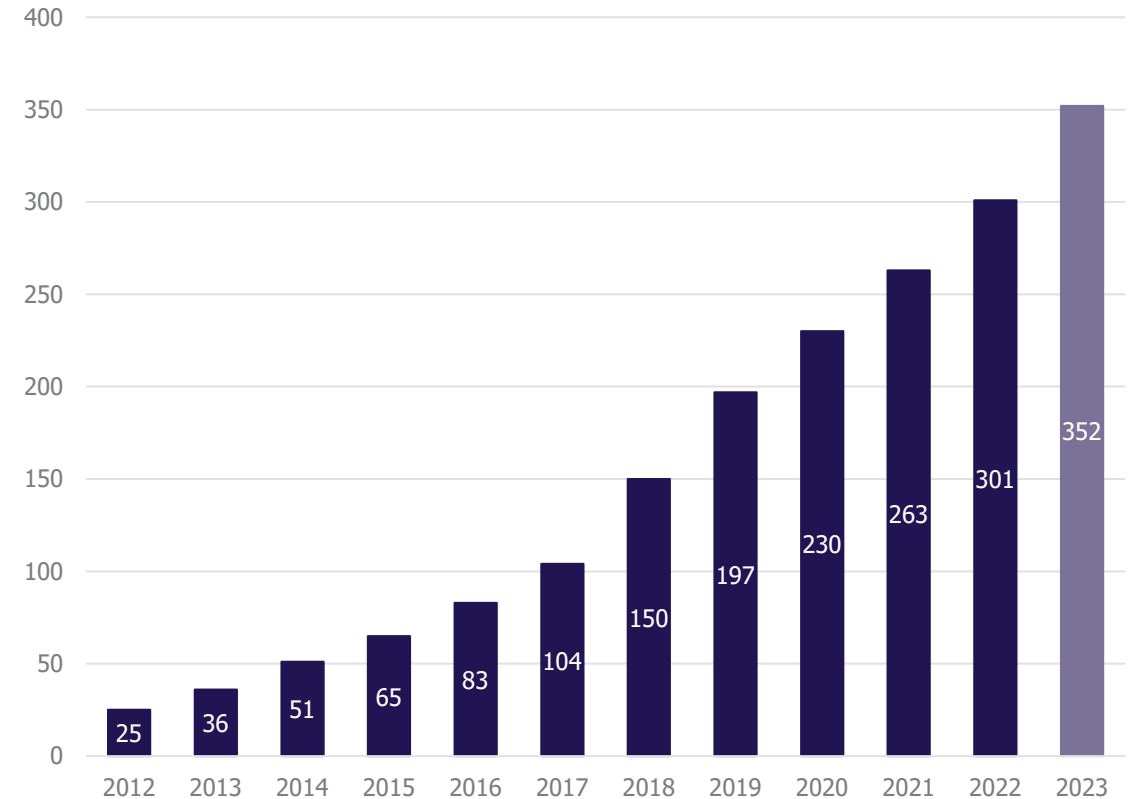
### New Account Rigid Tower Installations

Q1 2023: 18 installations  
Q2 2023: 8 installations  
Q3 2023: 15 installations  
Q4 2023: 10 installations

### 137 Saphira™ towers installed since Q3 2022 launch;

81 New & 56 Upgrades

## Cumulative Installed Base in U.S. (Rigid Only)



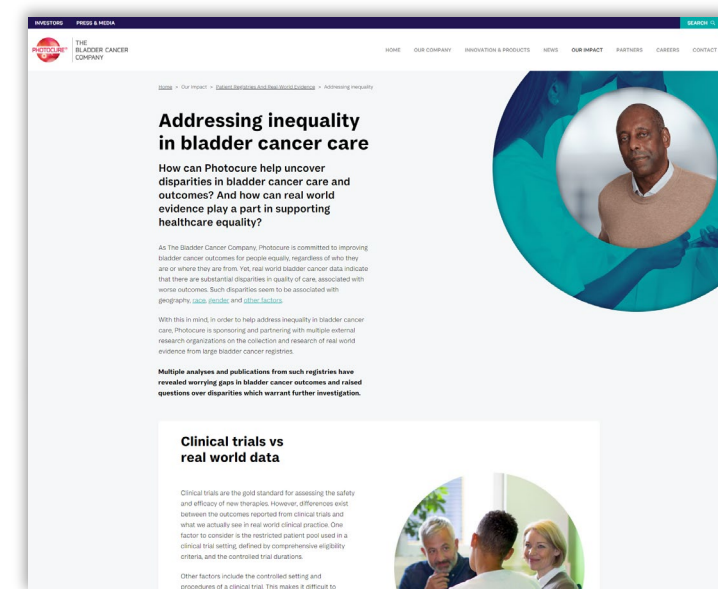
\*2012 – 17 of the 23 installations were converted clinical sites upon Cysview approval

# Q4 2023 Trends in North America



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- **Q4 revenues increased 21%, in-market unit sales rose 7%;** Cysview unit sales growth outweighed the ongoing effects of flexible BLC phase down during the quarter
- **Highest number of rigid towers placed per year in history:** 51 new Saphira™ installs and 30 upgrades in FY 2023
- **Karl Storz extended tower promotion program through year-end 2023.** 10 new towers and 7 upgrades installed in Q4; Large tower order now anticipated in Q2 2024
- **Continued strong interest in U.S. Registry** – largest U.S. Bladder Cancer Registry (>3,000 patients), rich data set is a strategic asset for Photocure
- **Key initiatives to accelerate unit sales growth**
  - Increase Cysview kit usage in existing account base for TURBTs / Accelerate kit adoption of new accounts initiating use of blue light
  - Reactivate low users or inactive accounts through upgrades
  - Continue to expand BL penetration throughout the U.S. VA system leveraging VA BRAVO study data
  - Maintain as many of the 27 remaining Flex accounts as possible for continued U.S. registry data collection and planned flex BLC reintroduction
- **Citizen's Petition for BLC reclassification**
  - If FDA approved, would enable expedited pathway to expand the number of BLC equipment manufacturers in the U.S.
  - Flex tower discontinuation highlights the need for BLC reclassification
  - Public comments by KOLs, BCAN (U.S. Patient Advocacy), Health systems, and Equipment Manufacturers



Photocure White Paper on the role of RWE in uncovering inequalities in BCa care and outcomes – Dec 2023

# Q4 2023 Trends in Europe



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- **Q4 revenues increased 19% year-over-year** driven by unit growth and a benefit from foreign exchange in the quarter. In-market unit sales increased 4% compared to the same period in 2022.
- **Investment in priority growth markets paying off.** UK and Italy both demonstrating consistent double-digit growth in Q4 from significant negative trend when first acquired in 2020. Significant image quality upgrades in France during 2023 and current pipeline expected to yield similar durable turn-around trend going forward.
- **Blue light continues to gain traction in urology community across Europe;** Significant increase in KOL support, EAU guidelines strengthened with additional data, strong presence at congresses, events and workshops – a total of 165 in 2023.
- **Key initiatives to accelerate unit sales growth**
  - 1,400 TURBT-performing centers, approximately 50% have BL equipment
  - Actively targeting 590 hospitals/clinics; approximately 2/3 still underpenetrated
  - Continuing to execute image quality upgrades (146 in 2023 – 25% of targeted clinics)
  - 23 new blue light accounts opened in 2023



Photocure Booth at AFU, Paris, Nov 2023

## Top French KOLs visiting Photocure booth at AFU congress:

Prof. Morgan Rouprêt:

- Chief of French Urology onco-committees
- Member of the EAU Guidelines on bladder
- Chief Editor of the European Onco - Urology Journal

Dr. Benjamin Pradère

- Member of the French Bladder committee
- Member of the EAU Guidelines on Bladder

Dr. Gauthier Marcq

- Member of the French Bladder committee





# Significant progress with our partner Asieris

## Hexvix China

### Recent News

**Phase III Trial  
Enrollment  
Completed**

**Primary Endpoint  
Successfully Met;**  
  
**Data presented  
at SIU Congress  
12 Oct 2023**

**Strong Results  
( $p < 0.0001$ )**  
  
**First RCT Trial  
Conducted with  
High Def. BLC**

### Going forward

**NDA Submitted  
November 2023;  
Chinese FDA  
(NMPA) Review  
Time Typically 18  
Months**

**Photocure  
eligible for  
additional  
milestones  
& royalties upon  
Asieris' regulatory  
achievements,  
market  
authorizations,  
& potential  
sales**

## Cevira

### Recent News

**1st Non-Invasive  
Candidate for  
Cervical HSIL;  
Phase III Results  
China & Europe**

**Primary Endpoint  
Successfully Met**

### Going forward

**Phase III Results  
to be Presented  
at the EUROGIN  
2024 HPV  
Congress (March  
13-16)**

**Asieris  
Communication  
with Regulatory  
Authorities in  
Coming Months**

# Q4 Financials

# Consolidated Income Statement

## Fourth Quarter 2023



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<i>Amounts in NOK million</i>	Q4 '23	Q4 '22	Change	FY '23	FY '22	Change
Hexvix/Cysview Revenue	114.2	94.9	20%	443.3	373.0	19%
Other Revenue	28.4	9.3		57.4	20.1	
<b>Total Revenue</b>	<b>142.5</b>	<b>104.2</b>	37%	<b>500.7</b>	<b>393.1</b>	27%
<b>Gross Profit</b>	<b>136.7</b>	<b>98.6</b>	39%	<b>474.5</b>	<b>370.4</b>	28%
Operating Expenses excl BD	-107.1	-105.4	2%	-409.1	-372.1	10%
Business Development Expenses	0.3	-10.0		-9.9	-23.0	
<b>EBITDA – excluding BD</b>	<b>29.6</b>	<b>-6.8</b>		<b>65.4</b>	<b>-1.6</b>	
<b>EBITDA – including BD</b>	<b>29.9</b>	<b>-16.9</b>		<b>55.5</b>	<b>-24.6</b>	
Depreciation & Amortization	-7.4	-6.2		-27.7	-24.4	
<b>EBIT</b>	<b>22.5</b>	<b>-23.1</b>		<b>27.8</b>	<b>-49.0</b>	
Net Financial Items	-5.9	-5.5		-18.1	-22.1	
<b>Earnings before Tax</b>	<b>16.6</b>	<b>-28.6</b>		<b>9.7</b>	<b>-71.1</b>	
Tax Expenses	-4.1	7.1		-9.5	-0.7	
<b>Net earnings</b>	<b>12.5</b>	<b>-21.5</b>		<b>0.3</b>	<b>-71.9</b>	

### Revenue

- Q4 total revenue increased YoY 37%. The revenue increase is driven by 20% product sales growth and a milestone payment received from Asieris of USD 2.5 million
- Q4 Hexvix/Cysview revenue increased 20% vs. last year, driven by unit and price increases, and FX
  - Consolidated volume impacted negatively by the phase down of Cysview usage in the flexible BLC setting

### Operating Expenses

- Q4 operating expenses excluding business development costs increased 2% YoY, mainly due to FX which was offset by cost containment
- Operating expenses within business development projects relate to life cycle management for Hexvix/Cysview

### EBITDA

- Q4 EBITDA including BD expenses NOK 29.9 million

### Net Financial Items

- Includes Ipsen earn-out payments

# Segment Performance Fourth Quarter 2023



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## North America Segment

<i>Amounts in NOK million</i>	Q4 '23	Q4 '22	Change	FY '23	FY '22	Change
<b>Total revenues</b>	<b>46.7</b>	<b>38.7</b>	21%	<b>178.6</b>	<b>150.8</b>	<b>18%</b>
Gross profit	45.0	37.5	2%	172.8	145.9	18%
<i>% of revenue</i>	<i>97%</i>	<i>97%</i>		<i>97%</i>	<i>97%</i>	
Direct costs	-41.1	-46.0	-11%	-163.6	-162.9	0%
<b>Contribution <sup>(1)</sup></b>	<b>4.0</b>	<b>-8.5</b>		<b>9.1</b>	<b>-16.9</b>	
<b>EBITDA, excl BD</b>	<b>-5.3</b>	<b>-17.5</b>		<b>-29.5</b>	<b>-49.5</b>	
<i>% of revenue</i>	<i>-11%</i>	<i>-45%</i>		<i>-16%</i>	<i>-33%</i>	

- Q4 revenue growth 21% driven by volume and price increases, and FX, partially offset by phase down of Cysview usage in the flexible BLC setting
  - In-market unit sales increased 7%, USD appreciated 6%, price increase 5% in US
- Q4 direct costs decreased, despite negative impact of FX
- Contribution improved by NOK 12.5 million YoY driven by revenue growth and cost containment

## Europe Segment

<i>Amounts in NOK million</i>	Q4 '23	Q4 '22	Change	FY '23	FY '22	Change
<b>Total revenues</b>	<b>66.8</b>	<b>56.2</b>	19%	<b>263.5</b>	<b>221.8</b>	<b>19%</b>
Gross profit	62.3	52.1	20%	244.3	205.0	19%
<i>% of revenue</i>	<i>93%</i>	<i>93%</i>		<i>93%</i>	<i>92%</i>	
Direct costs	-37.1	-29.5	26%	-122.8	-102.9	19%
<b>Contribution <sup>(1)</sup></b>	<b>25.2</b>	<b>22.6</b>		<b>121.5</b>	<b>102.1</b>	
<b>EBITDA, excl BD</b>	<b>8.8</b>	<b>5.7</b>		<b>52.4</b>	<b>42.2</b>	
<i>% of revenue</i>	<i>13%</i>	<i>10%</i>		<i>20%</i>	<i>19%</i>	

- Q4 revenue increased 19% YoY
  - In-market unit sales increased 4% YoY and EUR appreciated 12%. In addition, the net of price, stocking and mix contributed positively to the growth
- Q4 Expenses were driven by the negative impact of FX and one-off costs
- Contribution improved by NOK 2.6 million YoY, driven by revenue growth

# Cash Flow & Balance Sheet Fourth Quarter 2023

<i>Amounts in NOK million</i>	Q4 '23	Q4 '22	FY '23	FY '22
<b>Operations Cash Flow</b>	<b>19.6</b>	<b>0.7</b>	<b>48.3</b>	<b>-2.0</b>
Earnings before tax	16.6	-28.6	9.7	-71.1
Depreciation & amortization	7.4	6.2	27.7	24.4
Working capital	-8.2	13.2	-18.1	-1.4
Other	3.8	10.0	29.0	42.2
<b>Investments Cash Flow</b>	<b>1.2</b>	<b>0.8</b>	<b>-0.6</b>	<b>-1.5</b>
<b>Financing Cash Flow</b>	<b>-16.4</b>	<b>-17.3</b>	<b>-56.3</b>	<b>-51.3</b>
<b>Net Change in Cash</b>	<b>4.4</b>	<b>-15.8</b>	<b>-8.6</b>	<b>-54.8</b>

<i>Amounts in NOK million</i>	31.12.23	31.12.22
Non-current assets	338.8	360.8
Inventory & receivables	112.9	90.2
Cash & short-term deposits	259.5	268.1
Equity	482.1	462.7
Long-term liabilities	151.6	167.1
Current liabilities	77.5	89.2
<b>Total balance</b>	<b>711.3</b>	<b>719.0</b>

## Cash Flow

- Q4 net cash flow from operations in Q4 was NOK 19.6 million, driven by EBITDA adjusted for non-cash cost items and working capital
- Q4 net investment cash flow includes interest received offsetting investments in tangible and intangible assets
- Q4 net cash flow from financing NOK -16.4 million includes earnout payments to Ipsen
  - Term loan was fully repaid in Q2 2023
- Net cash flow in Q4 was NOK 4.4 million, cash balance end of Q4 was NOK 259.5 million

## Financial position

- Non-current assets include intangibles and goodwill from Ipsen transaction totaling NOK 256.5 million
- Long-term liabilities includes deferred Ipsen earnout totaling NOK 127.7 million
- Equity NOK 482.1 million, 68% of total assets

# Summary



# Summary of Q4 results

- 20% Product rev. gr. / 4% unit sales growth YoY; several initiatives to accelerate unit sales momentum in 2024
- EBITDA of NOK 29.9 million; Commercial business contribution-positive in Q4
- 17 Saphira™ towers installed in U.S. (10 new, 7 upgrades); Large rigid tower order anticipated in Q2
- Installed base of 137 Saphira™ towers since launch; now represents 39% of rigid towers in U.S.
- Flex phase-down remains a challenge but growth of rigid (TURBT) towers & kit sales outweighed flex pressure
- Priority Growth Markets in Europe responding well to turn-around efforts and starting to show double-digit growth
- BLC attention continues to rise in urology community, growing KOL support & equipment/image quality upgrades
- Cash balance strong at NOK 259.5 million; no term debt

# Anticipated Milestones & Corporate Objectives

- 2024 Guidance: 6-9% product revenue growth (constant currency), positive EBITDA, 40-70 Saphira™ installs (new + upgrades)
- Increase Hexvix®/Cysview® kit throughput, continue to grow rigid BLC tower base in U.S. and image quality upgrades in Europe, pursue strategy to establish a durable solution for flexible BLC equipment globally
- Proactively support the Citizen's Petition for the U.S. FDA to reclassify BLC equipment from Class 3 to Class 2, potentially creating an expedited pathway for additional BLC manufacturers to enter the U.S. market
- Present/publish additional data from real world evidence patient registries and other studies supporting the use of BLC® with Hexvix/Cysview
- Progress for Asieris Assets: Cevira Phase III data presentation anticipated at EUROGIN in March, potential regulatory submission in 2024, Hexvix (China) undergoing regulatory review, add'l. milestones anticipated
- Continue to geographically expand commercial business by penetrating untapped European markets, and through additional Hexvix licensing agreements ROW



# Leading change in bladder cancer

## Q&A

