



Brilliance in photodynamic technology™

Photocure ASA

Fourth Quarter and Full Year Results - 2008

27 February 2009

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Highlights Q4 and 2008

- Sales revenues of MNOK 33.2 for Q4 (+41%)
- Profit of MNOK -9.4 in Q4, up from MNOK -16.3 in Q4 2007

- Sales revenues of MNOK 100.9 for 2008 (+31%)
- Profit of MNOK -64.4 in 2008, up from MNOK -75.0 in 2007

- Significant progress in regulatory and clinical programs



Brilliance in photodynamic technology™

Financial statements



Profit & Loss

- Record sales in Q4 & 2008
- Sales revenue growing steadily
- Reduced losses
 - Manageable R&D expenses
 - Increased Marketing & Sales expenses to boost sales further
- Note: PCI Biotech included until Q2 2008

<i>Numbers in NOK thousand</i>	Q408	Q407	2008	2007
Sales revenue	33 190	23 587	100 917	75 252
Signing fee & milestone revenues	0	3 908	1 309	23 754
Total revenues	33 190	27 495	102 220	99 006
Cost of products sold	-5 914	-2 967	-19 074	-17 326
Gross profit	27 277	24 528	83 147	81 679
Other income	1 223	3 187	6 257	7 625
Indirect manufacturing expenses	-1 787	-1 598	-8 607	-8 512
R&D expenses	-25 508	-28 873	-84 303	-112 098
Marketing & sales expenses	-12 559	-11 429	-45 916	-39 766
G&A expenses	-3 113	-6 114	-17 951	-16 378
Operating profit/ loss (EBIT)	-14 469	-20 300	-67 374	-87 450
Net financial items	5 222	3 991	2 991	12 480
Profit/ loss before tax (EBT)	-9 246	-16 308	-64 382	-74 970
Tax expenses	0	0	0	0
Net profit/ loss	-9 246	-16 308	-64 328	-74 970



Segment information – Q4

	Q4 2008					Q4 2007			
<i>Numbers in NOK thousand</i>	Own	Partner	R&D*	Total	% vs. 07	Own	Partner	R&D*	Total
Sales revenue Metvix/ Aktilite	7 421	12 223		19 644	33%	7 642	7 149		14 791
Sales revenue Hexvix	3 368	10 178		13 546	54%	1 988	6 807		8 795
Total sales revenues	10 789	22 401		33 190	41%	9 630	13 956		23 587
Milestone revenue	0	0		0		0	3 908		3 908
Total revenues	10 789	22 401		33 190	21%	9 630	17 865		27 495
Cost of goods sold	-810	-5 104		-5 914	99%	-589	-2 378		-2 967
Gross profit	9 980	17 297		27 277	11%	9 041	15 487		24 528
Gross profit (ex milestones)	92%	77%		82%		94%	83%		87%
Operating expenses	-10 729	-3 236	-27 780	-41 745	7%	-11 101	-3 892	-29 833	-44 827
Operating profit	-749	14 061	-27 780	-14 469	29%	-2 060	11 595	-29 833	-20 299
Net finance	0	0	0	5 222	31%	0	0	0	3 991
Profit before tax	-749	14 061	-27 780	-9 246	43%	-2 060	11 595	-29 833	-16 308
<i>* Including share of general & administrative expenses</i>									



Segment information – 2008

	2008					2007			
<i>Numbers in NOK thousand</i>	Own	Partner	R&D*	Total	% vs. 07	Own	Partner	R&D*	Total
Sales revenue Metvix/ Aktilite	24 895	39 168		64 063	18%	23 053	31 168		54 221
Sales revenue Hexvix	10 190	26 664		36 855	75%	6 016	15 016		21 031
Total sales revenues	35 085	65 832		100 917	34%	29 069	46 183		75 252
Milestone revenue	0	1 303		1 303		0	23 754		23 754
Total revenues	35 085	67 135		102 220	3%	29 069	69 937		99 006
Cost of goods sold	-2 431	-16 643		-19 074		-2 515	-14 812		-17 326
Gross profit	32 654	50 492		83 146	2%	26 555	55 125		81 680
Gross profit (ex milestones)	93%	75%		81%		91%	68%		77%
Operating expenses	-39 110	-17 414	-93 997	-150 521	11%	-35 863	-14 605	-118 661	-169 129
Operating profit	-6 456	33 078	-93 997	-67 374	23%	-9 308	40 519	-118 661	-87 449
Net finance	0	0		2 991		0	0		12 479
Profit before tax	-6 456	33 078	-93 997	-64 382	14%	-9 308	40 519	-118 661	-74 970
<i>* Including share of general & administrative expenses</i>									



Balance sheet - assets

- Shares in PCI Biotech Holding ASA written down by NOK 9.4 million in Q4 to NOK 11.5 million
- Cash and cash equivalents of NOK 179.9 million

<i>Numbers in NOK thousand</i>	FY 2008	FY 2007
Non-current assets		
Intangible assets, software	534	779
Machinery & Equipment	3 939	3 436
Other investments	11 528	
Total non-current assets	16 001	4 215
Current assets		
Inventory	12 792	12 504
Receivables	29 158	32 222
Cash & cash equivalents	179 897	252 452
Total current assets	221 846	297 179
Total assets	237 847	301 394



Balance sheet - equity & liabilities

- NOK 199.7 million in shareholder's equity
- No interest bearing debt

<i>Numbers in NOK thousand</i>	FY 2008	FY 2007
Paid-in capital	11 047	11 047
Other paid-in capital	15 467	10 984
Retained earnings	173 181	237 472
Shareholders' equity	199 694	259 503
Minority interest	0	491
Total equity	199 694	259 994
Current liabilities	38 153	41 400
Total liabilities	38 153	41 400
Total equity and liabilities	237 847	301 394



Cash Flow

- NOK -1.7 million in Net change in cash during Q4 due to strong sales, cost control and one time effects
- NOK 36 million improvement in net cash flow from operations from 2007 to 2008

<i>Numbers in NOK thousand</i>	Q4 2008	FY 2008
Income/ loss before tax	-9 426	-64 382
Other operational items	16 805	4 704
Net cash flow from operations	7 559	-59 677
Cash flow from investments	-6 138	-12 865
Cash flow from capital transactions	-3 101	-13
Net change in cash during the period	-1 680	-72 555
Cash & cash equivalents beginning of period	181 578	252 452
Cash & cash equivalents beginning end period	179 897	179 897



Financial summary

- Record sales in Q4 and FY 2008
 - Sales revenues growing steadily
 - Manageable R&D expenses
 - Demerged PCI Biotech Holding ASA in 2008
 - Increased Marketing & Sales expenses to boost sales further
 - €20+ million in cash
 - Significantly improved cash flow
- ➡ Financial freedom and strength to explore market opportunities

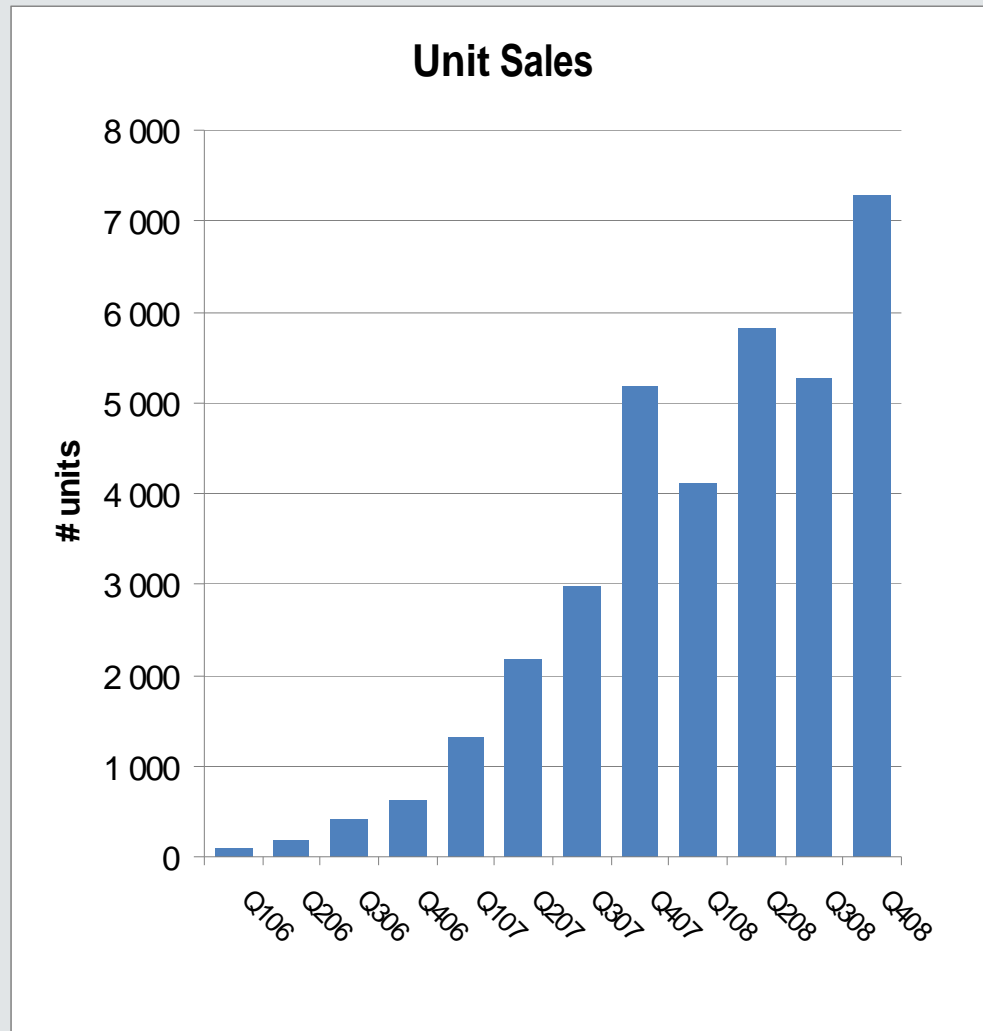


Brilliance in photodynamic technology™

Hexvix®

- a breakthrough in bladder cancer diagnostics

- sales increase of 41% in Q4 and 93% in 2008 in units



- Q4: Partner sale of 6,240 units in 2008 vs. 4,570 units in 2007.
- Q4: Own sale of 1,050 units in 2008 vs. 611 units in 2007.
- Full year: Partner sale of 19,513 units in 2008 vs. 9,897 units in 2007.
- Full year: Own sale of 3,009 units in 2008 vs. 1,777 units in 2007.

Hexvix®



- Large phase III study completed in US/EU with excellent results for detection and recurrence

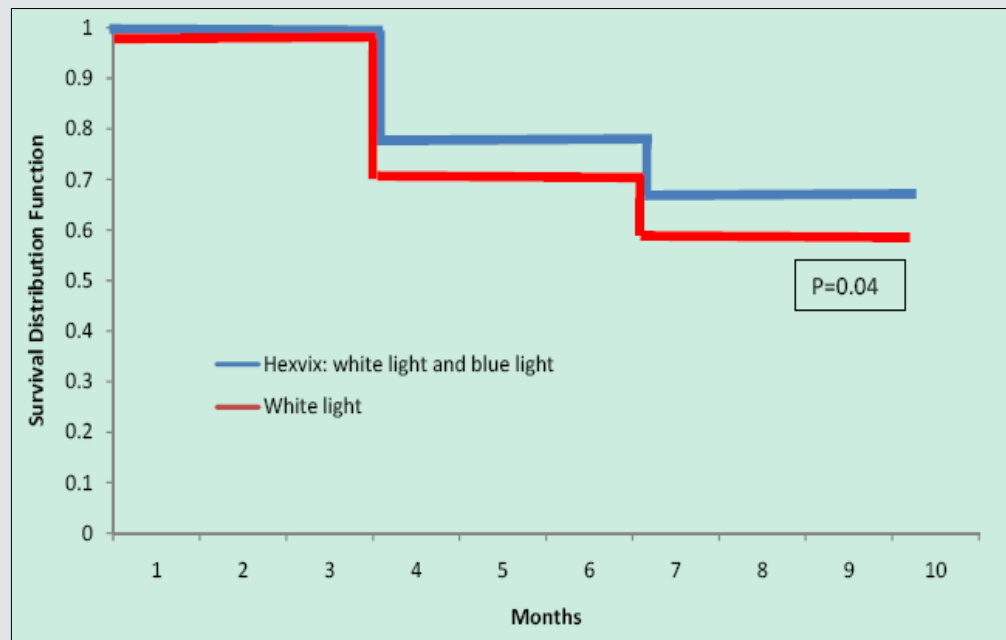
- Hexvix cystoscopy was compared with standard white light cystoscopy in patients with non-muscle invasive bladder cancer (Ta/T1 tumors)
- 789 patients included at 28 centers in EU and USA included
- 9 months follow-up after initial cystoscopy for possible disease recurrence

Detection

- Additional Ta/T1 tumors detected in 16.9% of the patients ($p= 0.001$)
- The improved detection of patient with carcinoma in situ (CIS) (46%) confirmed the earlier Phase 3 studies

Recurrence

22 % relative reduction in recurrence at 9 months



Hexvix®



- phase III study completed in Denmark
in 2008 confirming the reduction in recurrence rates

- Hexvix cystoscopy was compared with standard white light cystoscopy in patients with non-muscle invasive bladder cancer
 - 233 patients with bladder cancer at 2 centers in Denmark
 - Started inclusion in Q3 2005 with last patient follow-up in Q4 2008
 - Endpoint: Reduction in recurrence rates after 12 months
- ➡ The preliminary results confirm the reduction in recurrence for Hexvix users as shown in the larger multicenter study



Hexvix[®] - roadmap

Regulatory progress in the USA

- Constructive and progressive interaction with FDA in co-operation with GE Healthcare
- Submission to FDA planned in Q3 2009

Commercial process in Europe

- Promote Hexvix in co-operation with GE Healthcare
 - EAU 2009 in Stockholm – symposium and press meeting
 - Recurrence results from finalized studies adding very important benefit to Hexvix



Brilliance in photodynamic technology™

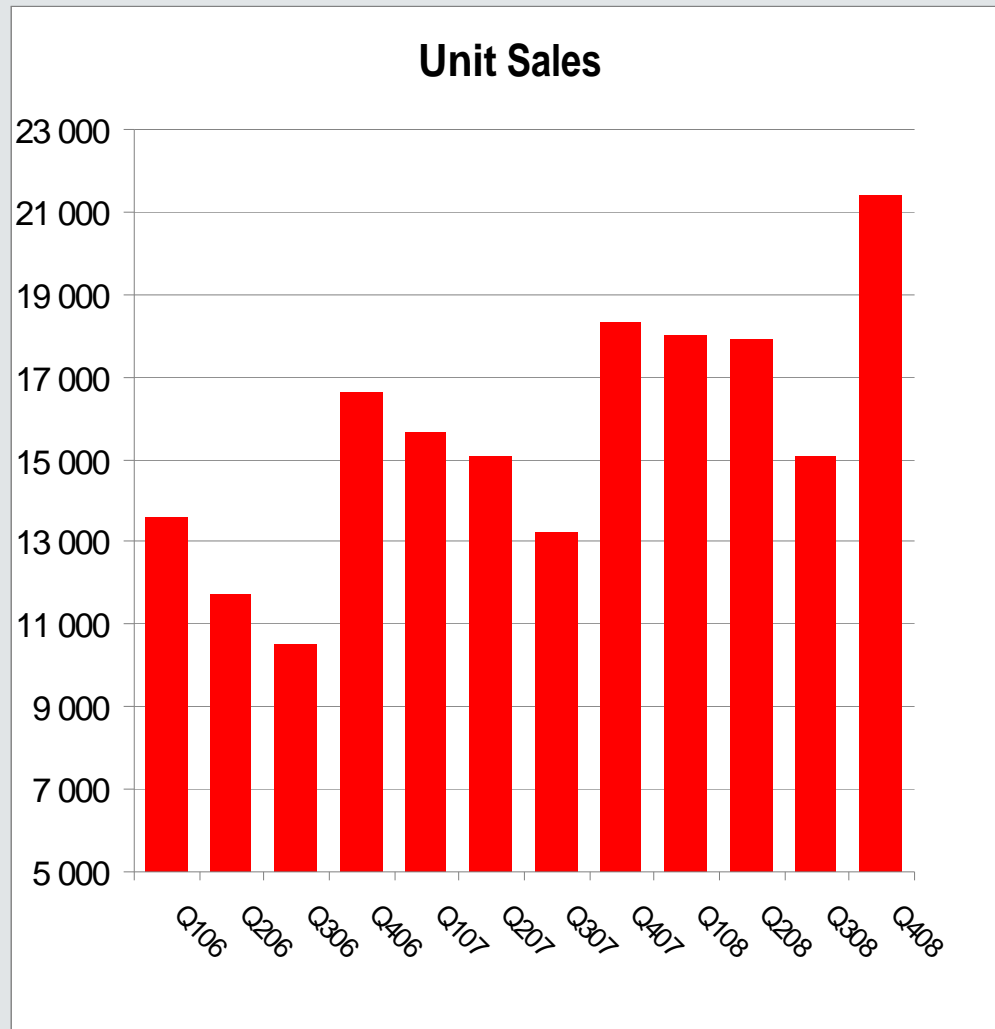
Metvix® and Aktilite®

- treatment of skin cancer without scarring

Metvix®



– sales increase of 17% in Q4 and 16% in 2008 in units



- Q4: Partner sale of 17,256 units in 2008 vs. 13,628 units in 2007.
- Q4: Own sale of 4,156 units in 2008 vs. 4,674 units in 2007.
- Full year: Partner sale of 59,332 units in 2008 vs. 46,675 units in 2007.
- Full year: Own sale of 13,063 units in 2008 vs. 15,596 units in 2007.



Metvix[®] – roadmap

- **US launch in progress**
- **Improve payment/reimbursement conditions in co-operation with Galderma**
- **Establish new centers and increase use at established centers**
- **Improve procedure**

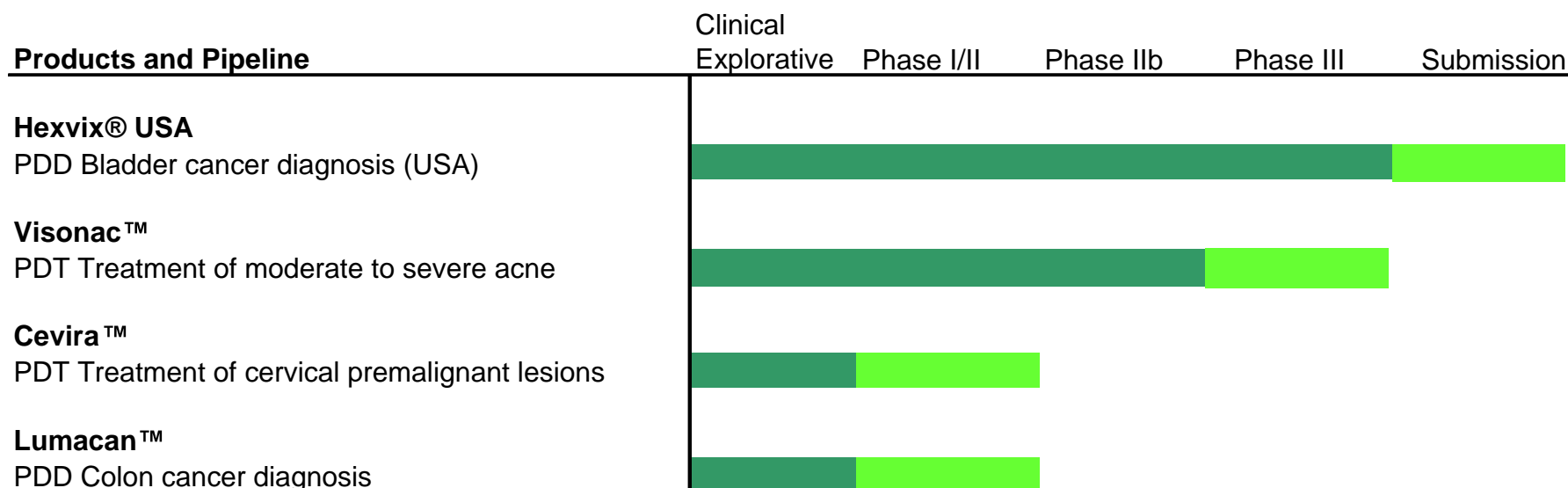


Brilliance in photodynamic technology™

Research & Development



Progress in the R&D programs



■ = completed ■ = ongoing

- Hexvix® – preparing for submission to FDA
- Visonac™ - preparing for phase III
- Cevira™ - ongoing Proof-of-Concept study in patients with low grade dysplasia
- Lumacan™ – ongoing Proof-of-Concept with oral formulation

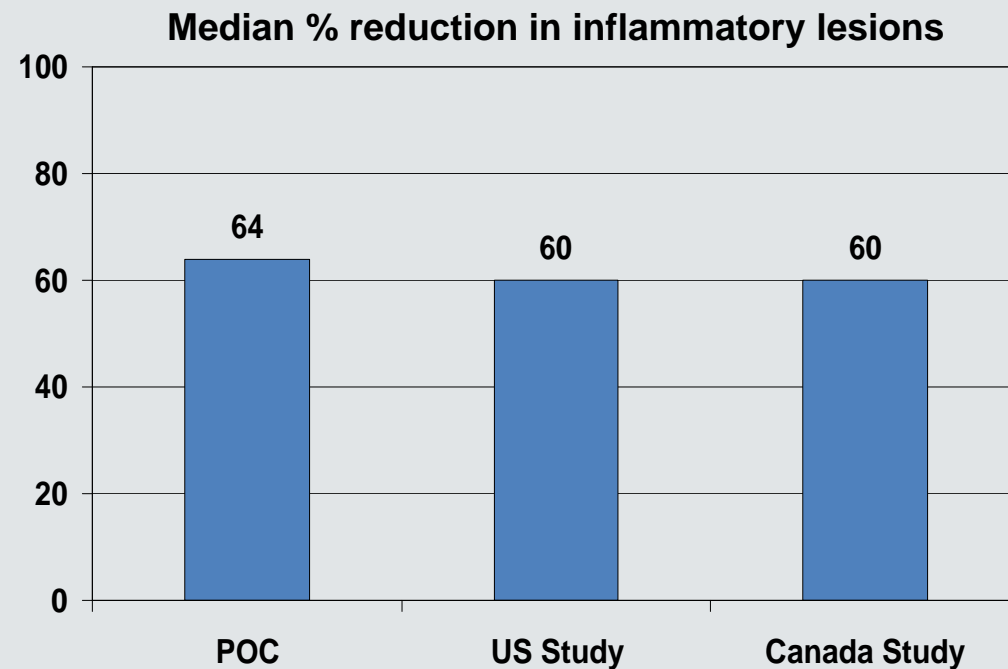
Visonac™

- Phase II study demonstrated significant and sustained effect on treating moderate to severe acne vulgaris



Sustained improvement in lesion count owing to bacteria killing effect and sebum reduction effect of Visonac™

Significant improvement in tolerability measures of pain and erythema



Visonac™

- next steps – planning phase III



USA

Guidance meeting held with FDA in January

- Positive feedback on Visonac™ documentation
- Discussions on the clinical development program

Europe

Guidance meeting scheduled in Sweden/EU in Q2

- Plan to discuss the clinical development program in EU

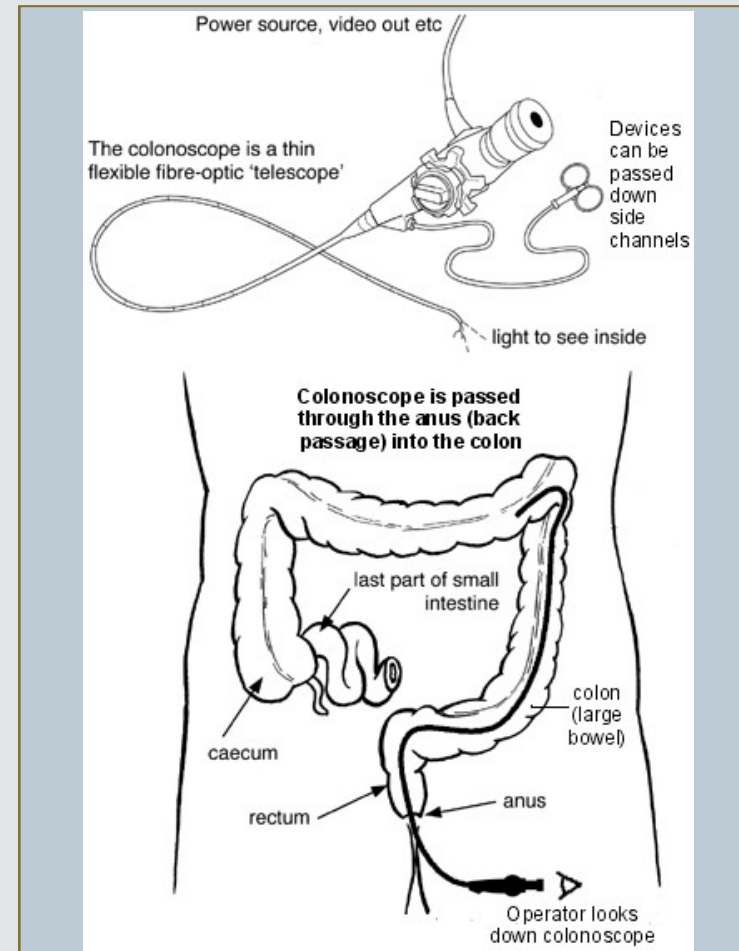
➡ Plan to start phase III H2 2009

Colorectal cancer



- growing health problem, among most lethal cancers

- Over 500,000 cases of colon cancer are diagnosed each year in the US and EU combined
- Five years survival rate is 50 – 60%.
- Colonoscopy screening may prevent up to 80% of deaths from CRC
- Lumacan™ improves CRC diagnosis based on established technology

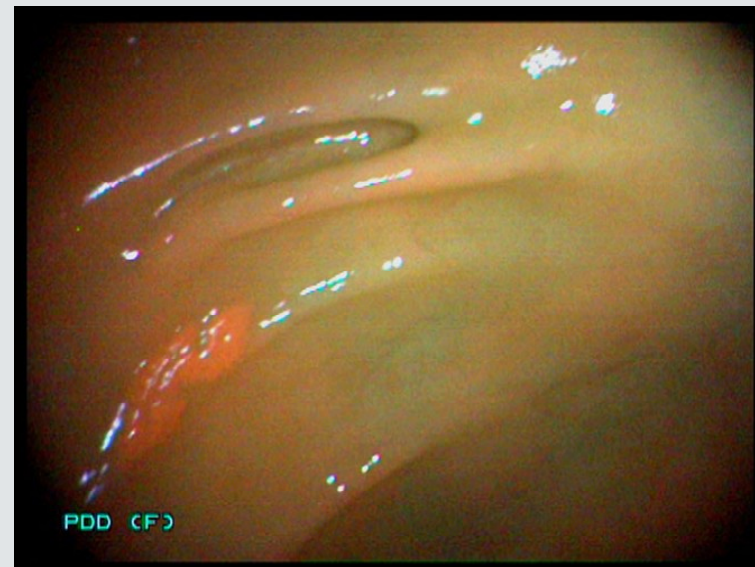


Lumacan™

- diagnosis of colon cancer



- Completed Phase I/II study in 2008; Proof-of-Concept with enema- early detection of premalignant conditions in the colon:
 - open dose-finding
 - 2 centres in Germany - 38 patients
 - 37% improvement in detection over standard method
- Started Phase I/II study in 2009; Proof-of-Concept with oral formulation:
 - Open, dose-finding
 - 4 centres in Germany and 50-70 patients
 - Sponsored by Norwegian Research Council
 - Planned completion in 2009



First PoC-study in Munich, Germany.
One flat lesion showing fluorescence in colon.
Courtesy: Prof. Dr. B. Mayinger

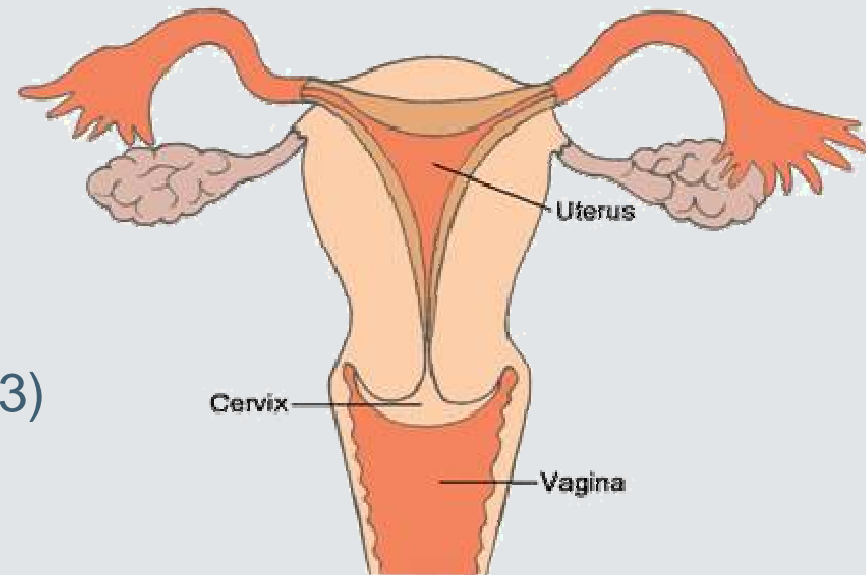
Premalignant lesions in Cervix

- HPV Infections and Cervical Abnormalities



Clinical challenges:

- Patients with mild lesions (CIN1)
 - poor diagnosis (20-30% CIN2/3)
 - patient anxiety
 - no standard therapy
 - costly follow-ups
 - poor patient follow up
- Patients with severe lesions (CIN2/3)
 - invasive surgery
 - requires anaesthesia



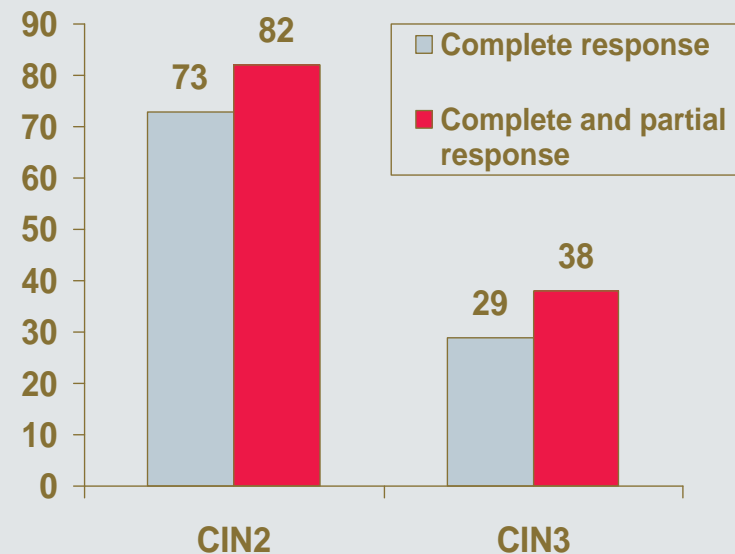
Cevira™- the Therapeutic Option



- PDT treatment of cellular abnormalities in the cervix

- Phase I/II dose-finding study:
 - 92 patients with CIN2/3
 - Oslo and Hannover
 - Endpoint: 6 months response
 - Interim result Oslo 35 patients
 - Final 12 month results 4Q 2009
- New drug/device patent filed
- Phase II proof-of-concept study
 - Placebo-controlled
 - 70 patients with CIN1
 - Patient inclusion started in 1Q 2009
 - Norway, Germany, France
 - Endpoint; 6 months response
 - Planned completion H2 2010

Interim results
Lesion response rate %, Oslo





Strategic and operational goals

Maximize value of the existing product portfolio

- Continue Nordic leadership
- Support Galderma in strengthening Metvix/Aktelite – follow-up on US
- Seek Hexvix approval in the US

Develop new products

- Seek regulatory advice and start phase III in EU for Visonac™
- Complete Proof-of-Concept for oral formulation for Lumacan™
- Complete Proof-of Concept for early stage cervical cancer for Cevira™

Licence out Visonac™, Lumacan™ and Cevira™