PCI Biotech

Fourth Quarter and Preliminary 2012 Results

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February 2013

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Highlights 2012

- Initiated the ENHANCE study – a Phase II study in head & neck cancer patients
  - Preliminary results suggest that treatment with intra-tumour illumination produce stronger local treatment effects than expected and desired
  - The Independent Data Monitoring Board suggested pausing patient inclusion requiring intra-tumour illumination until optimisation of this treatment regimen has been established
  - The company has initiated a process to determine the best approach going forward, to be completed in February
- Bile duct cancer (cholangiocarcinoma) selected as next indication for PCI with Amphinex™, using the marketed drug gemcitabine
  - A Phase 1/2 study has been designed, sites selected and all regulatory approvals in UK granted
  - Patient inclusion will start in Q1 or early in Q2 2013
- Promising results from preclinical program to investigate PCI used with vaccines.
  - Decided to continue the preclinical program to optimise a treatment regime, and to start a clinical study if beneficial

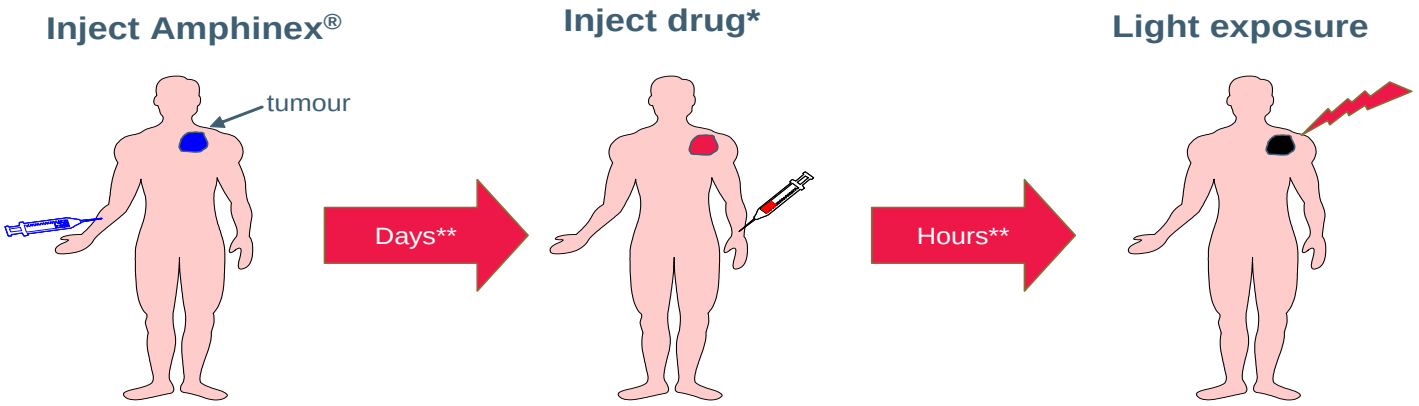
PCI Biotech
– Focused on Localised Cancer Treatment

PCI Technology

Photochemical Internalisation – a new technology for localised cancer treatment

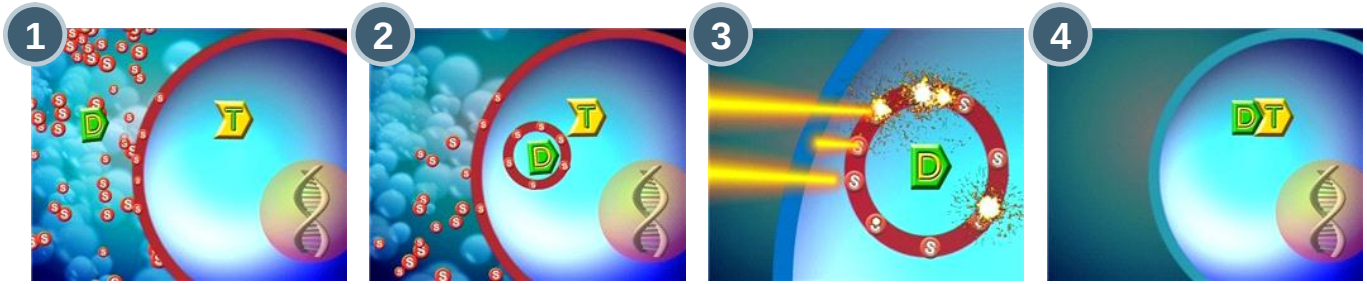
- Light-induced enhancement of various drugs, using a unique and patented photosensitiser, Amphinex to induce the enhancement
- PCI Biotech is developing Amphinex for local enhancement of marketed cancer drugs
- First clinical PCI study with Amphinex for enhancement of the generic cytotoxic bleomycin completed. The results indicate that the treatment induce strong tumour response and is well tolerated
- Preclinical studies suggest that Amphinex may enhance the effect of several important marketed cancer drugs

Significantly enhancing the local effect of cancer drugs



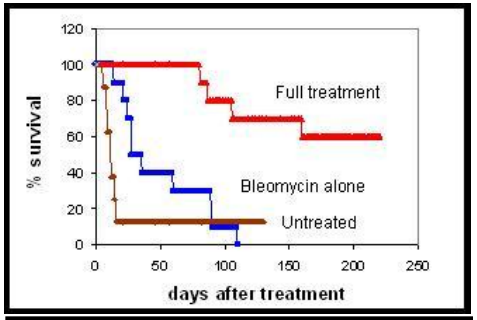
* PCI Biotech currently focus on generic drugs, such as bleomycin
** The optimal timing of injections and light exposure may vary with the drug to be delivered

Enabling drugs to reach intracellular therapeutic targets



Amphinex may enhance the localised effect of a wide range of different cancer drugs

- Positive *in vivo* results with several marketed cancer drugs
  - Enhancement of the local effect of bleomycin in several models
  - Significant enhancement of three widely used cancer drugs, including gemcitabine
- Effective delivery of macromolecules
  - Proven effective delivery of several types of macromolecules, including targeted immunotoxins



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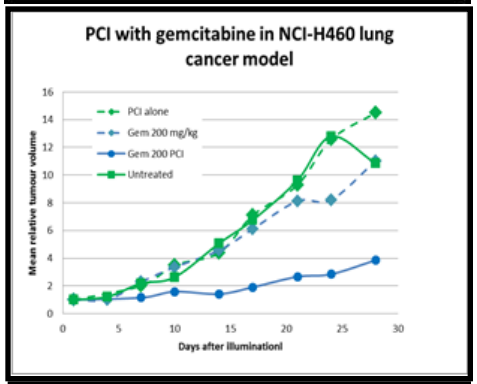

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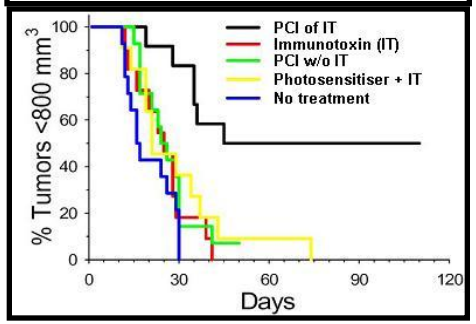

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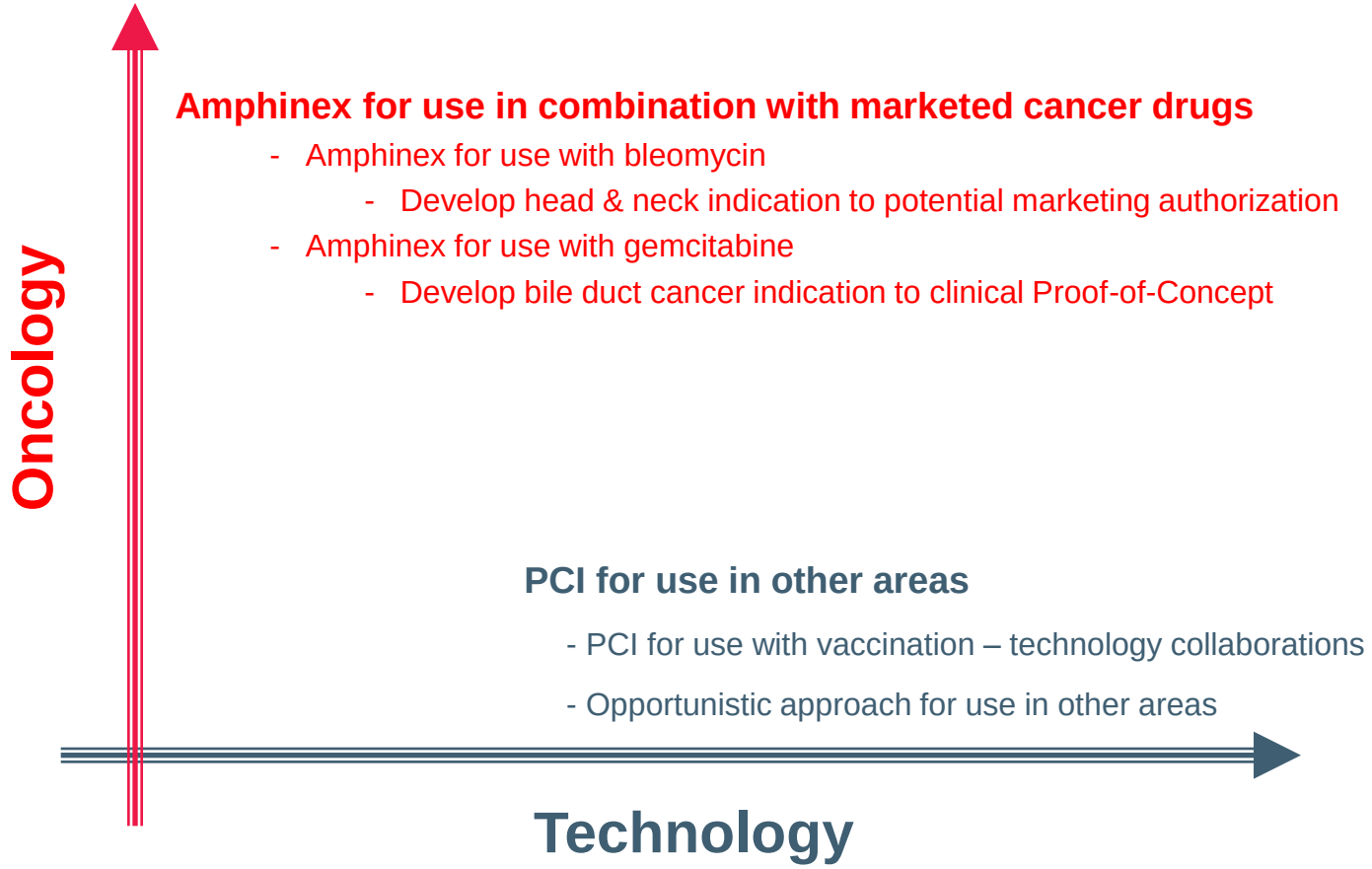
*Berg, K. *et al*. (2005) *Clin. Cancer Res*. 11, 8476
**Unpublished results
***Selbo, *et al*. (2009). *PLoS ONE*, 4, e6691

PCI Biotech
– Focused on Localised Cancer Treatment

Strategy

Growth of PCI Biotech via 2 axes

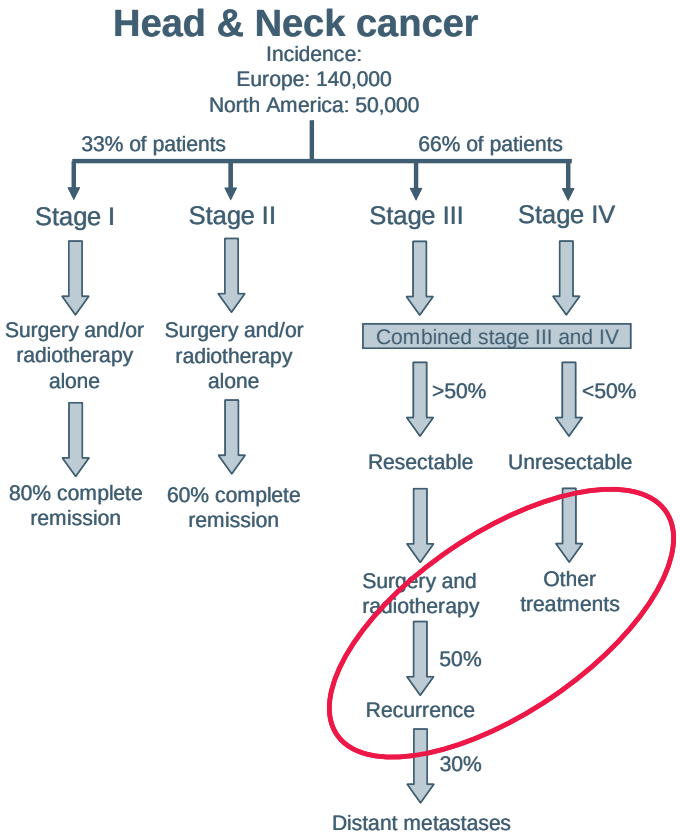


Amphinex

Head & neck cancer

Head & neck cancer – a disease in need of better localised treatment options

- Large patient population with high medical unmet need
  - Need of new treatments able to improve quality of life, reduce recurrence rates and prolong life
  - A field with lack of new innovations
- Current localised treatment options are often associated with functional and cosmetic impairments
  - Surgery
  - Radiotherapy
- Recurrent disease mainly given palliative treatment
  - Quality of life is an important endpoint in this population
  - Palliative chemo/targeted combination therapy is often the only possible choice



Source: Datamonitor Stakeholder Opinions: Head and Neck Cancer (2004), GLOBOCAN (www-dep.iarc.fr, accessed March 2010)

Head & neck cancer – market assessment by Bridgehead International

- Market assessment performed in France, Germany, Italy, UK and US
  - 65,000 - 70,000 head & neck cancer patients in EU big 5, representing approximately 50% of all European H&N cancer patients
  - 45,000 - 50,000 head & neck cancer patients in US

- Key findings from Key Opinion Leader interviews:
  - Large patient population with need of new treatments able to reduce recurrence rates and prolong life
  - Quality of life and locoregional control considered more important than overall survival
  - Cetuximab (Erbitux) most relevant price comparator
  - Approximately 20% of head & neck cancer patients eligible for Amphinex

Amphinex induced PCI of bleomycin in head & neck cancer – Phase II study

• Patient inclusion	2012 – 2014
• Target population	Recurrent head & neck squamous cell carcinoma without distant metastases, unsuitable for radiotherapy and surgery
• Type of study	Single arm, open label
• Primary endpoint	Progression free survival at 6 months
• Number of patients	70-80
• Where	Europe

Amphinex induced PCI of bleomycin in head & neck cancer – Phase II study

- First patient treated in Q2 2012 at The National Center for Tumor Diseases (NCT), University Hospital Heidelberg, Germany
- Six University hospitals currently involved in the study and further European hospitals in process
- Preliminary results suggest that treatment with intra-tumour illumination produce stronger local treatment effects than expected and desired
  - The Independent Data Monitoring Board suggested pausing patient inclusion requiring intra-tumour illumination until optimisation of this treatment regimen has been established
  - The company has initiated a process to determine the best approach to optimise the intra-tumour treatment regimen, to be completed in February

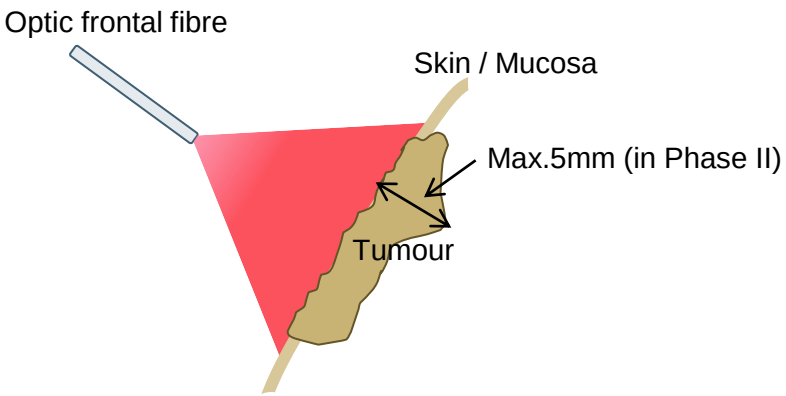
Light application procedures for PCI – surface and intra-tumour illumination

Surface illumination

Used in both Phase I & II

Applied to surface tumours
(max 0,5 cm depth in Phase II)

Light dose established in Phase I

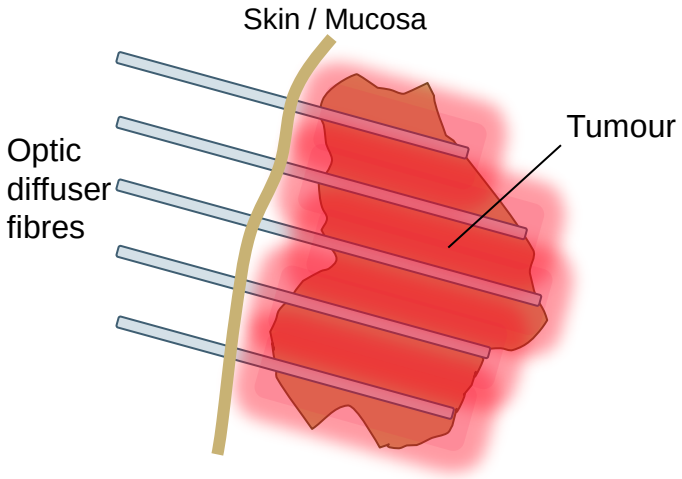


Intra-tumour illumination

Used in Phase II

Applied to deeper tumours,
such as tongue-base

Light dose theoretically estimated from Phase I



Phase II – findings and plan

Assessment by Independent Data Monitoring Board (IDMB)

⇒ Local effects with intra-tumour treatment are stronger than expected and desired – recommend to pause inclusion and optimise intra-tumour treatment procedure

- Patients experience a destruction of the treated area leading to side effects and functional defects
- Light dose translation from surface to intra-tumour illumination needs to be reassessed, and the intra-tumour illumination procedure optimised

Plan and actions

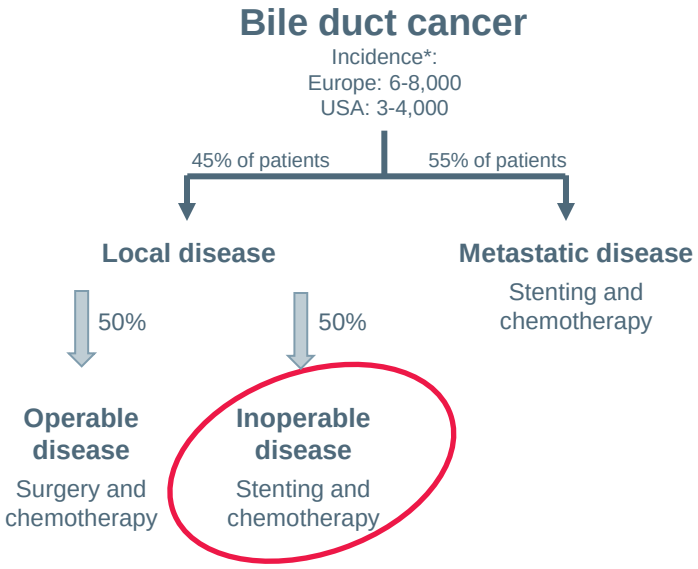
- Paused intra-tumour treatment and continued inclusion of surface treatment patients only, while actions to correct the intra-tumour illumination procedure is assessed and agreed
- Process expected to be completed and agreed in February – will then initiate regulatory interactions to re-start inclusion of intra-tumour treatment patients for optimisation
- Patient inclusion expected to continue into 2014

Amphinex

Bile duct cancer

Bile duct cancer– selected as second indication for the development of Amphinex

- Patient population with high medical unmet need
  - Tumour resection is currently the only potential cure
  - Majority of patients are inoperable at presentation
  - Incidence and mortality rates are increasing worldwide
  - Remarkable resistance to common chemotherapy
  - Need of new treatments able to prolong and improve quality of life



*Source; Khan et al, Lancet 2005; 366:1303
Gatta et al, Eur J Cancer 2011; 47:2493

- Could PCI play a role in treatment of bile duct cancer?
  - Medical need for better local treatment methods
  - Easy access with light through the endoscopic methods routinely in use
  - Gemcitabine is one of the drugs that in preclinical studies are significantly enhanced by PCI, and is one of the most studied and used chemotherapies in bile duct cancer

Amphinex induced PCI of gemcitabine in bile duct cancer – Proof of Concept study

- Patient inclusion — Start by end of 1H 2013; finish 2014
- Target population — Patients with inoperable bile duct caner
- Study design — Open-label, multi-center Phase I/II study in up to 45 patients to assess the safety and efficacy of Amphinex induced PCI of gemcitabine, followed by systemic cisplatin/gemcitabine

  Phase I: A dose escalation study to assess the tolerance of local bile duct treatment

  Phase II: randomized double-arm Phase II study

  - PCI arm: stenting followed by Amphinex induced PCI treatment of gemcitabine, followed by gemcitabine/cicplatin chemo
  - Control arm: stenting alone followed by gemcitabine/cicplatin chemo
  - Randomization ratio 2.5;1 in favor of the PCI arm

Amphinex induced PCI of gemcitabine in bile duct cancer – Proof of Concept study

- Endpoints in Phase II — Primary endpoint – progression free survival
  Secondary endpoints include overall survival
- Number of patients — Phase I: up to 12 patients. Patient inclusion approx. 6 months
  Phase II: up to 35 patients. Patient inclusion approx. 10 months
- Follow up in Phase II — 15 months
- Where — Phase I: 4-5 European hospitals
  Phase II: Approx. 10 European hospitals
- Cost — Phase 1: approx. NOK 7 million
  Phase 2: approx. NOK 12 million
- Status — All regulatory approvals in UK granted
  Patient inclusion to start in Q1 or early in Q2 2013

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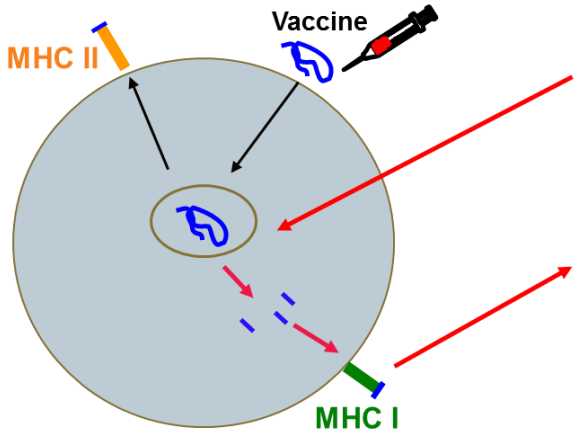
Vaccines

PCI for vaccination

- Therapeutic vaccines – an area with increased focus world wide
  - Rapid marked growth expected within therapeutic vaccines – first product on the market in 2010 and many products under development
- Vaccines identified as an interesting area for PCI, good strategic and mechanistic fit with the PCI technology
- Need of products that can enhance the therapeutic effect of vaccines

PCI for vaccination – enhancing cytotoxic T-cell response

- PCI – induce antigen presentation on MHC class I
  - Make it possible to achieve cytotoxic T-cell response with protein/peptide vaccines
  - Can solve a central problem for many vaccine approaches:
    - Therapeutic vaccines
      - Cancer
      - Chronic viral diseases
    - Some prophylactic vaccines



PCI - induce antigen presentation on MHC class I

- Make it possible to achieve cytotoxic T-cell response with protein/peptide vaccines
- This can solve a central problem for many vaccine approaches

- In addition PCI can give a more unspecific ”adjuvant” immuno-stimulatory effect

PCI to enhance vaccines

- Promising results from preclinical studies performed at NTNU in Norway and University Hospital Zurich, Switzerland
  - Results show that under certain conditions, PCI can increase the effect of different antigens
  - Preclinical proof-of-principle established for *ex vivo* vaccination, studies ongoing for in vivo vaccination
- PCI to enhance *ex vivo* vaccines – preclinical program ongoing at University Hospital Zurich, CH
  - Will be completed by end of 1H 2013.
  - If positive results => Further development by partners
- PCI to enhance *in vivo* vaccines – preclinical program ongoing at University Hospital Zurich, CH
  - Optimised treatment regime to be developed during 2013 and start of a clinical study if considered beneficial
  - If positive results => Further development by partners

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Financial results

Financial key figures 2012 and 2011

P&L (TNOK)	Q4 2012	Q4 2011	2012	2011
Grants	1 398	2 765	6 765	7 423
Research and development costs	8 565	6 913	31 263	22 226
General and administrative costs	1 634	667	2 856	2 273
Total operating costs	10 199	7 580	34 119	24 499
Operating results	- 8 801	-4 815	-27 354	-17 076
Profit before tax	**-8 363**	**-3 939**	**-25 259**	**-13 749**
Cash flow (TNOK)				
Net cash flow from operations	-4 892	-3 683	-22 032	-15 699
Net cash flow from investments				
Net cash flow from financials				
Net cash flow	**-4 892**	**-3 683**	**-22 032**	**-15 599**

Financial key figures 2012 and 2011

Balance (TNOK)	31.12.2012	31.12.2011
Fixed assets	0	17
Short term receivables	5 118	5 033
Cash & cash equivalents	**73 083**	**95 115**
Equity	69 706	92 533
Long term debt	0	0
Short term debt	8 495	7 632

PCI Biotech
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Summary

PCI Biotech – well positioned for attractive development opportunities

Amphinex with bleomycin

- Phase I/II study successfully completed – well tolerated & strong tumour response
- Phase II study in head & neck cancer started
  - Initiated process to optimise intra-tumour treatment
  - Patient inclusion expected to continue into 2014

Amphinex with gemcitabine

- Bile duct cancer and gemcitabine selected as next clinical indication
- Clinical proof of concept study planned to start by end of 1H 2013

Vaccination

- Proof of principle for *ex vivo* PCI enhancement of vaccination
- Further pre-clinical work initiated
- Start clinical study in 2013 if beneficial

Other

- PCI 652 medical laser designed and approved for PCI treatment

2013	2014
Start PoC study in bile duct cancer	Complete inclusion of Phase II head & neck cancer study
Complete pre-clinical vaccination project	Complete inclusion of PoC study in bile duct cancer
Start clinical vaccination study if beneficial	Amphinex and/or vaccination partnering

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