Localised Cancer Treatment

PCI Biotech

Second Quarter and First Half 2011 Results

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PCI Biotech
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- Developing a new concept in treatment of localised cancer
  - Local enhancement of well established cancer drugs via Photochemical Internalisation (PCI)
- Lead combination product PC-A11 completed Phase I/II clinical trial in cancer patients
  - PC-A11 = Amphinex + bleomycin: Well tolerated and strong tumour response; apparent high cancer specificity
- Positive initial results with additional cytotoxic agents in pre-clinical tumour models
  - Further studies being performed to validate the results
- Opportunistic approach to macromolecules (proteins and gene therapy)
  - PCI is excellent for intracellular delivery of large molecules
- Good financial position for further development of the platform technology
  - Well funded; with cash to support the planned milestones

Highlights 2011

- Completed the Phase I/II study of PC-A11
- Decided next clinical study of PC-A11 in Head & Neck cancer patients
- Initiated compassionate use of PC-A11 on a named patient basis
- Finalized the initial preclinical efficacy studies to select new product combinations for clinical Proof of Concept studies
- Awarded NOK 10.85 million in BIA grant from The Research Council of Norway

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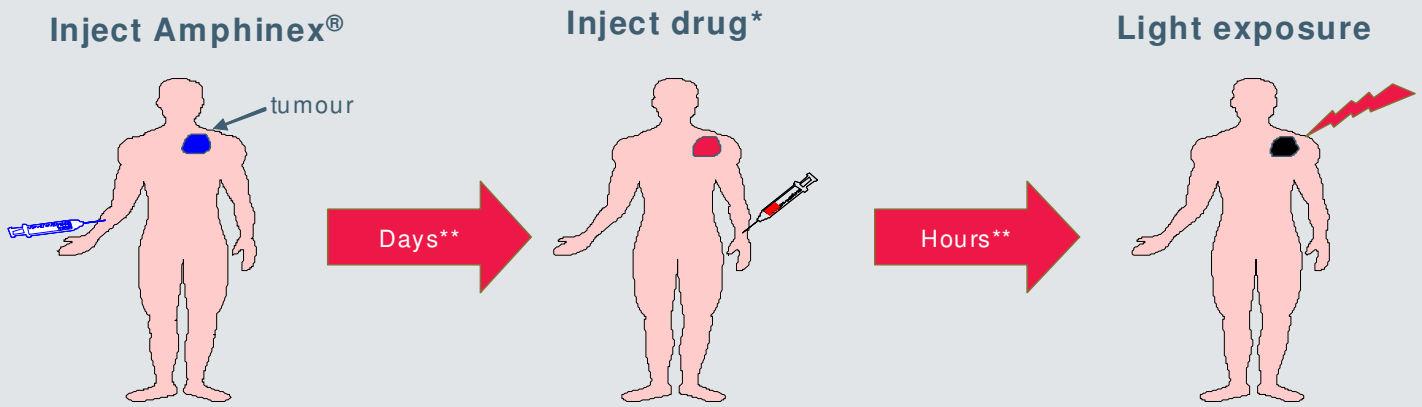
PCI Technology

Photochemical Internalisation – a new technology for localised cancer treatment

- Light-induced chemistry for local enhancement of the effect of various drugs, using a unique and patented photosensitiser, Amphinex® to induce the enhancement
- PCI Biotech is developing fixed combination products with Amphinex® and different generic cytotoxics
- First clinical PCI study with PC-A11, based on Amphinex® and the well established generic cytotoxic bleomycin, has completed all patient visits at University College Hospital in London:
  - Included patients with some of the most difficult tumours to treat; osteosarcoma and squamos cell carcinoma of the head and neck, and skin metastases from breast cancer
  - The results indicate that PC-A11 induce strong tumour response and is well tolerated
- Preclinical studies suggest that PCI may also enhance the effect of several other marketed cancer drugs
- Initiated a project to document the immunological mechanisms of the PCI technology and to develop a treatment regime for optimal use of this mechanism, and this project is financially supported by the Norwegian Research Council

Significantly enhancing the local effect of cancer drugs



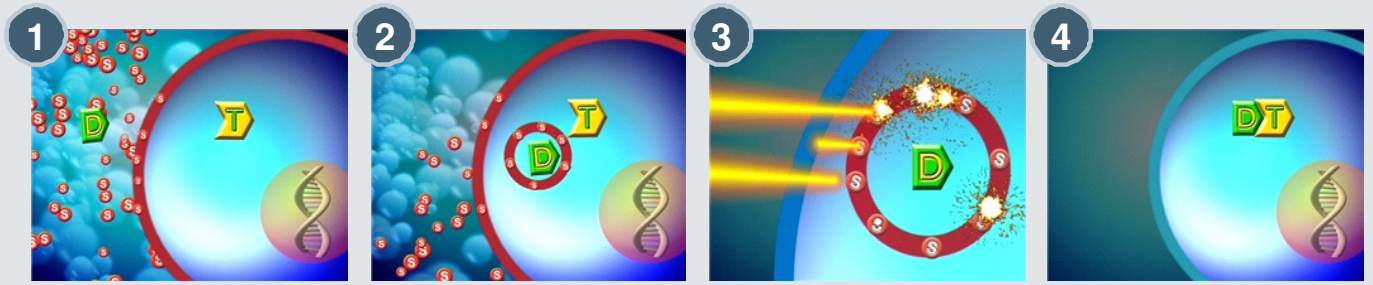
Amphinex® taken up by tumour cells

Drug taken up by tumour cells

Drug activated only in illuminated cells

* 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

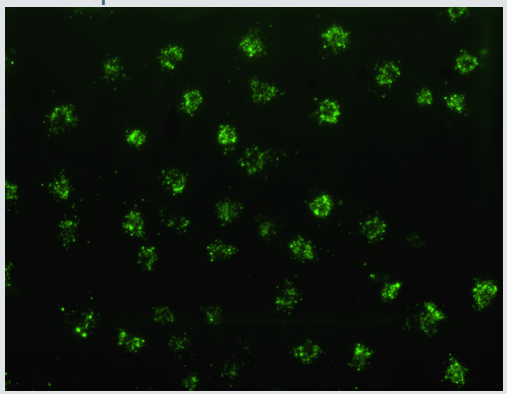
Enabling drugs to reach intracellular therapeutic targets



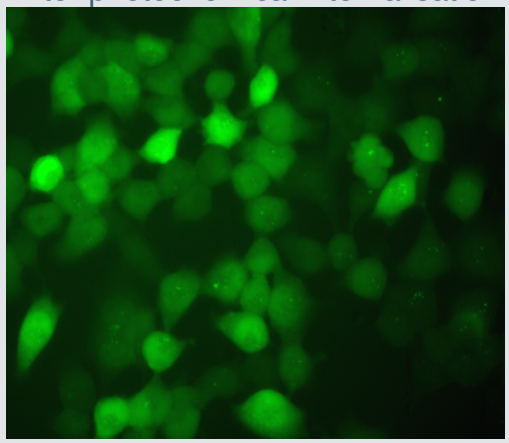
A versatile technology with many different potential applications

Efficiently releasing molecules from intracellular endosomes

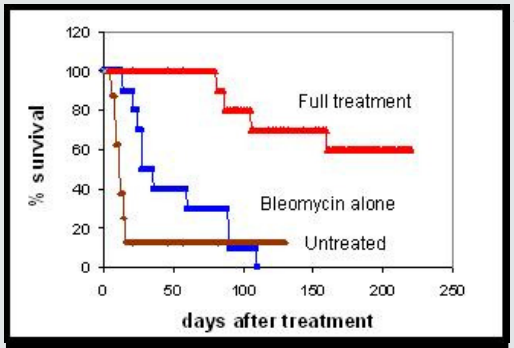
Before photochemical internalisation



After photochemical internalisation



- **Potentiating the localised effect of drugs on the market**
- **Designing specific drugs for photochemical internalisation**
- **Delivering the promise of gene therapies for localised treatment**



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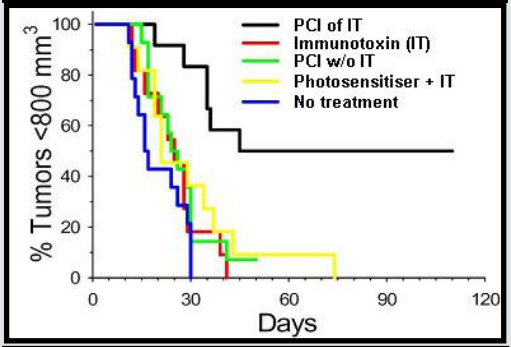

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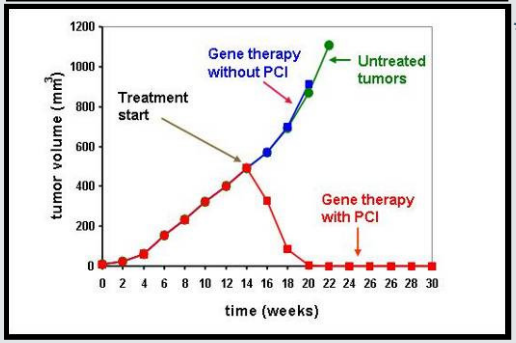

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*Berg, K. *et al.* (2005) *Clin. Cancer Res.* 11, 8476
**Selbo, *et al.* (2009). *PLoS ONE*, 4, e6691
***Ndoye, A. et al. (2006). *Mol. Ther.* 13, 1154

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Strategy

Regulatory combination route opens up multiproduct opportunities

Conceptually a new product modality

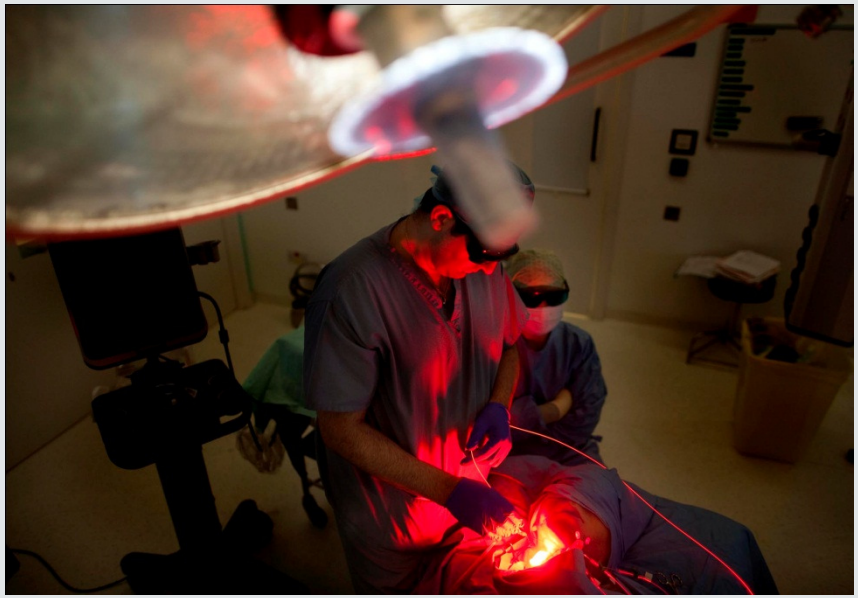
- Close contact with regulatory authorities through early discussions on applicable regulatory guidelines and development requirements

Scientific advice meetings

- Meeting held with European Medicines Agency, Innovation Task Force
- Meetings held with National Health Authorities (SE, NL, GB)
- Formal Scientific Advice with European Medicines Agency
  - Non-clinical and clinical development requirements for the combination product PC-A11
  - Feedback considered valid also for other Amphinex® based combination products
- Continued regulatory interactions with Health Authorities in relevant markets

Unmet need in local treatment of cancer – need for improved local control

- Local control – the arrest of cancer growth at the site of origin
- Improved local control is needed for a number of different cancers, e.g.:
  - Head & neck cancer
  - Colorectal cancer
  - Lung cancer
  - Pancreatic cancer
  - Esophageal cancer
  - Cholangiocarcinoma
  - Mesothelioma
  - Sarcoma
  - Glioblastoma
  - Cervical cancer
  - Prostate cancer
- Current local treatments vary between cancers and stages, but there is a general need of better treatment options



Multiple opportunities for value creation based on the PCI platform

- Focus area:
  - Combination products based on generic cancer drugs
    - PC-A11 – develop to marketing authorization
    - Pipeline – develop to clinical proof of concept for out-license

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- Opportunistic approach:
  - Combination products based on patented drugs
    - Drug delivery of marketed drugs – lifecycle collaborations
    - Drug delivery of macromolecules – technology collaborations

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PC-A11

PC-A11: Status & key clinical results

- PC-A11 is an Amphinex® based combination product containing the well established generic cytotoxic bleomycin

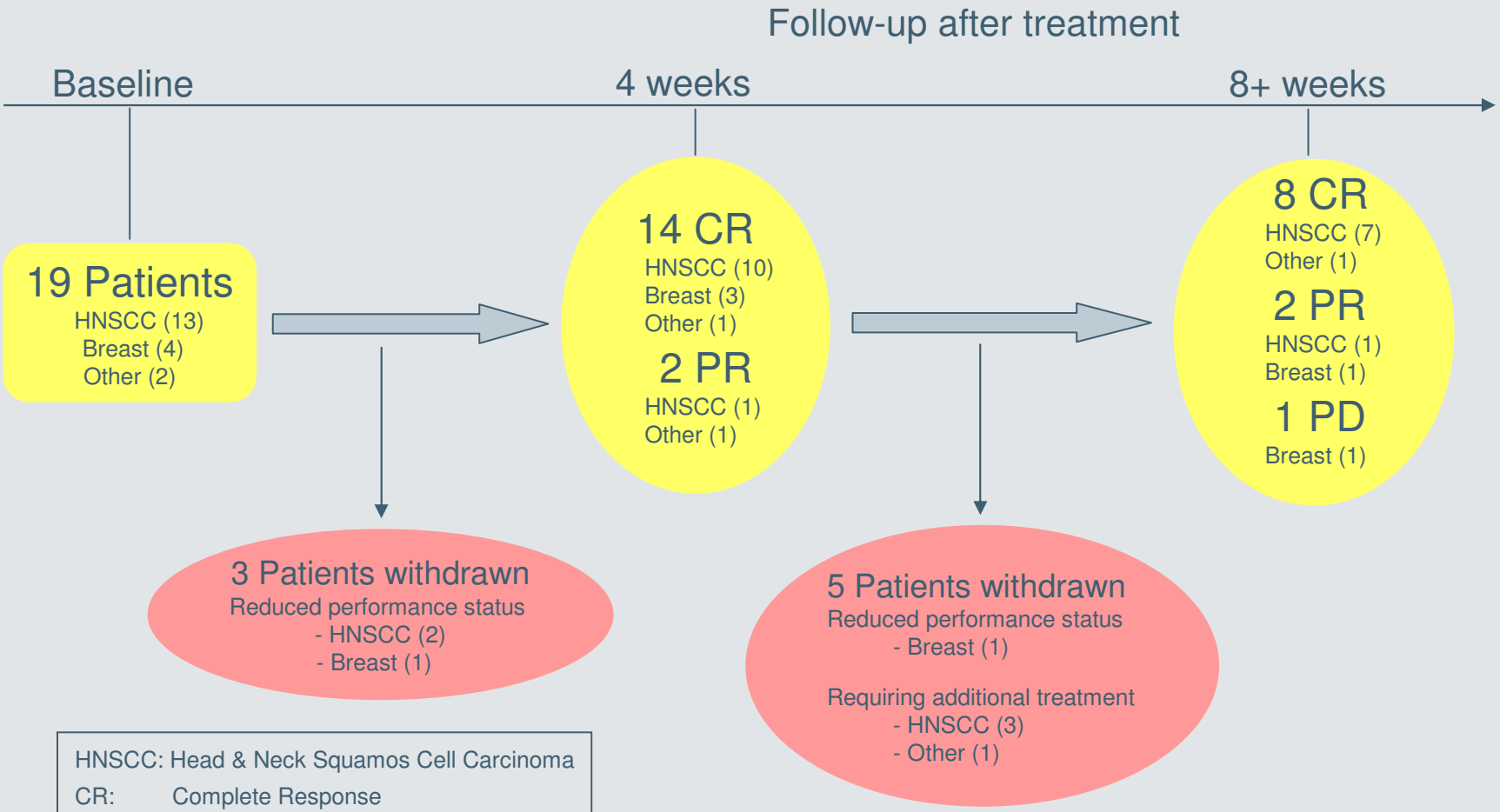
- Bleomycin is indicated for several different cancers, including head & neck

Amphinex®

- Phase I/II study with PC-A11 finished in 1H 2011 – the results indicate good safety and efficacy
  - Strong tumour response at all dose levels and complete clinical regression of a majority of the target tumours
  - Good safety and tolerability - primary endpoint (dose-limiting toxicity) reached at the 4th dose group
  - Expansion group at selected dose level
    - MR imaging done at this group – hard to interpret as it turns out to be difficult to discriminate reactive swelling from progression

Phase I/II study – dose escalation part

Patient flow & efficacy results



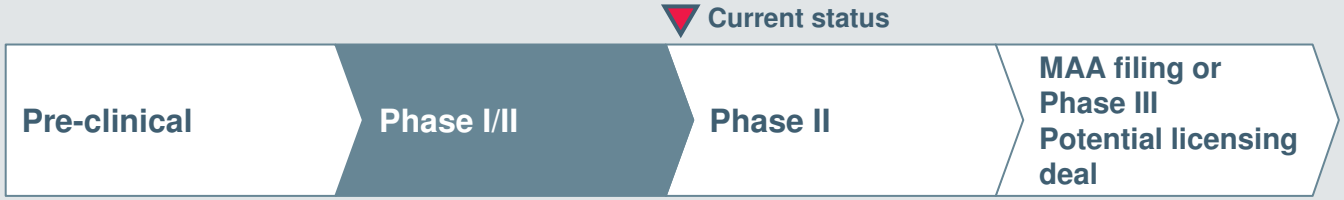
HNSCC: Head & Neck Squamos Cell Carcinoma
CR: Complete Response
PR: Partial Response
PD: Progressive Disease

Summary of Market assessment

- Market assessment performed in France, Germany, Italy, Spain, UK and US
  - 65,000 - 70,000 head & neck cancer patients in EU big 5, representing approximately 50% of all European head & neck 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
  - An indication with lack of new innovations
  - Quality of life and locoregional control considered more important than overall survival
  - Level of skin photosensitivity important for commercial success
  - Cetuximab (Erbitux) most relevant price comparator
  - Approximately 20% of head & neck cancer patients eligible for PC-A11

PC-A11: Clinical development plan

Head & Neck (PC-A11)



- Completed Phase I/II study at University College Hospital in London
  - Study will be extended with up to 9 patients to study lower dose levels
- Aiming to start Phase II study within selected indication in 2011
  - Recurrent H&N squamos cell carcinoma without distant metastases, unsuitable for radiotherapy and surgery
  - Single arm, open label, at the lowest dose level from Phase I/II
  - Primary endpoint – progression free survival at 6 months
  - 50-80 patients
  - 4-6 sites in 4-5 European countries
- Aim to apply for Marketing Authorisation if Phase II results are sufficiently positive
- Custom made light source for PC-A11 established – testing for CE approval ongoing
- EMA has recently granted orphan designation for a new treatment of H&N squamos cell carcinoma

* MAA: Marketing Authorisation Application

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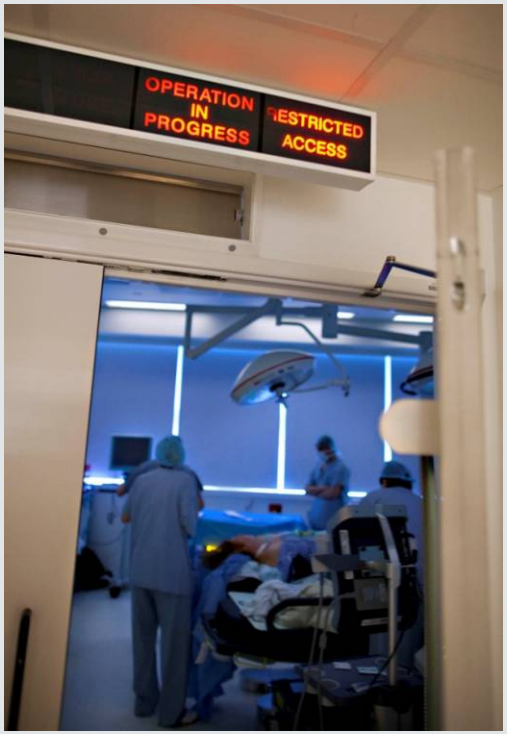
Pipeline

First clinical study yields promise for clinical success in additional indications

- **Aim to initiate further Proof of Concept studies with selected PCI combination products in interesting disease areas**
  - Further cancer indications to be decided based on predetermined indication selection criteria, including:
    - Locally treated disease
    - Unmet medical need
    - Access with light
    - Products potentiated by PCI
    - Time to Proof of Concept
    - Market and regulatory considerations
  - Positive initial results with several cytotoxic agents in pre-clinical tumour models
    - Further studies to validate the results are ongoing
  - Aim to initiate clinical Proof of Concept studies in 2012 based on the results of the preclinical studies



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Financial results

Financial key figures 2011 and 2010

P&L (TNOK)	Q2 2011	Q2 2010	1H 2011	1H 2010	2010
Grants	885	1 789	2 446	3 151	10 444
Research and development costs	5 482	5 561	10 494	10 816	20 185
General and administrative costs	531	2 620	1 118	4 429	6 502
Total operating costs	6 013	8 818	11 612	15 245	26 687
Operating results	-5 128	-6 392	-9 166	-12 094	-16 243
Profit before tax	**-4 297**	**-6 222**	**-7 494**	**-11 751**	**-13 940**
Cash flow (TNOK)					
Net cash flow from operations	-3 766	-2 215	-8 306	-5 867	-8 283
Net cash flow from investments					
Net cash flow from financials		83 369		83 369	83 274
Net cash flow	**-3 766**	**81 154**	**-8 306**	**77 502**	**74 991**

Financial key figures 2011 and 2010

Balance (TNOK)	30.06.2011	30.06.2010	31.12.2010
Fixed assets	44	115	78
Short term receivables	3 755	3 859	3 649
Cash & cash equivalents	**102 508**	**113 325**	**110 814**
Equity	98 409	107 255	105 423
Long term debt	0	0	0
Short term debt	7 898	10 044	9 118

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Summary

PCI Biotech – well positioned for attractive development opportunities

PC-A11

- Completed Phase I/II study – extension to study lower doses
- Positive initial clinical results – a safe product with good effect in head & neck cancer
- Decided next clinical study with the aim to start in 2011

Pipeline

- Identified relevant new product combinations and cancer indications
- Finalised the initial preclinical tests in animal models with new combination products
- Positive with several cytotoxic agents – further studies initiated to validate the results
- Aim to start further clinical proof of concept studies in 2012

Finance

- Good financial position for further development of PC-A11 and the PCI platform

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2011

- Preclinical evaluation of new product combinations finished
- Start of phase II head & neck cancer (PC-A11)

2012 - 2013

- Phase II PoC second/third indication study initiated
- Phase II/III head & neck cancer finished (PC-A11)
- Phase II PoC second indication study finished
- 1-3 licensing deals signed

Enquiries

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