PCI Biotech

Fourth Quarter and Preliminary 2010 Results

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PCI Biotech
– Focused on Localised Cancer Treatment

- Developing a new concept in localised cancer treatment
  - Local enhancement of well established cancer drugs via Photochemical Internalisation (PCI)
- Combination product PC-A11 in Phase I/II clinical trial in cancer patients
  - Preliminary data: well tolerated; good tumour response; high cancer specificity
- Preclinical pipeline of alternative combination products
  - Initiated animal studies of drug combinations with positive results in cancer cell cultures
- Opportunistic approach to macromolecules (proteins and gene therapy)
  - PCI is excellent for intracellular delivery of large molecules
- Experienced management team ensuring focused development progress
  - 2010: Equity raise; Clinical Phase I/II results; Regulatory advice; Amphinex® production
- Good financial position for further development of the platform technology
  - 111 MNOK in cash at the end of 2010

Highlights 2010

- Completed dose escalation, selected clinical dose, and commenced inclusion of the last patients at selected dose in the PC-A11 Phase I/II study
  - Fourth dose group successfully completed – primary endpoint (dose limiting toxicity) reached
  - Inclusion of additional last patients at selected dose ongoing
- Several important issues concerning the Phase II/III study with PC-A11 discussed at EMA Scientific Advice
  - The feedback from EMA enables us to continue our plans to start a confirmatory Phase II/III study in 2011
  - Some items remains to be discussed and the advice process continues into 2011
- Initiated preclinical efficacy studies to select combinations for further clinical proof of concept
  - Preclinical studies ongoing at a well known international specialist CRO
- Produced and released new formulation Amphinex® product sufficient for next clinical trials
  - Have invested in finished product that will cover for the planned clinical trials
- Secured financing of further development through a rights issue of NOK 90 million

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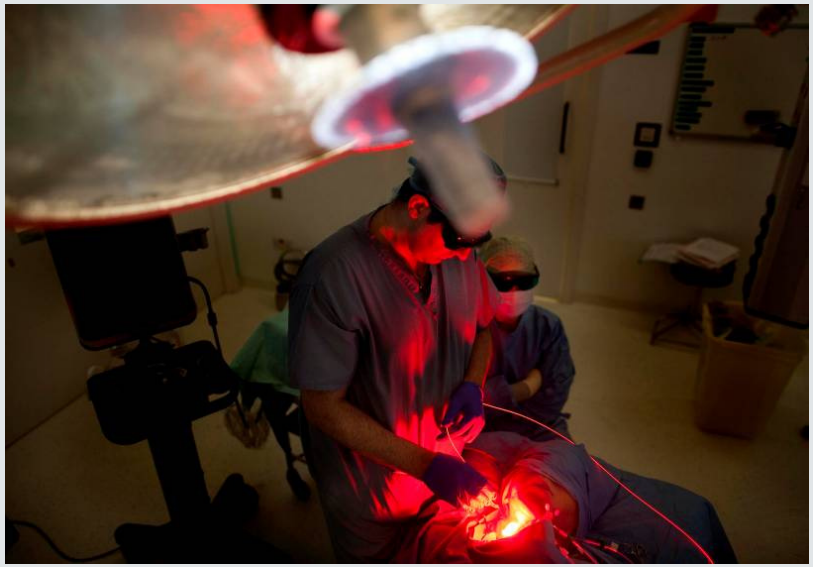
PCI Technology

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
- Amphinex® is first administered to the patient, followed a few days later by the cancer drug and thereafter illumination of the diseased area
- Targeted light-directed delivery of effective cancer drugs to solid tumours is feasible for most cancers and locations in the body, by either superficial, endoscopal or interstitial illumination
- Planning to start a confirmatory Phase II/III study in 2011 with the first combination product PC-A11, based on Amphinex® and the well established generic cytotoxic bleomycin



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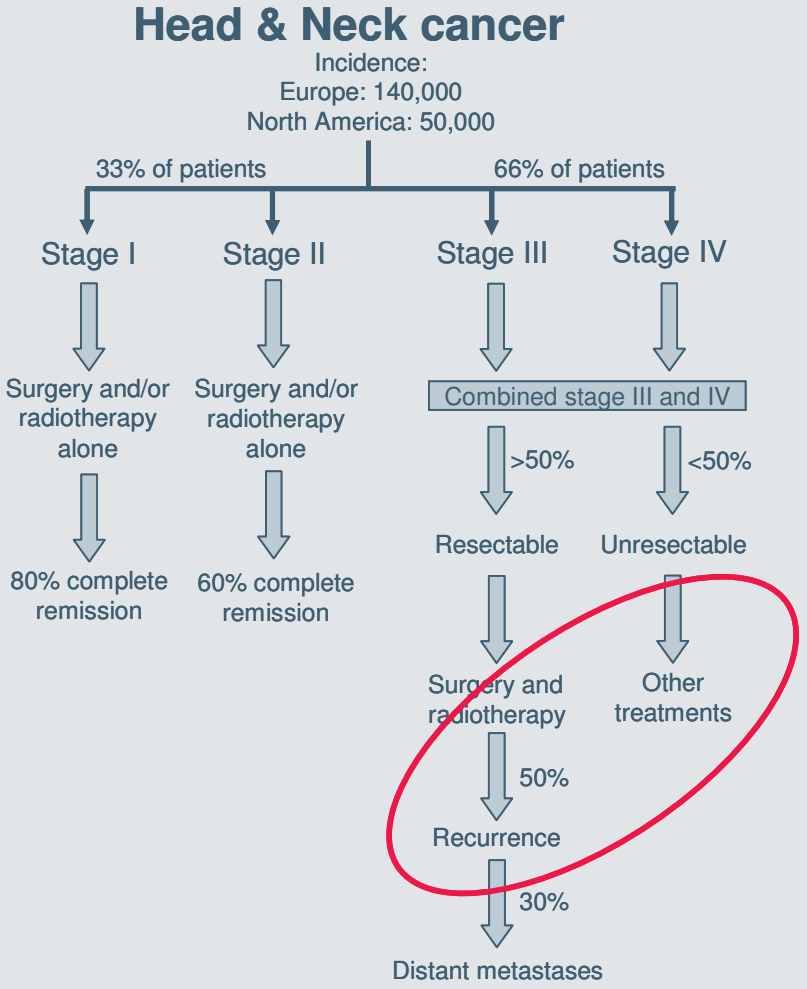
PC-A11

PC-A11: Local Treatment of H&N Cancer

PC-A11
Head & Neck Cancer

PCI has the potential to solve localised treatment challenges

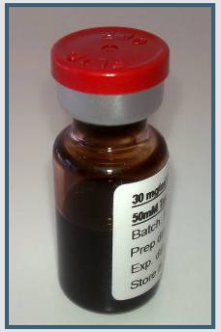
- Globally >640,000 new cases annually, and >140,000 in Europe
- Often not diagnosed until at advanced stage
- Current treatments expensive, and often associated with functional and cosmetic impairments
- Recurrence is common (20-30%) and problematic, as prior treatments often compromise treatment of recurrences
- 3 yr overall survival rate in patients with advanced cancer is ~30%



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

PC-A11: Status & key clinical results

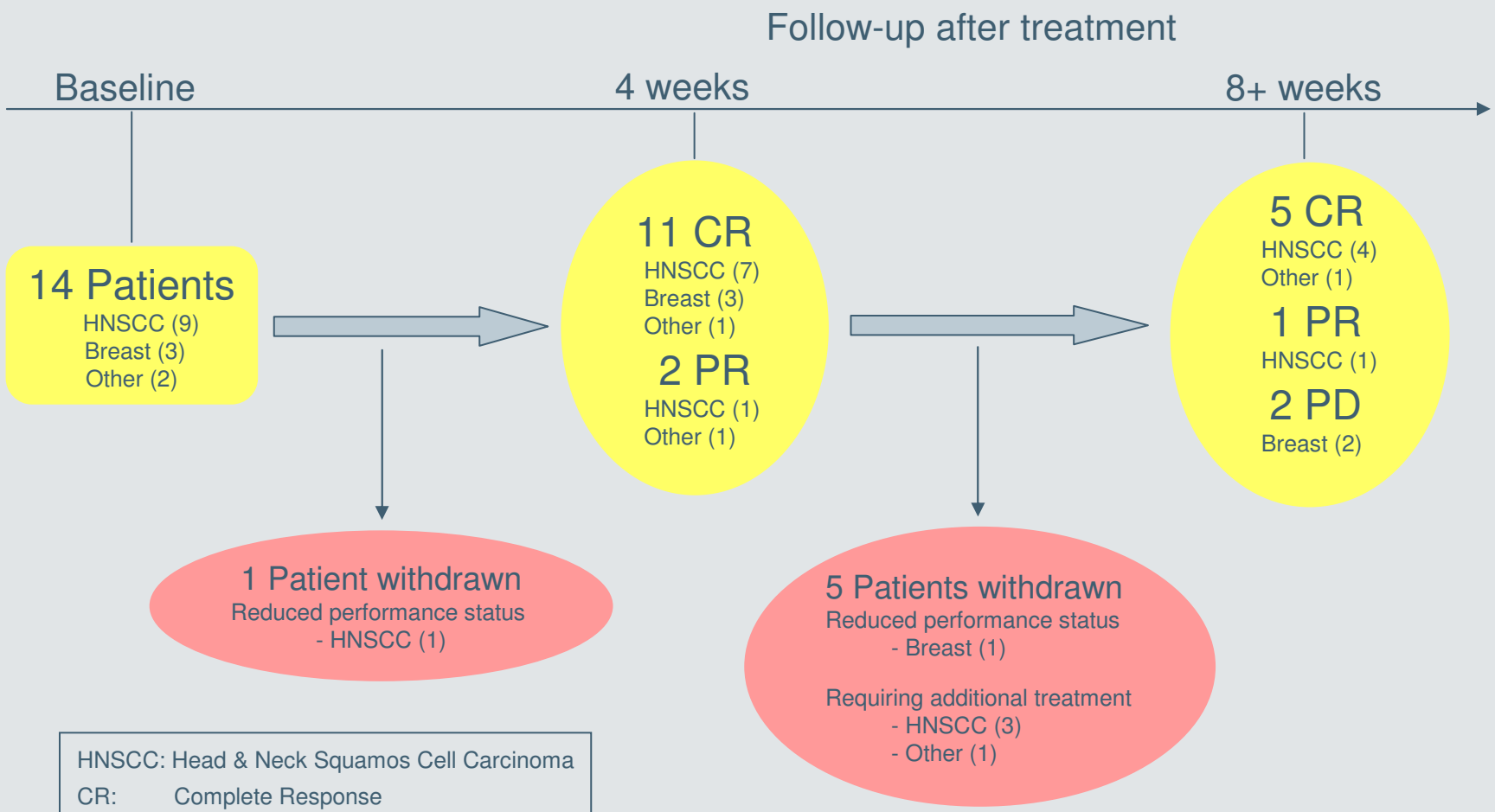
- PC-A11 is an Amphinex® based combination product containing the well established generic cytotoxic bleomycin
- Bleomycin is indicated for several different cancers, including head & neck
- PC-A11 is in Phase I/II at University College Hospital in London, in patients with cutaneous and/or subcutanous tumours
  - Mainly head & neck cancer patients are being included
  - 16 patients included across 4 dose groups as per year end
- Dose-escalation part of the Phase I/II study finished in 2010 – preliminary results indicate good safety and efficacy
  - Complete clinical regression of almost all target tumours within 28 days of treatment
  - Good safety and tolerability in the first three dose groups
  - Primary endpoint (dose-limiting toxicity) reached at the 4th dose group, completing the dose-escalation part of the study
  - Interim report of the dose-escalation part will be used for the regulatory applications for the Phase II/III study
  - Up to 6 additional patients will be included at the selected dose, to further strengthen the data at this dose – two patients included in 2010



Amphinex®

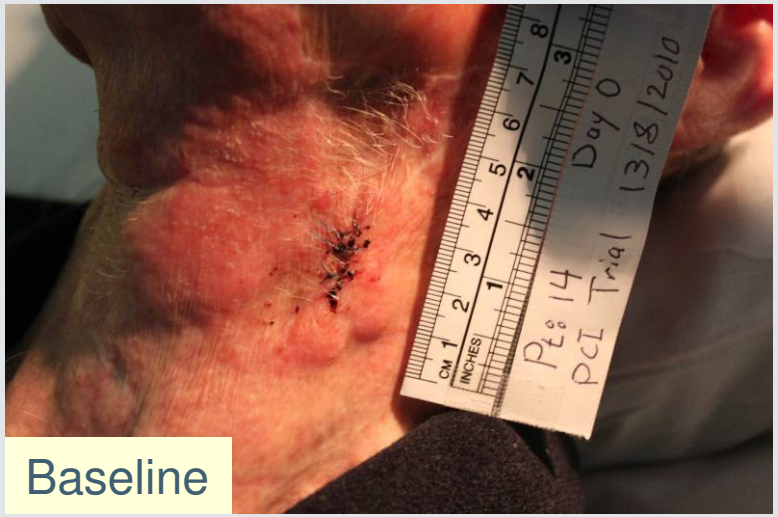
Phase I/II study – dose escalation part

Patient flow & efficacy results

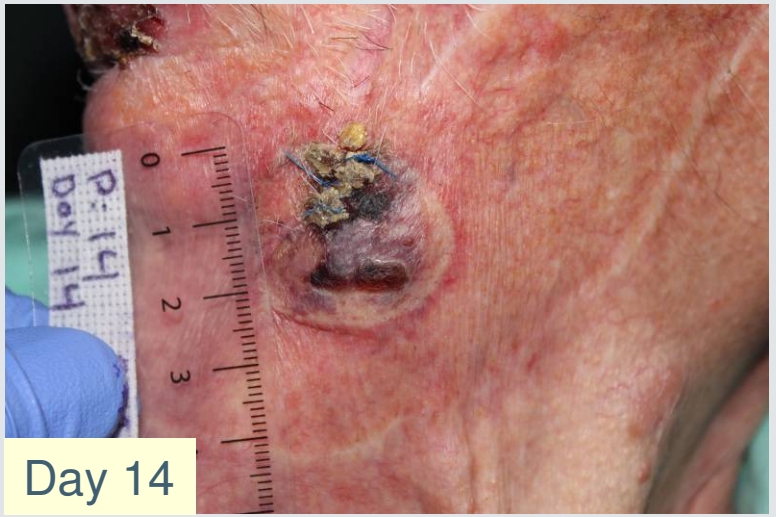


HNSCC: Head & Neck Squamos Cell Carcinoma
CR: Complete Response
PR: Partial Response
PD: Progressive Disease

Malignant skin adnexal tumour



Baseline



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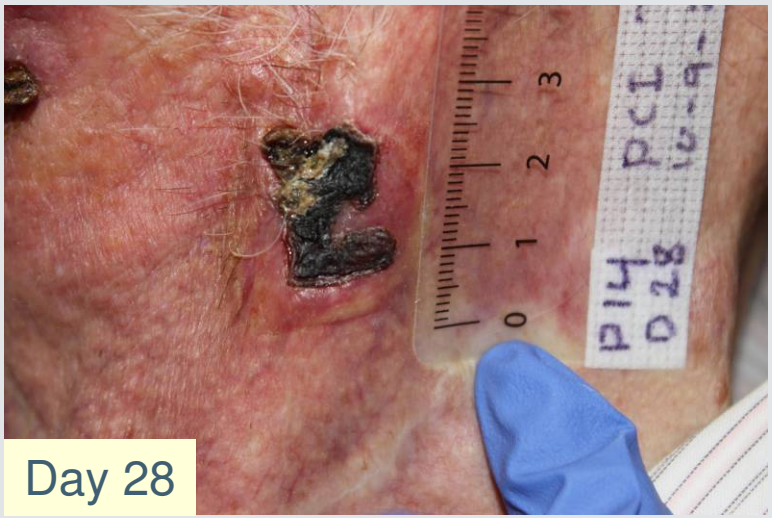

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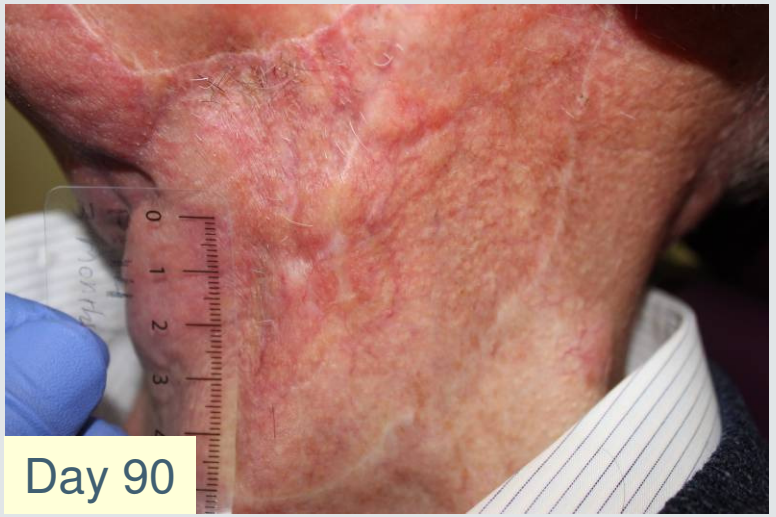
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PC-A11: Aiming to file MAA after Phase II/III

Head & Neck (PC-A11)

- Ongoing Phase I/II study at University College Hospital in London
- Aiming to start Phase II/III study within selected indication in 2011
  - Identify indication that could justify filing based on limited data
  - EMA interaction ongoing – several important issues discussed
  - FDA interaction being planned
- Aim to apply for Marketing Authorisation if Phase II/III results are sufficiently positive
- Size, timing, sites, etc to be determined depending on issues still under discussion
- Custom made light source for PC-A11 under establishment

* MAA: Marketing Authorisation Application

EMA scientific advice

Formal scientific advice with the European Medicines Agency

- Process started in 2010 – ongoing discussions in the autumn / winter
- Several important issues have been discussed
  - Target population for Phase II/III
  - Comparator treatment in Phase II/III
  - Pharmacokinetic design in Phase II/III
  - Dose selection based on Phase I/II
  - Preclinical requirements for MAA
- Some important issues are still under discussion
  - Endpoints in Phase II/III
  - Response measurement in Phase II/III

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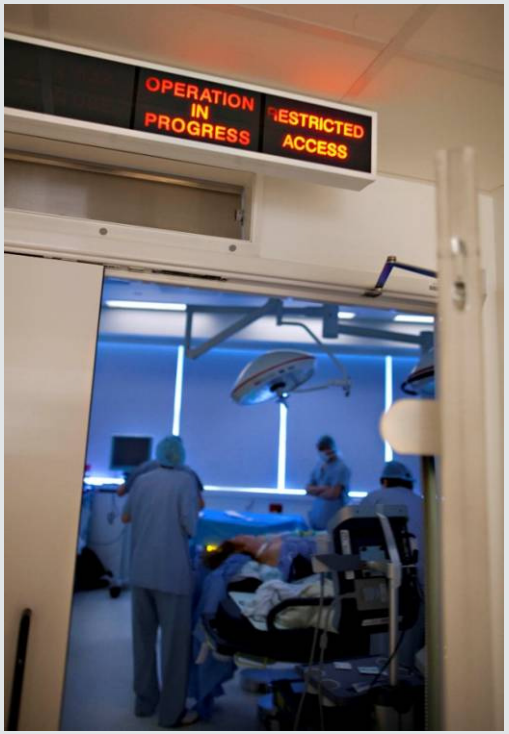
Pipeline

First clinical study yields promise for success in additional indications

- **Aim to initiate further Proof of Concept studies with selected PCI combination products in interesting disease areas**
  - Engaged International advisors to assess KOL input and provide market analyses
  - 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
  - Initiated preclinical efficacy studies with most promising combinations in 2010, to select product combinations for further development
  - Aim to initiate clinical Proof of Concept studies in 2011/2012 based on the results of the preclinical studies
  - Discussing potential investigator initiated studies in relevant disease areas



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Financial results

Financial key figures 2010 and 2009

P&L (TNOK)	Q4 2010	Q4 2009	2010	2009
Grants	1 741	2 395	10 444	8 612
Research and development costs	4 344	5 150	20 185	19 319
General and administrative costs	2 488	1 263	6 502	6 979
Total operating costs	6 832	6 413	26 687	26 298
Operating results	-5 091	-4 018	-16 243	-17 686
Profit before tax	**-4 130**	**-3 605**	**-13 940**	**-15 015**
Cash flow (TNOK)				
Net cash flow from operations	-571	-3 494	-8 283	-14 206
Net cash flow from investments				-113
Net cash flow from financials			83 274	0
Net cash flow	**-571**	**-3 494**	**74 991**	**-14 319**

Financial key figures 2010 and 2009

Balance (TNOK)	31.12.2010	31.12.2009
Fixed assets	78	181
Short term receivables	3 649	5 017
Cash & cash equivalents	**110 814**	**35 823**
Equity	105 423	35 077
Long term debt	0	0
Short term debt	9 118	5 944

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Summary

PCI Biotech – well positioned for attractive development opportunities

PC-A11	• Positive initial clinical results – a safe product with good effect in head & neck cancer • Last patients being included in Phase I/II on the selected dose level • Regulatory discussions for Phase II/III – important issues discussed with EMA
Pipeline	• Identified relevant new product combinations and cancer indications • Initiated preclinical tests with new combination products • Aim to start further clinical proof of concept studies in 2011/2012
Amphinex®	• Well documented and patented product for the proprietary PCI platform • Produced and released 2,000 vial of the new formulation of Amphinex®
Finance	• Good financial position for further development of PC-A11 and the PCI platform

2011

- Preclinical evaluation of new product combinations finished
- Ongoing Phase I/II finished (PC-A11)
- Phase II/III head & neck cancer initiated (PC-A11)
- Phase II PoC second indication study initiated

2012 - 2013

- Phase II PoC 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

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